Biotech Daily

Tuesday March 22, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 12%; USCOM DOWN 9%**

*** AVITA: BARDA BACKS RECELL SOFT TISSUE TRIAL**

*** NOXOPHARM: VEYONDA SOFT TISSUE SARCOMA FDA ORPHAN STATUS**

*** RESAPP CLAIMS 92% COVID-19 DETECTION**

*** ALCIDION: $1.35m HEREFORDSHIRE, WORCESTERSHIRE NHS MIYA DEAL**

*** MEMPHASYS: 'SAMSON 90% PREGNANCY PREDICTION RATE'**

*** NEXT SCIENCE SHARE PLAN RAISES $4.8m; TOTAL $14.8m**

*** TELIX STARTS BELGIUM RADIO-PHARMACEUTICAL FACILITY**

*** TOTAL BRAIN TO REPAY $3.2m LOANS, EXPECTS R&D TAX INCENTIVE**

*** INCANNEX REQUESTS 'ACQUISITION' TRADING HALT**

*** BIO-MELBOURNE FORUM ON CYTIVA BIO-CHALLENGE**

*** BOTANIX APPOINTS DANIEL SHARP DIRECTOR**

*** MAYNE APPOINTS ANN CUSTIN DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.86 percent on Tuesday March 22, 2022, with the ASX200 up 62.6 points to 7,341.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and one was untraded.

Actinogen was the best, up 1.1 cents or 12.4 percent to 10 cents, with 4.96 million shares traded. Emvision and Micro-X climbed more than 10 percent; Oncosil was up 8.8 percent; Starpharma rose 6.25 percent; Alcidion was up 5.6 percent; Impedimed improved 3.3 percent; Dimerix rose 2.6 percent; Clinuvel, Genetic Signatures, Mesoblast, Next Science, Orthocell, Paradigm, Telix and Universal Biosensors were up more than one percent; with Avita and Cochlear up by less than one percent.

Uscom led the falls, down 0.9 cents or 9.2 percent to 8.9 cents, with 93,373 shares traded. Prescient lost 8.6 percent; Neuren was down five percent; Atomo, Immutep and Proteomics fell more than four percent; Antisense, Imugene and Medical Developments were all down 3.7 percent; Kazia, Nanosonics and Opthea shed more than two percent; Cyclopharm, Cynata and Resmed were down more than one percent; with CSL and Pro Medicus down by less than one percent.

AVITA MEDICAL

Avita says the US Biomedical Advanced Research and Development Authority (BARDA) will support its Recell for soft tissue reconstruction trial.

Avita did not disclose the amount of funding but company said the project was “funded in whole or in part with Federal funds from … [BARDA]”.

In 2020, Avita said it had enrolled the first patient in its up to 65-patient pivotal study of Recell spray-on skin for soft tissue reconstruction at the Arizona Burn Center and this year said it had completed patient enrolment (BD: Mar 3, 2020; Jan 16, 2022).

In 2017, Avita said BARDA had expanded its burns research contract valued at about $US24.3 million to fund clinical and health economics research in US paediatric burn care to September 2022 (BD: Sep 21, 2017)

In 2015, the company said it signed its first five-year BARDA contract worth up to $US53.9 million, then worth $A77 million, to provide more than 5,000 Recell wound treatment units (BD: Sep 30, 2015).

Today, Avita said that soft tissue reconstruction was of “particular concern” to BARDA as skin grafting, the current standard of care for soft tissue reconstruction, required the harvesting of donor skin which could result in an additional wound to the patient.

The company said that significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring were associated with donor site wounds.

Avita said that while skin grafting was commonly associated with burn treatment, in 2017, about 80 percent of acute wounds that required skin grafting were non-burn related injuries accounting for more than 200,000 procedures in the US.

The company said it was completing the pivotal trial of Recell spray-on skin for soft tissue reconstruction, with topline data to be available “later this year”.

Avita chief executive officer Dr Mike Perry said that “the Recell system has already proven itself as a safe and effective tool for those with burns, and we are committed to expanding its use to include all acute wounds”.

“We are please BARDA recognizes the potential it holds for a broader group of patients experiencing trauma,” Dr Perry said.

Avita was up two cents or 0.9 percent to $2.21.

NOXOPHARM

Noxopharm says the US Food and Drug Administration has granted Veyonda, or NOX66, orphan drug designation for soft tissue sarcoma.

Noxopharm said that the orphan drug designation program was established by the “to encourage companies to develop treatments for less common disorders” and would provide seven years of market exclusivity, waiver of new drug applications fees worth about $2.9 million, opportunities for grant funding, and regulatory guidance and assistance from the FDA with the drug development process.

Noxopharm chief executive officer Dr Gisela Mautner said that of about 360 approved designations last year “only four went to Australian companies, [demonstrating] the high bar that is being set by the FDA”.

“[Orphan status] will significantly increase the value proposition of Veyonda to potential purchases or licencees by both lowering current development costs and by providing future competitive and financial advantages as Veyonda progresses through the clinical trial stages towards registration and approval for sale in the US,” Dr Mautner said.

In February, Noxopharm said it had treated the first of 30 patients in its phase I trial of Veyonda, with doxorubicin for metastatic soft tissue sarcoma (BD: Feb 28, 2022).

Noxopharm was up six cents or 18.2 percent to 39 cents with 1.3 million shares traded.

RESAPP HEALTH

Resapp says its 741-paitent pilot trial shows that its cough diagnostic screening test can "correctly detect Covid-19 in 92 percent of people with the infection".

Resapp said that its test, using machine learning, achieved an area-under-the-curve (AUC) of 0.93 using cough audio and patient-reported symptoms across both trials.

The company said that an AUC value of 1.0 was a perfect test and a value greater than 0.9 was considered "outstanding".

Resapp said that with this area-under-the-curve it could select different operating points to achieve either high sensitivity, high specificity or a balance of sensitivity and specificity.

Resapp did not provide the trial data, but said that for use as a screening test prior to a rapid antigen or polymerase chain reaction (PCR) test to rule out Covid-19, an operating point that provides a 92 percent sensitivity and 80 percent specificity could be selected … [and] "this sensitivity exceeds the real-world measured sensitivity of rapid antigen tests".

Resapp said that the combination of high sensitivity and 80 percent specificity meaning eight of 10 people without Covid-19 would being correctly screened as negative and not require a rapid antigen or PCR test.

Resapp said it would initially target use where frequent testing was required, such as employee, healthcare worker and student screening, travel, sports, entertainment and aged care, in which a high sensitivity test that only required a smartphone would "significantly reduce the number of rapid antigen or PCR tests required".

The company said that its algorithm was testing against the Breathe Easy dataset and achieved greater than 90 percent specificity for 1,007 patients with a variety of non-Covid-19 related respiratory conditions.

Deakin University chair of epidemiology and Resapp adviser Prof Catherine Bennett said that "by rapidly ruling out Covid-19, Resapp's Covid-19 test would significantly reduce the number of rapid antigen and PCR tests required, while still maintaining the disease surveillance needed to manage the continued impact of Covid-19".

Resapp managing director Dr Tony Keating said he was "very excited about these preliminary results for detecting Covid-19 using cough audio recorded on a smartphone".

"These algorithms offer a unique opportunity to provide a rule-out screening test for Covid-19 at scale across the world, reducing the distribution challenge, the cost and the environmental impact of rapid antigen and PCR testing," Dr Keating said.

"We intend to accelerate commercialization by immediately engaging with regulators globally and we have already commenced discussions with global health and technology companies with the goal of rapidly brining this product to market," Dr Keating said.

Resapp was up 2.2 cents or 35.5 percent to 8.4 cents with 57.25 million shares traded.

ALCIDION GROUP

Alcidion says Herefordshire and Worcestershire NHS Trust will pay $1.35 million over five years for the Miya Flow module of Miya Precision for patient management.

Alcidion said the Herefordshire and Worcestershire National Health Service (NHS) was the first community trust to use its Flow technology which would "enable community hospitals across Worcestershire to streamline patient journeys, ensure timely care and discharge and more easily and efficiently management beds across multiple sites".

The company said the system would provide staff with the information to help manage the flow of patients via interactive electronic journey boards across six community hospitals.

Alcidion chief executive officer Kate Quirke said the Herefordshire and Worcestershire Trust had an "appetite for technology" that improved the lives of healthcare professionals.

Alcidion was up one cent or 5.6 percent to 19 cents with 2.5 million shares traded.

MEMPHASYS

Memphasys says that its Samson stallion fertility diagnostic device is up to 90 percent accurate in predicting pregnancy of an inseminated mare within an hour.

Last year, Memphasys said that it had data on 240 mare inseminations for its Samson stallion sperm quality test, with results expected by April 2022 (BD: Dec 2, 2021).

Today, the company said that it had undertaken field trials on Samson's ability to predict the change of a pregnancy within an hour of a stallion-mare coupling, whether naturally or by artificial insemination.

Memphasys said that thoroughbreds can only be legally bred using natural mating not using artificial insemination, whereas other horses such as standardbreds could use artificial insemination.

The company said that pregnancy in a mare could not be ascertained until 14 days after coupling, by which time the mare might have missed her chance of pregnancy.

Memphasys said that the use of the Samson diagnostic "could dramatically increase the overall mare pregnancy rates within the season".

The company said that the study was run by the New South Wales' University of Newcastle reproductive science department, led by Prof John Aitken, and field trialled at a thoroughbred and a standardbred stud farm, both in New South Wales, during the September-to-November 2021 Australian horse breeding season.

Memphasys said that the trial showed the ability of Samson to provide accurate on-site pregnancy predictions, provided that a reasonable quality sample of the stallion ejaculate was collected.

Memphasys said that for thoroughbred stallions, the analysis generated a "predictive accuracy of 75 percent when all stallions' data was combined" but that pregnancy prediction accuracy was "improved to 80-90 percent for thoroughbred stallions when the Samson algorithm was optimized for each stallion, by determining which variables are best used for each stallion to improve pregnancy prediction accuracy".

The company said that the Samson diagnostic had a large addressable market, with major breeding activities in the US, Australia, Japan, Ireland, New Zealand and other countries.

Memphasys said that along with the need for improvements in fertility assessments to bolster mare pregnancy, service fees for successful fertilization were as high as $200,000 per fertilization.

The company said that no regulatory approvals were required before the Samson device could be sold commercially.

Memphasys said it planned to test a modified version for bulls to determine whether a similar capability could be developed for beef and dairy cattle.

Memphasys fell 0.4 cents or 5.7 percent to 6.6 cents with 2.1 million shares traded.

NEXT SCIENCE

Next Science says it has raised $4.8 million in a share purchase plan at 90 cents a share, taking the total raised to $14.8 million.

In February, the company said it had raised $10 million in a placement at 90 cents a share and hoped to raise a further $5 million in a share plan (BD: Feb 24, 2022).

Today, Next Science managing-director Judith Mitchell said that the funds would "provide important working capital needed to fund investment in clinical studies to provide further evidence of the efficacy of Xperience and to accelerate the growth profile of the business and invest in sales and marketing".

Next Science was up 1.5 cents or 1.7 percent to 88.5 cents.

TELIX PHARMACEUTICALS

Telix says it has started development of its radio-pharmaceutical production facility in Brussels South in the Wallonia region of Belgium.

Telix said that the facility would be its primary European manufacturing site, aligning with its strategic objective of maintaining control and reliability of its supply chain, cost control and acting as a hub for its research and development activities, specifically in relation to the scale-up of radioisotope production.

The company said that following the decommission and removal of two pre-existing cyclotrons on the site in late 2021, it secured an EUR12.1 million ($A18.2 million) loan to help fund first-stage building works, which would include a radio-pharmacy as well as installation of the first cyclotron, clean rooms and purification suites.

Telix said the finance had been structured through low-cost loans with BNP Paribas and IMBC Group, funded by the Walloon Regional Government and local private investors.

The company said BNP Paribas and IMBC loans totalled EUR10.1 million on a 10-year term, with a EUR2 million loan from BNP Paribas on a two-year, extendable term.

Telix said all three loans had a two-year repayment holiday period to March 2024.

The company said it had applied for EUR2 million in grants from the Wallonia Export-Investment Agency, which would be used to repay the two-year loan, and it would contribute EUR2 million from existing cash reserves for stage 1, projected for completion by mid-2023, with a total planned capital expenditure of EUR14.1 million.

Telix said that on completion, stage 1 would be able to “produce a wide range of medical isotopes, for use in its own … programs, as well as for other organizations”.

Telix said it hoped the site would become a hub for radio-pharmaceutical research and development including collaborations with pharmaceutical and biotech companies, hospitals and universities.

The company said that the facility was located within an operational hub that was home to many pharmaceutical and logistics companies, several of whom it had existing relationships with, and was in close proximity to logistics networks.

Telix managing-director Dr Christian Behrenbruch said the facility and its integrated operations would “differentiate Telix as a … leader in the radiopharmaceutical industry”.

“It is our vision that having the Brussels South manufacturing facility, with its central European location, will provide us with greater control over our supply chain and form an integral part of our [research and development] capability, which will become increasingly important as we increase our commercial, clinical and compassionate use activity,” Dr Behrenbruch said. “It has always been our goal to source low-cost capital to fund the build-out of this site and preserve cash reserves to advance the development and expansion of our diagnostic and therapeutic pipeline.”

Telix was up seven cents or 1.4 percent to $5.01 with 879,443 shares traded.

TOTAL BRAIN

Total Brain says it has paid $560,462 in principal and interest to F45 Inc to finalize the repayment of a $US380,000 ($A514,806) loan.

Total Brain said it had a five-day extension of the loan term for its $US500,000 ($A675,616) loan with Hong Kong’s Varga Capital to “allow for ongoing negotiations regarding the potential extension of the term to be completed by March 28, 2022”.

The company said that its $2,000,000 loan with Melbourne’s Mitchell Asset Management Pty Ltd was due May 31, 2022 and it expected a Federal Research and Development Tax Incentive sufficient to repay the loan prior to the due date.

Total Brain fell one cent or 8.3 percent to 11 cents.

INCANNEX HEALTHCARE

Incannex has requested a trading halt pending an announcement regarding “a potential business acquisition transaction”.
Incannex said trading would resume on March 24, 2022 or on an earlier announcement.
Incannex last traded at 70 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its March Bio-Forum will address ‘Biotech Innovations – A Bio Challenge Winner Showcase’.
The Network said the event would showcase the industry researchers and companies who finished in the top four places in Cytiva’s Australia and New Zealand Bio Challenge.
In February, Melbourne’s Vivazome Therapeutics said it won the $200,000 top prize in the Cytiva Life Sciences Australia and New Zealand Bio-Challenge (BD: Feb 2, 2022).
Vivazome said at that time that the Marlborough, Massachusetts-based Cytiva, formerly known as General Electric Life Sciences, had 32 applications from universities and companies in its inaugural Australia and New Zealand challenge.
Today, the Bio-Melbourne Network said that guest speakers would include MTP Connect executive Jarrod Belcher, Therapeutic Innovation Australia chief executive officer Dr Stuart Newman, Vivazome chief executive officer Dr David Haylock, Macquarie University strategic research initiatives director Dr Brenton Hamdorf and Cytiva executive Dr Tim O’Meara.
The Network said the virtual event would be held on March 30, 2022 from 1pm to 2pm (AEDT)
For details and registration, go to: https://bit.ly/3NdAx2P.

BOTANIX PHARMACEUTICALS

Botanix says it has appointed Daniel Sharp as a non-executive director and would issue him 5,000,000 options.
Botanix said that in addition to director fees, it would issue Mr Sharp 1,000,000 options with an exercise price to be the lower of the closing share price on the previous days’ trading before issue and the seven-day volume-weighted average price of the shares traded before the day of issue, expiring one year after the date of issue.
The company said it would issue Mr Sharp an additional 4,000,000 options with an exercise price at a 33 percent premium to the lower of the closing share price on the previous day’s trading before the date of issue and the seven-day volume-weighted average price of the shares traded before the date of issue, expiring three years after the issue date, vesting progressively over three years.
Botanix said that Mr Sharp had more than 30 years’ experience in capital markets, advising technology and healthcare-based organizations.
Botanix said that most recently Mr Sharp was Canaccord Genuity corporate finance executive director and previously headed the corporate finance departments at Shaw and Partners and Lodge Partners.
The company said that Mr Sharp was currently a director of Alcidion Group and was on the investment committee of the Baker Heart and Diabetes Institute.
Botanix said Mr Sharp held a Bachelor of Economics and a Bachelor of Laws from Melbourne’s Monash University.
Botanix fell 0.7 cents or nine percent to 7.1 cents with 2.6 million shares traded.

MAYNE PHARMA

Mayne says it has appointed Ann Custin as a non-executive director, effective from March 23, 2022.

Mayne said that Ms Custin had almost 40 years of experience in the healthcare sector and was most recently a director and chief financial officer of the Malvern, Pennsylvania-based Siemens Medical Solutions

The company said that previously Ms Custin was the Philadelphia, Pennsylvania-based Scient'x Group chief operating and financial officer, and the Andover, Massachusetts-based USA Draeger Medical Systems chief executive officer.

Mayne said that Ms Custin held a Bachelor of Accounting from New York's City University.

Mayne fell half a cent or two percent to 24 cents with 2.7 million shares traded.