Biotech Daily

Thursday March 9, 2023

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: PRESCIENT UP 29%;**
- MEDICAL DEVELOPMENTS DOWN 5%

*** MACH7 WINS ADVENTIST $7.1m PACS ORDER**

*** VOLPARA: $1.37m SUTTER BREAST TEST SOFTWARE CONTRACT**

*** EXOPHARM OVER-SUBSCRIBED $1m NOTE ISSUE, RIGHTS FOR MORE**

*** EXOPHARM TAKES $431k RADIUM RDTI LOAN**

*** PRESCIENT WINS PTX-100 T-CELL LYMPHOMA FDA ORPHAN STATUS**

*** BIOTRON COMPLETES 2 HIV-1 PHASE II BIT225 TRIALS**

*** CHIMERIC MANUFACTURES CHM2101 FOR TUMOR TRIAL**

*** BIONOMICS CONFIRMS BNC210 MISSED ANXIETY ENDPOINT, TRENDS**

*** BIONOMICS TELLS ASX: NEWS NOT ANNOUNCED PUSHED PRICE 16%**

*** ANALYTICA, NUHEARA FILE REPORTS, RESUME TRADING**

*** PERENNIAL TAKES 10.3% OF LUMOS**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Thursday March 9, 2023, with the ASX200 up 3.3 points to 7,311.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and five were untraded. All three Big Caps fell.

Prescient was the best, up 2.8 cents or 28.9 percent to 12.5 cents, with 7.8 million shares traded. Immutep, Kazia, Nanosonics, Oncosil and Volpara climbed more than three percent; Amplia, Cyclopharm, Next Science, Nova Eye and Paradigm rose more than two percent; Antisense, Avita and Opthea were up more than one percent; with Pro Medicus up by five cents or 0.08 percent to $62.49 with 117,133 shares traded.

Medical Developments led the falls, down seven cents or 5.2 percent to $1.275, with 159,056 shares traded. Imugene lost 3.7 percent; Clinuvel, CSL, Neuren, Polynovo and Telix shed more than two percent; Actinogen, Emvision, Impedimed, Mesoblast, Proteomics, Resmed, Starpharma and Universal Biosensors were down one percent or more; with Cochlear down by 0.9 percent.

MACH7 TECHNOLOGIES

Mach7 says it has a $7.1 million sales order from Adventist Health System for its picture archiving communication system, for remaining contracted hospitals.

In 2021, Mach7 said the Roseville, California-based Adventist Health System had expanded the contract for its picture archive communication system (PACS) and services to a total value of more than $7.9 million (BD: Jan 27, 2021).

At that time, the company said that the deal included migration services and five years of support and maintenance, replacing the existing Adventist archive at 22 of its hospitals.

Today, Mach7 said the order forms for the remaining 15 Adventist contracted hospitals had been received, with a total value of $7.1 million, “including scope expansion” and was expected to contribute $3 million in 2022-’23.

Mach7 chief executive officer Mike Lampron said the company had “developed a strong and collaborative partnership with Adventist Health over the last few years and we are delighted that its enterprise imaging growth strategy will soon be fully realized”.

Mach7 was up half a cent or 0.9 percent to 57.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has a $US900,000 ($A1,366,341) three-year, volume-based contract with Sutter Health for its mammography analytics and risk pathways software.

Volpara said the contract with the Sacramento, California-based Sutter was for an initial three-year licence, with annual payments and annual recurring revenue of $US374,000.

The company said that it expected installation of its risk pathways software “within the next six months”.

Volpara was up 2.5 cents or 3.8 percent to 68 cents.

EXOPHARM

Exopharm says it has subscriptions of $1,000,000 in an over-subscribed convertible note issue at $1.00 a note.

Last month, Exopharm said it hoped to raise $2.1 million through $600,000 in convertible notes, with a one-for-one $1.5 million rights issue at one cent a share (BD: Feb 13, 2023).

At that time, the company said the notes would convert at a 20 percent discount to the rights issue price subject to the completion of the issue.

Today, Exopharm said the conversion price was 0.8 cents, and subject to investor approval, the notes could be converted between May 1 and December 9, 2023 or automatically on completion of the rights issue.

Exopharm said the notes matured on March 9, 2024, at no interest, and the funds would be for working capital and to extend its cash runway; with Alto Capital and Canary Capital joint lead managers of the note issue and joint lead managers of the rights issue.

Exopharm was up 0.1 cents or 6.7 percent to 1.6 cents.

EXOPHARM

Exopharm says it has borrowed $430,746 from Radium Capital, against part of its expected Federal Government Research and Development Tax Incentive.

Exopharm said the advance from the Melbourne-based Radium was “expected in the next week” and was at a compounding interest rate of 1.25 percent a month, with repayment timed to coincide with the receipt of its tax incentive, expected by November 30, 2023.

PRESCIENT THERAPEUTICS

Prescient says the US Food and Drug Administration has granted PTX-100 orphan drug designation for T-cell lymphomas, including cutaneous lymphomas.
In 2022, Prescient said the US FDA had granted orphan drug designation to PTX-100 for peripheral T-cell lymphoma (BD: Jul 15, 2022).
Today, the company said the FDA had granted "a broader designation than Prescient requested, which encompasses all [T-cell lymphomas]".
Prescient said that T-cell lymphomas were a group of lymphomas that developed "when a group [of] white blood cells called lymphocytes grow out of control".
The company said that orphan drug designation provided benefits to incentivize drug development in less common diseases and included guaranteed market exclusivity of seven years from granting of regulatory approval, as well as a waiver of prescription drug user fee act fees for orphan drugs, which had a value of more than $US3.1 million ($A4.7 million) in 2022.
Prescient managing-director Steven Yatomi-Clarke said the company was "delighted to be granted this orphan drug designation by the FDA, and is pleasantly surprised for the granting of the designation that is broader than our request".
"This now confers the certainty of seven years of market exclusivity for PTX-100 in a broader range of diseases with unmet or poorly met clinical," Mr Yatomi-Clarke said.
Prescient was up 2.8 cents or 28.9 percent to 12.5 cents with 7.8 million shares traded.

BIOTRON

Biotron says it has completed dosing in its two phase II trials of BIT225 for HIV-1, with preliminary results expected by "mid-2023".
In 2021, Biotron said it had begun a 27-patient, Thailand phase II trial and a 20-patient, Sydney phase II trial of BIT225 in HIV-1-positive populations (BD: Nov 1, 2021).
In 2022, the company said it had recruited its Australian phase II trial (BD: Oct 4, 2022).
Today, Biotron managing-director Dr Michelle Miller said the company was "very pleased to have reached this important milestone; completing not one, but two, phase II trials is a remarkable achievement and adds significant value to the company's portfolio".
"We look forward to completing the detailed laboratory studies on the samples collected during the trials and reporting preliminary results in mid-2023," Ms Miller said.
Biotron was up 0.3 cents or 11.5 percent to 2.9 cents with 1.6 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has completed manufacturing CHM2101 viral vector for an upcoming phase Ia trial in gastrointestinal and neuroendocrine tumors.
Last year, Chimeric said CHM2101 was a "first in class, third generation autologous" chimeric antigen receptor T-cell (CAR-T-cell) therapy which targeted the cell surface marker CDH17 and had previously "completely eradicated tumors" with no relapse or toxicity, in mice with eight types of cancer (BD: Mar 23, 2022).
Chimeric managing-director Jennifer Chow said "vector supply continues to significantly challenge the cell therapy industry with current backlogs of more than a year to access vector manufacturing".
"Securing vector supply for the CHM2101 phase Ia clinical trial marks a significant milestone for advancing CHM2101 towards the clinic and patients that need novel therapies to treat advanced gastrointestinal and neuroendocrine tumors," Ms Chow said.
Chimeric was unchanged at 6.6 cents.

BIONOMICS

Bionomics says its 151-patient phase II trial of BNC210 for social anxiety disorder “did not meet the primary endpoint [but] consistent trends were observed”.

In December, Bionomics said BNC210 did not meet the primary endpoints in its 151-patient, phase II study for social anxiety disorder but “exhibited trends towards improvements” (BD: Dec 19, 2022).

At that time, the company said participants were treated with a single oral dose of either placebo or 225mg BNC210 or 675mg BNC210, which was followed by a public speaking challenge consisting of a two-minute preparation period and a five-minute speech, which was self-assessed using the subjective units of distress scale (Suds)

Today, Bionomics said that “while the Prevail did not meet its primary endpoint, the December 2022 topline data readout revealed encouraging trends in the pre-specified endpoints that focused on individual phases of the public speaking task”.

In a separate presentation, the company reported non-significant “p” values ranging from 0.088 to 0.312 for the difference between BNC210 and placebo, in the public speaking task.

In 2018, Bionomics fell 69 percent when its 193-patient, phase II trial of BNC210 for post-traumatic stress disorder (PTSD), missed its primary endpoint (BD: Oct 2, 2018). In 2019, the company said its phase II trial of BNC210 for agitation “did not differentiate from placebo on the primary and secondary efficacy end points” (BD: Jun 26, 2019).

The company said that the study was intended "to evaluate the efficacy and safety of BNC210, a novel α7 nicotinic acetylcholine receptor negative allosteric modulator, for the acute treatment of social anxiety disorder”.

Bionomics said that the data supported late-stage development of BNC210 for social anxiety disorder.

The company said that BNC210’s therapeutic potential was “not limited to a single task phase but was present throughout the speaking task, including the performance phase of the public speaking challenge and the anticipatory period immediately prior”.

Bionomics said that administration of both 225 mg and 675 mg BNC210 doses resulted in therapeutic responses of similar magnitude, which allowed for the data from the two arms to be combined, enhancing the dataset’s statistical power”.

The company said that BNC210 participants had “significantly less anxiety during the public speaking task … [compared to] placebo” as measured by the subjective units of distress scale, the study’s primary outcome measure ($p = 0.037$) with similar results observed when combining the two high-anxiety phases ($p = 0.044$).

Bionomics said the therapeutic effects were “comparable to those reported with benzodiazepines supporting the clinical meaningfulness of BNC210’s anxiolytic effects”.

The company said that subgroup analyses indicated that younger participants (30 years and below) showed stronger responses to BNC210 with significant separation from placebo ($p = 0.023$).

Bionomics said that the primary outcome was a self-assessment during the speaking challenge using the subjective units of distress scale, with secondary measures including self-assessment during the preparation-anticipation phase, and self-assessment with the state-trait anxiety inventory, a self-reported questionnaire with 20 anxiety-related questions marked on a 4-point scale.

The company said that social anxiety disorder was “a significant and persistent fear of social and performance-related situations [and] one of the most common mental disorders in the US” with an estimated 31 million Americans to suffer from the disorder at some point in their lives.

Bionomics was up 0.7 cents or 19.4 percent to 4.3 cents with 5.9 million shares traded.

BIONOMICS

Bionomics says that it was aware of information concerning it that had not been announced, which if known, could explain the recent trading in its securities.
In a price query, the ASX noted a 15.6 percent rise in the price of Bionomics' shares from a low of 3.2 cents to a high of 3.7 cents on March 8, 2023, and a "significant increase in the volume of … securities traded".
The ASX asked Bionomics if it was aware of any information that had not been announced, that could explain the recent trading in its securities?
Bionomics said: "Yes, at the time of receipt of the letter from ASX, Bionomics was aware of information concerning it that has not been announced, which, if known by some in the market, could explain the recent trading in its securities" (see above).

ANALYTICA, NUHEARA

Analytica and Nuheara say they have filed their relevant periodic audited reports.
Last week, the ASX suspended the companies for failing to lodge their reports by the due date (BD: Mar 1, 2023).
Today, Nuheara said revenue for the six months to December 31, 2022 was down 74.25 percent to $765,622 with net loss after tax down 6.6 percent to $6,460,729.
Analytica said revenue for the six months to December 31, 2022 was up 1,054.0 percent to $33,258 with net loss after tax down 4.85 percent to $1,306,506.
Analytica remained in a suspension and last traded at 0.1 cents.
Nuheara fell one cent or 4.9 percent to 19.5 cents with 1.3 million shares traded.

LUMOS DIAGNOSTICS

Perennial Value Management says it has increased its holding in Lumos from 21,997,010 shares (9.19%) to 24,554,466 shares (10.26%).
The Sydney-based Perennial said that it bought the shares between February 28 and March 7, 2023, with the single largest purchase on March 6 of 821,482 shares for $34,510 or an average of 4.2 cents a share.
Lumos fell 0.6 cents or 15.4 percent to 3.3 cents with 6.4 million shares traded.