Biotech Daily

Friday September 22, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: STARPHARMA UP 15%, AVITA DOWN 9.5%**

*** DR BOREHAM'S CRUCIBLE: ACRUX**

*** STARPHARMA SAFETY, EFFICACY TAKES DEP-DOCETAXEL TO PHASE II**

*** MACH7 IMAGING DEAL WITH VERMONT UNI MEDICAL CENTRE**

*** ONCOSIL PANCREATIC TRIAL: 23 RECRUITED, 10 IMPLANTED**

*** ATCOR SHARE PLAN RAISES $350k OF HOPED-FOR $500k, TOTAL $1.2m**

*** INVION PLEADS SCHULTZ TO ASX 33% QUERY, ASX MISSES 34%**

*** PHOSPHAGENICS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** SIRTEX $1.4m CEO 'PERFORMANCE RIGHTS' AGM**

*** ACRUX $620k CEO 'PERFORMANCE RIGHTS' AGM**

*** CLJE TAKES 10% OF ALLEGRA**

*** NARHEX DIRECTOR IAN REYNOLDS TAKES 6% OF RESAPP**

MARKET REPORT

The Australian stock market was up 0.47 percent on Friday September 22, 2017 with the ASX200 up 26.7 points to 5,682.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and six were untraded.

Starpharma was the best, up 16 cents or 15.2 percent to $1.21 with 2.6 million shares traded. Living Cell climbed 9.4 percent; Airxpanders was up 8.5 percent; Actinogen was up 5.45 percent; Reva improved 3.4 percent; Pro Medicus rose 2.3 percent; Admedus, Bionomics, Compumedics, LBT and Neuren were up more than one percent; with Clinuvel, Cochlear, CSL, Mesoblast and Nanosonics up by less than one percent.

Avita led the falls, down 0.6 cents or 9.5 percent to 5.7 cents with 6.3 million shares traded. Uscom lost 5.7 percent; Cellmid, Orthocell, Prima and Viralytics fell more than four percent; Genetic Signatures and ITL shed more than two percent; Pharmaxis, Resmed and Sirtex were down more than one percent; with Medical Developments and Opthea down by less than one percent.

DR BOREHAM'S CRUCIBLE: ACRUX

By TIM BOREHAM

ASX Code: ACR

Market cap: $25.8 million; **Share price:** 15.5 cents; **Shares on issue:** 166,521,711

Chief executive officer: Michael Kotsanis

Board: Ross Dobinson (chairman and founder), Michael Kotsanis, Bruce Parncutt, Dr Tim Oldham, Dr Geoff Brooke, Dr Simon Green

Financials (year to June 30 2017): revenue $23.93 million (down 16 percent), ***** net loss $243,000 ($11.1 million profit previously), cash of $34 million (versus $29.3 million)

Identifiable holders: ** Hugh Elphinstone 3.06 percent, Asia Union 2.10 percent, Paul Cozzi 1.80 percent, Ian and Debra Lancini 1.23 percent, Michael and Rechaelle Sylvester 0.87 percent, Christopher Abbott 0.84 percent

***** Net loss includes a non-cash impairment of $10.68 million
****** Allan Gray, held 14 per cent but has since gone below the substantial threshold.

In a nasty case of corporate detumescence, shares in the developer of the roll-on testosterone product Axiron are trading at less than their cash backing.

While Acrux's woes in the US have been well-documented, it's an intriguing valuation given the company could receive a substantial damages pay-out should a US legal appeal prove successful (more on that later).

And while Axiron is effectively dead and buried in the US, the company hopes to pave an alternative revenue path by developing up to 12 topical and transdermal generic drugs.

Acrux shares tumbled 30 percent on September 6 when Acrux and distributor Eli Lilly "mutually agreed" to terminate their Axiron distribution agreement. The divorce is effective immediately in the US and elsewhere 90 days thereafter. And for what they're worth now, the global rights revert to Acrux.

When the tie-up was unveiled in 2010 it was one of the biggest in Australian biotech history with a trumpeted value of $US335 million in upfront payments, approval payments and commercialization milestones.

Testosterone deficiency - or hypogonadism - is linked with a number of clinical problems, with an estimated 40 percent of blokes aged under 45 years being deficient in the hormone.

Founded in 1998 by Prof Barrie Finnin and Ross Dobinson as a Monash Uni spin-off, Acrux developed Axiron from its 'Patchless Patch' fast drying topical technology.

In 2011, Axiron was approved in US, which until recently has accounted for 95 percent of global testosterone sales.

The reason is not just because Yanks want to be more virile: because the drug cost much more in the US than elsewhere, drug companies have had more incentive to market the hormone harder.

According to reliable sources - Biotech Daily editor David Langsam actually - Eli Lilly has reaped revenue of more than $US800m from Axiron over the product's six-year life.

On Prof Langsam's back of the serviette sums, Acrux over this time has received $156 million in milestone payments and more than $145 million in royalty revenue.

A catalogue of woes

Axiron's woes began in 2014 when the Food and Drug Administration voiced its concerns about suspected linkages between testosterone treatment and heart attacks and strokes.

As a result the regulator requires a post-marketing clinical trial to address these risks.

In 2013 Acrux launched - and lost - a court action against four generic companies planning generic alternatives. As a result, in July this year, Perrigo launched a generic version of Axiron and then Teva did the same in July. Prasco then launched an authorised generic (licenced by Eli Lilly) in August.

The incursion of competitors saw a dramatic slide in Acrux's share of the topical testosterone market: from 14 percent at the start of the year to around 10 percent now.

Given the emergence of generic competition, Acrux and Eli Lilly decided the investment in the mandated clinical trials - and we're talking potentially hundreds and millions of dollars - was not worth it. And Axiron will be withdrawn from the US market.

The other headwind is that the FDA has limited testosterone prescriptions to "men with low testosterone levels caused by certain medical conditions and confirmed by lab tests".

Sounds reasonable to us. The result of this dictate was that testosterone sales plunged by 50 percent overnight, which presumably means the hormone was widely being used by 'off label' by ageing Lotharios.

Generics: friend or foe?

While generics have been a curse for Acrux, they are also integral to the company's future. Two years ago, the company realised it couldn't rely on Axiron and resolved to enter the generics game itself.

The company cites seven generics under development, increasing to 12 next year.

Acrux is keeping the nature of the indications close to its hairy chest, but the target market is worth more than $US1 billion in a topical US generic sector worth $US7 billion overall. The company hopes to initiate clinical trials next year.

Acrux's other path to redemption is using its compound ACR065 to treat onychomycosis. While this sounds like a nasty cancer, it's a fungal infection of the toenails and fingernails (and not very nice either presumably).

Lawyers: friends or foe?

In August last year, the US District Court ruled that the Axiron formulation was invalid, thus spurring the generic rivals to market.

Acrux and Eli Lilly have appealed the decision, with an appeal hearing scheduled for October 5.

The beauty for Acrux is that Eli Lilly has stumped up the costs for the legal groundwork, leaving a minimal cost for Acrux.

Given the valuation of Acrux shares ascribes no worth at all to the legal dispute, a successful appeal (and a chunky damages award) is all upside.

Dr Boreham's diagnosis:

Despite the travails, Acrux 2016-'17 year-end cash balance edged up 15 percent to $33.94 million.

The market cap of $26 million implies management could return all the funds to shareholders and have some lollies left over.

Acrux will continue to receive Axiron royalties while the Eli Lilly tie-up winds down; other than that, it's a case of back-to-the-future as a development company.

But Acrux boasts a hidden asset: it is a pooled development fund (PDF); one of the few ASX listed vehicles structured as such.

Introduced by Paul Keating, PDFs offer advantages including not being subject to capital gains tax and non-taxed dividends. The downside is that losses can't be claimed against capital gains.

With Mr Dividend likely to be absent for some time, Acrux cannot reap the advantage. But because PDFs have been discontinued there's intrinsic value in the PDF structure.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His last testosterone fuelled romp was as a randy teenager.

STARPHARMA

Starpharma says its phase I trial of dendrimer-enhanced docetaxel shows it is safe with “encouraging signs of efficacy” and it will proceed to a phase II trial.

Starpharma said the 27-patient trial of the dendrimer-enhanced product (DEP) docetaxel had “no reports of neutropenia, a life-threatening toxicity seen in virtually all patients treated with conventional docetaxel formulations [with] encouraging signs of efficacy observed for multiple tumor types”.

The company said that DEP-docetaxel showed a longer half-life, lower peak blood concentration and extended exposure, compared to docetaxel.

Starpharma said the 52-patient, phase II trial would be in lung and prostate cancer and would begin immediately with DEP-docetaxel as a monotherapy and in combination with nintedanib for lung cancer

The company said that “encouraging signs of efficacy were observed in 13 of 27 DEP-docetaxel-treated patients, including stable disease in patients with lung, pancreatic and gastro-oesophageal cancers and in other patients with brain and renal cancers”.

Starpharma said that some of these tumor types were unresponsive to docetaxel, and most patients had been heavily treated with multiple other anti-cancer therapies, including taxanes, such as docetaxel.

The company said that one patient with pancreatic cancer had stable disease for more than 20 weeks and one patient with oesophageal cancer had stable disease for more than 18 weeks following treatment with DEP-docetaxel, and substantial decreases in tumor size were observed for a number of patients.

Starpharma said the pharmaco-kinetic data supported earlier findings that the dendrimer acted as a depot for the drug, resulting in the slow release of docetaxel from the dendrimer and drug exposure was “substantially higher for DEP-docetaxel than for an equivalent dose of conventional docetaxel” with DEP-docetaxel resulting in a significantly lower peak blood plasma level compared to docetaxel.

Starpharma said DEP-docetaxel achieved the objective of finding a recommended phase II dose, with no reports of protocol-defined dose-limiting toxicities, phase II ethics and regulatory approvals had been granted and recruitment was underway.

Starpharma said the 27 phase I trial patients had advanced solid cancers, including lung, prostate, pancreatic, gastro-oesophageal, breast, cervical, renal and brain cancer and they received DEP-docetaxel at a range of doses in up-to six cycles, but due to the absence of dose-limiting toxicities, a formal maximum dose was not determined.

The company said the phase II open-label study would establish anti-tumor efficacy and safety of DEP-docetaxel at 60mg per metre squared of skin surface.

The company said the trial would enrol about 20 patients with lung or prostate cancer, a second stage would enrol a further 20 patients with tumour types based on results from the first stage, and in parallel DEP-docetaxel would be combined with nintedanib, approved for lung cancer in combination with docetaxel, in 12 patients.

Starpharma chief executive officer Dr Jackie Fairley said that “as well as the very promising signs of efficacy observed, what is truly remarkable is that there was not a single report of neutropenia amongst patients dosed with DEP-docetaxel”.

“Neutropenia is a life-threatening side-effect that usually affects more than 90 percent of Taxotere patients,” Dr Fairley said. “We are also delighted that no hair loss with DEP-docetaxel was reported apart from one patient who experienced a mild case of alopecia.”

“The reduction in these significant side-effects and others such as anaemia, diarrhoea and anaphylaxis means that DEP-docetaxel has the potential to have a positive impact on the quality of life of cancer patients undergoing treatment,” Dr Fairley said.

Starpharma climbed 16 cents or 15.2 percent to $1.21 with 2.6 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has licenced its imaging products to the University of Vermont Medical Centre, with $US1,200,000 ($A1,513,984) expected in the first year.
Mach7 said it would provide its suite of imaging products to the Burlington, Vermont-based University's medical sites located across the state of Vermont and northern New York.
The company said there would be recurring annual support fees from the University of Vermont Medical Centre, which serves a population of one million across its 144 medical sites.
Mach7 was up two cents or 13.8 percent to 16.5 cents with 2.5 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has recruited 23 patients and treated 10 patients in its trial of Brachysil radiation for pancreatic liver cancer.
In April, Oncosil said it had implanted the first of 300 patients in the multi-centre, randomized, open-label safety and efficacy Oncopac-1 trial at up to 30 centres in the US, UK, Europe and Australia for patients with locally advanced, unresectable pancreatic adeno-carcinoma (BD: Apr 26, 2017).
Today, the company said it had "positive interim data" relating to tumour response and disease control from the implanted patients, which would be updated at the European Association of Nuclear Medicine meeting in Vienna, in October.
Oncosil chief executive officer Daniel Kenny said that implanting 10 patients and recruiting the twentieth patient were "important milestones in our effort to generate supplemental data required for [Conformité Européenne] mark certification in as short a timeframe as possible".
Oncosil said that two subjects withdrew due to illness unrelated to the device and it would continue to recruit subjects beyond the initial European regulatory approval-required 20 subject target "to gather additional valuable clinical experience and to account for subject loss due to factors such as withdrawal on clinical grounds prior to implantation or protocol ineligibility".
The company said that data gathered would contribute to the 20-subject supplemental data request to secure CE mark approval, which was its immediate focus.
Oncosil was unchanged at 10 cents with 1.3 million shares traded.

ATCOR MEDICAL

Atcor says it has raised $350,000 of a hoped-for $500,000 in a share plan at 2.7 cents a share, taking the total raised to $1,175,000.
Atcor said it had applications for $341,000 new shares, including $80,000 from the company's directors and affiliates.
The company said Taylor Collison brought $9,000 in shares, as its $270,000 underwriting commitment.
In August, the company raised $825,000 in a placement to institutions and sophisticated investors (BD: Aug 8, 2017).
Atcor said the funds would be used in initiatives including "increased focus on advanced strategic options, securing new sales and restructuring operations to maximise profitability".
Atcor was untraded at 2.7 cents.

INVION

Invion has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 33.3 percent from 0.3 cents to 0.4 cents today, September 22, 2017 and noted a significant increase in the trading volume.
Invion closed up 0.2 cents or 66.7 percent to 0.5 cents with 69.7 million shares traded.

PHOSPHAGENICS

Phosphagenics has requested a trading halt pending an announcement "in relation to a proposed capital raising".
Trading will resume on September 26, 2017 or on an earlier announcement.
Phosphagenics last traded at 1.8 cents.

SIRTEX MEDICAL

Sirtex will vote to grant chief executive officer Andrew McLean 102,723 'performance' rights worth about $1,409,360 at tonight's closing price of $13.72.
Sirtex said the rights would vest subject to the achievement of a total shareholder return of 50 percent and an earnings per share of 50 percent hurdles over the performance period of July 1, 2017 to June 30, 2020.
The company said that the meeting would vote on the remuneration report and the re-election of directors Mr McLean, Helen Kurincic, Neville Mitchell.
The meeting will be held at the Royal Auto Club of Australia, 89 Macquarie Street, Sydney on October 24, 2017 at 10am (AEDT).
Sirtex fell 16 cents or 1.15 percent to $13.72 with 327,009 shares traded.

ACRUX

Acrux will vote to grant chief executive officer Michael Kotsanis 4,000,000 'performance' rights worth about $620,000 at tonight's closing price of 15.5 cents.
Acrux said the rights would vest in four equal tranches, providing the total shareholder return in the year preceding vesting was equal or more than 12 percent, with non-vested rights "rolled-over" to the next year.
The company said that the meeting would vote on the remuneration report, the omnibus equity plan, and the re-election of chairman Ross Dobinson.
The meeting will be held at Pitcher Partners, Level 19, 15 William Street, Melbourne on October 26, 2017 at 10am (AEDT).
Acrux was unchanged at 15.5 cents.

ALLEGRA (FORMERLY ADVANCED SURGICAL DESIGN & MANUFACTURE)

CLJE Investments says it has increased its substantial holding in Allegra from 6,883,579 shares (8.34%) to 8,883,579 (10.11%).
The Baulkham Hills, Sydney-based CLJE said it bought 613,333 shares on April 13 at 12.5 cents a share and 2,000,000 shares on September 19, 2017 for 15 cents a share.
Earlier this month, Allegra said it raised $1.3 million at 15 cents a share and said it would seek shareholder approval to raise a further $1.4 million in private placement at 15 cents a share (BD: Sep 8, 2017).
Allegra was untraded at 15 cents.

RESAPP HEALTH (FORMERLY NARHEX LIFE SCIENCES)

Former Narhex director Ian Reynolds says he has become a substantial shareholder in Resapp with 36,930,633 shares (5.6%).

The Melbourne-based Mr Reynolds said that 13,352,973 shares were acquired with CEM International and Tittel Pty Ltd between July 13 and August 14, 2017 at an average price of 15 cents a share.

Mr Reynolds was a director of Narhex Life Sciences before it acquired Resapp Diagnostics and began trading as Resapp (BD July 3, 2015).

Resapp was up 0.2 cents or 2.9 percent to seven cents with 3.15 million shares traded.