Biotech Daily

Tuesday October 6, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 20%; ACTINOGEN DOWN 7%**

*** MTP CONNECT 2nd COVID-19 IMPACT REPORT**

*** TELIX 18F-FET WINS FDA ORPHAN STATUS FOR GLIOMA IMAGING**

*** BARDA PAYS VAXXAS $31m FOR 'NO-NEEDLE' PANDEMIC 'FLU VACCINE**

*** RESONANCE DEVELOPS ALERT-PE AI FOR PULMONARY EMBOLISM**

*** UNIVERSAL BIOSENSORS: PROMEDEUS XPRECIA STRIDE DISTRIBUTOR**

*** AUSTRALIAN PATENT FOR PATRYS DEOXYMAB FOR CANCER**

*** RHYTHM 1.5m M-D TREVOR LOCKETT OPTIONS AGM**

*** NOXOPHARM AMENDS $4.2m NORA GOODRIDGE LOAN**

*** ALTERITY FILES $70m US SEC REGISTRATION FORM**

MARKET REPORT

The Australian stock market was up 0.35 percent on Tuesday October 6, 2020, with the ASX200 up 20.5 points to 5,962.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell and seven traded unchanged.

Patrys was the best, up 0.3 cents or 20 percent to 1.8 cents, with 56.1 million shares traded. Telix climbed 11.25 percent; Amplia and Impedimed improved more than nine percent; Alterity was up 8.5 percent; Proteomics rose 6.4 percent; Immutep, Oncosil, Opthea and Paradigm were up more than four percent; Prescient was up 3.2 percent; Uscom and Volpara rose more than two percent; with Cynata, Cyclopharm, Imugene, Orthocell and Starpharma up by more than one percent.

Actinogen led the falls, down 0.2 cents or 6.9 percent to 2.7 cents, with 1.3 million shares traded. Mesoblast and Nanosonics fell more than four percent; Clinuvel, LBT and Resonance lost more than three percent; Neuren and Next Science shed more than two percent; Cochlear, Genetic Signatures, Kazia and Pharmaxis were down more than one percent; with CSL, Compumedics, Medical Developments, Polynovo and Pro Medicus down by less than one percent.

MTP CONNECT (MEDICAL TECHNOLOGIES & PHARMACEUTICALS GROWTH CENTRE)

The MTP Connect second 'COVID-19 Impact Report' says biotechnology has been impacted by the pandemic, is recovering and faces "challenges".

The report was prepared for the Federally-funded MTP Connect by LEK Consulting Australia Pty Ltd and discusses sector impacts, the road to recovery and future pandemic preparedness.

The report says that the pandemic "caused significant negative impacts to the … sector in the period March to May 2020 … up to 90 percent of clinical trials were put on hold, elective surgeries were banned and supply chain integrity for many companies was compromised as international borders were closed and air traffic ground to a halt".

MTP Connect said that the market capitalization of ASX-listed companies fell by $11 billion or five percent and "many … companies and organizations suffered from a severe decline in revenue and margins".

[The MTP figures include CSL which significantly skews the data. The BDI-40 is at its second highest level on record just below its January 31, 2020 all-time high.]

MTP Connect said that since May, the sector has begun its recovery "as case numbers reduced and restrictions across most of Australia began to ease, enabling the resumption of many activities … including clinical trials, pre-clinical [research and development] activity and elective surgeries".

The organization said a second wave of infections sent Melbourne into lockdowns in August, "creating challenges for the organizations that are either based in, or dependent on Victoria for revenue" and supply chain challenges persisted as international borders remained closed with both import and export air freight remaining limited and costly.

The report said universities were "under enormous financial pressure, with an estimated $2 billion lost in revenue from [foreign] student fees resulting in substantial job losses and the slowing down or stopping of research activities".

MTP Connect said that despite the challenges, the sector "played a key role in response to the pandemic" with organizations working closely with Federal, State and Territory governments to develop local manufacturing capabilities for essential medical equipment and supplies such as ventilators and personal protective equipment.

The report said universities stepped-up to maintain health and medical research efforts, including to develop a vaccine and Australia was involved in vaccine clinical trials.

MTP Connect said flexible regulatory and reimbursement pathways were developed to enable rapid innovation and adoption of technologies; industry and the research sector worked collaboratively with government to develop solutions to complex issues such as rapid scale-up of diagnostic testing and supply of medical equipment and components.

MTP said continuing challenges included the need for a therapy or vaccine, dealing with the increased healthcare burden, more than 2,000 jobs had been lost at universities, companies continued to face difficulty securing reliable and cost-effective international freight, while non-government funding for research and development amounted to 80 percent of activities, with research institutions "facing significant financial deficits".

The report said three key actions were: to codify lessons learned, embed and enhance what worked well during Covid-19; improve supply chain resilience and enhance sovereign supply and manufacturing capabilities; and invest in research and development and next generation technologies related to pandemics.

MTP Connect said Covid-19 had "also driven innovation, the adoption of new technologies and behavioral changes at an unprecedented rate" presenting opportunities for post-pandemic growth for the sector, including virtual consultations and remote monitoring along with the growth in home deliveries of medical supplies and medicines to patients.

Biotech Daily editor David Langsam contributed to the report.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has granted its l-tyrosine analog 18F-FET orphan drug designation for glioma positron emission tomography imaging.
Telix said it would be qualified for drug development incentives, including market exclusivity for seven years, waived FDA prescription drug user fees and tax credits for research and development and clinical development costs.
The company said gliomas were a group of primary brain tumors arising from glial cells that surrounded and supported brain neurons, with more than 22,000 US cases per year.
Telix said its O-(2-18-F-fluoroethyl)-L-tyrosine (18F-FET) enabling radio-pharmaceutical targeted the amino acid transport system L and was suitable as a companion diagnostic to TLX101 for glioblastoma, a form of glioma.
The company said the 18F-FET was used to select and track patients in its phase I/II trials of TLX101, currently recruiting in Europe and Australia (BD: Dec 23, 2019).
Telix chief executive officer Dr Christian Behrenbruch said “the granting of an orphan drug designation by the FDA for 18F-FET provides Telix with the option to develop this valuable [positron emission tomography] imaging agent commercially, to ensure it is available to patients with glioma across the disease spectrum”.
“18F-FET’s relevance as a patient selection and therapeutic monitoring tool for TLX101 is particularly beneficial to the company,” Dr Behrenbruch said.
Telix was up 18.5 cents or 11.25 percent to $1.83 with 1.2 million shares traded.

VAXXAS

Vaxxas says the US government will pay $US22 million ($A30.6 million) to test its “needle-free” vaccine technology for pandemic influenza.
In June, Vaxxas said that Merck Sharpe and Dohme would pay up to $18 million in cash to use its needle-free patch platform for a Merck vaccine (BD: Jun 1, 2020).
Today, the company said the award was funded by the US Biomedical Advanced Research and Development Authority for a phase I study of its high-density micro-array patch (HD-MAP) to deliver pandemic influenza vaccine to more than 400 people.
Vaxxas said the project was estimated to cost $US24.1 million, with the company contributing $US2.1 million, and pandemic influenza vaccine was selected for the study to set a baseline for the immune response and safety of its technology when used for pandemic preparedness and response.
Vaxxas said its micro-needle array technology was attractive for pandemic response as it had been used lower doses of vaccine for the same effect as intra-muscular injections.
The company said that in its first clinical study, the patch used one-sixth the dose for comparable immune responses as standard intra-muscular injections and the immune response was “significantly higher and have faster onset than by intramuscular injection at comparable doses”.
Vaxxas said the 9mm by 9mm array of thousands of 250 micro-metre projections were coated with vaccine and delivered to immune cells in the skin.
The company said that vaccines on its patch had been shown to be stable for 12 months at temperatures as high as 40°C, the patch enabled faster immune onset, higher antibody responses and potentially resulted in more rapid and durable disease protection.
Vaxxas said it had developed a compact manufacturing system to deliver more than 250 million vaccine doses each year and was actively investigating opportunities to improve the performance of other pandemic vaccines, including against Covid-19 and a range of non-pandemic infectious disease vaccines.
Vaxxas is a private company.

RESONANCE HEALTH

Resonance says it has developed an artificial intelligence (AI) radiological computer-assisted triage and notification software product, Alert-PE, for pulmonary embolism.
In 2017, Resonance said it had a collaboration with the Perth Radiological Clinic to provide access to its artificial intelligence technology to assess the viability of several diagnostic tools (BD: Oct 18, 2017).
Today, the company said it had performed neural network training to automate review of chest computed tomography (CT) scans, using data sets of lungs from the Perth Radiological Clinic collaboration.
Resonance said Alert-PE was intended to assist hospital networks and trained radiologists by flagging and communicating suspected pulmonary embolisms.
The company said it had filed a pre-submission to the US Food and Drug Administration to discuss requirements for a potential future submission for FDA clearance, with the pre-submission meeting scheduled for November 2020.
Resonance fell half a cent or 3.1 percent to 15.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed Promedeus as its Xprecia Stride distributor in the Czech and Slovak Republics.
Universal Biosensors said the deal included first year forecast sales of 30,000 strips and 200 Xprecia Stride analyzers and it had received and delivered the first order.
Last year, the company said paid Siemens $US12.5 million ($A18.2 million) for rights to its Xprecia Stride coagulation test, strips and products (BD: Sep 23, 2019).
Today, Universal Biosensors chief executive officer John Sharman said the appointment of Promedeus was the first time the company had directly promoted and sold Xprecia Stride product anywhere in the world".
"This is a result of the deal done with Siemen's Healthineers towards the end of 2019 to buy-back the global distribution rights for Xprecia Stride," Mr Sharman said.
Mr Sharman said the company had appointed a Europe-based executive to run the coagulation business and increase sales.
"There are more than 3,500 Xprecia Stride analyzers in use throughout Europe which we plan to leverage to deliver sales," Mr Sharman said.
Universal Biosensors was unchanged at 28 cents.

PATRYS

Patrys says it has been granted an Australian patent for the conjugated nanoparticle form of its Deoxymab 3E10 platform, including PAT-DX1 and PAT-DX3, for cancers.
Patrys said the patent, titled 'Antibody-mediated Autocatalytic, Targeted Delivery of Nanocarrier to Tumors' would protect its intellectual property until 2036.
The company said it had patents for other applications of the unconjugated form of PAT-DX1 in the US, Europe, China and Japan, with more than 19 pending patent applications across 10 patent families.
Patrys was up 0.3 cents or 20 percent to 1.8 cents with 56.1 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says its annual general meeting will vote to issue 1,500,000 unlisted options to founder and managing-director Trevor Lockett.
Rhythm said the options would be exercisable at 20 cents a share by September 14, 2023, with 750,000 options vesting on issue and 375,000 options each vesting on the grant of Conformité Européenne (CE) Mark approval and upon Australian Therapeutic Goods Administration registration.
The company said it would vote to adopt its employee incentive plan, amend its constitution, including to renew a proportional takeover provision, adopt its remuneration report, elect chair Otto Buttula, Louis Panaccio and Eduardo Vom as directors, and approve the 10 percent placement facility.
The virtual meeting will be held on November 18, 2020 at 11am (AEDT).
Rhythm was up three cents or 13.0 percent to 26 cents.

NOXOPHARM

Noxopharm says it has amended the terms of its $4.2 million loan with Nora Goodridge Investments to extend the termination date by six months to November 30, 2020.
In February, Noxopharm said it hoped to raise $8.1 million through a $3.09 million equity placement and $5 million loan from an existing shareholder, which would be repaid on receipt of its 2020 Research and Development Tax Incentive at a 10 percent interest rate (BD: Feb 14, 2020).
Today, the company said that the directors believed that retaining the Federal R&D Tax Incentive to expedite its Veyonda clinical program was in the company's best interests.
Noxopharm said it would have the option to extend the termination date for a further six months, with $1.5 million of the loan assigned to Link Traders Australia and $1.5 million assigned to chair Fred Bart's Bart Superannuation Pty Limited as trustee for 4F Investments Super Fund, subject to shareholder approval.
The company said interest would accrue at 10 percent per annum and each lender may elect to repay the amount owed through the issue of shares.
Noxopharm said that if conversion occurred, the price would be at a five percent discount of the first equity raising and if no raising occurred before the termination date, would be at a 20 percent discount to the five-day volume weighted average price.
Noxopharm was up two cents or 5.4 percent to 39 cents with 1.2 million shares traded.

ALTERITY THERAPEUTICS

Alterity has filed an F-3 US Securities and Exchange Commission registration statement to raise up to $US50,000,000 ($A69,614,228).
Alterity chair Geoffrey Kempler told Biotech Daily that the registration did not imply any imminent capital raising but rather "a long-standing tradition of maintaining financing flexibility".
Alterity was up 0.4 cents or 8.5 percent to 5.1 cents with 2.4 million shares traded.