Biotech Daily

Thursday May 25, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIO UP 11%; ATOMO DOWN 9%**

*** VOLPARA REVENUE UP 34% TO $33m, LOSS DOWN 40% TO $9m**

*** PACIFIC EDGE REVENUE UP 71% TO $18.5m; LOSS UP 36% TO $27m**

*** ADALTA RAISES $1.28m, COMMITMENTS FOR $1.87; TOTAL $3.15m**

*** IMPEDIMED: MICHIGAN'S MEDICAL POLICY BACKS SOZO**

*** IMMUTEP DOSES 1st AIPAC-003 EFTI BREAST CANCER PATIENT**

*** CLARIFICATION: ACTINOGEN MEDICAL**

*** RHYTHM TO ASX: UK CA MARK 'NOT MARKET SENSITIVE'**

*** ANTEOTECH PLEADS SCHULTZ TO ASX 69% QUERY**

*** IMAGION AGM: 25.2% REMUNERATION REPORT 1st STRIKE**

MARKET REPORT

The Australian stock market fell 1.05 percent on Thursday May 25, 2023, with the ASX200 down 75.6 points to 7,138.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Universal Biosensors was the best, up 2.5 cents or 10.6 percent to 26 cents, with 111,388 shares traded. Polynovo climbed 7.7 percent; Alcidion, Antisense and Starpharma were up five percent or more; Immutep and Nova Eye improved more than four percent; Telix was up 3.9 percent; Prescient rose 2.5 percent; Dimerix was up 1.4 percent; with Avita, Cochlear, CSL, Nanosonics, Neuren and Resmed up by less than one percent.

Atomo led the falls, down 0.3 cents or 9.4 percent to 2.9 cents, with 1.3 million shares traded. Actinogen and Oncosil lost more than seven percent; Amplia, Clinuvel, Cyclopharm, Imugene, Next Science and Paradigm fell more than four percent; Genetic Signatures, Impedimed and Micro-X were down more than three percent; Resonance retreated 2.5 percent; Medical Developments, Mesoblast and Orthocell were down more than one percent; with Emvision, Opthea, Pro Medicus and Proteomics down by less than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the year to March 31, 2023 was up 34.1 percent to $N35,010,000 ($A33,089,000), with net loss after tax down 40.4 percent to $NZ9,801,000 ($A9,263,000).

Volpara said revenue came from the sales of it breast mammography density and quality control software,

The company said that its annual recurring revenue was up 34.0 percent to $NZ42.6 million, as a result of subscription revenues.

Volpara managing-director Teri Thomas, said: “This year has been a banner year for Volpara but also for our industry, with validation of the importance of density via the [US Food and Drug Administration] ruling”.

“We are thrilled about the focus on breast cancer which validates the importance of our work,” Ms Thomas said. “We are energized and positioned well to achieve continued growth outlook for [the year to March 31] 2024.”

The company said its diluted loss per share was down 42.9 percent to 4.0 NZ cents for the year to March 31, 2023, with net tangible assets per share fell 60.0 percent to 2.0 NZ cents, and cash and cash equivalents of $NZ12,711,000 at March 31, 2023 compared to $NZ18,145,000 at March 31, 2022.

Volpara said it expected earnings before interest, taxation, depreciation and amortization (Ebitda) for the year to March 31, 2024 of $NZ500,000 to a loss of $NZ2.0 million.

Volpara was unchanged at 68.5 cents.

PACIFIC EDGE

Pacific Edge says revenue for the year to March 31, 2023 was up 71.4 percent to $NZ19,616,000 ($A18,540,000), with net loss after tax up 36.3 percent to $NZ26,965,000 ($A25,485,000).

Pacific Edge said revenue came from sales of its Cxbladder non-invasive urine tests for bladder cancer, with a 71 percent increase in sales in the US and operating expenses up 58 percent due to investment in sales, marketing and research and a volume increase of Cxbladder.

The company said its diluted loss per share was up 26.9 percent to 3.3 NZ cents for the year to March 31, 2023, with net tangible assets per share down 24.1 percent to 10.1 NZ cents, and it had cash and cash equivalents of $NZ33,229,000 at March 31, 2023 compared to $NZ35,412,000 at March 31, 2022.

Pacific Edge was untraded at 38 cents.

ADALTA

Adalta says its rights offer at 2.5 cents a share has raised $1,282,591, with commitments for a further $1,871,167 taking the total to the $3,153,760 target.

In April, Adalta said it hoped to raise $3.15 million in a two-for-five rights offer, with one option for every two shares purchased (BD: Apr 28, 2023).

The company said it had commitments for $2.49 million from managing-director Dr Timothy Oldham and substantial shareholder Platinum Asset Management.

The company said Platinum Asset Management would subscribe for up to $480,000 of the shortfall subject to its total shareholding not exceeding 19.9 percent.

Adalta said its corporate advisor for the offer Peak Asset Management had committed for up-to $1.5 million for any shortfall following subscriptions from all other investors.

Adalta was untraded at 2.3 cents.

IMPEDIMED

Impedimed says the Grand Rapids, Michigan-based Priority Health has published the first medical policy covering its Sozo test for lymphoedema in breast cancer.

Impedimed said the policy was “the first published medical policy covering bio-impedance spectroscopy (BIS) testing using [its] Sozo Digital Health Platform for lymphoedema in breast cancer patients and survivors”.

The company said the policy meant Sozo was “medically necessary in the detection, diagnosis or surveillance of secondary, sub-clinical breast cancer-related lymphoedema”.

Impedimed said it expected to be reimbursed at a rate more than 50 percent higher than the national average for US Medicare reimbursement for Sozo.

Impedimed chief executive officer Richard Valencia said the policy was a “key accomplishment in our reimbursement strategy to achieve broad coverage of lymphoedema testing using Impedimed’s Sozo Digital Health Platform, which is the only [US Food and Drug Administration]-cleared and commercially available BIS technology for lymphoedema assessment”.

“We expected the first published medical policy to be from a regional payor, and we continue to expect that this publication will start a domino effect, motivating other private payors, both in the same state and neighboring states, to publish positive medical policies supporting the use of BIS,” Mr Valencia said.

Impedimed fell half a cent or 3.45 percent 14 cents with 8.1 million shares traded.

IMMUTEP

Immutep says it has dosed the first of 12 patients in its Aipac-003, phase II/III trial of eftilagimod alpha, or efti, for metastatic breast cancer at “a European clinical site”.

Immutep said it was evaluating Efti, formerly IMP-321, at 90mg doses in combination with standard-of-care paclitaxel at about 17 sites in Europe and the US.

The company said it would follow the open-label dosing of 12 patients with a 58-patient randomized phase II trial, with patients receiving either 30mg or 90mg doses.

Immutep said that, depending on the phase II results, it would develop a randomized, double-blinded, placebo-controlled phase III portion of the trial to focus on the overall survival as the primary objective.

Immutep chief scientific officer Frédéric Triebel said the aim was to “improve clinical outcomes, focusing on a robust primary endpoint later in the phase III, overall survival, for patients with standard-of-care chemotherapy”.

“Our previous trial, Aipac, showed encouraging efficacy and safety results, including a 2.9-month median overall survival benefit and statistically significant median overall survival improvements of between 4.2 to 19.6 months across three pre-specified subgroups,” Dr Triebel said. “We look forward to seeing how 90 milligram Efti dosing, along with same-day administration of Efti plus paclitaxel until disease progression, may build upon these prior results.”

Immutep was up 1.5 cents or 4.2 percent 37 cents with 5.3 million shares traded.

CLARIFICATION: ACTINOGEN MEDICAL

Last night’s edition reported Actinogen expecting the US Food and Drug Administration to approve changes to its Xanamem for Alzheimer’s trial by the end of 2023.

In fact, the company has told Biotech Daily that it expects FDA approval of the protocol changes “shortly”, with results by the end of 2025.

Actinogen fell 0.4 cents or 7.55 percent to 4.9 cents with 2.4 million shares traded.

RHYTHM BIOSCIENCES

Rhythm has told the ASX it did not consider its May 17, 2023 announcement of UK Conformity Assessment mark approval to be market sensitive.

Following the announcement, Rhythm climbed as much as 48 cents or 137.1 percent from 35 cents at the previous close to a day high of 83 cents, before closing up 33.5 cents or 95.7 percent at 68.5 cents, with 7.4 million shares traded (BD: May 17, 2023).

The ASX said the announcement was marked “market sensitive”.

The ASX said that Rhythm executive chair Otto Buttula had disclosed a purchase of 683,895 shares on May 15, 2023.

On May 15, Mr Buttula said he increased his substantial shareholding in the company from 23,427,501 shares (10.82%) to 24,111,396 shares (11.10%), through Newfound Investments Pty Ltd and Webinvest Pty Ltd, buying the shares from May 10 to May 12 for $248,246 or an average of 36.3 cents a share.

Rhythm said that its May 9 share price was a two and half year low “seemingly being caused by added selling pressure from a previous officer of the company, being the recently departed [chief executive officer Glenn Gilbert] … much of the selling volume during this period came from the selling by the departed CEO”.

According to Commsec, Rhythm traded above $1.00 a share for most of 2021 and 2022.

The company told the ASX that before and around this time Mr Buttula had comments from shareholders about whether he would be buying shares to show his support.

On May 17, the 7pm ABC Television News reported that Rhythm had climbed 96 percent on news of a UK approval for its blood-based colorectal tests.

Responding to the ASX query, Rhythm said the announcement was “incorrectly ticked as market sensitive”, since all its announcements had been habitually marked as such.

The company said Mr Buttula sought approval to purchase up to $250,000 shares through an email correspondence with the full board of directors and only became aware of the announcement’s information on May 16.

Rhythm said the UK Conformity Assessment was largely equivalent to its previously announced Conformité Européenne (CE) mark certification in 2021 and the expansion announcement announced in January 2022 (BD: Nov 30, 2021).

The company said both these announcements had previously confirmed that its Colostat colorectal cancer blood test could be marketed and sold in Great Britain.

Rhythm said it first became aware of the information in the announcement on May 9, 2023, when its head of regulatory affairs received the UK notice of registration and forwarded it to the chief operating officer, who then sent it to the chief financial officer on the same day, after the market closed.

The company said the chief financial officer then emailed the company’s public relations and media firm NWR a copy of the notice and requested an ASX announcement be drafted.

Rhythm said that, at this point in the email chain, the chief executive officer and board of directions were not informed, as this was considered “business as usual”.

Biotech Daily believes this reference to the chief executive officer was in error.

In April, Rhythm chief executive officer Glenn Gilbert resigned; with Mr Buttula to “assume additional executive duties, spending more time in the company’s Melbourne offices, alongside [its] expanded executive team” (BD: Apr 19, 2023).

The company said that on May 16 the chief operating officer and head of regulatory affairs confirmed receipt of confirmation and completion of the UK Conformity Assessment mark in a management meeting, with the chief financial officer confirming this to the executive chair in the early afternoon and a final ASX release concluded for board approval.

Rhythm fell 3.5 cents or 8.2 percent to 39 cents with 1.5 million shares traded.

ANTEOTECH

Anteotech has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 68.75 percent from 3.2 cents on May 23 to 5.4 cents on May 25, 2023 and noted a "significant increase in trading volume".
Anteotech was up 1.4 cents or 35 percent to 5.4 cents with 12.6 million shares traded.

IMAGION BIOSYSTEMS

Imagion says its annual general meeting voted up to 25.20 percent against the adoption of its remuneration report.
Imagion said that 132,434,432 shares (74.80%) supported the remuneration report resolution with 44,624,043 shares (25.20%) opposed.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election within 90 days.
The company said that all other resolutions faced dissent between 12.81 percent and 22.03 percent, including the placement capacity, adoption of a new constitution and the re-election of directors.
According to the company's most recent notice it had 1,167,665,778 shares on issue meaning that the 44,624,043 votes against the remuneration report amounted to 3.8 percent of shares on issue, not sufficient to requisition extraordinary general meetings.
Imagion was unchanged at 1.5 cents with 1.9 million shares traded.