Biotech Daily

Monday March 25, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LBT UP 20%; ONCOSIL DOWN 69%**

*** ONCOSIL FALLS 87% ON PANCREATIC CANCER RADIOTHERAPY DOUBTS**

*** PRESCIENT TO RAISE $9.1m IN PLACEMENT, RIGHTS ISSUE**

*** FDA ISSUES WEHI-DISCOVERED ABBVIE VENETOCLAX WARNING**

*** REVA $4.2m LOAN; JEFF ANDERSON REPLACES CEO REGGIE GROVES**

*** USCOM WINS CHINESE MEDICAL DEVICE CERTIFICATE**

*** MESOBLAST, JCR STEM CELL LICENCE FOR EPIDERMOLYSIS BULLOSA**

*** RACE FILES BISANTRENE FOR AML IND WITH US FDA**

*** FACTOR RECEIVES $2.5m R&D TAX INCENTIVE**

*** SIMPLE SLEEP SERVICES CLOSES OWING SOMNOMED $1.1m**

*** UK NHS MOVES NUHEARA IQBUDS BOOST TO 'HEARABLE'**

*** THORNEY, TIGA TAKE 17% OF TPI**

*** THC REQUESTS CANADA ACQUISITION TRADING HALT**

MARKET REPORT

The Australian stock market fell 1.11 percent on Monday March 25, 2019, with the ASX200 down 69.0 points to 6,126.2 points. Thirteen Biotech Daily Top 40 stocks were up, 21 fell, three traded unchanged and three were untraded. All three Big Caps fell.

LBT was the best on no news, up 1.2 cents or 19.7 percent to 7.3 cents, with 302,168 shares traded. Patrys climbed 8.3 percent; Airxpanders and Prana were up more than six percent; Cynata improved 5.9 percent; Medical Developments, Orthocell and Universal Biosensors were up more than three percent; Compumedics, Immutep, Mesoblast and Telix rose more than two percent; with Dimerix up 1.15 percent.

Oncosil led the falls (see below), down 11.1 cents or 69.4 percent to 4.9 cents, with 58.2 million shares traded. Both Antisense and Benitec lost 7.7 percent; Ellex shed 6.45 percent; Imugene was down 5.3 percent; Genetic Signatures, Impedimed and Proteomics fell more than four percent; Nanosonics and Paradigm were down more than three percent; Kazia, Optiscan and Starpharma shed more than two percent; Actinogen, Clinuvel, Neuren, Pharmaxis, Polynovo, Prescient, Pro Medicus and Volpara were down by more than one percent; with Cochlear, CSL and Resmed down less than one percent.

ONCOSIL MEDICAL

Oncosil shares fell as much as 86.9 percent on news that a European committee found "insufficient clinical benefit" to approve its pancreatic cancer radiotherapy.

Oncosil chief executive officer Daniel Kenny told Biotech Daily the company was "extremely disappointed" with the finding, would address issues in the report and would work to overturn the decision to a positive recommendation.

In a media release to the ASX, the company said that an independent advisor to the British Standards Institute, known as the Clinical Oversight Committee "determined that at this time insufficient clinical benefit has been demonstrated to recommend approval" for the radiotherapy as an adjunct to chemotherapy for late stage pancreatic cancer.

Oncosil said the Committee would send the recommendation to the British Standards Institute (BSI) medical device group for final determination.

"Although the company is still assessing the feedback to determine the next steps, on its initial assessment it is extremely disappointed with the determination given the strong data package that was presented," Oncosil said.

"The company will look to clarify the issues with BSI and update the market when a course of action has been formulated," the company said.

Mr Kenny told Biotech Daily that the company had "excellent" data including better resection rates for the Oncosil radiotherapy with chemotherapy than chemotherapy alone.

"We are comfortable with our safety and efficacy data," Mr Kenny said.

"In conjunction with chemotherapy, our data shows better results than chemotherapy alone, with resection rates showing a clear benefit," Mr Kenny said.

"It's not a rejection, but if we don't overturn the decision it could lead to a rejection [of CE mark approval]," Mr Kenny said.

"We have to overturn this ruling and we have a lot of issues to be addressed, particularly with the way in which they have assessed the data," Mr Kenny said.

Oncosil fell as much as 86.9 percent from 16 cents to 2.1 cents in early trade, before closing down 11.1 cents or 69.4 percent to 4.9 cents with 58.2 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it expects to raise $9.1 million in a placement and rights issue at five cents a share.

Prescient said it had commitments for a $7.0 million placement and an underwritten $2.1 million one-for-five rights issue.

The company said it would issue one option for every two shares subscribed in the placement and rights issue, exercisable at 6.25 cents a share by March 31, 2023.

Prescient said 35.3 million shares and 17.7 million attaching options would be unconditional and 104.7 million shares and 52.3 million attaching options would be approved at an extraordinary general meeting expected on April 26, 2019.

The company said Bell Potter Securities and Aurenda Partners were the placement's joint lead managers and Roth Capital Partners LLC would be its US placement agent.

Prescient said Bell Potter Securities would underwrite the $2.1 million rights issue, which had a record date of March 29, opening on April 3 and closing on April 23, 2019.

The company said funds raised would be used for its clinical programs, "including additional drug manufacture and clinical trial management, funding the costs associated with the capital raising and for working capital".

Prescient fell 0.1 cents or 1.8 percent to 5.5 cents with 2.4 million shares traded.

US FOOD AND DRUG ADMINISTRATION, WALTER AND ELIZA HALL INSTITUTE

Last week, the US Food and Drug Administration issued a partial clinical hold and warning on the Walter and Eliza Hall Institute co-developed venetoclax for multiple myeloma.

Venetoclax, marketed by Chicago's Abbvie as Venclexta, is approved for chronic lymphocytic leukaemia and was in a clinical trial for multiple myeloma.

Venetoclax was developed in a collaboration between the Walter and Eliza Hall Institute, Abbvie and Roche's Genentech, and in 2017, Federal Health Minister Greg Hunt and then Victoria Health Minister, now Attorney-General, Jill Hennessy attended the announcement of a $405 million licence of the venetoclax rights to the Canada Pension Plan Investment Board (BD: Jul 27, 2017).

Earlier in 2017, the Institute said that venetoclax had been approved by the Australian Therapeutic Goods Administration for chronic lymphocytic leukaemia, following US and European approvals. (BD: Jan 22, 2017).

Abbvie said the drug was approved for acute myeloid leukaemia in the US.

Last week, the FDA said that it was "alerting health care professionals, oncology clinical investigators and patients about the risks associated with the investigational use of Venclexta for … patients with multiple myeloma based on data from a clinical trial".

The FDA said Venclexta was not approved for multiple myeloma and an FDA review of data from the Bellini clinical trial evaluating Venclexta combined with bortezomib, a proteasome inhibitor, and dexamethasone in multiple myeloma patients showed "an increased risk of death for patients receiving Venclexta as compared to the control group".

The FDA said that on March 6, 2019, it required that no new patients be enrolled in the Bellini trial but said that patients receiving clinical benefit could continue treatment in the trial after they reconsented.

"This statement does not apply to patients taking Venclexta for an approved indication," the FDA said.

"Patients taking Venclexta for an approved indication should continue to take their medication as directed by their health care professional," the FDA said.

"Venclexta is safe and effective for its approved uses," the US regulator said.

The FDA said it had suspended enrollment in other Venclexta multiple myeloma trials, but patients receiving clinical benefit could continue treatment after they reconsented and it would work with the Venclexta sponsors and other investigators conducting clinical trials in multiple myeloma patients, to determine the extent of the safety issue.

The FDA said it analyzed data from 291 randomized patients in the phase III, double-blind, randomized, controlled study, comparing bortezomib and low-dose dexamethasone with or without venetoclax in patients with relapsed and refractory multiple myeloma who had received one to three prior lines of therapy.

The FDA said there were 41 deaths of 194 patients (21.1%) in the venetoclax arm and 11 deaths of 97 patients (11.3%) in the placebo arm.

The FDA said the median progression-free survival was 22.4 months for the venetoclax arm and 11.5 months for the placebo arm; with an objective response rate of 82.0 percent in the investigational arm compared to 68.0 percent in the placebo arm; the minimal residual disease rate was 13.4 percent for venetoclax and 1.0 percent in the placebo arm; and the incidence of severe, grade 3-5 toxicity and serious adverse events were similar.

WEHI director Prof Doug Hilton told Biotech Daily that the Institute was "aware of the FDA's decision to place a partial clinical hold on clinical trials for venetoclax in multiple myeloma".

"Clinical trials are a vital process for comparing treatment options and assessing the risk versus benefit of new treatment approaches," Prof Hilton said. "This FDA decision does not impact any of the approved indications for venetoclax," Prof Hilton said.

REVA MEDICAL

Reva says it has a loan commitment for up to $US3 million ($A4,243,320) and will replace chief executive officer Dr Reggie Groves, with Jeff Anderson as president.
Reva said Dr Groves was appointed chief executive officer in 2015 (BD: Aug 21, 2015).
The company said that previously Mr Anderson was the head of clinical and regulatory affairs and had worked with the company for 12 years.
Reva said Dr Stephen Oesterle would take over as strategic advisor and had resigned from the board.
The company said the $US3 million in funding would be made by existing lenders on an interim basis, subject to negotiation and definitive agreements.
Reva was in an extended voluntary suspension at 17 cents.

USCOM

Uscom says China's National Medical Product Administration has granted a type II medical device business registration certificate allowing it to sell type II devices in China.
Uscom said it could now sell all type II medical devices, including its Uscom 1A, Uscom BP+ and Spirosonic ultrasonic spirometers directly in China.
The company said it was currently undertaking regulatory re-approval of Uscom 1A and initial approval of Uscom BP+ and Spirosonic from the Chinese National Medical Product Administration (NMPA).
Uscom executive chairman Prof Rob Phillips said the company was "not just selling products into China, we are building a long-term business in China based on a new business model".
"Following this certification, we can now import, support and sell medical devices independently as we bring our seven new products to the Chinese market," Prof Phillips said. "As our NMPA submissions progress, we are preparing by building the on-ground resources to expand operations in the China market."
"We are also focused on expanding our current distribution, to create a wide-reaching sales organization that can cover the expansive geography of China," Prof Phillips said.
"This new business model provides us with transparency of our distribution, sales and pricing in China, critical aspects of our growing China business," Prof Phillips said.
"This new licence also permits us to import non-Uscom type II medical devices with NMPA approvals and sell them through our expanding national distribution channels as agents for other manufacturers," Prof Phillips said.
Uscom was unchanged at 15.5 cents.

MESOBLAST

Mesoblast says Japanese licencee JCR Pharmaceuticals will extend the marketing approval of Temcell from graft versus host disease to epidermolysis bullosa.
Mesoblast said that epidermolysis bullosa patients had fragile skin that blistered and tore from minor friction or trauma, the disease affected internal organs and bodily systems and could be lethal before 30 years of age.
The company said its expanded licence agreement would give JCR access to its wound healing mesenchymal stem cell patents to develop Temcell for epidermolysis bullosa and it would receive royalties from product sales.
Mesoblast said it would access JCR clinical data to support the development of its MSC product remestemcel-L for epidermolysis bullosa outside Japan.
Mesoblast was up three cents or 2.2 percent to $1.415 with 1.2 million shares traded.

RACE ONCOLOGY

Race says it has filed its investigational new drug application for Bisantrene for acute myeloid leukemia with the US Food and Drug Administration.
Race said the investigational new drug (IND) application would allow it to undertake a registration-directed clinical trial of Bisantrene for acute myeloid leukemia in adults.
Race chief executive officer Peter Molloy said the submission was “a major milestone”.
“The filing of the [application] definitively brands Bisantrene as a phase III asset,” Mr Molloy said.
Race said the application was subject to a 30-day review period and the FDA question and answer process was likely to push the start of the trial “into the second half of 2019”.
The company said it had FDA rare paediatric disease designation and the investigational new drug application would be a “springboard” for its planned paediatric acute myeloid leukaemia trial, which could lead to a priority review voucher.
“I regard this IND as our most important achievement to date,” Mr Molloy said.
Race was up half a cent or 6.9 percent to 7.7 cents.

FACTOR THERAPEUTICS

Factor says it has received $2,488,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Factor said the incentive related to research and development expenditure for its US phase II clinical trial for the year to June 30, 2018.
Factor was up 0.05 cents or 14.3 percent to 0.4 cents with 2.0 million shares traded.

SOMNOMED

Somnomed says it is owed $US805,000 ($A1,138,624.20) from its Texas-based customer, Simple Sleep Services, which closed business on March 15, 2019.
Somnomed said according to legal advice, it may not recover between $US400,000 and $US805,000.
The company said its net profit after tax for the six months to June 30, 2019 would be affected as would its earnings before interest, taxation, depreciation and amortization (Ebitda) guidance of between $5.0 and $5.5 million.
Somnomed chief executive officer Neil Verdal-Austin said the closure of Simple Sleep Services (S3) was a surprise and said the company “successfully traded in the direct-to-consumer market in Texas for over six years and had become a significant Somnomed customer in a short period of time.”
“S3’s unit sales in November and December 2018 were good but further changes in regulations and reimbursement amounts introduced in Texas at the beginning of the 2019 insurance year changed the economic viability of its business,” Mr Verdal-Austin said.
“S3 seems to have succumbed to the same issues which led to the recent closure of our entity Renew Sleep Solutions,” Mr Verdal-Austin said. “Given the direct-to-consumer nature of this business and the changes in regulations and reimbursement levels relevant to both RSS and S3, this will not impact our other dental customers and we have not seen any change to our receivables balances outside of S3.”
Somnomed said S3 accounted for about nine percent of its North American revenue.
Mr Verdal-Austin said the company was working with Texas legal advisors to collect the outstanding debt, but a write-off “seems to be unavoidable and will unfortunately have a one-off impact on our earnings”.
Somnomed fell seven cents or 3.8 percent to $1.78.

NUHEARA

Nuheara says Iqbuds Boost has been recategorized in its UK National Health Service contract from “a hearing aid/accessory” to a niche innovation “hearable”.
Nuheara said its UK distributor Puretone advised that the new categorization would begin in May 2019 and followed a similar move by the Scottish National Health Service.
Nuheara fell one cent or 14.5 percent to 5.9 cents with 14.5 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

Thorney Opportunities and Thorney Investment Group Australia say they have increased their holding in TPI from 11,349,996 shares (14.00%) to 13,795,629 shares (17.01%).
The Melbourne-based Thorney Opportunities and Tiga Trading said that between December 13, 2018 and March 22, 2019 it acquired 1,149,182 shares for “market prices” and 1,296,451 shares for no money, failing to state the price paid, as required under the Corporations Act 2001.
TPI fell half a cent or 0.5 percent to $1.055.

THC GLOBAL

THC has requested a trading halt “pending an announcement with respect to the completion of an acquisition in Nova Scotia, Canada”.
Trading will resume on March 27, 2019 or on an earlier announcement.
THC last traded at 54.5 cents.