Biotech Daily

Thursday October 3, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 24%; PATRYS DOWN 9%**

*** MESOBLAST RAISES $75m**

*** TELIX BUYS BELGIAN RADIOPHARMACEUTICAL PRODUCTION SITE**

*** CYNATA READY FOR PHASE II CYMERUS OSTEOARTHRITIS TRIAL**

*** FDA ALLOWS CLARITY SARTATE NEUROBLASTOMA TRIAL**

*** FEDERAL $8m FOR FIVE COLLABORATIVE TRIALS**

*** FEDERAL REGIONAL QUEENSLAND STEM MENTORING LAUNCH**

*** PHARMAUST RAISES $2.4m**

*** ALCHEMIA RAISES $5.7m TO BECOME AUSTRALIAN PRIMARY HEMP**

*** SUDA TELLS ASX: ACCOUNTS IN ORDER, ARTIMIST WORTH $5m'**

*** OPTISCAN RECEIVES $227k R&D TAX INCENTIVE**

*** CARDIEX SPHYGMOCOR XCELL Q1 SALES UP 88% TO $900k**

*** MGC PASSES 400 CANNEPIL, MXP100 PRESCRIPTIONS**

*** PHARMACIELO, CRESO ACQUISITION SCHEME MEETING**

*** MEDADVISOR REQUESTS PLACEMENT TRADING HALT**

*** BARD1 GRANTS CEO DR LEANNE HINCH 15m INCENTIVE OPTIONS**

*** INVEX 2.2m DIRECTOR 'INCENTIVE' OPTIONS AGM**

*** SABBY TAKES 9% OF BENITEC**

MARKET REPORT

The Australian stock market fell 2.21 percent on Thursday October 3, 2019, with the ASX200 down 146.9 points to 6,493.0 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Actinogen was the best, recovering 0.9 cents or 23.7 percent to 4.7 cents with 105.8 million shares traded. Optiscan climbed 14.3 percent; Antisense was up 12.8 percent; Neuren improved 3.8 percent; Medical Developments and Oncosil rose more than one percent; with Cynata and Starpharma up by less than one percent.

Patrys led the falls, down 0.2 cents or 9.1 percent to two cents, with 6.7 million shares traded. Prescient fell 7.9 percent; Mesoblast and Telix lost more than six percent; Impedimed, Opthea and Pharmaxis fell more than five percent; Dimerix was down 4.8 percent; Clinuvel, Compumedics, Ellex, Next Science, Paradigm, Polynovo, and Resmed were down more than three percent; CSL, Genetic Signatures, Nanosonics and Orthocell shed more than two percent; Amplia and Cochlear were down more than one percent; with Avita and Pro Medicus down by less than one percent.

MESOBLAST

Mesoblast says it has raised $75 million in a placement to new and existing Australian and global institutional investors at $2.00 a share.
Mesoblast said that the $2.00 a share placement price was a 3.15 percent discount to the 10-day volume-weighted average price (BD: Oct 1, 2019).
The company said Bell Potter Securities was lead manager and bookrunner and Aitken Murray Capital Partners was co-manager to the placement.
Mesoblast fell 14.5 cents or 6.8 percent to $1.995 with 3.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says it will acquire a Seneffe, Belgium licenced radio-pharmaceutical production facility from Eckert & Ziegler Strahlen und Medizintechnik Aktiengesellschaft.
Telix said it would pay a nominal cash sum and assume future decommissioning liabilities associated with the site, estimated to be up to EUR5.2 million ($A8.5 million), as payment for the 35,000 square metre (m2) site (8.6 acres).
Telix said the facility had 2,350m2 (0.6 acres) of building space and included 1,000m2 (10,764 square feet) of laboratory and production space and 300m2 of logistics space.
The company said two cyclotron vaults already installed in a controlled area, with capacity for an addition six cyclotron vaults and it could support radiometals and radio halogens.
Telix said the acquisition would meet future European manufacturing needs, but it would continue to work with existing European contract manufacturing partners for back-up manufacturing and product delivery.
The company said the timing was important as it expected to complete two European product launches in the next 18 to 24 months, subject to approvals, and there was a significant lead-time to complete regulatory and compliance requirements for the site.
Telix chief executive officer Dr Christian Behrenbruch said the acquisition was “a big step forward for Telix, but it is a commercially necessary step given the company’s commercial trajectory over the next two years”.
Telix fell nine cents or 6.3 percent to $1.33 with 1.9 million shares traded.

CYNATA THERAPEUTICS

Cynata says it is preparing for a 448-patient, phase II trial of its Cymerus mesenchymal stem cells for osteoarthritis, to begin by April 2020.
Last year, Cynata said the National Health and Medical Research Council had approved a $1,982,802 grant for the 448-patient, placebo-controlled phase II trial of its Cymerus stem cells for osteoarthritis, led by the University of Sydney’s Prof David Hunter in Tasmania and Sydney (BD: Dec 13, 2018).
Today, the company said the osteoarthritis trial was the third phase II indication for its Cymerus mesenchymal stem cells.
Cynata said it had a research support agreement to accelerate trial planning and start-up activities, was nearing completion of trial design and continuing protocol development.
The company said the trial would assess the effect of its Cymerus stem cells on osteoarthritis of the knee compared to placebo in terms of clinical outcomes and knee joint structure over two years.
Cynata said that if results of the trial were used to support regulatory marketing approval, it would potentially pay fees of up to $2.1 million to the University of Sydney, with the first $100,000 due when phase II data was used in a marketing approval submission.
Cynata was up one cent or 0.6 percent to $1.59.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has approved its 34-patient, phase I/IIa trial of 64Cu- Sartate and 67Cu-Sartate for paediatric neuroblastomas.
Clarity said that the diagnostic and therapy trial of 64-copper and 67-copper Sartate would be administered to paediatric patients with somatostatin receptor-2 positive, relapsed or refractory, high-risk neuroblastomas.
The company said the multi-centre, dose escalation, open-label, non-randomized, trial would use 64Cu-Sartate for positron emission tomography (PET) imaging and 67Cu-Sartate for therapy.
Last month, Clarity said it had filed a US investigational new drug application for the brain cancer trial and today noted the speed of approval (BD: Sep 4, 2019).
Today, Clarity said the FDA response "suggests not only the importance of the study in the treatment of neuroblastoma, but also validates the manufacturing of 64Cu-Sartate and 67Cu-Sartate to levels suitable for diagnostic and therapeutic use, as well as the suitability of the centralized manufacturing concept of this theranostic [therapy and diagnostic] pairing".
The company said that the study was supported by a human imaging study in 10 adults with neuroendocrine tumors and preliminary results of a first-in-human study of adult patients with meningioma, who were administered a diagnostic dose of 64Cu-Sartate followed by up to four doses of the therapeutic product,67Cu-Sartate.
Clarity executive chairman Dr Alan Taylor said the acceptance of the company's first investigational new drug application "indicates the quality and importance of work conducted by our preclinical, clinical and manufacturing teams in the field of theranostics and reflects the support for the development of novel treatments for children with cancer".
Clarity is a public unlisted company.

FEDERAL GOVERNMENT

The Federal Government says it will provide $8 million for five heart, pre-term baby lung, brain, infection control and dementia trials.
A media release from Federal Health Minister Greg Hunt said the funding was part of the Medical Research Future Fund International Clinical Trial Collaboration program.
The Government said that each trial would run at least one clinical trial site in Australia and would collaborate with international researchers or trial teams.
The media release said Macquarie University would receive $3.1 million to investigate how lifestyle changes protect brain health and reduce the risk of dementia.
The Government said the University of Western Australia would receive $1.8 million to study the best approach to treat aortic stenosis, or the severe narrowing of the aortic heart valve, and to test if earlier valve replacement improved patient outcomes.
The media release said Murdoch Children's Research Institute at Melbourne's Royal Children's' Hospital would receive $1.4 million to investigate the best ways to support fragile lungs in pre-term babies, which were prone to collapse, causing injury from the first time they breathe.
The Federal Government said the Sydney-based George Institute for Global Health would receive $902,000 to assess treatments for aneurysmal subarachnoid haemorrhage caused by a bust artery of the brain.
The media release said the University of Newcastle would receive $782,000 to use a new type of wound dressing to reduce infections following emergency abdominal surgery.

FEDERAL GOVERNMENT

The Federal Government says it has launched the Industry Mentoring Network in science, technology, engineering and maths (Stem) in regional Queensland.
A media release from Federal Industry, Science and Technology Minister Karen Andrews said the Industry Mentoring Network in Stem would boost regional Queensland Stem mentoring and strengthen industry research connections and collaboration.
The Government said the mentoring network aimed to connect up to 12 post-doctoral students with industry mentors at the Townsville and Cairns-based James Cook University and the Rockhampton-based Central Queensland University.
Ms Andrews said Stem education was “the key to the future of high-tech employment, such as we see in the medical technologies and pharmaceuticals industry”.
“Promoting Stem education is a passion of mine and I’m particularly interested in providing opportunities to those in regional areas to grow jobs and boost the economy,” Ms Andrews said.
The Government said it established Medical Technologies and Pharmaceuticals (MTP) Connect in November 2015 as part of its Industry Growth Centre initiative to champion the growth of the Australian life sciences industry.
The media release said that $26 million had been provided for 48 projects through MTP Connect and the Medical Research Future Fund’s Biomedtech Horizons program, funding projects ranging from 3D anatomical printing and precision medicine to clinical trials, advanced manufacturing and industry mentoring.

PHARMAUST

Pharmaust says it has raised $2.4 million in a placement to institutional ad sophisticated investors at 12 cents a share.
Pharmaust said the share price was a 7.5 percent discount to the 30-day volume weighted average price of 12.93 cents a share.
The company said the funds would be used to progress its human trial program, including further development of its formulation and the manufacture of additional tablets.
Pharmaust said JP Equity Partners was the lead manager to the placement.
Pharmaust was unchanged at 15 cents with three million shares traded.

ALCHEMIA

Alchemia says it has become Australian Primary Hemp, raising $5.7 million at 20 cents a share and changing its ASX ticker code to APH.
In June, Alchemia said it would acquire the Geelong-based Australian Primary Hemp in a share sale agreement, would raise $6 million and would conduct a 20-to-one consolidation to become a hemp growing company (BD: Jun 21, 2019).
Last month, the company said its annual general meeting voted for the company to become Australian Primary Hemp and to reduce the shares on offer by 20-to-one (BD: Sep 16, 2019).
Today, Alchemia said it completed the acquisition.
The company said Pauline Gately, Charles Mann and James Hood would be appointed to the board effective from October 2, 2019, with Melanie Leydin and Lynden Polonsky resigning as directors.
Alchemia was in a suspension and last traded at a consolidated 22 cents.

SUDA PHARMACEUTICALS

Suda has told an ASX query that it is financial and that the $5,338,148 carrying value of its Artimist oral paediatric malaria spray is “appropriate”:

In a series of questions, the ASX asked Suda whether its financial condition was “sufficient to warrant continued listing on ASX”, whether its full year accounts complied with the relevant accounting standards and gave a true and fair view of the company’s financial performance and position, and to explain the underlying assumptions used to conclude that Artimist was worth $5,338,148.

On Tuesday, the Australian Therapeutic Goods Administration refused Suda’s appeal to the Australian regulator’s refusal of marketing approval (BD: Jul, 18, Oct 1, 2019).

In 2013, Suda said its 151-subject, phase III trial of sub-lingual Artimist showed significant superiority to intravenous quinine for severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications (BD: Apr 30, 2013).

The company said at that time that 95.6 percent of Artimist patients had reduced parasite counts by more than 90 percent in the first 24 hours, compared with 40.6 percent using intravenous quinine ($p < 0.005$).

Suda said in 2013 that Artimist clearly met both primary efficacy endpoints, but under secondary endpoints, there was no significant difference in complete cure rates.

The company’s trial report said there were no serious adverse events related to Artimist, local tolerability was good and there were no adverse events related to local tolerability.

Today, Suda said it reviewed its financial position and performance and considered its financial condition was sufficient to warrant continued listing on the ASX, noting it had $4.3 million in cash following an oversubscribed capital raising in June 2019, with trade and other receivables totaling $1.2 million and current liabilities totaling $1.3 million.

The company said that the accounts comply with accounting standards and gave “a true and fair view of Suda’s financial performance and position”.

Suda said that the directors determined the Artimist carrying value by and an assessment of the likely sale value, based on discussions between the chief executive officer “and business development management of various pharmaceutical companies who had expressed an interest in the product”.

The company said the process was informal and primarily evidenced by email exchanges and verbal discussions”.

Suda said that the assessed likely sale value was then discounted to take into account the TGA’s notice of denial for marketing approval of the product, and further discounted for the time value of money.

The company said that an independent valuation of Artimist was obtained in 2012 and, while “the performance of the product and the number of cases of malaria in sub-Sahara Africa had not materially declined, the auditors were of the opinion that the independent valuation was not sufficiently current to be relied upon”.

Suda said the directors consider they have taken a conservative approach determining the carrying value of Artimist as at June 30, 2019, but they noted that the basis for the qualified opinion was limited to the recoverable amount of Artimist.

The company said that if a decision was made not to exercise its further appeal rights, the directors would carry out a full assessment of the viability of the product after taking advice from its advisers.

Suda said that one possible outcome of this assessment may be to fully impair the carrying value of Artimist, but if a further appeal was made and was ultimately successful, the directors would consider obtaining a further independent valuation of the product to provide the auditors with additional audit evidence of the product’s carrying value.

Suda fell 0.05 cents or 14.3 percent to 0.3 cents with 5.7 million shares traded.

OPTISCAN IMAGING

Optiscan says it has received $226,506 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Optiscan said the rebate related to research and development expenditure for the year to June 30, 2019.
Optiscan was up 0.6 cents or 14.3 percent to 4.8 cents.

CARDIEX

Cardiex says Sphygmocor Xcell sales were up 88 percent to more than $900,000 for the three months to September 30, 2019 compared to the previous corresponding period.
Cardiex said it was “the highest sales number for the period in the last five years”.
The company said sales increased in the Asia Pacific by 52 percent, in Europe and the Middle East by 129 percent, in US pharmaceuticals by 132 percent and in US clinical research by 57 percent.
Cardiex said the revenue excluded sales of the Oscar 2 ambulatory blood pressure monitoring (ABPM) medical device.
Cardiex chief executive officer Craig Cooper said, “as we continue to roll out new pricing, sales, lead generation, and marketing campaigns we are starting to see the results of these efforts in our monthly growth and revenues”.
“This is a great start to the first quarter, and we look forward on building on these revenues throughout the year as part of our plan to return the Atcor medical device division to profitability this year,” Mr Cooper said.
Cardiex was up 0.4 cents or 16.7 percent to 2.8 cents with 6.9 million shares traded.

MGC PHARMACEUTICALS

MGC says it has passed 400 prescriptions for its 5.0 percent tetrahydrocannabinol Cannepil and 100 percent cannabidiol MXP100 products in Australia and the UK.
Last month, MGC said it passed 200 prescriptions, an increase on 100 prescriptions in mid-August 2019 (BD: Sep 18, 2019).
Today, the company said it had a 100 percent increase in two weeks, with 202 new prescriptions to September 30, 2019.
MGC fell 0.1 cents or 2.6 percent to 3.8 cents with 14.3 million shares traded.

CRESO PHARMA

Creso says the Supreme Court of Western Australia has ordered it can proceed with the share and scheme meeting related to the proposed acquisition by Pharmacielo.
Creso said it would release the scheme booklet on the ASX shortly.
The meetings will be held at Steinepreis Paganin, Level 4, The Read Buildings, 16 Milligan Street, Perth Western Australia on November 11, 2019 at 10:00am (AWST).
Creso was in a suspension at 38.25 cents.

MEDADVISOR

Medadvisor has requested a trading halt “pending the release of an announcement regarding a share placement to institutional and strategic investors”.
Trading will resume on October 7, 2019 or on an earlier announcement.
Medadvisor last traded at 4.5 cents.

BARD1 LIFE SCIENCES

Bard1 says it will grant chief executive officer Dr Leanne Hinch 15,000,000 unlisted options under its incentive option plan.
Bard1 said the 10,000,000 tranche one options would be issued on October 4, 2019, exercisable at 3.5 cents a share.
The company said the 5,000,000 tranche two options would be issued as soon as practicable after November 8, 2019, exercisable at 1.5 times the five-day volume weighted average price up to and including November 8.
Bard1 said the tranche one options would lapse four years from the date of issue and tranche two options would lapse three months from when Dr Hinch no longer holds a position at Bard1.
The company said the options would vest on issue and it would consider the potential issue of five million tranche three options to Dr Hinch, which would be at 1.5 times the 5-day volume-weighted average price to November 6, 2020.
Bard1 was unchanged at 4.8 cents with 23.9 million shares traded.

INVEX THERAPEUTICS

Invex says it will vote to issue up to 2.2 million “incentive” options to four directors exercisable at 60 cents each in its annual general meeting.
Invex said it would vote to issue 200,000 incentive options to director David McAuliffe, 800,000 incentive options to director Jason Loveridge, 400,000 incentive options to director Narelle Warren and 800,000 incentive options to director Prof Alexandra Sinclair at an exercise price of 60 cents a share, vesting on the condition of remaining with the company for 12 and 24 months.
The company said its last traded price before the date of the notice on September 26, 2019 was 65.5 cents a share.
Invex said the meeting would vote to elect Mr McAuliffe, Mr Loveridge and Ms Warren as directors, to adopt the renumeration report and appoint BDO Audit as its auditor.
Invex said it would vote to approve a 10 percent placement capacity.
The meeting will be held at Level 2, 16 O’Connell Street Sydney on November 21, 2019 at 10am (EDST).
Invex fell three cents or 4.55 percent to 63 cents.

BENITEC BIOPHARMA

Sabby Management and associated parties say they have become substantial in Benitec with 28,000,000 shares or 8.94 percent.
In 2015, the New Jersey and Cayman Islands-based Sabby became a substantial shareholder with 11,000,000 shares or 7.54 percent but decreased their holdings in 2016 to 7,351,471 shares or 5.02 percent (BD: Sep 11, 2015; Apr 7, 2016).
Today, Sabby said it acquired 1,400,000 American depositary shares or 28,000,000 shares on October 1, 2019 for $US980,000 ($A1,456,000) or 5.2 cents a share.
Benitec was up 0.4 cents or 7.1 percent to six cents.