Biotech Daily

Friday November 3, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PRANA UP 11%; ELLEX DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: REVA MEDICAL**

*** ELLEX PLACEMENT RAISES $23m, SHARE PLAN FOR $5m MORE**

*** WEARABLE SENSOR PROJECT WINS $10m ANU GRANT**

*** NOXOPHARM: 'NYX-104 INHIBITS LOSS OF BRAIN FUNCTION IN MICE'**

*** NANOSONICS 21% OPPOSE DIRECTOR RICHARD ENGLAND**

*** RESAPP PASSES REMUNERATION REPORT, 2nd STRIKE AVERTED**

*** MERCHANT REDUCES TO 9% OF POLYNOVO**

*** VISIONEERING LOSES GARY STEVENSON**

*** NUHEARA APPOINTS DAVE THOMPSON BUSINESS DEVELOPMENT**

MARKET REPORT

The Australian stock market was up 0.48 percent on Friday November 3, 2017 with the ASX200 up 28.2 points to 5,959.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and three were untraded.

Prana was the best, up 0.7 cents or 10.9 percent to 7.1 cents with 353,940 shares traded.

Avita, Factor Therapeutics and Living Cell climbed more than five percent; Clinuvel and Neuren improved more than four percent; Benitec and Osprey rose more than two percent; Cochlear, Compumedics, Genetic Signatures and Viralytics were up more than one percent; with CSL, Impedimed and Starpharma up by less than one percent.

Ellex led the falls, down nine cents or 7.9 cents to $1.05 with 821,342 shares traded.

Admedus and Cellmid fell more than four percent; Airxpanders, Mesoblast and Oncosil were down more than three percent; Nanosonics and Resmed shed more than two percent; Actinogen, Bionomics, ITL and Polynovo lost more than one percent; with Medical Developments and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: REVA MEDICAL

By TIM BOREHAM

ASX code: RVA

Market cap: $228.6 million

Share price: 70 cents

Shares on issue: 412,320,170 * (Chess depository instruments)

Chief executive officer: Dr Regina Groves

Board: Charles Ray Larkin (chairman), Dr Regina Groves, Brian Dovey, Dr Ross Breckenridge, Scott Huennekens, Bob Stockman, Robert Thomas

Financials (September quarter 2017): receipts $US41,000 ($A53,522), cash outflows $US4.9 million, estimated current-quarter outflows $US4.3 million, cash balance $US22.6 million.

Major shareholders: Senrigan Capital 20.7 percent, Goldman Sachs 18.8 percent, Domain Partners 6.1 percent, Elliott Associates 5.8 percent, Saints Capital 5.3 percent, Brookside Capital 4.9 percent, Cerberus and Associates 4.8 percent, Medtronic 4.7 percent.

***** CDIs, worth one-tenth of a US share

Ahead of the San Diego-based Reva's ASX listing in December 2010, the bio-resorbable coronary stent (BRS) developer targeted European regulatory approval for its product, then named Rezolve, by the end of 2013.

Well, that one took a tad longer than expected to Rezolve, with Reva finally gaining approval for its all new and improved replacement, the Fantom, in April this year.

The so-called Conformité Européenne (CE) mark consent finally paves the way for Reva to market Fantom on the Continent and in June signed a German hospital as its first customer.

(If you really need to know it was the Kiel based stent specialist Universitätsklinikum Schleswig-Holstein).

The company is now selling in Germany, Switzerland and Austria, where it's targeting hospitals that carry out 1,000 or more stent procedures a year. The devices started selling at the end of June, with the company accruing a modest $US41, 000 in revenue.

Notably, Reva does not have approval from the US Food and Drug Administration and is yet to apply, with no stated time line for doing so.

The benefits of bio-resorbable stents

Reva competes in the $US3.9 billion stent market, with the bio-resorbable sub-sector currently worth a modest $US127 million.

In theory, bio-resorbable stents offer several advantages, one of which is they don't have to be plucked out again when their work is done.

A tubular sleeve in a lattice formation, Fantom is made out of advanced polymers and is thinner than rival stents with "enhanced deliverability while being visible under X-ray".

The scaffold is drug eluting, which means it can house and slowly release a drug to prevent the growth of cells causing the artery blockage.

The absorption allows for restoration of the 'natural movement' of the artery.

In a crucial test, a 240-patient trial (Fantom II) delivered a number of positive results: major adverse cardiac events (MACE) were limited to 4.2 percent of patients after 12 months, with faster healing and no incidence of a condition called scaffold thrombosis.

The company has just reported interim results from a sub pool of 125 patients, showing a 5.6 percent incidence of cardiac events after 24 months. An expanded trial of 1,800-2,200 patients (Fantom III) is scheduled for 2018.

Heart-wrenching tale of setbacks

The Reva story is typical of the setbacks faced by makers of bodily-inserted medical devices: they have to be tickety-boo for obvious reasons and the development times invariably become elongated.

Even before listing, the company spent $100 million developing the stent over 10 years. Along the way it was backed by Boston Scientific and Medtronic, with the latter remaining a Reva shareholder.

In a typical case of Founders' Syndrome, co-founder, chairman and chief executive officer Bob Stockman stepped down in late 2015, in favour of ex-Medtronic vice president Dr Reggie Groves. Mr Stockman remains on the board, though.

Like Prime Minister Malcolm Turnbull, Reva is troubled by an Abbott: rival stent maker Abbott Laboratories, which cast a pall over the sector after recalling its Absorb bio-resorbable stent product in Europe.

This was after a clinical trial in late 2016 detected adverse events including elevated risk of heart attacks and blood clots.

Locally, the Therapeutics Goods Administration ordered the product to be recalled, while in the US the FDA has warned physicians about “adverse cardiac events”.

Absorb was sold in 100 countries and In September, Abbott said it had halted further sales due to low sales.

Cashed up

Fantom’s prospects were promising enough for unnamed investors to pony up a net $US34.6 million for unsecured convertible notes with attached options.

Dr Boreham’s diagnosis

Morgans bio-watcher Derek Jellinek notes the company has stockpiled at least two years’ supply and estimates the initial market at 10,000 units with the potential for 25,000 units.

Dr Jellinek said in June that Reva’s peak sales for Fantom could be $US700 million in the US and $US300 million for the rest of the world.

A key negative is the inability to sell in the US, the home of obesity and coronary occlusions. Dr Jellinek warns the FDA bio-resorbables warning is “likely to hamstring adoption until more data alleviates concerns”.

Of course the US market is the crucial one to tap for any medical device maker.

To distort the words of former director Anne Keating’s ex-Prime Ministerial brother: “If you’re not in the US, you’re just camping out.” (St Paul of Balmain was, of course, talking about his beloved Sydney).

Given the lingering safety concerns, this one doesn’t send our hearts a flutter but at least the company is getting revenue through the door.

In the cheery words of Reva’s half-year filing to the US Securities and Exchange Commission: “Even if we do attain revenue we may never become profitable and even if we do ... we may not be able to sustain profitability and cash flows on a recurring basis.”

REVA, by the way, derives from REstoringVAscular function and one can only ponder how much the brand guru’s invoice contributed to REva’s $US388 million of accrued losses over the years.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His knowledge of scaffolds extends only to building sites and Ned Kelly’s final minutes.

ELLEX MEDICAL LASERS

Ellex says it has raised $23,200,000 through a placement at $1.05 a share and hopes to raise up to $5,000,000 through a share plan.
Ellex chief executive officer Tom Spurling said it was “the largest capital raise in the company’s history and is primarily targeted at accelerating the growth of Ellex Itrack into the fast growing [minimally invasive glaucoma surgery] market”.
The company said the placement was in two tranches with the second tranche requiring shareholder approval.
Ellex said the record date for the share plan was November 2, with details to follow.
The company said that Bell Potter Securities was the lead manager for Australia and other non-US jurisdictions, with Maxim Group LLC as lead US placement agent.
Ellex fell nine cents or 7.9 cents to $1.05.

AUSTRALIAN NATIONAL UNIVERSITY

The Australian National University says a wearable sensor project for personalized healthcare has won the University’s first $10 million Grand Challenge Scheme.
The ANU said the project, entitled “Your Health in Your Hands: Future Personalised Medical Technologies for a Sustainable and Effective Healthcare” was a five-year program, involving more than 60 researchers from a range departments, including immunologists, engineers, physicists, chemists and health services experts.
The University said that vice-chancellor Prof Brian Schmidt established the $50 million Grand Challenge “to help … solve some of the biggest problems facing the world”.
ANU nanotechnology researcher Prof Antonio Tricoli said that people would be able “to collect essential information about their health, just by going about their normal daily activities such as brushing their teeth or taking a walk”.
Co-lead researcher Prof Matthew Cook said that “diagnosing chronic diseases earlier and treating them more effectively would be enormous progress”.
“There’s going to be a huge gain from combining wearable sensor technology with genomics to understand the mechanism of disease better,” said Prof Cook.

NOXOPHARM

Noxopharm says its NYX-104 compound inhibits loss of brain function following a stroke or concussion in an undisclosed number of mice.
Noxopharm said it had a collaboration with the University of New South Wales to develop NYX-104 to mitigate secondary damage following brain trauma.
The company said it had “key proof-of-concept evidence of its ability to significantly reduce the area of brain death in a mouse model of human stroke”.
Noxopharm said NYX-104 would address an unmet need to prevent “follow-on damage” after events such as stroke, concussion, head injury or severe seizures, and had shown potential in a mouse model of human stroke.
The company said that University of New South Wales neuroscientists identified a target in the secondary damage process, Noxopharm had designed a drug able to hit this target, delivered across the blood-brain barrier with its Liprose technology.
University of New South Wales neuroscientist Prof Gary Housley said the collaboration with Noxopharm “has been highly effective in enabling us to achieve the molecular targeting of this primary brain injury process and then validate the significant neuroprotection in-vivo”.
Noxopharm was up two cents or 3.5 percent to 59.5 cents.

NANOSONICS

The Nanosonics annual general meeting voted 20.5 percent against the re-election of director Richard England.
Nanosonics said that the re-election of Mr England received 117,825,344 votes (79.0%) in favor and 30,594,436 votes (20.5%) against, with 0.5 percent at the proxy's discretion.
The company said that 15,120,073 votes (10.3%) opposed the issue of 45,513 "performance" rights to chief executive officer Michael Kavanagh, but all other resolutions, the issue of 25,733 performance rights and 340,424 options to Mr Kavanagh, the re-election of director Dr David Fisher and the remuneration report were passed overwhelmingly.
The company's most recent Appendix 3B new issue announcement said that Nanosonics had 299,263,438 shares on issue, meaning that the 30,594,436 votes against the re-election of Mr England, amounted to 10.2 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.
Nanosonics fell seven cents or 2.4 percent to $2.81 with 1.2 million shares traded.

RESAPP HEALTH

Resapp says its annual general meeting overwhelmingly passed the remuneration report following a first strike at last year's meeting.
Resapp said the remuneration report was supported by 216,098,355 votes (92.7%) and opposed by 17,024,080 votes (7.3%).
Last year, the remuneration report was lost with 42,246,469 votes (26.4%) against the report and 117,895,328 votes (73.6%) in favor (BD: Nov 3, 2016).
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with a vote of 25 percent or more against the remuneration report in two successive meetings is required to vote on a board spill.
The company said the other resolutions, including the re-election of chairman Dr Roger Aston and approval of the 10 percent placement facility were passed overwhelmingly.
Resapp was up 0.1 cents or 1.3 percent to 7.8 cents with 9.3 million shares traded.

POLYNOVO

Merchant Funds Management says it has reduced its substantial shareholding in Polynovo from 62,897,664 shares (11.29%) to 60,500,000 shares (9.29%).
The Perth, Western Australia-based Merchant Capital said that between June 9 and 22 and on October 19 it bought shares and between June 20 and October 16, 2017 it sold shares, with the single largest sale 1,290,171 shares for $315,629 or 24.5 cents a share.
Polynovo fell half a cent or 1.4 percent to 36 cents with 2.4 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says that MB Venture Partners representative on the board Gary Stevenson has resigned.
Visioneering said Mr Stevenson had been on the board since 2008.
The company said a search for an independent non-executive director.
Visioneering fell half a cent or 1.3 percent to 37.5 cents.

NUHEARA

Nuheara says it has appointed Dave Thompson as head of strategy and business development.

Nuheara said that Mr Thompson was a product and brand development innovator for consumer and professional headsets and was the founder and chief executive officer of Audiofly a manufacturer of headphones.

The company said that Mr Thompson held a Bachelor in Commerce for the Perth, Western Australia-based Edith Cowan University.

Nuheara was up 0.2 cents or 3.1 percent to 6.6 cents with 11.4 million shares traded.