Biotech Daily

Tuesday February 14, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CYNATA UP 5%; RESONANCE DOWN 14%**

*** CSL H1 REVENUE UP 19% TO $10.3b, PROFIT DOWN 7% TO $2.4b**

*** VITURA (CRONOS) H1 REVENUE UP 111% TO $58m, PROFIT UP 127% TO $8m**

*** RESPIRI SHARE PLAN RAISES $1.9m**

*** ENA: 'INNA-051 SIGNIFICANT FOR VIRAL INFECTION, NOT SYMPTOMS'**

*** OSTEOPORE AXOPORE LONG BONE WINS UK REGISTRATION**

*** ANTISENSE: TURKEY 1st APPROVAL FOR ATL1102 DMD TRIAL**

*** NEUROTECH WINS EXTENSION TO MARIJUANA NTI164 AUTISM TRIAL**

*** RADIOPHARM STARTS NASDAQ ADS PROCESS**

*** CHIMERIC RECEIVES $3.1m FEDERAL R&D TAX INCENTIVE**

*** TOTAL BRAIN TO DELIST ON MARCH 1**

*** BOTANIX REQUESTS 'PRESS ARTICLE' TRADING HALT**

*** REGAL REDUCES TO 6.6% OF PHARMAXIS**

*** GENESIS CARE SELLS CLARITY HOLDING**

MARKET REPORT

The Australian stock market was up 0.18 percent on Tuesday February 14, 2023, with the ASX200 up 13.1 points to 7,430.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and two were untraded.

Cynata was the best, up 1.5 cents or 4.8 percent to 32.5 cents, with 27,032 shares traded. Antisense climbed 4.2 percent; Avita rose 2.3 percent; Actinogen, Amplia, Nanosonics, Orthocell, Pharmaxis and Universal Biosensors were up more than one percent; with Clinuvel, CSL, Impedimed, Mesoblast, Neuren, Resmed and Telix up by less than one percent.

Yesterday's 10 percent best, Resonance, led the falls, down 0.9 cents or 13.6 percent to 5.7 cents, with 42,040 shares traded. Oncosil lost five percent; Emvision fell 4.5 percent; Atomo and Opthea were down more than three percent; Volpara shed 2.5 percent; Genetic Signatures and Immutep were down more than one percent; with Cochlear, Medical Developments, Paradigm, Pro Medicus, Proteomics and Starpharma down by less than one percent.

CSL

CSL says revenue for the six months to December 31, 2022 was up 18.9 percent to $US7,183,500,000 ($A10,324,000,000), with net profit after tax down 6.8 percent to $US1,640,200,000 ($A2,357,000,000).

CSL said that research and development expenditure increased 18.7 percent to $US576.5 million for the six months to December 31, 2022 or 8.03 percent of total revenue, compared to 8.04 percent for the six months to December 31, 2021.

The company said an interim unfranked dividend up 2.8 percent to $US1.07, would be paid on April 5, for a record date of March 10, 2023.

CSL said diluted earnings per share fell 12.5 percent to $US3.36 and that it had cash and cash equivalents of $US1,507,900,000 at December 31, 2022 compared to $US6,334,300,000 at December 31, 2021.

CSL managing-director Paul Perreault said that given the challenges the company faced over the pandemic he was proud of the way CSL responded.

“CSL’s largest franchise, the immunoglobulin portfolio, grew strongly, up 19 percent, driven by the significant increase in plasma supply and the increased patient demand,” Mr Perreault said.

Mr Perreault said plasma collections were up by 36 percent and the increase in supply drove growth in albumin sales by 11 percent.

“This acceleration in plasma collections underpins our ability to manufacture our plasma products going forward which is excellent news for patient care”, Mr Perreault said.

Mr Perreault said that sales of leading recombinant haemophilia B product Idelvion, rose percent “with its compelling clinical profile driving patient demand and market share”.

He said that despite reduced rates of immunization, Seqirus revenue rose nine percent and Kcentra sales increased eight percent as demand returned to pre-pandemic levels.

CSL said that in the five months to December 31, 2022 after it acquired Vifor, it had a revenue increase of about 15 percent compared to the prior corresponding period.

Last year, CSL said it had completed its acquisition of the St Gallen Switzerland-based Vifor Pharma AG (BD: Aug 2, 2022).

CSL was up $2.74 or 0.9 percent to $307.75 with 909,618 shares traded.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Vitura says that revenue for the six months to December 31, 2022 was up 110.6 percent to $57,644,481 with net profit after tax up 127.2 percent to $7,679,713.

In 2021, the then Cronos said it had acquired the Varsity Lakes, Gold Coast, Queensland-based CDA Health (formerly Cannabis Doctors Australia) which generated more than $21 million in sales in 2020-’21 (BD: Sep 14, Dec 16, 2021).

Yesterday, Vitura said that revenue came mainly from the sales of medicinal marijuana products, its on-line portal and clinic-related fees.

Vitura said diluted earnings per share rose 69.6 percent to 1.34 cents, net tangible asset backing per share was up 94.9 percent to 3.84 cents, and it had cash and equivalents of $14,822,587 at December 31, 2022 compared to $12,943,868 at December 31, 2021.

Vitura chief executive officer Rodney Cocks said the company’s financial report showed “significant growth across all key financial metrics”.

“Revenue in this half is 86 percent, and net profit after tax is 127 percent of the same metrics achieved in the full year of 2022,” said Mr Cocks. “This growth is underpinned by key operational milestones including the commissioning of the Melbourne distribution centre, rollout of Canview 2.0 and the transition of our clinics to 100 percent telehealth.”

Vitura was up 2.5 cents or 4.1 percent to 63 cents.

RESPIRI

Respiri says its share plan to raise $1.5 million at five cents a share has had over-subscriptions of $435,000, raising a total of $1,935,000 (BD: Jan 22, 2023).
Respiri said it would allow the oversubscriptions and the funds would be used for the company's "working capital requirements".
Respiri was unchanged at 4.9 cents.

ENA RESPIRATORY

Ena says a 123-volunteer, phase IIa, randomized, controlled influenza challenge showed that INNA-051 is able "to significantly impact the course of viral infection".
Ena said that patients received two high doses or two low doses of INNA-051 or placebo, then challenged with a substantial dose of H3N2 influenza A virus.
The company said that a post-hoc analyses excluding those with pre-existing immunity showed that INNA-051-treated participants with polymerase chain reaction (PCR) laboratory-confirmed infection "had a statistically significant shorter duration of infection".
Ena said the effect was greater with the higher dose of the INNA-051 immuno-modulator for the prevention of respiratory viral infections, and provided a graphical representation showing the higher dose was statistically significant duration than placebo ($p = 0.0173$).
"Although not statistically significant, a dose-related reduction in the duration of symptoms was also observed," the company said.
The company said that the viral inoculum was expected to result in a large majority of participants being infected, but interpretation of the study was complicated by lower than expected rates of infection in the placebo arm and an unexpectedly large proportion of participants having pre-existing immunity to the challenge strain across all groups.
The company said the study confirmed the safety of INNA-051 and compared with the placebo group, participants receiving INNA-051 showed "no increase in the incidence, magnitude, or duration of any 'flu symptom, nor enhanced local or systemic signs or symptoms associated with the viral challenge", with the most common adverse events "mild, short-lived and similar to those observed during the initial phase I study".
Ena managing-director Dr Christophe Demaison said the study "further supports the concept that boosting the local innate immune response to common respiratory viruses has potential clinical benefit".
"In this study, INNA-051 was found to be safe and to significantly impact the course of infection," Dr Demaison said.
"We are eager to investigate INNA-051's clinical benefit in the context of natural viral respiratory tract infections in individuals at increased risk of more severe illness," Dr Demaison said.
Ena said that previous research had shown that INNA-051 activated the innate immune system in the nose, a common site of infection.
Ena chief medical officer Dr Scott White said that many people had been impacted by a "tripledemic" of influenza, respiratory syncytial virus (RSV) and severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) viruses circulating together in recent months. "The surge in illness and hospitalization demonstrates the urgent need for a broad-spectrum treatment to boost immunity against common respiratory illnesses, and these data suggest INNA-051 is a promising option," Dr White said.
Ena said the results "support the further clinical development of INNA-051 to mitigate the impact of natural infection by respiratory viruses such as Sars-Cov-2 and its variants, [as well as] influenza, RSV and the common cold, in individuals at risk of more severe illness".
Ena is a private company.

OSTEOPORE

Osteopore says its Axopore long bone implant has been registered with the UK Medicines and Healthcare Products Regulatory Agency.

Osteopore said that Axopore was a customized implant used in long bone reconstruction surgery to replace bone loss as a result of trauma, surgery or pathological conditions.

The company said that Axopore custom-made device (CDM) was made from polycaprolactone and tricalcium phosphate, a composite biomaterial with “structural and regeneration advantages for bone reconstruction applications”.

Osteopore said that Axopore was allowed to be used in the UK and could be used by surgeons for treatment of their patients.

The company said it would “engage with hospitals and key surgeons and will also seek potential distribution partners who have the network to support and scale the adoption of Axopore CMD in Great Britain”.

Osteopore executive chair Mark Leong said the approval was “a major milestone for us”.

“Through the launch of Axopore CMD, Osteopore has now entered the orthopaedic market,” Mr Leong said.

“In addition, this registration is a stepping stone towards expanding our scope of applications to cover the entire body,” Mr Leong said.

“Our team will now seek out surgeons and partners to drive the adoption of Axopore CMD across Great Britain,” Mr Leong said.

Osteopore fell half a cent or 3.7 percent to 13 cents.

ANTISENSE THERAPEUTICS

Antisense says Turkey has approved its 45-patient, double-blind, placebo-controlled phase IIb trial of ATL1102 for Duchenne muscular dystrophy (DMD).

Antisense said the Turkish Medicines and Medical Device Agency was the first regulator to approve the trial following its application to conduct the trial in UK, Bulgaria and Turkey.

The company said the approval was “an important milestone … affirming the quality and acceptability of the phase IIb trial design and critically, in providing the green light for trial initiation at expected high patient enrolling sites”.

Antisense said patients would be treated with either placebo, 25mg or 50mg ATL1102 once weekly for six months and then continue an open-label treatment for six months.

The company said that results from the blinded phase was expected by July 2024.

Antisense was up 0.4 cents or 4.2 percent to 10 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has ethics committee approval to extend its phase I/II trial of its marijuana-based NTI164 for autism spectrum disorder by up to six months.

Neurotech executive director Dr Thomas Duthy said the extension was important because “under the revisions made to the original 28-day protocol through to 54 weeks, due to clinician, patient/caregiver request to stay on treatment with NTI164, that current approval would no longer be active once our [autism] kids moved beyond 54 weeks of treatment, which is expected in late February”.

“We anticipate the results of the full 54 weeks of treatment to be available [by April] 2023, which we hope will confirm the long-term durability of the improvements we have seen across a range of clinically accepted doctor, caregiver and patient assessments … coupled with no long-term safety concerns.

Neurotech fell 0.2 cents or 3.6 percent to 5.3 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has begun the process of a secondary listing on the Nasdaq and expects to begin trading in late March under the code RADX.
Radiopharm said it had filed a form 20-F registration document with the US Securities and Exchange Commission.
The company said its Nasdaq listing would be a level 2 American depositary receipt program, with each American depositary share (ADS) equal to 100 Australian shares.
Radiopharm said the listing would “not involve the raising of any capital”.
The company said that Deutsche Bank Trust Company Americas would be the depositary, custodian and registrar of the ADSs.
Radiopharm managing-director Riccardo Canevari said the Nasdaq listing would “complement our loyal existing Australian shareholder base by expanding Radiopharm’s access to investors globally, and thereby driving increased shareholder value with enhanced liquidity for all shareholders”.
The company said that the program was part of its strategy to expand its reach to US institutional and retail investors by enabling them to purchase shares through a US stock market, in the American time zones and in US dollars.
Radiopharm said there was “no assurance as to the completion or timing of this process or such a listing”.
Radiopharm was up one cent or 7.7 percent to 14 cents with 1.3 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has received $3,061,205 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Chimeric said the rebate related to research and development expenditure for the year to June 30, 2022.
Chimeric was unchanged at 7.3 cents.

TOTAL BRAIN

Total Brain says it has conditional approval from the ASX to delist effective from the close of trading on March 1, 2023.
Total Brain fell 0.4 cents or 57.1 percent to 0.3 cents with 13.5 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt pending an announcement in “in relation to a press article published this morning”.
Trading will resume February 16, 2023 or on an earlier announcement.
Botanix last traded at 6.4 cents.

PHARMAXIS

Regal Funds Management says it has reduced its substantial shareholding in Pharmaxis from 56,749,640 shares (7.89%) to 47,336,848 shares (6.58%).
The Sydney-based Regal said that between December 7, 2022 and February 9, 2023 it sold a total of 9,412,792 shares in 20 transactions, with the largest sale on February 9 of 2,233,312 shares for $130,425 or 5.84 cents a share.
Pharmaxis was up 0.1 cents or 1.75 percent to 5.8 cents.

CLARITY PHARMACEUTICALS

Genesis Care says it has ceased its substantial holding in Clarity selling all 15,362,700 shares for $11,061,144, or 72 cents a share.

On September 2, 2021, the Sydney-based Genesis said it became substantial in Clarity buying 15,362,700 shares (6.0%) prior to the company listing on August 25, 2021.

Clarity was up 5.5 cents or 7.3 percent to 81 cents.