



Biotech Daily

Friday August 4, 2017

Daily news on ASX-listed biotechnology companies

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- * **DR BOREHAM'S CRUCIBLE: AIRXPANDERS**
- * **OSPREY RAISES \$22m, 1-FOR-10 RIGHTS OFFER FOR \$10m MORE**
- * **BOSTON SCIENTIFIC PASSES ON REVA DISTRIBUTION RIGHTS**
- * **BARD 1 SHARE PLAN RAISES \$416k OF HOPED-FOR \$1m, TOTAL \$1.5m**
- * **ACCC REVIEWS CRYOSITE ASSET SALE, LICENCE WITH CELL CARE**
- * **ATCOR REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.25 percent on Friday August 4, 2017 with the ASX200 down 14.5 points to 5,720.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and two were untraded.

Prima was the best, up 0.1 cents or five percent to 2.1 cents with 8.4 million shares traded.

Benitec climbed four percent; Admedus, Medical Developments, Nanosonics, Oncosil and Resmed rose more than two percent; Clinuvel, Factor Therapeutics, Orthocell, Pharmaxis and Viralytics were up more than one percent; with CSL and Sirtex up by less than one percent.

Yesterday's 9.1 percent best, Dimerix, led the falls, down 0.1 cents or 8.3 percent to 1.1 cents with 10.0 million shares traded, followed by Reva down 6.5 cents or 8.1 percent to 73.5 cents with 106,250 shares traded.

Mesoblast lost 6.4 percent; Psivida was down five percent; Airxpanders, Compumedics and Living Cell fell more than four percent; Acrux, Cellmid and Impedimed were down more than three percent; Atcor, Polynovo, Pro Medicus and Uscom shed two percent or more; Actinogen, Ellex, ITL, Osprey and Starpharma were down more than one percent; with Cochlear down 0.3 percent.

DR BOREHAM'S CRUCIBLE: AIRXPANDERS

By TIM BOREHAM

ASX Code: AXP

Market cap: \$201.4 million; **Share price:** 70 cents; **Shares on issue:** 287.7 million

Chief executive officer: Scott Dodson

Board: Barry Cheskin (chairman), Greg Lichtwardt, Dennis Condon, Elizabeth Hammack, Zita Peach

Financials (June second quarter): receipts* \$US391, 000 (\$488,000, half year to date \$US566, 000), cash burn \$US8.36 million, cash and short-term investments \$US27.2 million, estimated September quarter outflows \$US8.8 million.

* Also reports revenue (including billed but not received) of \$US701, 000, up 474 percent year on year

Identifiable major holders: GBS Venture Partners 15.6 percent, Vivo (venture funds) 4.1 percent, Correlation Ventures 2.6 percent, Prolog Capital 1.7 percent, Heron Capital 0.7 percent

Having won strong investor backing since listing in mid-2015, the Californian-based novel breast reconstruction outfit presents a boom or bust scenario for investors.

That is, the company's Aeroform product either gains acceptance among US plastic surgeons, or stumbles along as a niche offering, at a time when US mastectomy rates are increasing significantly.

As with most medical endeavours the US market is crucial for Airxpanders and its flagship product Aeroform, which expands residual tissue to prepare the area for a breast reconstruction.

Having soft-launched Aeroform in the US in January, Airxpanders is girding for a full commercial US release in the current half.

Airxpanders cites an addressable market of \$US800 million, with 300,000 new cases of breast cancer detected annually.

Put another way, that's 300,000 eligible breasts (or, strictly speaking, pairs thereof). Currently, around 36 percent of the early-stage cases and 60 percent of the late-stage patients opt for a mastectomy.

Of these, 72 percent opt for a reconstruction using a tissue expander.

Devised in the early noughties by Californian plastic surgeon Dr David Jacobs, Aeroform is a nifty device indeed. The crucial components are an inserted bag and a cylinder of carbon dioxide, controlled by the patient via a handheld remote.

The CO2 is gradually released and expands the bag, thus stretching the tissue in preparation for the breast reconstruction. The current practice entails the patient receiving painful saline injections over week or months.

Local regulator well-abreast

The Aeroform won US Food and Drug Administration approval as a de novo (new) device in December last year and European (CE Mark) consent way back in in 2012.

Our own beloved Therapeutic Goods Administration approved the device in November 2014, with Aeroforms sold here since mid-2015.

With Aeroforms snaring a 10 percent market share within 90 days of launch, Airxpanders hopes that Australia is the flagship experience for its global ambitions.

Of the 297 units Aeroforms sold in the June quarter, 121 were sold in Australia (compared with 67 in the first quarter) and 176 in the US (38).

We're told that along with golf handicaps and alimony pay-outs, the Aeroform was a hot topic at the recent annual plastic surgeons' shindig on the Gold Coast.

Airxpanders presentation and chief executive officer Scott Dodson says the company is ahead of schedule in the US, where 80 of 120 targeted surgeons across about 100 hospitals have been approved to use the device.

"Of those, 40 have done their first case and are re-ordering," says Mr Dodson.

As always, reimbursement is crucial and providently the device falls under the same established codes for the saline devices in the US.

"We thought we could sell them for \$US2,500 but we are getting about a 10 percent premium on top of that," Mr Dodson says.

In Australia, they are classed as a prostheses with a set reimbursement of \$2,450.

In all, Airxpanders has sold 900 devices since 2015, but many more have been used in clinical trials.

Busting with funds

Airxpanders has not exactly been a shrinking violet when it comes to raising capital. The ASX listing raised \$36 million at 50 cents apiece. The company then raised \$20 million at 76 cents in a placement last year and then \$45 million at 92 cents a pop last February.

The shares peaked at \$1.43 in October last year.

Broker Cannacord (the lead manager for the placement) estimates Airxpanders should manage \$US6.4 million of sales in 2017, for a net loss of \$US25.6 million. On the current revenue run rate, this forecast seems ambitious.

The broker forecasts 2018 sales to stiffen to \$US20 million, with a \$US7 million gross profit and \$US13.3 million bottom-line loss.

Dr Boreham's diagnosis:

There are plenty of rosy precedents for ASX listed medical device plays, notably Nanosonics (sterilising equipment) and Impedimed (fluid measurement).

The question is whether Airxpanders ample share run already accounts for the upside.

The Aeroforms haven't wanted for promotion, winning airtime on all the main teevee networks and the biggest US medical program, The Doctors.

While some surgeons may prefer to minimize the amount of tissue removed with breast conservation surgery, in the US and some parts of Europe mastectomies and double mastectomies have increased significantly, despite no evidence in favour of double mastectomies where tumors have been found in one breast alone. There are a range of explanations for the differences over time and geography.

A technique called acellular dermal matrix is a direct-to-implant option that does not require an expander, but that practice comes with its own array of difficulties.

Another factor is that like all of us, surgeons like familiarity and may be reluctant to change from the tissue expanders to which they are used.

Mr Dodson says acellular dermal matrix has been an option for some time.

"The American Society of Plastic Surgeons charts the number of breast reconstruction and tissue expanders used," Mr Dodson says.

"The numbers show that 125,000 tissue expanders were sold in the US every year and that number continues to go up," Mr Dodson says.

Also, Airxpanders may only need to glean a small market share to be successful.

Whatever the case, we'll know in about 12 months whether this one's the Next Big Biotech Thing or just another biotech storm in a D-cup.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Given this, some readers think he is a complete boob.

OSPREY MEDICAL

Osprey says it has commitments to raise \$22,185,630 in a placement at 40 cents and has offered a one-for-10 rights issue to raise a further \$10,314,370.

Osprey said the placement was over-subscribed and the non-renounceable entitlement offer was fully underwritten by Canaccord Genuity Australia and Bell Potter Securities.

The company said the funds raised would be used to expand its US sales force to geographies with a high share of acute kidney injuries, begin a pilot European sales program in Germany, support post-approval market trials and physician sponsored trials for scientific presentation and publications, as well as continuing research and development of the product portfolio.

Osprey said that Canaccord and Bell Potter were the joint lead managers to the placement and entitlement Offer with Evans and Partners co-lead manager and Vesparum Capital acting in an independent capital markets advisory role.

The company said that Brandon Capital Partners had subscribed for its pro-rata allocation of 13,002,674 Chess depository instruments for about \$5.2 million, and would further take up a minimum of its pro-rata entitlement in the entitlement offer and fully sub-underwrite the remainder of the entitlement offer.

The entitlement offer opens on August 14 and closes on August 25, 2017.

Osprey fell half a cent or 1.15 percent to 43 cents with 1.7 million shares traded.

REVA MEDICAL

Reva says that Boston Scientific Corp has allowed its exclusive right to negotiate for distribution of Reva's bio-resorbable scaffolds to expire.

Reva said that Boston Scientific right to negotiate under a 2007 agreement would have required it to pay 50 percent of the average selling price on all product sales, with other commercial terms not yet negotiated.

The company said that Boston Scientific's option was triggered when Reva delivered an extensive set of positive clinical data supporting the performance of its Fantom drug-eluting coronary scaffold (BD: May 17, 2017).

Reva said that all aspects of the 2007 agreement had been concluded and its direct selling effort was underway.

The company said that the first customer contract was signed in June and sales momentum had increased with two additional commercial contracts and more than 10 potential customers in negotiations.

Reva said it had appointed Joann Lofgren Yao as head of marketing.

The company said that Ms Yao previously worked for Abbott Vascular, responsible for marketing of the Xience drug-eluting stent.

Reva chief executive officer Dr Reggie Groves said that "the timing and economics of the proposed arrangement led to [Boston Scientific's] decision not to exercise their right to negotiate".

"We are pleased to retain complete control of the marketing and distribution for Fantom and any of our future scaffolds," Dr Groves said.

"This allows us to have the latitude to drive product positioning and distribution, and customer relationships," Dr Groves said.

"The market's reaction to our launch has been very supportive and we are optimistic that Fantom will fulfil the market's desire for bio-resorbable coronary scaffolds," Dr Groves said.

Reva fell 6.5 cents or 8.1 percent to 73.5 cents.

[BARD1 LIFE SCIENCES](#)

Bard1 says its share plan at 0.8 cents a share has raised \$416,000 of a hoped-for \$1 million, taking the total raised with a \$1,097,000 placement to \$1,513,000 (BD: Jul 12, 2017).

Bard1 said that the funds would be used “to advance ongoing research and development programs, commercial initiatives and for general working capital”.

Bard1 was unchanged at 0.9 cents.

[CRYOSITE](#)

Cryosite says the Australian Competition and Consumer Commission will publicly review its proposed licence and sale of assets to Cell Care Australia Pty Ltd (BD: Jun 23, 2017).

Cryosite said it proposed to licence the future collection, processing and storage of umbilical cord and tissue and to sell certain assets of its cord blood and tissue banking business to Cell Care and focus on its clinical trials logistics and biorepository services.

The company said it was “considering its position in light of this notification ... [but was] proceeding with its plans to seek shareholder approval to the proposed transaction”.

In 2015, Cell Care Australia and related parties reduced their substantial shareholding in Cryosite from 22.96 percent to 19.79 percent (BD: Nov 26, 2015).

Cryosite was untraded at 18 cents.

[ATCOR MEDICAL](#)

Atcor has requested a trading halt pending “an announcement to the market in relation to a potential capital raising”.

Trading will resume on August 8, 2017 or on an earlier announcement.

Atcor last traded at 4.9 cents.