Biotech Daily

Wednesday October 11, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: FACTOR THERAPEUTICS UP 12%; AVITA DOWN 24%**

*** MEDIBIO 'MISUNDERSTANDING' LEAKS NEWS BEFORE ASX TOLD**

*** BIOTECH DAILY EDITORIAL: SELECTIVE BRIEFINGS**

*** PARADIGM TELLS ASX: 'OLDS, NOT NEWS LEAK, PUSHED PRICE 20%'**

*** PRANA REFRESHES $64m AT-THE-MARKET FACILITY**

*** AZURA RAISES $21m FOR MEIBOMIAN GLAND DYSFUNCTION**

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*** BENITEC TO LOSE COO DR CLIFF HOLLOWAY**

MARKET REPORT

The Australian stock market was up 0.59 percent on Wednesday October 11, 2017 with the ASX200 up 34.0 points to 5,772.1 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and three were untraded.

Factor Therapeutics was best, up 0.6 cents or 12.0 percent to 5.6 cents with 1.25 million shares traded. Orthocell climbed 10.7 percent; Actinogen was up 9.6 percent; Uscom was up 6.25 percent; Oncosil and Volpara improved more than four percent; Airxpanders, Benitec, Ellex, ITL, Pharmaxis and Polynovo were up more than three percent; Compumedics, Living Cell, Medical Developments and Nanosonics rose more than two percent; with Osprey, Sirtex and Viralytics up more than one percent.

Avita led the falls, down two cents or 23.5 percent to 6.5 cents with 75.3 million shares traded. Dimerix lost 12.5 percent; Neuren was down 7.1 percent; Impedimed fell 6.25 percent; Prana was down 5.1 percent; LBT lost 3.1 percent; Starpharma shed 2.4 percent; with Clinuvel, Cyclopharm, Mesoblast and Pro Medicus down more than one percent.

MEDIBIO

Medibio says a “misunderstanding” led to a newspaper being informed of its Otsuka deal before the ASX and shareholders, breaching Listing Rule 15.7 (BD: Oct 9, 2017).

The ASX said that on Monday October 9, 2017 Medibio told the ASX at 8.52am that it had the deal with Otsuka, but the news had been published previously in a daily newspaper.

The ASX told Medibio that Listing Rule 15.7 stated: “An entity must not release information that is for release to the market to any person until it has given the information to ASX and has received an acknowledgement that ASX has released the information to the market.”

“Listing Rule 15.7 prohibits an entity from releasing information which is for release to the market to any person, including the media, even on an embargoed basis, until it has given the information to [the] ASX and received an acknowledgment that [the] ASX has released it to the market,” the ASX said.

“As the article appeared in The Australian newspaper prior to any announcement being released to ASX, it appears that the company may be in breach of listing rules 3.1 and/or 15.7,” the ASX said.

Medibio said the information was supplied by Medibio’s shareholder engagement and public relations consultants, NWR Communications, on October 8, 2017 and said that they were involved in the ASX announcement drafting.

“It was supplied on the understanding that it was embargoed and the announcement would be released at the earliest possible time which was pre-market opening [on] Monday October 9, 2017,” Medibio said.

“The release to The Australian was the result of a misunderstanding of the disclosure requirements,” Medibio said.

“Medibio now understands it is not appropriate to provide information to the media on an embargoed basis prior to confirmation of its release through the ASX,” the company said.

“The company takes its disclosure obligation very seriously and this incident was the result of a misunderstanding about the timing of the release of information,” Medibio said.

“The company will conduct further training on listing rules 3.1 and 15.7 with its directors, senior management and advisors,” Medibio said.

Medibio was in a trading halt for a capital raising and last traded at 40.5 cents.

BIOTECH DAILY EDITORIAL

Medibio is far from the first company to have found its way into a mass-market publication prior to making its announcement to the ASX.

In recent days Epat and Paradigm have also had articles published about their activities before making the announcement to the ASX (BD: Jul 19, Oct 10, 2017).

The practice is known as selective leaking and public relations and marketing companies think it is clever to provide a media release early to one tame journalist who can then claim it as a “scoop exclusive”.

A media release can never be a “scoop”, which requires original research, and it is not very exclusive if the whole world will be told the same news a little bit later.

One thing it does guarantee is that every other journalist will dislike both the public relations company and company employing them for playing favorites.

It is also in breach of the ASX Listing Rules.

The ASX told Biotech Daily that repeated breaches or breaches while the market was trading could result in an immediate suspension and a referral to the Australian Securities and Investments Commission.

David Langsam, Editor

PARADIGM BIOPHARMACEUTICALS

Paradigm has told the ASX that month-old news, rather than leaking a media release to a mass-market newspaper, pushed yesterday's share price up 20 percent.

The ASX said that during the course of trading yesterday the company's securities were up 20 percent on the day to 42 cents and asked whether Paradigm was in compliance with Listing Rule 15.7, which required announcements to be made to the ASX prior to general release, including media outlets.

Paradigm said that yesterday's announcement "was a follow up with data as foreshadowed in the previous ASX announcement".

In September, Paradigm reported a case study of one woman with osteoarthritis and bone marrow oedema lesions who was treated with pentosan polysulfate sodium (PPS) reducing her pain response from eight of 10 to zero of 10 and following PPS treatment, the patient discontinued the use of a non-steroidal anti-inflammatory drug and a surgical procedure was no longer required (BD: Sep 11, 2017).

The company said in September that 30 people with bone marrow oedema lesions and osteoarthritis had been treated with PPS with similar outcomes to the single patient study and it expected to start a 100-patient, randomized, double-blind, placebo-controlled phase IIb trial of PPS for bone marrow oedema lesions and osteoarthritis "later this year".

Yesterday, following publication in a mass-market newspaper, Paradigm told the ASX that 24 patients were treated with pentosan polysulfate sodium under the TGA special access system, with joint pain reduced in 83 percent, or 20 patients, and knee function was improved in 80 percent or 19 patients.

The ASX asked what arrangements the company had to ensure compliance with Listing Rule 15.7 and Paradigm said it "monitors its ASX listing rule obligations with a particular emphasis on continuous disclosure".

"We immediately publish any information which may be market sensitive," the company said. "Paradigm places a high importance on compliance and is fully compliant with the listing rules."

"In Paradigm's view, the ASX market was already fully aware on September 11, 2017 of the results of the 30 patient study," the company said.

"The ASX announcement published today was primarily used to reduce enquiry from existing Paradigm shareholders reading The Australian article today and wanting to understand if it was the same study as published on September 11," the company said.

"Paradigm expects that the movement in share price today was as a result of investors reading the company's announcement of September 11 today prompted by The Australian article today," the company said. "Paradigm does not believe that the ASX announcement today of itself would support the share price increase in the light of the announcement on September 11."

Paradigm provided no specific data on either the 24 patients or the 30 patients in the September 11 announcement but published specific data in yesterday's media release.

Paradigm was up two cents or 5.2 percent to 40.5 cents.

PRANA BIOTECHNOLOGY

Prana says it has filed a US Securities and Exchange Commission Form F-3 to refresh its $US50 million ($A64.2 million) at-the-market facility.

Prana executive chairman Geoffrey Kempler told Biotech Daily that the company had drawn down $US5,539,213 since establishing the facility in 2015.

Mr Kempler said the SEC filing expired after time and required re-filing.

Prana fell 0.3 cents or 5.1 percent to 5.6 cents.

AZURA OPHTHALMICS

Azura says it has raised $US16 million ($A20.6 million) for a 120-patient phase IIa trial of its MGT001C1 treatment for meibomian gland dysfunction.

Azura chief executive officer Marc Gleeson said that the Brandon Capital managed Medical Research Commercialisation Fund (MRCF), along with the San Francisco-based TPG Biotech, New York's Orbimed and Paola Alto, California-based Ganot Capital contributed equally to the capital raise.

The Sydney-based Mr Gleeson said that the Israeli-Australian company would use the funds to take the drug to the next clinical stage in the development of its treatments for meibomian gland dysfunction, in which the eyelid's meibomian glands become dysfunctional, resulting in rapid evaporation of the tear film.

In its media release Azura said the meibomian glands in the upper and lower eyelids were responsible for producing the oily layer that formed the outer layer of a person's tear film and worked with the watery layer of the tear film to maintain clear vision and ocular health.

Mr Gleeson said that meibomian gland dysfunction was responsible for more than 70 percent of dry eye cases and affected about 300 million people worldwide.

"Despite significant efforts there are no pharmaceutical treatments available for this condition," Mr Gleeson said.

"Azura has generated promising results in a phase I study … [and] we are therefore optimistic that Azura's treatment could one day provide the first effective treatment for [meibomian gland dysfunction]," Mr Gleeson said.

Mr Gleeson said that Azura was founded in Tel Aviv, Israel in 2014 and had conducted the research to this point but all further research, clinical trials and the development of the drug treatment would be conducted in Australia.

Brandon director and MRCF chief executive officer Dr Chris Nave said Australia was a medical research leader, but a lack of investment meant discoveries left the country".

Dr Nave said the Research and Development Tax Incentive and $500 million Biomedical Translation Fund were attracting foreign life science companies like Azura, stimulating the industry, creating jobs and retaining clinicians, scientists and their research.

Azura is a private company.

AVITA MEDICAL

Avita says it has commitments from investors for a $4.5 million placement at 4.5 cents a shares and a fully underwritten rights issue for a further $12.4 million.

Avita said the funds would be used for its US Recell commercialization for burn injuries and to further evaluate new indications.

The company said it would offer a one-for-2.8 shares rights issue for investors on the record date of October 18, it would open on October 20 and close on November 2, 2017.

Avita said the rights offer was underwritten by Bell Potter.

Avita chief executive officer Dr Mike Perry said the placement indicated "confidence in Avita's pursuit of its future milestones" including US approval in 2018 followed by a successful commercial launch of Recell in the US burns market.

Avita fell two cents or 23.5 percent to 6.5 cents with 75.3 million shares traded.

IMUGENE

Imugene says it has received $1,136,765 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imugene was up 0.1 cents or 6.7 percent to 1.6 cents with 1.7 million shares traded.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri has told the ASX that reports by media personality Alan Kohler may have pushed its share price 50 percent to 5.7 cents a share.

The ASX said the company's share price climbed 50.0 percent from 3.8 cents on October 5 to 5.7 cents on October 10, 2017, and noted a significant increase in trading volumes.

According to the ASX, poker machine entrepreneur Bruce Mathieson is a major holder through his Investment Holdings Pty Ltd with 71,999,999 shares or 16.55 percent.

Respiri said that on October 4, 2017 Mr Kohler published a report on 'The Constant Investor' website and his Twitter feed saying "One of the most exciting stocks I've brought you so far Respiri … creates technologies to better manage asthma".

"Alan Kohler believes it's one of the most exciting stocks The Constant Investor has ever brought to the table," Respiri said, quoting the website and Twitter feed.

Respiri, and previously Isonea and Karmelsonix, has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006).

In 2015, the then Isonea said it had lost its fourth chief executive officer in 12 months and later said one of the issues with its asthma diagnostic was that it did not detect breath sounds (BD: Jan 23, Aug 6, 2015).

The company changed its name to Respiri at the end of 2015 and earlier this year lost the services of its founding company secretary, the CFO Solution.

Respiri fell 0.8 cents or 15.1 percent to 4.5 cents with 2.95 million shares traded.

OVENTUS MEDICAL

Oventus says that a seven patient study shows its O2Vent reduces obstructive sleep apnoea events by 79.65 percent from 34.4 to 7.0 events/hour ($p = 0.03$).

Oventus said the O2Vent was "as effective for patients with and without high nasal resistance" and increased nasal resistance could be a reason for non-response when using other oral appliances.

The company said the interim results from a study conducted with Neuroscience Research Australia would be presented at the World Sleep Congress in Prague, Czech Republic October 7 to 11 October, 2017, entitled 'The effects of posture and mandibular advancement on nasal resistance and obstructive sleep apnoea treatment outcome with a novel oral appliance therapy device' and presented by Prof Danny Eckert.

The company said the study would recruit 40 patients in the first year, 40 in the second year and 100 patients in the third year and was funded by a Federal Government $2.95 million co-operative research centre program grant.

Oventus said that nasal resistance could be a reason for treatment failure when using a device that only provided mandibular advancement which managed tongue base obstructions, but its O2Vent managed tongue base obstructions and bypassed nasal obstruction, soft palate collapse and reduce airway collapsibility.

Oventus said that tongue base might be involved in 40 percent of obstructions and the O2 Vent was "the only oral appliance that manages other levels of obstruction such as the nose and soft palate".

The company said that patients in the study would typically be using a continuous positive airways pressure (CPAP) device with a facial mask, but reducing obstructive sleep apnoea events to 7.0 per hour meant they no longer require a CPAP device.

The company said that final results from the first 40 patients were expected by July 2018.

Oventus fell half a cent or 1.3 percent to 38 cents.

PSIVIDA CORP

Psivida says it has a collaboration with Nicox SA to combine their technologies to lower intraocular pressure (IOP) in patients with glaucoma or ocular hypertension.

Psivida said the collaboration would combine its bio-erodible sustained release drug delivery system with the Valbonne, France-based Nicox's nitric oxide-donating compounds, to develop a sustained release drug to lower intraocular pressure.

The company said the partnership would select nitric oxide-donating candidates, with Psivida responsible for initial development activities of ocular insert formulations, for which it will receive undisclosed sums by Nicox.

Psivida said the companies could elect to proceed with further development, including more detailed non-clinical studies to generate pre-clinical data, and the evaluation of further compounds under the collaboration.

The company said that Nicox would make additional payments for any incremental development activities and new intellectual property would be jointly owned.

Psivida said the companies would negotiate a separate licence agreement for any product candidate that they wanted to develop and commercialize.

The company said the expected payments were not considered material to Nicox's financial statements.

Nicox chief scientific officer Michael Bergamini said that there was “strong pre-clinical data demonstrating the IOP lowering effect of our novel stand-alone [nitric oxide] donors, such as our lead NCX667 and believe that their profile makes them product candidates for potential sustained release delivery”.

“The bio-erodible technology in development by Psivida, combined with their proven success in developing sustained delivery devices for the eye, puts them at the forefront of this exciting area,” Mr Bergamini said.

Psivida chief executive officer Nancy Lurker said the “novel approach to IOP-lowering with our bio-erodible, sustained delivery device could offer a unique therapy alternative or adjunct to existing therapies to lower IOP in order to help prevent the development and progression of glaucoma”.

The company said that glaucoma was a group of ocular diseases in which the optic nerve was injured, leading to peripheral and, ultimately, central visual loss, and blindness, if not treated and was frequently linked to abnormally high intraocular pressure due to blockage or malfunction of the eye’s aqueous humor drainage system”.

Psivida was untraded at $1.50.

ACTINOGEN MEDICAL

Actinogen says Canada has granted a patent covering Xanamen for use in a metabolic and neurological diseases including Alzheimer’s disease.

Actinogen said the patent, entitled ‘3,3-disubstituted-(8-aza-bicyclo[3.2.1]oct-8-yl)-[5-(1h-pyrazol-4-yl)-thiophen-3-yl]-methanone and related compounds and their use’ would provide coverage until 2031.

The company said that key patents had been granted in the US, UK, European Union, Japan, China, Canada and Australia, extending to at least 2031.

Actinogen chief executive officer Dr Bill Ketelbey said “the strength of the Xanamem [intellectual property] we are developing is reaffirmed with the grant of patents in these key countries”.

“Xanamem is now patent protected in more than 80 percent of the global Alzheimer’s market,” Dr Ketelbey said.

Actinogen was up half a cent or 9.6 percent to 5.7 cents.

PATRYS

Patrys says it has been granted a key US patent for its immunoglobulin M (IgM), anti-cancer, pre-clinical candidate PAT-LM1.

Patrys said the patent, entitled 'LM-1 antibodies, functional fragments, LM-1 target antigen, and methods for making and using same' and would provide intellectual property coverage until March 14, 2034.

The company said that the US patent was derived from one of a series of patent applications submitted to cover the PAT-LM1 product and target and the claims in the patent covered PAT-LM1 for treating colon cancer metastasis.

Patrys said that eight patents across the PAT-LM1 families had been granted in the US, Europe and UK with an additional application pending in Europe.

Patrys chief executive officer Dr James Campbell said the company had "an ongoing program to out-licence PAT-LM1 and the granting of this additional patent strengthens the [intellectual property] portfolio for business development efforts".

Patrys climbed 25 percent to 20 cents but closed unchanged at 1.6 cents with 37.6 million shares traded.

ORTHOCELL

Orthocell says it has appointed the Sydney-based Surgical Specialties Pty Ltd as its exclusive distributor for Australia and New Zealand.

Orthocell said that under the five year agreement, Surgical Specialties would assume distribution responsibilities for its Ortho-ACI cartilage and Ortho-ATI tendon regeneration cell therapies, including promotion activities, sales and assisting with expanding the network of referring doctors and physicians.

Orthocell managing-director Paul Anderson said that Surgical Specialties was a "leading distributor of innovative medical devices and one of the few local companies with its own national sales force and marketing teams".

"Surgical Specialties is the ideal partner with established relationships with leading orthopaedic surgeons and sports physicians, a successful track record and a highly skilled and dedicated national sales force," Mr Anderson said.

Surgical Specialties chief executive officer Phil Nicholl said Orthocell had "the only cell therapy intervention listed on the Australian Register of Therapeutic Goods for the repair of damaged or degenerate cartilage in the knee or ankle joint, and an innovative market leading approach for the repair of degenerate tendons".

"Both products are based on ground-breaking technology and [address] a significant clinical need, particularly in the orthopaedic and sports physician market," Mr Nicholl said.

Orthocell was up three cents or 10.7 percent to 31 cents.

OPTISCAN IMAGING

Robert Peters and Peters Investments say they have increased their substantial share in Optiscan from 25,031,112 (6.69%) to 43,431,112 (10.32%).

In 2016, the Cottesloe, Western Australia-based Mr Peters said he was a director of Peters Investments (BD: Jan 22, 2017).

Today, Mr Peters said that between March 23 and 30, 2017, he acquired 587,100 shares for $38,892 or an average of 6.6 cents a share on-market and on October 4 bought 16,400,000 shares for $1,312,000 or eight cents a share in the recent share plan and placement, which raised $3.5 million (BD: Oct 4, 2017).

Optiscan was up 1.7 cents or 17.35 percent to 11.5 cents with one million shares traded.

BENITEC BIOPHARMA

Benitec says that chief business and operations officer Dr Cliff Holloway has resigned effective from “early January 2018 … to pursue other interests overseas”.

Benitec said that in the event of any transition period chief executive officer Greg West would manage Dr Holloway’s responsibilities.

Benitec was up half a cent or 3.3 percent to 15.5 cents.