Biotech Daily

Tuesday October 3, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEXT SCIENCE UP 11%; AVITA DOWN 20%**

*** PHARMAXIS MANNITOL SALE, BOARD CHANGES, SYNTARA RENAME**

*** FIREBRICK: 'NO DATA ISSUE' IN NASODINE COLD TRIAL RESULTS**

*** CLARITY DOSES 1st COPPER-67 PROSTATE CANCER TREATMENT PATIENT**

*** CYCLOPHARM: SNMMI WELCOMES FDA TECHNEGAS APPROVAL**

*** NOXOPHARM REQUESTS 'FDA DESIGNATION' TRADING HALT**

*** EXOPHARM REQUESTS 'MATERIAL ACQUISITION' SUSPENSION**

*** VANGUARD TAKES 5% OF COCHLEAR**

*** AUSTRALIAN ETHICAL DILUTED TO 12.7% OF SOMNOMED**

*** IMPEDIMED APPOINTS MCGREGOR GRANT CHAIR, LOSES JANET WEST**

*** DIRECTOR LIL BIANCHI REPLACES 4D MEDICAL CHAIR BRUCE RATHIE**

MARKET REPORT

The Australian stock market fell 1.28 percent on Tuesday October 3, 2023, with the ASX200 down 89.8 points to 6,943.4 points. Nine of the Biotech Daily Top 40 stocks were up, 21 fell, nine traded unchanged and one was untraded.

Next Science was the best, up 4.5 cents or 10.7 percent to 46.5 cents, with 410,913 shares traded. Antisense climbed 7.35 percent; Pharmaxis was up 6.1 percent; 4D Medical and Neuren rose more than two percent; CSL, Cyclopharm, Opthea and Universal Biosensors were up one percent or more; with Emvision and Resmed up by less than one percent.

Avita led the falls on last night's news, down 89 cents or 19.9 percent to $3.58, with 1.9 million shares traded. Actinogen lost 9.5 percent; Nova Eye was down 8.7 percent; Imugene, Kazia, Resonance and Starpharma were down six percent or more; Polynovo and Proteomics fell more than five percent; Volpara was down 4.9 percent; Clinuvel, Cynata, Genetic Signatures, Nanosonics and Telix were down more than three percent; Impedimed, Orthocell and Mesoblast shed more than two percent; Dimerix and Pro Medicus were down more than one percent; with Cochlear and Paradigm down by less than one percent.

PHARMAXIS, BTC HEALTH

Pharmaxis says Arna Pharma will buy its mannitol business, chair Malcolm McComas and director Dr Neil Graham will resign and it will change its name to Syntara.

Pharmaxis said the sale to Sydney's Arna Pharma would reduce expenses by more than 60 percent, or $14 million a year, residual exit costs would be less than $1 million, and it would receive ongoing royalties for eight years from the Arna Pharma.

The company said it would be reimbursed by Arna Pharma for the majority of the expenses it would incur through to May 2024, as well as ongoing royalties for eight years from Arna Pharma's Sydney-based business including Bronchitol and Aridol.

Pharmaxis said the sale was scheduled to be completed by the end of October 2023 and Arna Pharma would begin an eight-month process of transferring production of Aridol and Bronchitol.

The company said that the reduced costs were due to a headcount drop from about 70 employees to 25 employees.

Pharmaxis said that as part of its restructure it would reduce the board, with director Dr Kathleen Metters replacing Mr McComas as chair and the retirement of director Dr Neil Graham, effective from today.

The company said that directors Dr Simon Green and Hashan De Silva would continue, as would managing-director Gary Phillips.

Pharmaxis said with the sale of its mannitol business it had become a "clinical-stage drug development company primarily focused on blood related cancers" and devote the majority of its resources to its lead drug candidate PXS-5505, a lysyl oxidase inhibitor for myelofibrosis, and advance both oral and topical pan-lysyl oxidase inhibitors.

The company said it would issue an update on PXS-5505 at the American Society of Hematology in December 2023, with the next phase of its development to be a study in combination with the standard-of-care Janus kinase (JAK) inhibitor.

Mr Phillips said the company had "built a commanding position in lysyl oxidase biology and chemistry research".

"Building on this heritage and the proven capability of our discovery and development teams, the restructure announced today and the creation of Syntara enables us to focus and accelerate our clinical development programs," Mr Phillips said.

"In PXS-5505 we have a best-in-class drug with an excellent safety profile that has the potential to offer disease modifying effect to patients with haematological malignancies," Mr Phillips said.

"Syntara and its shareholders are in the unique position of having five planned clinical programs that can deliver company transforming results within a two-year period and I am very excited to start on this new journey," he said.

Mr Phillips said Arna Pharma was placed to continue the work Pharmaxis had done in taking two drugs through regulatory approvals and marketed to patients worldwide.

"I am delighted that Bronchitol and Aridol will continue to be supplied without interruption," Mr Phillips said.

In 2021, BTC Health said it would pay Pharmaxis $2 million for a 10-year exclusive distribution agreement for Pharmaxis' mannitol business, which included its Bronchitol inhaled dry powder for cystic fibrosis and Aridol asthma test (BD: Jul 1, 2, 2021).

In a separate announcement, BTC Health said despite the sale of the mannitol business to Arna Pharma there was no change in respect of the licence and distribution agreement with subsidiary Bioimpact Pty Ltd and it expected the 10-year agreement "to be assigned from Pharmaxis across to Arna Pharma in due course".

Pharmaxis was up 0.2 cents or 6.1 percent to 3.5 cents.

BTC was up 0.1 cents or 2.5 percent to 4.1 cents.

FIREBRICK PHARMA

Firebrick says the preliminary investigation into its Nasodine phase III trial did not reveal "any systematic error or data issue that could explain or disclaim the reported results".
Last month, Firebrick said the Nasodine common cold trial did not meet its primary endpoint, with sterile water placebo better impacting cold severity (BD: Sep 13, 2023).
At that time, the company said it was concerned that the results were "so confounding and unexpected and at odds with previous data that there may be a systematic error or other issue in the data" and it would investigate the results.
Today, Firebrick said it had closed the preliminary investigation to avoid additional costs, but further internal analysis supported by expert advice would continue.
The company said it remained "committed to the development of Nasodine for the common cold" including alternative study designs and other aspects of the illness that might accelerate regulatory approvals.
Firebrick said it had reduced its cash expenditure to preserve funds and expected a substantial Federal Research and Development Tax Incentive payment this month.
Firebrick executive chair Dr Peter Molloy said the company believed "that the development of Nasodine as a treatment for the common cold ultimately will be successful, but proving this using a controlled clinical trial design is challenging".
Firebrick said the challenges included that there was no objective outcome measure, it was difficult to recruit subjects early enough to show a difference in a rapidly self-resolving illness and intranasal placebos could obscure the treatment effects.
The company said the trial was designed mainly to support EU registration of Nasodine for the common cold the EU filing had been deferred, pending decisions about a future trial and assessment of alternative approval pathways in the EU and elsewhere.
The company said that it planned to continue its discussions with the Australian Therapeutic Goods Administration, while its Administrative Appeals Tribunal appeal was ongoing (BD: Jul 20, 2023).
Last year, Firebrick said it would appeal against the Therapeutic Goods Administration (TGA) decision not to approve Nasodine nasal spray (BD: Mar 1, 2022).
Firebrick fell half a cent or 10 percent to 4.5 cents with 3.45 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has dosed the first of up-to 38 patients in its phase I/II trial of copper-64 and copper-67 Sar-bombesin for metastatic, castrate-resistant prostate cancer.
In June, Clarity said it had begun the safety and efficacy trial of its copper-64 and 67 Sar-bombesin for imaging and treating prostate cancer (BD: Jun 20, 2023).
Today, the company said the trial used its diagnostic copper-64 Sar-bombesin to visualize gastrin-releasing peptide receptor-expressing lesions and select candidates for subsequent copper-67 Sar-bombesin treatment in patients with low or negative prostate-specific membrane antigen (PSMA)-expressing lesions.
Clarity said the trial would test up-to 14 giga-becquerels (GBq) of copper-67 Sar-bombesin in up-to four cycles.
The company said no issues were observed with the starting dose of 6.0GBq of copper-67 and the patient would be monitored for further safety and efficacy assessments.
Clarity chair Dr Alan Taylor said that "combined with the logistical and manufacturing benefits of targeted copper 'theranostics' and with commercial quantities of the copper-67 radioisotope now being routinely produced domestically in the US, we see a clear path to bringing Sar-bombesin and Sar-bis-PSMA to the prostate cancer patient population".
Clarity was up 3.5 cents or 3.1 percent to $1.15.

CYCLOPHARM

Cyclopharm says Society of Nuclear Medicine and Molecular Imaging (SNMMI) has welcomed the US Food and Drug Administration approval of its Technegas.
Yesterday, Cyclopharm said the FDA had approved Technegas for pulmonary embolism imaging, opening a $US180 million a year market (BD: Oct 2, 2023).
Today, the company said that the Reston, Virginia-based Society of Nuclear Medicine and Molecular Imaging, a 20,000-member US nuclear medicine peak body, had "urged [the] FDA to begin a fast-track review" of Technegas in 2021.
The Society's president Dr Helen Nadel said the organization applauded "the FDA for the long-awaited approval of Technegas".
"Technegas will offer advantages in diagnostic accuracy, workflow and patient comfort for departments that adopt the technology and will have a large impact on those undergoing imaging for pulmonary disease," Dr Nadel said.
Cyclopharm was up three cents or 1.05 percent to $2.90.

NOXOPHARM

Noxopharm has requested a trading halt pending an announcement regarding "the designation by [the US] FDA for pancreatic cancer drug candidate CRO-67".
Trading will resume on October 5, 2023 or on an earlier announcement.
Noxopharm was up two cents or 47.6 percent to 6.2 cents with 4.5 million shares traded.

EXOPHARM

Exopharm has requested a voluntary suspension in relation to a "material acquisition" to last until its shareholders approve the acquisition.
Exopharm said that Listing Rules 11.1.2 and 11.1.3 would apply to the acquisition.
According to the ASX, Listing Rules 11.1.2 and 11.1.3 refer to a "proposed change to nature or scale of activities".
Exopharm said that the suspension would last until shareholders approved the acquisition and it was "able to recomply with chapters 1 (Admission) and chapter 2 (Quotation) of the ASX Listing Rules or otherwise makes an announcement in relation to the material acquisition".
Exopharm last traded at 1.1 cents.

COCHLEAR

The Philadelphia, Pennsylvania-based Vanguard Group says it has become a substantial shareholder in Cochlear with 3,282,658 shares, or 5.004 percent of the company.
The Vanguard Group said that between May 26 and September 27, 2023 it bought and sold shares in more than 200 transactions, at prices ranging from to $221.56 to $273.26
Cochlear fell 84 cents or 0.3 percent to $253.91 with 152,098 shares traded.

SOMNOMED

Australian Ethical Investment says its 13,835,756 shares substantial holding in Somnomed has been diluted from 13.96 percent to 12.74 percent.
In September, Somnomed said its retail rights offer raised $5.7 million, taking the total raised with the institutional offer and placement to $15.45 million (BD: Sep 26, 2023).
Somnomed was up half a cent or 0.7 percent to 71 cents.

IMPEDIMED

Impedimed says its newly constituted board has appointed McGregor Grant as its chair and one-year director Janet West has resigned, effective from October 2, 2023.

Last week, Impedimed said that all resolutions to replace chair Donald Williams and directors Amit Patel, David Anderson and Daniel Sharp, with McGregor Grant, Christine Emmanuel-Donnelly, Andrew Grant and Janelle Delaney were passed by about 58 percent of votes in favor to 42 percent of votes against (BD: Sep 28, 2023).

In August, the company said it had received a notice under section 249D of the Corporations Act 2001 requesting the replacement of directors (BD: Aug 3, 2023).

Today, Impedimed said that in the process leading to last week's extraordinary general meeting, the incoming and existing board members "met with numerous institutional and private investors, representing a significant proportion of the company's shareholder base".

"There were several clear messages that the board will prioritize, including strong governance, the evolution, articulation and execution of strategies towards maximizing shareholder value, a focus on cost management and profitable growth and clear communication," the company said.

Impedimed fell half a cent or 2.9 percent to 16.5 cents.

4D MEDICAL

4D Medical says non-executive director Lil Bianchi will replace retiring chair Bruce Rathie at its November 2, 2023 annual general meeting.

4D Medical said Ms Bianchi had been director since December 2019 and had worked as a chief executive officer in the health, finance and infrastructure sectors, and had a background in technology.

The company said Mr Rathie had been with the company for four years and the board thanked him for his significant contribution.

4D Medical chief executive officer Prof Andreas Fouras said Mr Rathie had led the company "through [the initial public offering] and subsequent capital raises, and all the while been a steady and patient hand guiding the board'.

4D Medical was up 1.5 cents or 2.9 percent to 54 cents.