



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## 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 CO<sub>2</sub> 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 is 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.***