Biotech Daily

Friday July 22, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OSPREY UP 11%; ANTISENSE DOWN 8%**

*** FACTOR THERAPEUTICS: 'US PHASE II VF-001 VENOUS ULCER TRIAL'**

*** APPLICATIONS OPEN FOR $25k SLATER & GORDON RESEARCH GRANTS**

*** US PATENT FOR REDHILL (GIACONDA) RHB-105**

*** ANATARA EARNS $2.3m REVENUE**

*** OPTISCAN $600,000 LOAN CONVERSION, TOTAL RAISED $2.8m**

*** RHINOMED SIGNS UNNAMED US PHARMACY CHAIN FOR MUTE TRIAL**

*** BT INVESTMENT INCREASES, DILUTED TO 5% OF MAYNE**

*** FOUNDER DR CHRIS HART TAKES 36% OF OVENTUS**

*** PARADIGM TO RELEASE 19.5m ASX ESCROW SHARES**

*** RESAPP WINS ASIA-PACIFIC TALENT UNLEASHED GONG**

*** BUCHAN APPOINTS ANALYST ELYSE SHAPIRO SENIOR CONSULTANT**

MARKET REPORT

The Australian stock market fell 0.26 percent on Friday July 22, 2016 with the ASX200 down 14.2 points to 5,498.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and one was untraded.

Osprey was the best, up three cents or 11.1 percent to 30 cents with 387,528 shares traded. Orthocell climbed 6.25 percent; Avita was up 4.4 percent; Bionomics improved 3.45 percent; Factor Therapeutics, Nanosonics and Reva rose more than two percent; Acrux, Compumedics, Pharmaxis and Universal Biosensors were up more than one percent; with Mesoblast, Resmed and Sirtex up by less than one percent.

Antisense led the falls, down 0.3 cents or 8.1 percent to 3.4 cents, with 70,084 shares traded. Prana lost 6.7 percent; Biotron and Genetic Technologies fell five percent or more; Atcor, Clinuvel, IDT and Viralytics were down more than three percent; Anteo, Living Cell, Medical Developments, Opthea and Prima shed two percent or more; Ellex lost 1.3 percent; with Cochlear, CSL, Impedimed, Pro Medicus and Starpharma down by more than one percent.

FACTOR THERAPEUTICS (FORMERLY TISSUE THERAPIES)

Factor Therapeutics says it hopes to start a 168-patient, phase II, US trial of VF-001 for venous leg ulcers by October 2016, with results by October 2017.

Factor Therapeutics executive director Dr Christian Behrenbruch told a Melbourne investor meeting that the company had undergone a complete "corporate turn-around" with significant staff changes including the appointment of the Boston, Massachusetts-based Bioprocess Technology Consultants (BPTC) for regulatory engagement and Boston's Parexel International as its contract research organization.

Dr Behrenbruch said that he hoped to file the investigational new drug application (IND) to the US Food and Drug Administration in August, have a two-year clinical hold lifted in September and start the trial at up to 26 sites immediately after approval.

Dr Behrenbruch said that the FDA considered VF-001, a variant of the previous Vitrogro, to be a biologic drug, whereas the European Medicines Agency defined it as "a class III device with a medical component".

The then Tissue Therapies attempted to win Conformité Européenne (CE) mark approval over several years but a range of regulatory issues prevented completion, including the classification as a drug or device.

In 2011, Tissue Therapies said it expected European sales of Vitrogro to begin by July 2012, but regulatory delays culminated in the request for data on the insulin-like growth factor-1 component of the compound (BD: Sep 30, 2011; Mar 26, 2015).

Dr Behrenbruch said that VF-001 was half matrix and half drug composed of vitronectin and insulin-like growth factor 1 (IGF-1).

Dr Behrenbruch said the compound had "a great safety profile [with] many applications beyond venous leg ulcers".

He said that completing the phase II trial would be pivotal for the company allowing it to answer all outstanding questions for CE mark registration, as well as preparing the way for a US phase III trial and potential partnership or licencing negotiations.

Dr Behrenbruch said the company had sufficient funds complete the phase II trial and continue to the end of 2017.

Dr Behrenbruch said that the Margolis severity scores for venous ulcer healing, devised by the University of Pennsylvania's Dr David Margolis categorized ulcers from least severe to moderate and severe.

He said that the five or six percent of severe patients had not responded well in the Vitrogro trials and required specialist care, while the least severe appeared to respond to the standard-of-care of bandaging and moisture dressings.

Dr Behrenbruch said that the company would target the middle 25 percent with moderate severity as well as those with mild ulcers that had not responded to the standard-of-care.

Dr Behrenbruch said that the trial would randomize the patients on a two-to-one basis with the primary endpoint wound closure after 12 weeks of once-weekly treatment and 12 weeks of follow-up.

He said that secondary endpoints included the percentage of patients fully-healed at 12 weeks as well as pain responses.

Dr Behrenbruch said that about two-thirds of the trial sites had been qualified and they were "a mix of high-end academic sites and some wound care specialist clinics".

Dr Behrenbruch said the company was actively searching for a permanent chief executive officer, but said that chief executive officer and former chief operating officer Nigel Johnson had been instrumental in the turnaround of the company.

Dr Behrenbruch said he was looking forward to returning to a non-executive director role.

Factor Therapeutics was up 0.1 cents or 2.3 percent to 4.3 cents.

SLATER AND GORDON LAWYERS.

Slater and Gordon says that applications are open for its Health Projects and Research Fund, which provides grants of up to $25,000.

Slater and Gordon said that it had allocated grants to 12 not-for-profit groups, health organizations and research bodies.

The publicly-listed law firm said that grants of up to $3,000 were available to support education initiatives of medical and allied health professionals.

Slater and Gordon chief executive officer Hayden Stephens said the fund was established to improve the care and treatment of people with asbestos-related diseases, occupation-caused cancer or significant disabilities from a catastrophic injury.

“Disability, illness and injury shapes the lives of the people and families we represent and we endeavour to make a positive impact on their quality of life,” Mr Stephens said.

“The Health Projects and Research Fund is an important way in which we can give back to people and communities in need, and ensure their best possible support and treatment,” Mr Stephens said.

Mr Stephens said that the “funding commitment of $2 million by the year 2020 demonstrates our continued commitment to the wellbeing of everyday Australians”.

For more information call +613 8644 8466, email: researchfund@slatergordon.com.au or visit www.slatergordon.com.au/researchfund.

Applications close on August 26, 2016.

REDHILL BIOPHARMA

Redhill says the US Patent and Trademark Office has allowed a new patent covering oral RHB-105 for Helicobacter pylori infection.

The Tel Aviv, Israel-based Redhill said that the patent, entitled ‘Pharmaceutical Compositions For The Treatment Of Helicobacter Pylori’ expands its patent portfolio covering RHB-105 and was expected to be valid until 2034.

The company said it was prosecuting additional US and international patent applications covering RHB-105.

In March, Redhill said a phase III trial of RHB-105, which was based on Sydney biotechnology company Giaconda’s Heliconda, showed safety and superior efficacy for Helicobacter pylori infection over the standard-of-care (BD: Mar 31, 2016).

In 2010, Giaconda sold its Myoconda, Heliconda and Picoconda patents to Redhill for $US500,000 plus seven percent of net sales (BD: Aug 17, 2010).

Today, Redhill intellectual property and research director Dr Danielle Abramson said the patent grant was “an important addition to Redhill’s expanding [intellectual property] portfolio covering RHB-105”.

Dr Abramson said that RHB-105 had been granted US Food and Drug Administration qualified infectious disease product designation, providing for eight years of US market exclusivity.

“We are making good progress with preparations for the confirmatory phase III study with RHB-105 for eradication of Helicobacter pylori, which follows the successful first phase III study with RHB-105 and a positive meeting with the FDA regarding the path to marketing approval,” Dr Abramson said.

Redhill said that Helicobacter pylori bacterial infection was “a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa-associated lymphoid tissue lymphoma” and was estimated to affect half of the adult population worldwide.

Last night on the Nasdaq, Redhill fell 14.9 US cents or 1.25 percent to $US11.75 with 40,770 shares traded.

ANATARA LIFESCIENCES

Anatara has filed an Appendix 4C Quarterly Report saying it has had receipts from customers of $2,283,000.

The Anatara notice did not explain the source of the revenue, but in January, Anatara said it had a licence option with the Florham Park, New Jersey-based Zoetis for its Detach non-antibiotic treatment for diarrhoea in farm animals (BD: Jan 27, 2016).

In April, the company said it would earn its first, confidential, non-refundable milestone payment for shipping Detach to Zoetis (BD: Apr 1, 2016).

Anatara said at that time that Zoetis would begin “an aggressive and comprehensive evaluation program using Detach in multifaceted trials across a range of livestock species”.

Anatara has previously said that it would develop the pineapple stem bromelain-based Detach for the treatment of diarrhoea in humans (BD: Oct 16, 2014).

The bromelain compound was originally being developed by Incitive as ACV0019 for cancer (BD: Oct 17, 2008).

Anatara was up seven cents or 5.6 percent to $1.33.

OPTISCAN

Optiscan says it will convert non-executive director Ian Mann’s $600,000 loan to 24,000,000 shares at 2.5 cents a share, subject to shareholder approval.

Optiscan said that entities associated with Mr Mann made the loans to the company and accrued interest would be discharged in cash.

The company said that the proposal by Mr Mann to convert the loan to equity “shows tremendous faith in the future of Optiscan from one of the directors”.

Optiscan said that the recent placement, rights issue and this conversion takes the total raised to $2,765,000.

Optiscan was untraded at two cents.

RHINOMED

Rhinomed says that an unnamed US pharmacy and drugs store chain will begin a trial of the Mute snoring and sleep technology in 100 of its shops.

Rhinomed said that the six month trial would begin in August and it had received an initial order for more than 5000 of the nasal plugs.

In March, Rhinomed said the Mute nasal plugs would be promoted through a 107-shop program in the New York-based Duane Reade chain of drug stores and Mute would be available in 891 Walgreens shops across the US (BD: May 29, 2016).

The company said that Mute was available in the US, Canada, UK and Australia.

Rhinomed was up 0.2 cents or 11.1 percent to two cents with 7.3 million shares traded.

MAYNE PHARMA GROUP

BT Investment Management says it has increased its holding in Mayne Pharma from 43,081,975 shares to 65,873,088 shares but has been diluted to 5.17 percent.

BT said it bought and sold shares between June 1 and July 19, 2016 in a large number of transactions through National Nominees, National Australian Custodian Services, National Australia Bank, JP Morgan Chase, HSBC Custody Nominees (Australia) and the ANZ Banking Group.

Mayne fell 3.5 cents or 1.8 percent to $1.93 with 6.9 million shares traded.

OVENTUS MEDICAL

Oventus founder and inventor Dr Chris Hart says he holds 26,126,513 shares or 36.29 percent of his company.
In a substantial shareholder notice, Dr Hart said he acquired the shares as trustee for the CHD (IP) Trust on September 23, 2015.
Oventus was unchanged at 89 cents.

PARADIGM

Paradigm says that 19,495,238 shares will be released from the ASX escrow on August 7, 2016.
Paradigm said that it had an agreement with the holders of 9,747,620 of the shares that they would remain in voluntary escrow for a further six months to February 7, 2017.
The company said that following the release of the 19,495,238 shares form ASX and voluntary escrow, there would be 43,916,982 shares available for trading on the ASX.
Paradigm was unchanged at 36 cents.

RESAPP HEALTH

Resapp says it has won the 'Best Tech IPO/Venture Capital Raising' award at the 2016 Talent Unleashed Awards Asia Pacific Division.
Resapp said the awards were judged by a panel including Apple co-founder, Steve Wozniak and Virgin Group founder Richard Branson and recognized "disruptive entrepreneurs who utilise innovative technology solutions to truly make an impact in their field".
The company said that it would proceed to the global grand finals to be held in Sydney on August 18, 2016, with prizes including a tour of Californian technology companies.
Resapp was up two cents or 6.1 percent to 35 cents with 9.7 million shares traded.

WE BUCHAN

WE Buchan says it has appointed consultant and equities analyst Elyse Shapiro as a senior consultant, in June.
Buchan said that Ms Shapiro was the third analyst to join the investor relations and communication agency following former Wilson HTM corporate finance analyst Catherine Ross and Goldman Sachs' Andrew Gibson.
The agency said that Ms Shapiro was previously employed with New York investment bank Cowen Group as a biotechnology equity research associate.
Buchan said that Ms Shapiro held a Bachelor of Arts in biology from New York's Columbia University.