Biotech Daily

Monday May 29, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 5%, DIMERIX DOWN 22%**

*** DEATH HALTS PRESCIENT PTX-200 TRIALS**

*** SIRTEX INJUNCTION DISMISSED, $30m BUY-BACK STARTS JUNE 7**

*** ONEVENTURES $10m FOR MCRI, PROTA PEANUT ALLERGY WORK**

*** PHOSPHAGENICS FILES UP-TO $404m CLAIM AGAINST MYLAN**

*** BIOXYNE RIGHTS ISSUE RAISES $2.5m, TOTAL $3.07m**

*** VOLPARA CONTRACTS UP, CURRENT REVENUE DOWN 22% TO $2m**

*** MEDADVISOR PARTNERS WITH IHEALTH FOR MOBILE PRODUCTS**

*** NOXOPHARM NOX66, LUPSMA RADIOTHERAPY FOR PROSTATE CANCER**

*** MICHAEL POWELL, JOLIMONT TAKE 5.5% OF SIMAVITA**

*** SARAH PRINCE REPLACES SIMAVITA JOINT CO SEC NATHAN BARTROP**

MARKET REPORT

The Australian stock market fell 0.78 percent on Monday May 29, 2017 with the ASX200 down 44.6 points to 5,707.1 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and four were untraded.

Oncosil was the best, up 0.5 cents or 4.55 percent to 11.5 cents, with 133,895 shares traded. Admedus, Benitec and Cyclopharm climbed more than three percent; Polynovo and Prana rose more than two percent; Psivida was up 1.6 percent; with CSL and Mesoblast up by less than one percent.

Dimerix led the falls, down 0.2 cents or 22.2 percent to 0.7 cents with 11.9 million shares traded. Osprey lost 7.7 percent; Avita and Impedimed retreated more than five percent; Ellex and IDT fell more than four percent; Airxpanders and Starpharma were down more than three percent; Acrux, Genetic Signatures and Orthocell shed two percent or more; Cellmid, Clinuvel and Medical Developments were down more than one percent; with Cochlear, ITL, Nanosonics, Opthea, Pharmaxis, Pro Medicus and Viralytics down by less than one percent.

PRESCIENT THERAPEUTICS

Prescient says it has paused recruitment to trials of PTX-200 following the death of the last of 29 patients in its phase Ib breast cancer trial.

Apart from breast cancer study, Prescient was trialling PTX-200, previously known as triciribine phosphate monohydrate (TCN-P) for breast, lung and oesophageal cancer, as well as acute myeloid leukaemia and ovarian cancer, and as recently as last month declared PTX-200 and Paclitaxel safe and had shown signs of efficacy for breast cancer (BD: Aug 26, 2015; Feb 17, Dec 8, 2016; Mar 8, Apr 6, 2017).

Today, Prescient said that the female patient had stage IV metastatic triple negative, or advanced poor prognosis, breast cancer and experienced liver failure while also being treated with paclitaxel, which can impact liver metabolism.

The company said that the principal investigator told the US Food and Drug Administration that the cause of the serious adverse event was possibly related to paclitaxel, possibly related to PTX-200, and possibly related to pioglitazone.

Prescient said that as per its operating procedures, it had “temporarily paused recruitment to each of its PTX-200 trials” to further investigate the serious adverse event with its consultants, review the protocols and update its risk mitigation plan, in order to maximize patient safety as well as ensuring maximum efficacy.

The company said that the FDA had been notified and in early interactions concurred with this approach and placed the trials on clinical hold while it requested further information and assisted Prescient update its risk mitigation plan.

Prescient said that once the process was completed it intended to re-commence enrolment following lifting of the FDA clinical holds.

Prescient chief executive officer Steven Yatomi-Clarke said the company was “in close dialogue with the FDA and expect to incorporate its recommendations and modifications into the trial protocols so that recruitment can re-commence at the earliest opportunity”.

Prescient fell 3.1 cents or 34.8 percent to 5.8 cents with 4.7 million shares traded.

SIRTEX MEDICAL

Sirtex says the Federal Court has dismissed an injunction application to delay its proposed $30 million, 2,000,000 share on-market buy-back.

Sirtex said the buy-back would begin after the American Society of Clinical Oncology meeting in Chicago, Illinois on June 7, 2017.

In March Sirtex delayed the start of the share buy-back to April 17, instead of March 27, 2017 “to allow sufficient time to respond to a threatened injunction as more fully detailed in the ASX release dated March 2, 2017”, with the matter further delayed pending the federal Court decision (BD: Mar 2, 13; Apr 11, 2017).

In February, Sirtex said it received a draft statement of claim from Todd Hayward who acquired 340 Sirtex shares for $9,449 on December 1, 2016 and held them when the company’s share price fell following a profit warning by former chief executive officer Gilman Wong, followed by Mr Wong’s dismissal (BD: Dec 9, 2016; Feb 1, 13, 2017).

Sirtex said in February that the correspondence threatened an injunction to stop the share buyback, “on the basis he alleges that the implementation of the share buyback will materially prejudice Sirtex’s ability to satisfy any liability arising in respect of the claims” and it would delay the buy-back while it addressed the allegation.

Today, the company said the Federal Court of Australia dismissed the injunction.

Sirtex said it had filed a stay application in relation to the previously announced class action, which was listed for hearing on August 15 and 16, 2017.

Sirtex was unchanged at $11.85 with 832,915 shares traded.

ONEVENTURES, PROTA THERAPEUTICS, MCRI

Oneventures says it has invested $10 million through its Oneventures Healthcare Fund III to Prota Therapeutics to develop a new treatment for peanut allergy in children.

Last year, Oneventures led a $15 million raising for the program (BD: Sep 29, 2016).

Today, Oneventures said that the $170 million Healthcare Fund III was established as part of the Federal Government's Biomedical Translation Fund initiative, awarded $85 million from the Federal Government, matched by Oneventures' investors.

Oneventures managing partner Dr Paul Kelly said that the funds would also allow Prota to explore indications for treating other food allergies, with work conducted at Melbourne's Murdoch Children's Research Institute.

A media release from Oneventures said that the treatment was "attracting the attention of global pharmaceutical companies and unlike other peanut allergy treatments in development, this new therapy is the first to allow children with peanut allergies to incorporate peanut and peanut products as a regular part of their diet".

Prota chief executive officer Dr Suzanne Lipe said that the funds meant the company could "accelerate our progress to delivering life-saving treatments for food allergies".

"It helps offer a real opportunity to develop Australia's first oral treatment for peanut allergies, and has the potential to be adapted to treat other common food allergies including allergies to milk, egg and other nuts," Dr Lipe said.

Oneventures said that the investment funds would assist Prota's trial program, including recruitment of the current multi-centre peanut allergy study, developing scaled-up manufacturing processes and preparation of documentation for discussions with regulatory agencies.

The company said that recruitment was expected to be completed by the end of 2018.

Oneventures said that the Murdoch Children's Research Institute researcher and Prota chief scientific officer Prof Mimi Tang developed the peanut allergy treatment.

PHOSPHAGENICS

Phosphagenics says that last week it filed its expert reports in the arbitration with Mylan Laboratories, including a maximum $404.1 million damages claimed.

Phosphagenics said that in 2016 it began confidential arbitration proceedings against Mylan Inc subsidiary Mylan Laboratories, filing notices of arbitration at the Singapore International Arbitration Centre (BD: Jan 25, 2016).

In March, the company said it was in a legal dispute with Mylan over its licence of tocopheryl phosphate mixture (TPM) daptomycin for complicated skin infections and staphylococcus aureus bloodstream infections licenced to Strides Arcolab subsidiary, the India-based Agila Specialties, which Biotech Daily estimated as worth "tens of millions" of dollars (BD: Oct 30, 2012; Mar 3, 2017).

Today, Phosphagenics said that on Friday May 26, 2017 it filed expert evidence in the arbitration relating to the net present value of the income stream which Phosphagenics could have expected, had the matters referred to in its claims not occurred and if it was to succeed on all aspects of its claims, the maximum damages was about $US300.4 million ($A404.1 million).

The company said that it was likely that Mylan would challenge the assumptions in the calculation and would continue to contend that it was not otherwise liable in respect of the various claims.

Phosphagenics said there could be "no assurance whatsoever in respect of the outcome of the arbitration proceedings" and it could consider settlement discussions with Mylan.

Phosphagenics rose 0.3 cents or 21.4 percent to 1.7 cents with 3.5 million shares traded.

BIOXYNE

Bioxyne says its rights issue at one cent a share has raised $2,537,826 with shareholders subscribing for 61.9 percent of the available shares.
Bioxyne said that 157,033,283 shares were subscribed in the offer with the balance of 96,749,342 shares taken up by the underwriters.
In April, Bioxyne said it raised $534,024 in a placement at 1.9 cents a share and hoped to raise $3,064,350 to acquire a business to sell products in Asia (BD: Apr 19, 2017).
Bioxyne was up 0.2 cents or 12.5 percent to 1.8 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the 12 months to March 31, 2017 was down 21.7 percent to $NZ2,047,000 ($A1,937,380) with net loss after taxation of $NZ9,571,000.
Volpara said that loss per share fell 94 percent to 0.07 NZ cents with cash and cash equivalents at March 31 of $12,876,000.
The company said that annual recurring revenue, the contracted revenue expected to be booked over the next 12 months from current contracts, was $NZ1.1 million up about 600 percent from the previous year.
Volpara said it had “strong year-on-year growth in terms of total contract value”, increasing subscription revenue to be recognised in future periods following the launch of its Volpara Enterprise software and the transition to a software-as-a-service model.
The company said that total contract value, including capital sales, service maintenance agreements and software-as-a-service contracts, was $NZ4.1 million in the year to March 31, 2017, compared to $NZ2.8 million the previous year.
Volpara chief executive officer Dr Ralph Highnam said that products and the business model had evolved over the past year with the launch of Volpara Enterprise software.
“The move to a [software-as-a-service] revenue model and the [internet] cloud has been well received by our customers and gives our investors a clearer view of potential future revenue and many advantages for future product development,” Dr Highnam said.
Volpara fell one cent or 2.8 percent to 35 cents.

MEDADVISOR

Medadvisor says it will integrate its pharmacy prescription reminder service with the Mountain View, California-based Ihealth Lab’s mobile telephone healthcare products.
Medadvisor that Ihealth Lab was a subsidiary of the Tianjin, China-based Andon Health and it would be Ihealth’s exclusive pharmacy mobile telephone application partner in Australia.
The company said that Ihealth was a provider of mobile health devices and applications that enable patients to measure and track a range of health metrics, including blood pressure monitors, blood glucose monitors, body analysis scales, pulse oximeters and activity and sleep trackers, all linked to a mobile application to enable users to store and share data with healthcare professionals.
Medadvisor said the agreement was the first time Ihealth had been integrated with a third party patient application in Australia, which would be enabled through its soon-to-be-launched health service hub, within Plusone, which enabled pharmacies to stay connected with their customers through the use of its platform.
The company said that pharmacies would be able to order Ihealth devices through its application creating a new incremental revenue stream.
Medadvisor was up 0.2 cents or 6.7 percent to 3.2 cents with 2.1 million shares traded.

NOXOPHARM

Noxopharm says its NOX66 will be trialled at Sydney's St Vincent's Hospital in combination with radiotherapy in 30 men with late-stage prostate cancer.
Noxopharm said the prospective, open label, single arm phase I study would administer four one-monthly cycles of a single intravenous injection of 177-lutetium-prostate specific membrane antigen (Lupsma) peptide complex followed by 10 days of NOX66.
The company said patients would be examined for tumor response after each cycle and at 12 months, with efficacy outcomes including serum prostate-specific antigen levels, tumor load by imaging, quality of life, pain scores, progression-free survival and overall survival.
Noxopharm said that NOX66 would be trialled with the experimental form of radiotherapy in men with metastatic, castrate-resistant prostate cancer who had failed to respond to all standard therapies and who had limited survival prospects, to begin in June 2017.
Noxopharm said it was developing NOX66 as "a radio-sensitizing drug intended to convert a palliative effect of radiotherapy in most forms of late-stage cancer into a meaningful clinical effect providing a significant survival advantage".
In March Noxopharm said it would investigate NOX66 and its active ingredient idronoxil for "the abscopal response … [which was] a rare phenomenon encountered in cancer patients undergoing radiotherapy …with the unexpected disappearance of all cancers in the body following exposure of only a limited number of those cancers to radiotherapy" (BD: Mar 3, 2017).
Today, the company said it was undertaking a program of trials evaluating NOX66's radio-sensitizing capacity across three forms of radiotherapy for late-stage prostate cancer.
Noxopharm said that Lupsma was effective at locating prostate cancer cells, including clusters too small to be seen by standard methods, with the drug delivering small doses of a radioactive emitter directly to the prostate cancer cells.
The company said the study was an extension of a pilot study by St Vincent's Hospital with Melbourne's Peter MacCallum Cancer Centre, which provided proof-of-concept of Lupsma to attack lesions in men with late-stage prostate cancer, with most men showing a reduction in the size and number of cancer lesions, but the response incomplete and relatively short-lasting and the new study hoped NOX66 would achieve a better response.
Noxopharm climbed 2.5 cents or 6.9 percent to 38.5 cents.

SIMAVITA

The Melbourne-based Michael Powell says he has become a substantial shareholder in Simavita with 15,912,265 Chess depository instruments (5.51%).
Mr Powell said the shares were held by Jolimont Lodge acting for the Powell Family superannuation fund and between June 20, 2013 and May 8, 2017 the group bought the shares for $1,223,421 or an average price of 7.7 cents a share.
Simavita was untraded at 3.8 cents.

SIMAVITA

Simavita says that Sarah Prince will replace her Company Matters Pty Ltd colleague Nathan Bartrop as joint company secretary, effective from May 26, 2017.
Simavita said that chief commercial officer Peta Jurd was the other company secretary.