Biotech Daily

Monday December 9, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: LBT UP 12%; PRESCIENT DOWN 12%**

*** AUSBIOTECH, MEDICINES AUSTRALIA HIT FEDERAL RDTI CHANGE**

*** INVITROCUE, CHINALINK: $15m AGREEMENT, HONG-KONG J-V**

*** SUDA, SANOFI OROMIST FEASIBILITY AGREEMENT**

*** ADMEDUS: LEMAITRE 12.5k UNIT CARDIOCEL, VASCUCEL ORDER**

*** BOTANIX READIES FOR CANNABIDIOL BTX1702 ROSACEA TRIAL**

*** CRESO AFRICA MARIJUANA CANNAQIX LAUNCH BY APRIL 2020**

*** CLAUDE SOLITARIO REPLACES MEDIBIO'S DAVID KAYSEN, RELOCATION**

*** MS FARRELL, MS DAHIYA REPLACE CANN CO SEC, CFO MR BAKER**

MARKET REPORT

The Australian stock market was up 0.34 percent on Monday December 9, 2019, with the ASX200 up 23.0 points to 6,730.0 points. Nine of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and two were untraded.

LBT was the best, up two cents or 12.1 percent to 18.5 cents, with 897,242 shares traded. Dimerix climbed eight percent; Genetic Signatures and improved more than four percent; Medical Developments and Neuren rose more than two percent; Kazia and Volpara were up more than one percent; with Cochlear, Paradigm and Resmed up by less than one percent.

Prescient led the falls for the second trading day in a row, down 1.2 cents or 12.0 percent to 8.8 cents, with 21.1 million shares traded. Antisense lost 9.4 percent; Imugene fell 8.1 percent; Actinogen was down 6.7 percent; Avita and Orthocell were down more than five percent; Opthea and Patrys fell more than four percent; Compumedics, Cynata, Pharmaxis, Polynovo, Proteomics and Starpharma were down more than three percent; Cyclopharm, Next Science, Osprey, Pro Medicus and Resonance shed two percent or more; CSL, Mesoblast, Nanosonics and Telix were down more than one percent; with Clinuvel down by 0.6 percent.

FEDERAL GOVERNMENT, AUSBIOTECH, MEDICINES AUSTRALIA

Ausbiotech and Medicines Australia have condemned the Federal Government's push to reduce the Research and Development Tax Incentive (RDTI).

In separate media releases, both organizations said they were disappointed that proposed changes to the Federal RDTI "were tabled without notice" or consultation in the Parliament on Thursday December 5, 2019, with Medicines Australia saying the proposed cuts were despite a Senate Committee recommendation "to defer the Bill until further consideration was given to the effects of the reforms".

Ausbiotech said that fixing the rate of the refundable research and development tax offset at 13.5 percent would "immediately hit biotech [small and medium sized enterprises] with a 2.5 percent loss of refund if passed, a move both significant and material".

The industry organization said that the Bill proposed a simplified research and development premium for conducting "high intensity" research and development for companies with an annual turnover of more than $20 million.

"Despite being simplified from the last Bill, the intensity measure still reduces the support for all but a few companies," Ausbiotech said. "It will prove hard to estimate in advance, which undermines the certainty that most companies have traditionally had in relation to future RDTI calculations."

The organization welcomed a proposed increase in the research and development expenditure threshold from $100 million to $150 million, but said it was "only applicable to a few companies, with the potential addition of one or two more in years to come".

Ausbiotech said the proposed Bill set the claim gap at $4 million, with an exemption for clinical trials and while the protection of trials was welcome, it was "tempered by the high degree of confusion that remains about the definition of clinical trial and which expenditure would be eligible for the RDTI under the proposed changes".

Medicines Australia said that the proposed changes would "discourage investment and undermine innovation".

Medicines Australia said that the recommendation of a Senate Committee inquiry to defer the Bill until further consideration was given to the effects of the reforms "acknowledged that further tinkering with the R&D Tax Incentive creates business uncertainty especially when incentives are seen to be weakened and not strengthened".

Medicines Australia chief executive officer Elizabeth de Somer said it was "troubling that the Bill persists with the introduction of an intensity threshold for the research intensive pharmaceutical sector, which would diminish Australia's attractiveness as a destination for clinical research at a time when we are seeking to expand Australia's export capacity in the knowledge economy that includes clinical research expertise and infrastructure".

"Medicines Australia supported the Inquiry's recommendations to reduce red tape, improve transparency and increase efficiencies. However, given the Bill's hasty introduction it is not possible to determine if real efforts have been made in this direction and we therefore believe this requires further consideration and consultation," Ms de Somer said.

In the past five months, Opthea received a $14.6 million Research and Development Tax Incentive, Bionomics $5.2 million, Actinogen $4.6 million, Pharmaxis $6.2 million and Telix $9.3 million (BD: Jul 18, Oct 1, 17, 24, Nov 11, 2019).

Medicines Australia said Australia attracted more than $1 billion a year in pharmaceutical research and development investment and the sector was one of the largest employers of medical science graduates in Australia and the "changes announced in this Bill could put a brake on investment at the very time when economic growth is essential".

Ausbiotech said "the proposed changes have the potential to significantly damage the sector and ultimately impact its capacity to deliver new, innovative treatments".

INVITROCUE

Invitrocue says the Hong Kong-based Chinalink fund will invest up-to $US10 million ($A14.6 million) and form a Hong Kong-based joint venture company.
Invitrocue said the Chinalink $US10 million would be invested in two tranches subject to shareholder approval and the completion of its clinical validation study of its Onco-patient-derived organoid (PDO) test for personalized cancer treatment.
The company said Chinalink would subscribe the first tranche investment of $US3 million following 25 successful Onco-PDO cases, with the second tranche of $US7 million vesting on the completion of up to 200 Onco-PDO cases.
Invitrocue said it expected to complete the first 25 cases by April 1, 2020.
The company said it expected the validation study to be completed in “one to two years”, with the investment “spanning over two or more financial years”.
Invitrocue said Chinalink would subscribe for an undisclosed amount of company shares at the lower of 4.5 cents each or the five-day volume weight average price of the shares prior to completion of each tranche.
The company said that every five shares would have one free attaching option exercisable at the subscription price until October 1, 2022.
Invitrocue said it entered the joint venture agreement through the issue of 50 percent of its subsidiary, Invitrocue Hong Kong to Chinalink.
The company said the joint venture would be the sole shareholder of all Invitrocue China operations.
Invitrocue said the joint venture would be directed by three people; one director appointed by each company and a third director mutually agreed by both parties.
The company said that the joint venture would establish a laboratory facility in Hong Kong for research and development and commercial purposes, allowing Invitrocue to provide Onco-PDO service to oncologists and hospital groups in Hong Kong, mainland China and Macau.
Invitrocue said that with Chinalink it would inject $US250,000 ($A365,964) into the joint venture and it would raise the funds through an unsecured convertible loan to Chinalink with interest set at 10 percent a year, maturing on October 1, 2022, with the option to convert to shares.
The company said Chinalink would finance Invitrocue China operations with a $US500,000 ($A731,928) convertible loan under the same terms, which will be issued on or before December 31, 2019.
Invitrocue was in a suspension and last traded at six cents.

SUDA PHARMACEUTICALS

Suda says it has a feasibility agreement with the Paris-based Sanofi-Aventis Groupe to investigate its Oromist spray technology with an undisclosed active ingredient.
Suda said the active ingredient would be Sanofi’s choice.
The company said the study was fully funded and was expected to be completed by March 30, 2021.
A Suda executive told Biotech Daily that Sanofi would pay for the study and the terms of the agreement were confidential.
Suda said it did not expect the study to “generate significant revenue” but it “may enter into further collaboration” with Sanofi based on the outcomes of the study.
Suda was up 0.3 cents or 4.55 percent to 6.9 cents.

ADMEDUS

Admedus says the Burlington, Massachusetts-based Lemaitre Vascular has ordered 12,500 units of Adapt tissue technologies Cardiocel and Vascucel.
In October, Admedus said it had sold the distribution rights of Cardiocel and Vascucel to Lemaitre for up to $36.2 million which included $11.4 million for milestone achievement and had retained manufacturing rights for the technologies for three years and all intellectual property rights (BD: Oct 14, 2019).
Today, the company said that the quantity ordered “significantly” exceeded its unit sales for the products over the previous 12 months.
Admedus said that it had received its first milestone payment of $200,000 last month “for completion of reporting procedures by October 31, 2019”.
Admedus was up 0.2 cents or 2.2 percent to 9.2 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has ethics approval for a 120-patient, phase Ib study of synthetic cannabidiol BTX1702 for moderate to severe papulo-pustular rosacea.
Botanix said the randomized, double blind, vehicle-controlled study would be held at six dermatology clinics in Australia, with the first patient expected to be enrolled by April 2020.
In October, the company said its 368-patient, phase II trial of synthetic cannabinoid BTX1503 for moderate to severe acne did not meet its primary endpoint for reduction of inflammatory lesions, or pimples, at 12 weeks (BD: Oct 23, 2019).
Today, Botanix said that the BTX1702 rosacea trial would be “based on the recent phase II acne study data and mechanistic data … that showed synthetic cannabidiol exerts powerful anti-inflammatory and antimicrobial actions in skin, two key activities that are critical to successfully treating rosacea”.
The company said that previous studies suggested “that synthetic cannabidiol delivered using the Permetrex skin delivery technology could represent a safe and effective new treatment option for rosacea patients”.
Botanix said the primary endpoint of the study was safety and tolerability over a six-week treatment period, with exploratory endpoints including change in inflammatory lesion counts; proportion of subjects with a clear or almost clear investigators global assessment; and reduction of erythema, or redness.
Botanix fell 0.2 cents or 2.15 percent to 9.1 cents with 3.2 million shares traded.

CRESO PHARMA

Creso says that it will launch its marijuana-based Cannaqix products for stress and mental functions with Pharma Dynamics in nine African countries by April 1, 2020.
In August, Creso said the Capetown, South Africa-based Pharma Dynamics would distribute Cannaqix10 in South Africa, Namibia, Botswana, Zimbabwe, Swaziland, Lesotho, Angola, Mozambique and Uganda and it expected it to be available in South African retail pharmacies by the end of the year (BD: Aug 22, 2019).
Today, the company said that Pharma Dynamics had “the sole distribution rights of … [the] Cannaqix product range” and had made two initial orders valued at $300,000.
Creso said Pharma Dynamics was a subsidiary of the Mumbai, India-based Lupin Limited.
The company said Cannaqix products were “broad spectrum organic hemp oil”-based lozenges with cannabidiol designed for buccal absorption to dissolve in the mouth.
Creso said that Cannaqix was distributed in the UK, Australia, Brazil and New Zealand.
Creso fell two cents or 14.3 percent to 12 cents with 5.8 million shares traded.

MEDIBIO

In an announcement described as a 'Company Update', Medibio says chief executive officer David Kaysen will resign and operations will return from the US to Australia.

The media release, titled 'Report to Shareholders on Company Activities and Outlook for 2020' said it would appoint founder, director and major shareholder Claude Solitario as managing director, with Mr Kaysen to remain with the company until December 31, 2019 "to ensure a smooth transition".

Last year, the company said that it had appointed Mr Kaysen as chief executive officer and managing director, starting on $US360,000 ($A500,367) and "implemented cost reduction measures that included eliminating certain staff positions in Minneapolis, Minnesota" (BD: Nov 2, 2018).

Today, Medibio it would relocate its corporate, financial and administrative activities from the US to Australia, effective as of 31 December 2019, including the "significant downsizing of the Minneapolis office".

The company said that Mr Solitario was "suitably qualified to oversee the transition well into the new year … [to ensure the company] maintains and builds on the momentum" of its Ilumen heart rhythm-based mental health assessments and its US Food and Drug Administration program.

Medibio said that Peter Carlisle would continue as "lead non-executive director" and Melanie Leydin would continue as non-executive director and joint company secretary.

The company said that "no further board appointments are envisaged at this time".

Medibio fell 0.1 cents or 8.3 percent to 1.1 cents with 51.8 million shares traded.

CANN GROUP

Cann Group says that Geraldine Farrell and Reena Dahiya have replaced Richard Baker as company secretary and chief financial officer, effective December 6, 2019.

Cann said Ms Farrell had been appointed company secretary and had more than 25 years' experience in commercial, corporate, and intellectual property law.

The company said Ms Dahiya had been appointed acting chief financial officer and had more than 25 years' experience within finance and accounting across a diverse range of industries.

Cann Group fell five cents or 10.9 percent to 41 cents with 1.7 million shares traded.