Biotech Daily

Tuesday October 16, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: BENITEC UP 13%; PRANA DOWN 6%**

*** FDA APPROVES EYEPOINT (PSIVIDA) YUTIQ (DURASERT)**

*** TELIX: SEIBERSDORF TO MANUFACTURE TLX101 FOR GLIOBLASTOMA**

*** CARDIEX TO PAY MORE THAN $4.6m FOR 50.5% OF INHEALTH**

*** FACTOR HIRES TAYLOR COLLISON FOR VF001 LEG ULCER DEALS**

*** MEDIBIO BACK TO BIOPROSPECT FUTURE BOARD SPILL AGM**

*** PHYLOGICA 10m CEO DR ROHAN HOCKINGS OPTIONS AGM**

*** ANTISENSE PLEADS SCHULTZ TO ASX 59% QUERY; ASX MISSES 159%**

*** MGC REQUESTS 'ASX PRICE QUERY' TRADING HALT**

*** PRUDENTIAL (M&G) REDUCES TO 14% OF MESOBLAST**

*** AUSTRALIAN ETHICAL TAKES 7.4% OF ACTINOGEN**

*** PETER, DIANA DIAMOND TAKE 12.2% OF NOVITA**

*** HYDROPONICS WELCOMES CANADA RECREATIONAL MARIJUANA**

*** ESENSE REQUESTS 'COMMERCIAL SUPPLY AGREEMENT' TRADING HALT**

MARKET REPORT

The Australian Stock Market was up 0.56 percent on Tuesday October 16, 2018 with the ASX200 up 32.8 points to 5,869.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and six were untraded.

Benitec was the best, up two cents or 12.9 percent to 17.5 cents, with 226,595 shares traded. Impedimed climbed 11.0 percent; Osprey improved 7.3 percent; Telix was up 6.1 cents; Imugene rose five percent; Avita, Neuren and Reva were up more than four percent; Ellex and Medical Developments were up more than three percent; Actinogen, Immutep and Oncosil rose more than two percent; Prescient and Volpara were up more than one percent; with Cochlear up 0.2 percent.

Prana led the falls, down 0.3 cents or six percent to 4.7 cents, with 32,715 shares traded. Compumedics lost 5.95 percent; Cyclopharm fell 4.6 percent; Clinuvel and Paradigm were down more than three percent; Bionomics and Orthocell shed more than two percent; Mesoblast, Nanosonics, Opthea, Pharmaxis, Pro Medicus, Resmed and Starpharma were down more than one percent; with CSL and Polynovo down by less than one percent.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA CORP)

Eyepoint says the US Food and Drug Administration has approved Yutiq, formerly known as Durasert and Medidur, for posterior uveitis.

In March, the then Psivida said the FDA had accepted its new drug application for Durasert three-year treatment for posterior segment uveitis and said it had a Prescription Drug User Fee Act (PDUFA) date of November 5, 2018, which was the goal date for the FDA to complete its review (BD: Mar 20, 2018).

The company said that the application included data from two phase III studies which showed that each achieved the primary efficacy endpoint at six months ($p < 0.001$).

Today, Eyepoint said that Yutiq used the Durasert drug delivery technology and was a non-bio-erodible, intra-vitreal micro-insert containing 0.18mg fluocinolone acetonide, designed to release consistently over 36 months.

The company said that Yutiq was supplied in a sterile, single-dose, preloaded applicator that could be administered in the physician's office.

Eyepoint said that in clinical trials, Yutiq "significantly reduced the rate of recurrent uveitis flares versus sham and the most common adverse reactions reported were cataract development and increase in intraocular pressure".

Eyepoint chief executive officer Nancy Lurker said the approval of Yutiq was "a significant milestone … and marks the second approved ophthalmic product in our pipeline that we plan to commercialize ourselves in the US".

"Yutiq was developed internally by our research team and this approval further validates our capabilities to successfully design, develop and gain regulatory approval for an ophthalmology product to address a disease with high unmet need," Ms Lurker said.

Ms Lurker said that chronic non-infectious posterior uveitis was the third leading cause of blindness in the US and she expected a product launch by April 2019.

Eyepoint said that 24-month and 36-month patient follow-up from the first phase III trial of Yutiq were expected by the end of 2018 and by July 2019, respectively.

The company said it was developing "a next-generation, shorter-duration treatment" for chronic non-infectious posterior uveitis, based on the Durasert technology and planned to file an application for approval in 2019 and it intended to launch Dexycu for post-operative inflammation at the end of cataract surgery, by July 2019.

On the Nasdaq, Eyepoint was up 22 US cents or 6.81 percent to $US3.45 ($A4.84) with 2.3 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has appointed the Austria-based Seibersdorf Labor GmbH for the commercial manufacture of TLX101 for glioblastoma.

Telix said it had been working with Seibersdorf under a technology transfer and research agreement for the past year, during which the parties have implemented and validated the use of an automated production system for the manufacture of TLX101 or 131-iodine-iodo-L-phenylalanine (131-I-IPA).

The company said that optimization of the manufacturing process resulted in "commercially viable radio-chemical yields and a product shelf-life exceeding 100 hours, suitable for centralized manufacturing and global distribution of product for both Telix-run trials and compassionate use".

Seibersdorf head of the radio-pharmaceuticals Dr Roland Müller said the TLX101 program was "an exciting opportunity for our organization and we are pleased to be working with Telix to deliver this drug product for both clinical trials and potentially commercial use".

Telix was up 4.5 cents or 6.1 percent to 78.5 cents.

CARDIEX

Cardiex says it will pay more than $4.6 million for up to 50.5 percent of the Inhealth Medical Services for its “health coaching and Telehealth services”.

Cardiex said that the Los Angeles-based Inhealth provided digital, electronic commerce and mobile telephone tools for patients to connect online with health coaches as part of a patient care management program.

The company said that the Inhealth coaching programs were based on multi-year published studies that showed clinically-based health outcomes through the use of its health coaching tools.

On its website, Inhealth said it offered programs in medical weight loss, sport nutrition, diabetes prevention, chronic care and population health “for a fun, safe effective way to reach your health goals”.

Cardiex said it would acquire the majority stake in Inhealth through three convertible notes worth $US3,250,000 ($A4,558,759) and 12 times the three months revenue to the earlier of the date of exercise or June 30, 2021, with all convertible notes carrying an interest rate of 6.0 percent per annum.

The company said it would have an option to acquire shares from Inhealth founders at 12 times the three months revenue to the earlier of the date of exercise or June 30, 2021

Cardiex said the first tranche convertible note was for $US250,000 for 7.7 percent stake, which was funded from existing cash reserves on October 15, 2018 with a maturity date of January 31, 2019.

The company said the second tranche $US3,000,000 convertible note would be invested on January 31, 2019 with a maturity date of July 1, 2020, providing a further 33.33 percent stake in Inhealth for a total investment of 41.33 percent.

Cardiex said the third convertible note would be worth 9.467 percent on Inhealth and take the total investment to 50.5 percent and would occur between June 30, 2020 and the maturity date of June 30, 2021, worth 12 times the three months revenue to the earlier of the date of exercise or June 30, 2021.

The company said that it would have the right to nominate two directors to the Inhealth board of up to four directors, with a third Cardiex director to join the expanded board of five directors on completion.

Cardiex said that pending the completion of due diligence the acquisition would be a “major step forward in Cardiex’s digital and consumer health strategy”

The company said that Inhealth would provide its core technology “with direct channels to both the consumer, health insurance, and practitioner markets” and gave it access to US health insurance companies and healthcare providers with multi-year contracts including American Well, the largest US tele-medicine operator and US health insurer Anthem.

Cardiex said that Inhealth provided a platform for the development and sale of insurance-backed technologies covering multiple health disorders, with a business model based on multi-tier revenue structures and would be “financially accretive to Cardiex in a short timeframe, with Inhealth … forecast to become profitable in 2019”.

The company said that Inhealth had an “in-house clinical trial group that can cost-effectively run and manage clinical trials for Cardiex group products”.

Cardiex said that the trials could be used for furthering US Food and Drug Administration approvals where relevant and support the validity and efficacy of Inhealth’s programs to new clients and partners”.

The company said that Inhealth had a “team of healthcare executives with a proven track record in developing reimbursement-based healthcare products and services”.

Cardiex was up 0.2 cents or 6.45 percent to 3.3 cents with 1.3 million shares traded.

FACTOR THERAPEUTICS

Factor says it has appointed Taylor Collison to assist with partnering discussions and advise on transactions following a successful phase II leg ulcer trial.
Factor said it was “in advanced discussions with potential partners pending the outcome of [its] phase II study of VF001 in venous leg ulcers”.
The company said that “following an extensive search and evaluation process … [it had appointed] Taylor Collison based on their transaction experience in healthcare, relevant expertise in the wound care space and close working history with the company”.
Factor chief executive officer Dr Rosalind Wilson said the company “evaluated several US and European firms … but, given the geographic range of potential partners and acquirers, we didn’t see a strong advantage working with an overseas firm”.
Factor Therapeutics was unchanged at 6.7 cents with 1.6 million shares traded.

MEDIBIO (FORMERLY BIOPROSPECT)

Medibio shareholders will vote to remove chairman Chris Indermaur and director Andrew Maxwell and appoint Benjamin Richardson, Peta Slocombe and Elias Khouri as directors
Earlier this month, Medibio said it received a Section 249D of the Corporations Act 2001 notice from Elias Leo ‘The Gun’ Khouri and associates requesting an extraordinary general meeting to remove Mr Indermaur and Mr Maxwell and appoint Mr Richardson, Ms Slocombe and Elias Khouri as directors (BD: Oct 1, 2018).
Medibio said the notice came from Carakho Holdings Pty Ltd, SEK Investments Limited, Bejjol Pty Ltd, Mining Investments Limited, Gun Capital Management Pty Ltd, Joshua Khouri, Benjamin Khouri and Ms Slocombe who claimed to hold about 6.29 percent of the company.
Today the company said the board considered that the resolutions one to five relating to the board spill were “not in the best interests of the company and recommends that you vote against the proposed resolutions”.
Medibio said the meeting would also vote on the remuneration report, the ratification of the prior issue of 15,225,000 options, the 10 percent placement capacity and the election of directors Peter Carlisle, Patrick Kennedy and Dr Franklyn Prendergast.
The meeting will be held at Chartered Accountants Australia and New Zealand, Level 18, 600 Bourke Street, Melbourne, on November 16, 2018, at 2pm (AEDT).
Medibio fell 0.6 cents or 11.3 percent to 4.7 cents.

PHYLOGICA

Phylogica says its annual general meeting will vote to issue chief executive officer Dr Rohan Hockings 10,000,000 options exercisable at 3.9 cents by November 16, 2021.
Phylogica said that the current indicative value of the options was $126,258 using the Black and Scholes pricing model.
The company said that Dr Rohan Hockings was the son of director Dr Bernard Hockings and therefore a related party.
Phylogica said that investors would vote on the remuneration report, the ratification of the issue of 146,166,674 placement shares, approval for directors to participate in the placement, termination benefits to Dr Rohan Hockings and the election of directors Sahm Nasseri, Alan Tribe and Dr Bernard Hockings.
The meeting will be held at Level 5, Perth Children’s Hospital, 15 Hospital Avenue, Nedlands, Western Australia, on November 16, 2018 at 2.30pm (AWST).
Phylogica was up 0.2 cents or 6.9 percent to 3.1 cents.

ANTISENSE THERAPEUTICS

Antisense 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 58.8 percent from 1.7 cents on October 15 to 2.7 cents today October 16, 2018 and noted a "significant increase" in trading volume.
Antisense said that a report on the company was published today in an online business report.
Antisense closed up 3.7 cents or 217.65 percent to 5.4 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a trading halt "pending our response to an ASX price query".
Trading will resume on October 18, 2018 or on an earlier announcement.
MGC last traded up 1.6 cents or 25.4 percent to 7.9 cents with 67.3 million shares traded.

MESOBLAST

Prudential PLC says with its subsidiaries it has reduced its holding in Mesoblast from equivalent to 69,390,670 shares (14.73%) to 68,041,831 shares (13.67%).
The London-based Prudential said that it bought and sold shares between December 13, 2017 and September 11, 2018.
Apart from buying 1,786,426 shares for $2,643,910 and selling 1,786,426 shares for $2,643,910 on May 21, 2018, Prudential said it sold 203,213 shares for $287,548 or $1.415 a share on May 15 and 188,929 shares for $301,660 or $1.597 a share on August 20, 2018.
Mesoblast fell three cents or 1.5 percent to $2.03 with 590,070 shares traded.

ACTINOGEN

Australian Ethical Investment says it has become a substantial shareholder in Actinogen with 80,323,117 shares or 7.37 percent of the company.
The Australian Ethical substantial shareholder said that between July 2 and October 12, 2018 it bought 37,323,117 shares for $1,517,163 or an average price of 4.06 cents a share.
Actinogen was up 0.1 cents or 2.2 percent to 4.6 cents with 1.7 million shares traded.

NOVITA HEALTHCARE

Peter and Diana Diamond say they have increased their holding in Novita from 52,500,000 shares (11.68%) to 55,000,000 shares (12.24%).
The Perth, Western Australia-based Peter and Diana Diamond said they bought the 2,500,000 shares on-market between September 14 and October 12, 2018 for $85,550, or 3.42 cents a share.
Novita was untraded at 3.2 cents.

THE HYDROPONICS COMPANY

Hydroponics says it welcomes the introduction of legal access to recreational marijuana in Canada from tomorrow, October 17, 2018.

Hydroponics said it would be legal for adults in Canada to purchase, possess, or grow recreational marijuana.

The company said its wholly-owned subsidiary Crystal Mountain manufactured and distributed hydroponic equipment and supplies, with Canada its principal market.

Hydroponics was up 6.5 cents or 11.8 percent to 61.5 cents.

ESENSE-LAB

Esense has requested a trading halt "pending an announcement regarding a commercial supply agreement".

Trading will resume on October 18, 2018 or on an earlier announcement.

Esense closed up 2.8 cents or 75.7 percent to 6.5 cents.