Biotech Daily

Thursday February 3, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 13%; NEXT SCIENCE DOWN 10.5%**

*** ADALTA RIGHTS RAISE $1.25m; TOTAL $5m**

*** CYCLOPHARM TO FILE FDA TECHNEGAS RESPONSE IN Q3**

*** STARPHARMA APPOINTS ETQAN & NAZAHAH GULF DISTRIBUTOR**

*** ONCOSIL: GERMAN INNOVATION FUNDING, CENTRALIZED ETHICS**

*** MEDICAL DEVELOPMENTS ENDS CSIRO API COLLABORATION**

*** CLARITY: 'UNAFFECTED BY FAILED BELGIUM NUCLEAR REACTOR'**

*** CRESO TO BUY SIERRA SAGE FOR $29.5m SCRIP**

*** WOKE IMPORTS SYNTHETIC PSILOCYBIN FOR DEPRESSION TRIALS**

*** TELIX CEO DR CHRIS BEHRENBRUCH, ELK RIVER TAKE 7.5%**

*** LAZARD TAKES 5% OF MAYNE PHARMA**

*** MALCOM MCCUSKER TAKES 5.6% OF PYC**

*** PHARMAUST LOSES EPICHEM CEO COLIN LA GALIA**

*** CHIMERIC APPOINTS KELLY THORNBURG HEAD OF QUALITY**

MARKET REPORT

The Australian stock market fell 0.14 percent on Thursday February 3, 2022, with the ASX200 down 9.7 points to 7,078.0 points. Seven of the Biotech Daily Top 40 stocks were up, 28 fell, four traded unchanged and one was untraded.

Oncosil was the best, up 0.5 cents or 12.8 percent to 4.4 cents, with 5.1 million shares traded. Amplia and Resonance climbed more than three percent; Antisense improved 2.9 percent; Resmed and Universal Biosensors were up more than one percent; with Neuren and Genetic Signatures up by less than one percent.

Next Science led the falls, down 13 cents or 10.5 percent to $1.11, with 238,271 shares traded. Cyclopharm lost 10.3 percent; Immutep, Imugene and Proteomics fell more than eight percent; Actinogen, Kazia, Paradigm, Patrys and Polynovo were down more than seven percent; Opthea shed 6.2 percent; Clinuvel, Impedimed and Nanosonics were down more than five percent; Avita, Cynata, Pro Medicus and Starpharma fell more than four percent; Alcidion, Medical Developments, Nova Eye, Orthocell and Telix were down more than three percent; Compumedics and Emvision shed more than two percent; with Cochlear, CSL, Dimerix, Mesoblast and Volpara were down by more than one percent.

ADALTA

Adalta says its one-for-eight rights issue at 7.3 cents a share has raised $1.25 million of the hoped for $2.2 million, taking the total raised to $5.0 million.
Last year, Adalta said it had raised $3.75 million in a placement at 7.3 cents a share and expected to raise $2.2 million in the rights issue (BD: Dec 15, 2021).
The company said at that time that the issue price was a 10.4 percent discount to the 15-day volume weighted average price to December 9, 2021.
Adalta fell 0.2 cents or 2.4 percent to 8.2 cents.

CYCLOPHARM

Cyclopharm says it expects to file its response to the US Food and Drug Administration complete response letter for Technegas by October 2022.
Cyclopharm said it had met with the FDA to discuss matters raised in the preapproval inspection and complete response letter for Technegas for lung imaging.
Last year, Cyclopharm said that an FDA complete response letter had delayed approval of Technegas by about nine months (BD: Jun 28, 2021).
Cyclopharm said at that time that the FDA was “unable to approve” its new drug application for Technegas in its present form and provided a definitive list of items and recommendations for outstanding elements to be addressed within a 12-month period.
The company said it expected to resolve all elements “with a view to securing approval for commercial sales of Technegas in the US market in 2022”.
Cyclopharm managing-director James McBrayer said that “while the elements in the … letter are attainable within the required time-frame, we are disappointed with this news of the additional technical information requests”.
In 2020, Cyclopharm said its 240-patient, phase III Technegas lung imaging trial was halted after data from 200 patients met the primary efficacy endpoint and in January the Society of Nuclear Medicine and Molecular Imaging called on the FDA to expedite the approval of Technegas (BD: Sep 15, 2020; Jan 22, 2021)
Today, the company said it expected to submit its formal and complete response to the FDA by October 2022 and the FDA would have up to six months to complete its review.
“Cyclopharm reaffirms its confidence that the actions taken to date and those proposed will fulsomely address the FDA’s outstanding requirements for approval,” Mr McBrayer said. “Once approved, Cyclopharm will be in a position to rapidly commercialize Technegas in the United States.”
Cyclopharm fell 18.5 cents or 10.3 percent to $1.605.

STARPHARMA

Starpharma says it has a five-year agreement with Etqan & Nazahah LLC to distribute its Viraleze anti-viral nasal spray in Saudi Arabia and the Gulf States.
Last year, Starpharma said that Saudi Arabia had registered Viraleze and it was in negotiations for local distribution (BD: Dec 14, 2021).
Today, the company said that Etqan & Nazahah would distribute Viraleze in Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Oman and Bahrain, pending approvals.
Starpharma said that Viraleze was registered in Saudi Arabia, its first in the Middle East and registration activities in other countries covered by this agreement had begun.
Starpharma chief executive officer Dr Jackie Fairley said the company was “negotiating an arrangement for sales and distribution to other neighboring countries”.
Starpharma fell five cents or 4.7 percent to $1.015.

ONCOSIL MEDICAL

Oncosil says that Germany's Institute for the Hospital Remuneration System has granted its radiation device 'Positive Status 1' classification for innovation funding.

Oncosil said the funding mechanism provided hospitals with additional funding "to adopt a method or procedure that uses a new device that is not covered through existing Federal hospital funding processes in Germany".

The company said that to secure funding each hospital or hospital network was required to apply individually to The Institute for the Hospital Remuneration System and funding was based on "a new device's demonstrated added clinical benefit compared with established procedures and devices and the number of patients being treated with the device".

Oncosil said that late last year, 25 German university hospital sites applied for its radiation device to be included in the funding program.

The company said that the number of devices to be reimbursed, and the reimbursed price and inclusions would be negotiated between individual hospitals and the Statutory Health Insurance providers.

Oncosil said that the University of Cologne Hospital had approved the Osprey Registry, acting as the central ethics approvals authority for German hospitals, allowing for the other 24 hospital sites who had submitted funding applications to complete their internal ethics processes in an expedited manner.

Oncosil managing-director Nigel Lange said that the Positive Status 1 classification was "an important step forward for Oncosil in Germany".

"The innovation funding process significantly accelerates the process for obtaining systematic funding for treatment utilizing the Oncosil device throughout all of Germany," Mr Lange said.

"Having experienced the positive uptake of a similar medical device following such classification, it bodes very well for delivering on Oncosil's commercialization plan," Mr Lange said.

Oncosil was up half a cent or 12.8 percent to 4.4 cents with 5.1 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Medical Developments says it has ended its active pharmaceutical ingredient (API) continuous flow technology project with the CSIRO.

Medical Developments said the project to develop continuous flow technology for the manufacture of Penthrox "delivered significant productivity and efficiency gains" and the collaboration sought to apply that expertise to other active pharmaceutical ingredients to generate additional income for the company.

"Despite considerable technical progress across multiple pharmaceuticals, notably with lidocaine, a careful prospective review indicates that significant commercial success is unlikely," the company said.

"This decision reflects both the commercial realities of the project and [the company's] decision to focus on its pain and respiratory businesses, Medical Developments said.

Medical Developments chief executive officer Brent MacGregor said the company wanted to direct resources and investment on the Penthrox inhaled methoxyflurane analgesic business.

"We are proud of our work with CSIRO and are exploring ways to continue this relationship in support of Penthrox," Mr MacGregor said.

Medical Developments fell 15 cents or 3.3 percent to $4.45.

CLARITY PHARMACEUTICALS

Clarity says that the recent outage at the High Flux Reactor (HFR) in Petten, Belgium does not affect its copper isotopes in any way.
Clarity said that in 2021, the Nuclear Medicine Europe Emergency Response Team said the reactor "did not resume operations after a planned shutdown on January 20, 2022, due to the detection of a water leak in the reactor beam tube cooling system" and more recently said a "target date for restart cannot be provided".
The company said the restart would impact the supply nuclear reactor produced medical radioisotopes including Molybdenum-99 Technetium-99m, lutetium-177 and iodine-131.
Clarity executive chair Dr Alan Taylor said his company "does not source any of its copper isotopes from the limited number of aging nuclear reactors around the world".
Dr Taylor said reactor outages would not affect Clarity "now or anytime in the future".
Clarity fell 2.5 cents or 3.4 percent to 70.5 cents.

CRESO PHARMA

Creso Pharma says it will buy the Lyons, Colorado-based Sierra Sage Herbs LLC for $US21 million ($A29.5 million) in shares upfront, with additional milestone payments.
Creso said Sierra Sage was a consumer goods company "focused on plant-based and [marijuana] products under the Green Goo, Southern Butter and Goodgoo brands offering products in the … first aid, beauty, sexual wellness, women's health and pet categories".
The company said Green Goo and Southern Butter were sold at 90,000 distribution points in the US with an additional 20,000 sales points expected to be added by April 2022.
The company said that Sierra Sage was a revenue generating acquisition, with sales of $US4.7 million in 2018, more than $US8 million in 2020 and $US5.7 million in 2021.
Creso said the milestone payments were based on Sierra Sage achieving sales of up to $US10 million in 2022 and up to $US20 million in 2023.
The company said Sierra Sage co-founder and chief executive officer Jodi Scott had been appointed a Creso executive director and head of US operations.
Creso said that the acquisition would help it enter the US marijuana market, "which is expected to grow in value to $US12 billion by 2026".
Creso managing-director William Lay said the acquisition of Sierra Sage and its product range was "a major milestone for Creso Pharma".
Creso was up half a cent or 5.9 percent to nine cents with 24.1 million shares traded.

WOKE PHARMACEUTICALS PTY LTD

Woke says it has imported its first order of synthetic psilocybin from the Athens, Georgia-based Purisys LLC for formulation of dose forms for its depression trials.
Yesterday, Woke said IDT would manufacture psilocybin and would be the "importer and warehouser of psilocybin" for its phase IIb trials to begin later this year (BD: Feb 2, 2022).
Today, Woke said that WP001 would be a 1mg to 5mg 'low-dose' rapid release capsule of psilocybin for moderate depression and WP002 would be a 25mg 'high dose' tablet for treatment-resistant depression.
Woke chief executive officer Nick Woolf said the "import of material is aligned with our formulation, manufacturing, and clinical plans".
"Psychedelics such as psilocybin have the potential to address unmet medical needs and benefit patients with depression as well as other mental health disorders," Mr Woolf said.
Woke is a private company.

TELIX PHARMACEUTICALS

Elk River Holdings as trustee for the Behrenbruch family says it has increased its holding from 22,675,000 shares (7.38%) to 23,075,000 shares (7.50%).
Telix chief executive officer Dr Christian Behrenbruch said he exercised 400,000 options at $1.09 each.
Telix fell 26 cents or 3.5 percent to $7.19 with 810,672 shares traded.

MAYNE PHARMA

Lazard Asset Management says it has become a substantial shareholder in Mayne Pharma with 90,410,198 shares or 5.12 percent.
The Sydney-based Lazard said that it bought 6,896,634 shares between October 10, 2021 and January 31, 2022 for $1,842,360 or an average of 26.7 cents a share.
Mayne was unchanged at 28.5 cents with 4.7 million shares traded.

PYC THERAPEUTICS

Malcolm McCusker says he has become a substantial shareholder in PYC Therapeutics with 180,250,000 shares or 5.6 percent.
The Nedlands, Western Australia-based Mr McCusker said he acquired shares between October 19, 2021 and February 2, 2022 at prices ranging from 12.46 cents to 15.49 cents a share.
PYC fell half a cent or 4.2 percent to 11.5 cents.

PHARMAUST

Pharmaust says that subsidiary Epichem chief executive officer Colin La Galia has resigned, effective from March 23, 2022.
Pharmaust said that Epichem was its wholly-owned synthetic and medicinal chemistry subsidiary.
The company said that Mr La Galia joined the company in 2019 and had resigned “to pursue another opportunity based in Perth … [which was] not a competitor to Epichem or Pharmaust” (BD: Oct 14, 2019).
Pharmaust said Mr La Galia would provide strategic and operational input into the Epichem business as a consultant beyond March 23.
The company said Epichem had begun a search for a general manager and a new business development executive.
Pharmaust said that Epichem’s head of chemistry Dr Gary Pitt would be responsible for the Drugs for Neglected Diseases Initiative contract and oversees all medicinal and synthetic chemistry projects (BD: Dec 15, 2021).
The company said that Mr La Galia signed new medicinal and synthetic clients and projects, with a focus on the development of new intellectual property research and development projects and several national awards.
Pharmaust said that Mr La Galia oversaw the development of the waste conversion and re-purposing technology, oxidative hydrothermal dissolution, employment for chemists and exports to more than 40 countries.
Pharmaust executive chair Dr Roger Aston said the company was “very pleased at what Colin achieved and he leaves the Epichem business well positioned for further growth led by its strong executive team”.
Pharmaust fell 0.2 cents or two percent to 9.8 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed Kelly Thornburg as its head of quality, effective from today, February 3, 2022.

Chimeric said Mr Thornburg had experience in the development and management of quality systems and prior to this appointment, had worked as a consultant to the company.

The company said Mr Thornburg was previously Kite Pharma's quality site head and had worked for Amgen, Xbiotech and AGC Biologics.

Chimeric fell half a cent or 2.2 percent to 22 cents with 1.3 million shares traded.