



Biotech Daily

Friday January 25, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: OSPREY UP 8%; REVA DOWN 21%**
- * **DR BOREHAM'S CRUCIBLE: NEUREN PHARMACEUTICALS**
- * **RESMED H1 REVENUE UP 10% TO \$1.75b, PROFIT UP 9.6% TO \$336m**
- * **BOTANIX BTX-1204 ECZEMA TRIAL ON-TRACK**
- * **AUSCANN BUYS PERTH MARIJUANA DRUG R&D FACILITY**
- * **CARDIEX 20m CEO PERFORMANCE SHARES, 3m DIRECTOR OPTIONS EGM**
- * **COLIN MACKINNON REPLACES ALCIDION CFO DUNCAN CRAIG**

MARKET REPORT

The Australian stock market was up 0.68 percent on Friday January 25, 2019, with the ASX200 up 39.9 points to 5,905.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and one was untraded.

Osprey was the best, up one cent or 8.3 percent to 13 cents with 71,889 shares traded.

Cyclopharm climbed five percent; Opthea, Patrys, Polynovo and Prescient improved four percent or more; Dimerix, Ellex and Oncosil rose more than two percent; Clinuvel, LBT and Nanosonics were up more than one percent; with Cochlear and CSL up by less than one percent.

Reva led the falls, down five cents or 20.8 percent to 19 cents with 20,000 shares traded.

Resmed lost 12.0 percent; Proteomics shed 10.1 percent; Kazia was down 9.4 percent; Antisense and Avita fell more than four percent; Actinogen and Medical Developments were down more than three percent; Benitec, Impedimed, Mesoblast, Neuren and Telix shed two percent or more; Pharmaxis, Pro Medicus and Starpharma were down more than one percent; with Cynata and Paradigm down by less than one percent.

DR BOREHAM'S CRUCIBLE: NEUREN PHARMACEUTICALS

By TIM BOREHAM

ASX code: NEU

Share price: \$1.35

Market cap: \$139.3 million

Shares on issue: 103,170,020

Executive chairman: Dr Richard Treagus

Board*: Dr Treagus, Dr Trevor Scott, Dr Jenny Harry, Patrick Davies, Dianne Angus

Financials (September quarter): licence revenue \$13.5 million, \$11.65 cash in (June: \$1.5 million burn), cash of \$23.85 million (\$11.4 million), estimated December quarter cash outflows \$1.94 million

Identifiable major shareholders: Lang Walker 17.8%, Lanstead Capital 2.5%, Cameron Richards Pty Ltd 3.57%, Essex Castle (Trevor Scott) 3.7%, Dr Treagus 2%

* Long-serving director Larry Glass retired in December, but continues to serve as chief scientific officer.

Six months after Neuren struck a company-changing partnering deal to develop its key asset Trofinetide - formerly known less romantically as NNZ-2566 - shares in the neurodegenerative disorders house are trading at about half the pre-deal value.

While most CEOs pretend not to follow their companies' daily share price fluctuations, Neuren's Dr Richard Treagus is openly frustrated about the market's reaction to the deal with the San Diego-based Acadia Pharmaceuticals, which has a headline value of \$US465 million (\$660 million).

"Fundamentally we are in a much better position now," Dr Treagus muses.

"It makes you contemplate whether we are doing the thing that matters in terms of getting a drug progressed to market."

We presume the answer is 'yes', despite the lukewarm response from Mr Market.

The deal gave Acadia the North American rights to Trofinetide, which is targeting the rare neurological conditions Rett syndrome and Fragile X syndrome.

Crucially, Acadia funds the estimated \$US55 million cost of a planned 180-patient phase III trial for Rett syndrome, to start in the second half of 2019.

A form of autism, Rett syndrome affects about one in 10,000 females and is characterized by intellectual disability, loss of motor control and muscle rigidity.

Fragile X is an inherited chromosome mutation known as a cause of autism, affecting about one in 4,000 males and one in 6,000 females.

Despite Dr Treagus's frustrations, Neuren isn't about to pack it in and join the pot stock or bitcoin brigade.

Quite the contrary in fact: now that Acadia has assumed the cost of the phase III trial of Trofinetide, the company can hop to work on its second drug candidate, NNZ-2591 for autism spectrum disorder.

Rest of the world deal pending?

To recap, the \$US465 million headline Acadia deal delivered Neuren an upfront fee of \$US10 million, with a further \$US105 million in development milestones and up to \$US350 million of sales-based payments.

Neuren also receives double-digit royalties.

There's also another potential source of revenue for Neuren in the guise of a Rare Paediatric Disease Review Voucher, an FDA concession aimed at providing drug makers with an incentive to develop new drugs.

Drug makers with an approved product may qualify for the Willy Wonka style vouchers, which can be redeemed to receive a priority review of a different product.

They can also be sold or transferred, with the vouchers changing hands for between \$US110 million and \$US150 million.

Under the deal with Acadia, Neuren gets one-third of any spoils.

While the afflicted population is small, Acadia expects US sales of \$US500 million a year plus.

Then there's the rest of the world, to which Neuren has retained the rights.

But not for long, perhaps: in early November, Neuren and Acadia entered three-month exclusive negotiations for these rights, with the exclusivity period expiring on January 31.

Yes - next week!

"They've really been going through the socks and undies draw," Dr Treagus says of Acadia's evidently thorough due diligence of the company's 'smalls'.

Acadia received unwanted publicity with safety concerns over its Parkinson's drug Nuplazid (pimavanserin), but in September the US Food and Drug Administration delivered the anti-psychotic drug a clean bill of health (being a good mate, Neuren helpfully disclosed this in its own ASX announcement).

In October, Acadia announced positive phase II results for the drug, which Neuren says "quite clearly demonstrates Acadia's capabilities in neurology drug development".

If a global forthcoming is not forthcoming, Neuren will still enjoy the advantage of full and free access to any of Acadia's clinical material pertaining to trofinetide.

Trofinetide, by the way, helps to restore equilibrium in the brain and reduce inflammation. It is a synthetic version of the neurotrophic peptide insulin-like growth factor-1 (IGF-1), a growth factor produced by brain cells.

Lest we forget NNZ-2591

Dr Treagus says NNZ-2591 has been a "footnote" in the company's activity statement, because the company didn't have the "bandwidth or money" to further it.

"It's a white space," Dr Treagus says of autism. "There are no drugs."

"We view autism spectrum disorder as a group of diseases with some element of autism. We are looking to opening an investigational new drug application with the FDA for human trials."

Finances and performance

Apart from the general share malaise, Neuren's share slump post the Acadia deal stems from the market's perception the deal is overly back-ended (others are criticized for giving too much away for too little, too early, so it's hard to strike the balance).

"The only disappointing part of the deal was the market's reception," Dr Treagus insists.

In November 2017, the company underwent a 40-for-one share consolidation, with the shares trading between \$1 and \$3.60.

Some investors appear to be discounting the benefit of Acadia assuming the cost of the phase III trials.

In May, Acadia showed the color of its money by spending \$US4 million on 1.3 million Neuren shares at \$4 apiece, a 30 percent premium to the prevailing share price.

Acadia last November raised \$US316 million, so there's no doubt it has enough folding stuff to fund the trofinetide trial.

Post the deal, Neuren has cash of \$24 million (as of the September quarter) with very few spending commitments. "We certainly don't need to raise any money," Dr Treagus says.

On that note, the then cash-strapped Neuren entered a funding deal with global firm Lanstead Capital in July 2017.

In effect a staged share placement, the deal involved \$1.5 million with a further nominal \$8.5 million delivered over 18 months with the value dependent on Neuren's share price.

A base price of 8.86c a share was struck - equivalent to \$1.772 post consolidation - which means that at current valuation of \$1.38 Neuren receives less rather than more.

The final payment to Neuren was due in February this year, but given the lowly share price, last August the company deferred this payment until June.

Dr Boreham's diagnosis:

Share valuation aside, Neuren has indeed come along since Dr Boreham applied a full body examination to the stock in March 2017.

At the time, Neuren was recovering from the failure of its Intrepid clinical program to treat traumatic brain injury.

Neuren's auditor also kindly pointed out a "material uncertainty" if it couldn't get hold of more cash.

Financially, Neuren has the advantage of being backed by property developer Lang Walker, who has invested in other ASX biotechs including the once promising but ultimately unsuccessful combination opioid developer QRX Pharma.

Neuren is ably led by Dr Treagus who ran the transdermal oestrogen and testosterone treatment house Acrux in the company's more virile days.

In the short term, the outcome of the global rights negotiations for trofinetide is a key driver, while investors can also expect management to outline the NNZ-2591 program.

The company's December 4C (quarterly) update lobs next week, while investors should also expect news on the rest of the world trofinetide rights.

"I think 2019 will be a good year for us," Dr Treagus says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Rest assured, his undies drawer is spick and span and should pass Ms Crucible's due diligence.

RESMED

Resmed says that revenue for the six months to December 31, 2018 was up 10.2 percent to \$US1,239,380,000 (\$A1,749,591,190) taking profit up 9.6 percent to \$US237,964,000 (\$A335,880,659)

Resmed cited both US generally accepted accounting principles (GAAP) and non-GAAP data, saying it “uses non-GAAP information internally in planning, forecasting, and evaluating the results of operations in the current period and in comparing it to past periods ... [and] believe this information provides investors better insight when evaluating ... performance from core operations and provides consistent financial reporting”. This report quotes the non-GAAP data.

Resmed said that research and development expenses were up 4.9 percent to \$US81,902,000 or 6.6 percent of revenue, compared to 6.9 percent for the six months to December 31, 2017.

The company said that non-GAAP diluted earnings per share fell 9.0 percent to \$US1.66, with cash and cash equivalents of \$149,468,000 at December 31, 2018, compared to \$858,899,000 at December 31, 2017.

Resmed said it would pay a quarterly dividend of 37 US cents per share for a record date of February 7, payable on March 14, 2019.

Resmed fell \$1.98 or 12.0 percent to \$14.47 with 7.4 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it expects its 200-patient, phase II trial of its synthetic cannabinoid BTX1204, for atopic dermatitis, or eczema, to be fully recruited by October 2019.

Botanix said it had held trial an investigator’s meeting with more than 40 participants from Australia, New Zealand and US, to discuss the study protocol, the practicalities of drug application, and specific instructions on patient assessment tools for the study outcomes. The company said the 12-week, randomized, double-blind and vehicle-controlled trial would evaluate the safety and efficacy of BTX1204 on moderate atopic dermatitis.

Last year, the company reported safety and efficacy from a 37-patient phase Ib trial of BTX1204 for eczema (BD: Jun 6, 2018).

Today, Botanix executive director Matt Callahan said the company was “overwhelmed with the level of interest at the investigator’s meeting in the potential for BTX1204 to provide a novel and safe treatment for their patients with moderate atopic dermatitis”.

Botanix was up half a cent or 5.8 percent to 9.1 cents with 3.6 million shares traded.

AUSCANN GROUP

Auscann says it has bought a 7,300square metre (1.8 acre; 78,577square foot) facility for marijuana pharmaceutical research and development in Perth, Western Australia.

Auscann said the facility would focus on its cannabinoid pharmaceutical product pipeline, supporting development of both innovative formulations and dose forms.

The company said that its commitment to a pharmaceutical development program from grow and extraction technologies, through formulation and dose form development, onto clinical research, was key to meeting its commitment to patients.

Auscann executive director and interim chief executive officer Dr Paul MacLeman said the acquisition of the research and development site was “a major stepping stone for Auscann as it allows the creation of a fully integrated, state-of-the-art facility for medicinal cannabis”.

Auscann was up two cents or 3.2 percent to 65.5 cents.

CARDIEX

Cardiex investors vote to approve 20,000,000 performance shares for chief executive officer Craig Cooper and 3,000,000 options for two directors.

The Cardiex notice of meeting said that Mr Cooper's performance shares would vest in three tranches pending 30-day volume-weighted average prices of eight cents, 12 cents and 15 cents.

The company said it proposed to issue directors Randall King Nelson and Niall Cairns 1,500,000 options each, exercisable at five cents within five years.

Cardiex said the meeting would vote to ratify a prior placement, participation of director Donal O'Dwyer in the placement, and the conversion terms of notes issued to Mr Cairns and Mr Cooper's C2 Ventures company

The meeting will be held at BDO, Level 11, 1 Margaret Street, Sydney on February 26, 2019 at 10 (AEDT).

Cardiex was up 0.3 cents or 5.9 percent to 5.4 cents with 20.0 million shares traded.

ALCIDION GROUP

Alcidion says Colin MacKinnon will replace chief financial officer Duncan Craig who has resigned "for personal reasons" effective from February 28, 2019.

Alcidion said that Mr Craig was also its company secretary and a new company secretary would be appointed prior to February 28.

The company said that executive chairman and co-founder Ray Blight would continue as non-executive chairman and chief executive officer Kate Quirke had been appointed managing-director.

Alcidion said that Mr MacKinnon was currently its commercial manager had been appointed chief operating officer as well as chief financial officer.

The company said that Mr MacKinnon was a co-founder of MKM Health where he had responsibility for the commercial operations and financial management of both MKM Health and Patientrack for the past 16 years.

Alcidion said that Mr MacKinnon had more than 35 years' experience in businesses offering information technology products and services in Australia, New Zealand and the UK including managing the operational integration of acquired businesses.

The company said that Mr MacKinnon held a Bachelor of Business from the Auckland New Zealand-based Massey University.

Alcidion was up 0.1 cents or 2.3 percent to 4.5 cents.