Biotech Daily

Tuesday December 18, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PARADIGM UP 13%; OSPREY DOWN 13%**

*** PARADIGM: 'PPS REDUCES OSTEOARTHRITIS PAIN'**

*** RESPIRI PLACES $3.2m; PLAN FOR $1m MORE; WORKPLACE WHEEZO**

*** MERCHANT PLACES BARD1 $1.1m SHORTFALL; TOTAL RAISED $3.3m**

*** DORSAVI RAISES $2.1m OF HOPED-FOR $3.2m**

*** AVITA RECEIVES $1.4m FEDERAL R&D TAX INCENTIVE**

*** BOTANIX READY FOR PHASE II BTX1204 ECZEMA TRIAL**

*** ANALYTICA RESUMES US PERICOACH SALES**

*** OBJ: PROCTER & GAMBLE LICENCE FOR 1st INTEGRATED PRODUCT**

*** CYNATA SENDS GVHD RESULTS TO FUJIFILM FOR OPTION DECISION**

*** MAYNE RE-ACQUIRES SUBA-ITRACONAZOLE RIGHTS FROM HEDGEPATH**

*** CARDIEX, UNNAMED COMPANY PARTNER FOR SLEEP DISORDERS**

*** RECCE CHAIR DR GRAHAM MELROSE LENDS $200k**

*** LIFESPOT TO RELEASE 28m ASX ESCROW SHARES**

*** MEDICAL DEVELOPMENTS LOSES ALLAN MCCALLUM; 'HELP WANTED'**

MARKET REPORT

The Australian stock market fell 1.22 percent on Tuesday December 18, 2018, with the ASX200 down 68.8 points to 5,589.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and six were untraded. All three Big Caps fell.

Paradigm was the best, up 17.5 cents or 13.3 percent to $1.495 with 5.3 million shares traded. Cyclopharm climbed 9.5 percent; both Orthocell and Proteomics improved 6.7 percent; Cynata was up four percent; Airxpanders climbed 3.85 percent; Optiscan rose two percent; Avita was up 1.3 percent; with Nanosonics, Opthea and Telix up by less than one percent.

Osprey led the falls, down 1.5 cents or 13.0 percent to 10 cents with 472,726 shares traded. Imugene, Mesoblast and Starpharma fell five percent or more; Impedimed, Prescient and Universal Biosensors lost more than four percent; Antisense, Immutep, Medical Developments and Patrys were down more than three percent; Actinogen, Oncosil, Pro Medicus, Resmed and Reva shed two percent or more; Clinuvel, Cochlear, CSL, Ellex and Volpara fell more than one percent; with Polynovo down 0.85 percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its 112-patient, phase IIb trial shows pentosan polysulfate sodium significantly reduces knee osteoarthritis pain compared to placebo (p = 0.031).

Paradigm said that 126 patients with knee osteoarthritis and bone marrow oedema lesions enrolled in the trial, with 112 evaluable after receiving 2mg/kg of pentosan polysulfate sodium (PPS) by subcutaneous injection, twice weekly for six weeks, or 42 days.

The company said that the primary endpoint was the change in knee injury and osteoarthritis outcome score (KOOS) from baseline to day-53, with secondary endpoints including safety, pain, symptom, function, quality of life, bone marrow oedema lesion volume and patient global impression of change.

Paradigm said that the study divided patients into two groups: moderate pain with a score of four to six with 39 patients receiving PPS and 40 receiving saline as a control and the high pain group describing their pain as seven or eight, with 16 receiving PPS and 17 receiving saline.

The company said that for all 112 evaluable patients there was a “clinically meaningful and statistically significant” change in KOOS pain score at day-53 (p = 0.031).

Two charts provided in its presentation showed a drop in the percentage of PPS patients with reduced pain at day-81 day.

Paradigm said that 46.2 percent of PPS subjects had a greater than 50 percent reduction in pain from baseline compared to 22.5 percent for those receiving placebo (p = 0.026).

The company said the results were “consistent with [its uncontrolled special access scheme study] with an average of 51.4 percent reduction of pain” (BD: Dec 7, 2018)/

Paradigm said that safety was confirmed with mild to moderate adverse event severity with no life-threatening adverse events.

The company said that secondary endpoint data analysis was clinical and statistical differences were achieved in pain scores at day-39 and day-53, along with patient global impression of change (p = 0.0062).

Paradigm said that full reporting on secondary endpoints would be provided by April 2019, likely with a peer reviewed publication and/or presentation at an orthopaedic conference.

The company said it expected to file an investigational new drug application with the US Food and Drug Administration for a phase III trial in osteoarthritis and bone marrow oedema lesions with the possibility of being granted fast-track status for the trial.

Paradigm chief executive officer Paul Rennie said that the clinical and regulatory team as well as the clinical trial recruitment and treatment centres had “done an extraordinary job to conclude this phase IIb clinical trial in just over 12 months”.

Last year, Paradigm said it treated the first patient in October, with trial sites for the randomized, double-blind, placebo-controlled trial in Queensland, South Australia, Victoria and Western Australia (BD: Sep 19, Oct 30, 2017).

Mr Rennie said that the Paradigm team was “incredibly happy with these positive phase IIb trial results and are very excited for the future of the company”.

“To achieve clinically meaningful and statistically significant results between PPS and placebo in the total population and highly clinically meaningful and highly statistically significant results in the [four to six pain score group] is truly an outstandingly positive trial outcome,” Mr Rennie said. “If you have clinical significance and statistical significance you have a high probability the drug will pass a phase III clinical trial and once registered a drug that can penetrate the market.”

“We are further impressed with the results given the widespread difficulty ASX-listed biotechnology companies have had in achieving positive phase IIb trial results over the last few years,” Mr Rennie said.

Paradigm was up 17.5 cents or 13.3 percent to $1.495 with 5.3 million shares traded.

RESPIRI

Respiri says it has raised $3.2 million through a private placement to sophisticated and professional investors at 8.0 cents a share and will offer a share plan for $1 million more.
Respiri said the funds would strengthen its balance sheet and provides “the financial capacity to progress to the launch and production of Wheezo, which is scheduled for early 2019”.
Respiri chief executive officer Mario Gattino said “we welcome our two world class development partners Grey Innovation and Two Bulls taking equity shares via this placement and the strategic partnership discussions we are having now clearly represents belief and expectation in us delivering on the potential of our technology”.
The company said that Grey Innovation bought 6,250,000 shares and Two Bulls acquired 5,000,000 shares.
The company said it hoped to raise up to $1 million in a share purchase plan for existing shareholders at the record date of December 17, 2018.
In a separate announcement, Respiri said it would develop a workplace version of its Wheezo asthma diagnostic.
Respiri was unchanged at 9.3 cents

BARD1 LIFE SCIENCES

Bard1 says it has raised $3.314 million for a total of 165,732,775 shares in its non-renounceable entitlement issue at two cents a share.
Last week, Bard 1 said it had applications for up to $1,184,484 million in its $3.3 million one-for-five entitlement issue and that Merchant Corporate Advisory would place or purchase all the shortfall shares (BD: Dec 13, 2018).
Today, the company said the shortfall shares had been issued to investors introduced by Merchant and the funds would be used for its pipeline, research and working capital.
Bard1 was up 0.3 cents or 15.8 percent to 2.2 cents with 10.6 million shares traded.

DORSAVI

Dorsavi says it has raised $2,088,616 in its one-for-three, non-renounceable, pro-rata rights offer at 5.8 cents a share, in which the company hoped to raise $3.2 million.
Dorsavi said it received applications for 36,010,620 shares including additional shares under the shortfall facility and the underwriting, leaving a shortfall of 19,704,036 shares.
The company said it would use the funds to continue its entry into the US for its wearable sensors and for working capital purposes.
Dorsavi said 170 shareholders participated, including Starfish Technology Fund II Nominees A and Starfish Technology Fund II Nominees B.
In November, the company said that two director Dr Michael Panaccio-related Starfish funds would take-up their entitlements of about $200,000 and underwrite up-to $800,000 of the offer (BD: Nov 21, 2018).
Dorsavi was untraded at 6.2 cents.

AVITA MEDICAL

Avita says it has received $1,421,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
The company said that the incentive payment was for the year to June 30, 2018.
Avita was up 0.1 cents or 1.3 percent to eight cents with 1.4 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has received ethics approval for a 200-patient phase II trial of its synthetic cannibidiol BTX1204 for atopic dermatitis, or eczema.

Botanix said the study would be a 12-week, randomized, double blind, vehicle-controlled study to evaluate the safety and efficacy of BTX1204 in patients with moderate atopic dermatitis.

The company said the study would assess for treatment effects on the key signs of atopic dermatitis and would monitor for safety, tolerability and patient satisfaction.

Botanix said it had shown safety and efficacy on its 37-patient, four-week, phase I trial earlier this year (BD: Jun 6, 2018).

Botanix executive director Matt Callahan said it was the second phase II program to be initiated in six months.

“BTX1204 has the potential to be an effective, topically applied product which is superior to other products currently available on the market,” Mr Callahan said.

Botanix fell 0.2 cents or 2.8 percent to seven cents with 6.8 million shares traded.

ANALYTICA

Analytica says it has resumed US sales of its Pericoach intra-vaginal pelvic floor exercise training system for women with stress urinary incontinence.

Analytica said it had re-opened sales in the US and its territories “after resuming production with a new contract manufacturer, re-registering its establishments with the [US Food and Drug Administration] and clearing the first shipment through US Customs.

Analytica was untraded at 0.5 cents.

OBJ

OBJ says it has a licence term sheet with Procter & Gamble for “the first fully integrated package product” using its magnetic transdermal technology.

OBJ said the product delivered skincare product with “precise placement and then drives the active ingredient more effectively into the deeper layers of the skin for enhanced performance”.

The company said the product was “the first to integrate OBJ’s magnetic microarray technology with a pre-filled, airless pump pack” and was expected to be used by Procter & Gamble’s SK-II skincare business, with a launch expected by July 2019.

OBJ said that previously licenced technologies provided the chemistry and the enhanced skin penetration technology separately.

The company said it would receive an increased royalty benefit from repeat purchases.

OBJ said it has negotiated undisclosed favorable terms including payment in advance rather than in arrears, with royalties to be recorded on shipment of the product by the manufacturer.

The company said it was developing additional products using the same integrated format.

OBJ managing director and chief technical officer Jeffrey Edwards said the planned launch of the first integrated product was “an important milestone in terms of delivering a greater return on our technology development”.

Mr Edwards said that changing its licence terms with Procter & Gamble was “a priority” and the company was “very satisfied with the outcome”.

OBJ said that the licence covered all territories worldwide and marked the fifth product licensed by OBJ to Procter & Gamble.

OBJ was up 0.1 cents or 5.9 percent to 1.8 cents with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has sent complete results from its phase I trial of CYP-001 for graft versus host disease to partner Fujifilm for review (BD: Aug 30, 2018).

In 2016, Cynata said it had an agreement with Japan's Fujifilm to develop and commercialize its Cymerus stem cell technology and last year said it had a $60 million partnership with Fujifilm for CYP-001 (BD: Sep 5, 2016; Jan 22, 2017).

Today, Cynata said that Fujifilm had 90 days to exercise the licence option.

The company said that in the phase I trial, 13 of 15 patients showed an improvement by at least one grade compared to the baseline and eight of 15 patients' symptoms were completely resolved by day-100 and there were no treatment-related serious adverse events or safety concerns.

Cynata said it would continue to collaborate with Fujifilm for a phase II trial in 2019.

Cynata chief executive officer Dr Ross Macdonald said that "completing the clinical study report is a major milestone for Cynata, as it marks the formal and successful completion of our phase I clinical trial of CYP-001 with the attainment of all safety and efficacy endpoints".

"We now look forward to accelerating phase II development of CYP-001 and to receiving Fujifilm's decision on exercising the licence option," Mr Macdonald said.

Cynata was up four cents or four percent to $1.04.

MAYNE PHARMA GROUP

Mayne Pharma says it has re-acquired the US rights for Suba-itraconazole for basal cell carcinoma nevus syndrome from Hedgepath Pharmaceuticals Inc.

Mayne said that under a new licence agreement it would pay a nine percent royalty on net sales of Suba-itraconazole for basal cell carcinoma nevus syndrome (BCCNS) in the US to Hedgepath and has committed up to $US5 million to Hedgepath, which had the rights to progress the development of Suba-itraconazole in a revised field of oncology indications including lung and prostate cancer and certain proliferative disorders.

The company said that the first $US3 million was expected to be paid by mid-2019 with the balance at Hedgepath's election based on meeting a funding milestone in the next two and a half years, with the funds "a discounted advance rate against future … royalties or, in certain circumstances, in return for equity".

Mayne said it had obtained US rights for all other oncology indications outside prostate cancer, lung cancer and certain proliferative disorders.

Mayne fell six cents or 6.45 percent to 87 cents with 8.3 million shares traded.

CARDIEX

Cardiex says it has a letter of intent with an unnamed electronic and medical device companies for telehealth programs for managing chronic sleep disorders.

Cardiex said that agreement, through its Inhealth subsidiary, covered the unnamed company's consumer customers as well as providing the same programs to sleep disorder practitioners for sale directly to their patients.

The company said that the jointly developed programs would be branded under the company's name and were "expected to be significantly financially accretive to Inhealth and Cardiex in 2019".

Cardiex said it expected to name the company at the product launch by April 2019.

Cardiex was unchanged at 3.1 cents.

RECCE PHARMACEUTICALS

Recce says that executive chair and chief research officer Dr Graham Melrose will provide a short-term, unsecured, two-year loan of $200,000 at five percent a year.
Recce said the funds would be used to support short-term cash flows as it develops its new class of a broad-spectrum antibiotic.
Recce fell 1.5 cents or 8.3 percent to 16.5 cents.

LIFESPOT HEALTH

Lifespot says it will release 28,347,299 shares from ASX escrow on January 11, 2019.
The company's most recent Appendix 3B new share announcement said it had 49,221,379 shares quoted on the ASX, implying 77,568,678 shares would be available following the release.
Lifespot was unchanged at 6.7 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says non-executive director Allan McCallum has resigned, effective from December 17, 2018.
Medical Developments said that Mr McCallum had been a director since the company listed on the ASX in 2003.
Medical Developments chairman David Williams thanked Mr McCallum for his work and said he had made "an invaluable contribution".
"We will use the retirements of Mr McCallum and Dr Harry Oxer as a catalyst to diversify the board with new members who have skills in drug manufacturing and international marketing," Mr Williams said.
"We also have some exciting initiatives with the CSIRO and new drug manufacturing technologies," Mr Williams said.
"We are looking for people to assist with this next stage of our growth," Mr Williams said.
Medical Developments fell 12 cents or 3.1 percent to $3.71.