Biotech Daily

Wednesday August 18, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PRO MEDICUS UP 16%; STARPHARMA DOWN 6%**

*** CSL REVENUE UP 7.2% TO $12.6b, PROFIT UP 9.6% TO $2.9b**

*** PRO MEDICUS REVENUE UP 20% TO $68m, PROFIT UP 34% TO $31m**

*** EDITORIAL: YOUR R&D TAX INCENTIVE IS NOT REVENUE**

*** NUHEARA REVENUE UP 374% TO $10.7m, LOSS DOWN 38% TO $7.2m**

*** PHARMAUST REVENUE DOWN 33% TO $2.1m, LOSS DOWN 2% TO $1.3m**

*** TOTAL BRAIN $1.9m OF $4m RIGHTS APPLICATIONS; TOTAL $6.5m**

*** AUSTRALIAN PATENT FOR ISLAND ISLA-101 FOR DENGUE FEVER**

*** TELIX, MERCK KGAA WORK ON CANCER; 2 BREAST CANCER TRIALS**

*** TALI: 'AKILI UP TO $51m ADHD DEAL'**

*** INCANNEX FILES US SEC REGISTRATION FOR NASDAQ IPO**

*** VOLPARA AGM 32% DISSENT; LOSES DIRECTOR DR MONICA SAINI**

*** LIFESPOT EGM TO BECOME INHALERX MARIJUANA VAPE COMPANY**

MARKET REPORT

The Australian stock market fell 0.12 percent on Wednesday August 18, 2021, with the ASX200 down 8.9 points to 7,502.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell and nine traded unchanged.

Pro Medicus was the best, up $8.85 or 15.7 percent to $65.35, with 665,960 shares traded. LBT and Telix climbed more than six percent; Antisense improved 5.9 percent; Impedimed and Polynovo were up more than four percent; Clinuvel and Uscom were up more than three percent; Neuren, Paradigm and Resmed rose more than two percent; Actinogen, Avita, Cochlear and Cynata were up one percent or more; with Cyclopharm, Kazia, Nanosonics, Universal Biosensors and Volpara up by less than one percent.

Yesterday's 3.5 percent best, Starpharma, led the falls, down eight cents or 5.95 percent to $1.265, with 651,343 shares traded. Prescient fell 5.1 percent; Alterity, Next Science, Opthea and Resonance retreated more than three percent; Compumedics, Immutep and Patrys shed more than two percent; CSL and Medical Developments were down more than one percent; with Genetic Signatures, Mesoblast and Proteomics down by less than one percent.

CSL

CSL says revenue for the year to June 30, 2021 was up 12.7 percent to $US10,310 million ($A14,189 million) with net profit after tax up 13.0 percent to $US2,375 million ($A3,268.6 million).

CSL chief executive officer Paul Perreault said the company had “a strong result against a backdrop of very challenging conditions brought on by the global Covid-19 pandemic”.

“Despite the uncertainty and complexities we have faced, our CSL Behring and Seqirus businesses maintained all critical operations and we have continued to deliver our life saving and life extending medicines around the world,” Mr Perreault said.

CSL said that plasma collections were “adversely impacted by US stimulus, stay-at-home orders [and] extended lockdowns” with collection volumes down 20 percent and increased costs.

The company said sales of Hizentra rose 15 percent, Haegarda sales were up 14 percent, Kcentra improved seven percent, with albumin sales up 61 percent and Seqirus seasonal influenza vaccine sales increasing 41 percent to a record 130 million doses, worldwide.

CSL said that the Behring division improved six percent to $US8.6 billion with North America up five percent, the Asia-Pacific up 44 percent, the European Union down six percent and the rest of the world constant.

The company said Seqirus improved 30 percent to $US1.7 billion, up 31 percent in North America, 58 percent in the European Union and fell six percent in the Asia Pacific.

The company said that a partly-franked dividend of $US1.18 ($A1.62) per share, up 10.3 percent compared to the previous year, would be paid on September 30 to shareholders at the record date of September 3, 2021, following the unfranked interim dividend of $1.04 US cents ($A1.43) per share paid on April 1, 2021.

The company said that its net tangible asset backing per share was up 29.9 percent from $US9.66 to $US12.55, but CSL restated the previous year’s net tangible asset backing per share to $US9.33, making this year’s up 34.5 percent on the restated basis.

CSL said that diluted earnings per share up 13.0 percent to $US5.21.

CSL said research and development spending increased 8.6 percent to $US1,001.4 million compared to the previous year and was 9.7 percent of the total revenue.

The company said it had $US1,808.8 million in cash and cash equivalents at June 30, 2021, compared to the previous corresponding period’s $US1,194.4 million.

Mr Perreault said that Covid-19 was “a once in a lifetime event [and] I’m proud of our company’s response and confident of a return to strong growth”.

“Demand for CSL’s core plasma products remains robust,” Mr Perreault said.

“Plasma collections are expected to continue improving following multiple initiatives we have implemented,” Mr Perreault said. “I’m optimistic of a global recovery with greater social mobility and more normalized conditions.”.

“Plasma therapies have a nine-to-12-month manufacturing cycle [so] increasing collections today underpins our expectation of an increase in supply of therapies to patients,” Mr Perreault said.

“Our influenza vaccines business Seqirus is expected to continue to perform well and deliver another strong year underpinned by its portfolio of differentiated products and the heightened demand for influenza vaccines,” Mr Perreault said.

Mr Perreault said that 2021-’22 would be “a transitional year” with net profit after tax for 2021-’22 expected to be in the range of $US2,150 million to $US2,250 million.

A CSL spokesperson told Biotech Daily that the expected fall in profit was primarily due to reduced plasma collections.

CSL fell $4.38 or 1.5 percent to $293.56 with 1.1 million shares traded.

PRO MEDICUS

Pro Medicus says that revenue for the year to June 30, 2021 was up 19.5 percent to $67,884,000 with net profit after tax up 33.7 percent to $30,850,000.

Pro Medicus said that European revenue from its hospital imaging software was up 25.7 percent, Australian revenue was up 23.4 percent with American sales up 18.0 percent.

The company said it had signed seven contracts and renewals worth $145.5 million over seven years and collaboration agreements with New York University and the Mayo Clinic.

Pro Medicus chief executive officer Dr Sam Hupert said that Covid-19 restrictions had "minimal impact on the company's operations, with sales and implementation activities at an all-time high during the year".

"It was our most successful year by any measure," Dr Hupert said.

"All of our key financial metrics headed in the right direction," Dr Hupert said.

"We foreshadowed a step-up in revenue this year despite currency headwinds and lower numbers in the first quarter due to Covid restrictions and we have delivered on that," Dr Hupert said.

"Margins continued to increase as did our cash and other financial assets," Dr Hupert said.

"It was also our biggest year in terms of both sales and implementations, laying the foundation for a further step-up in exam volumes in 2021-'22," Dr Hupert said.

Dr Hupert said that the US Food and Drug Administration clearance for the company's Breast Density AI Algorithm was an opportunity for the company to build on its position in the artificial intelligence space.

Pro Medicus said that a fully-franked dividend of 8.0 cents a share would be paid on October 2, 2020 for holders on the record date of September 11, following the fully franked 7.0 cents interim dividend, compared to the previous year's fully-franked final dividend of 6.0 cents and interim dividend of 6.0 cents.

The company said net tangible assets per share were up 53.125 percent to 49 cents, with diluted earnings per share up 33.5 percent to 29.5 cents for the year to June 30, 2021.

The company said it had cash and cash equivalents of $42,039,000 compared to $43,413,000 at June 30, 2020.

Pro Medicus was up $8.85 or 15.7 percent to $65.35 with 665,960 shares traded.

BIOTECH DAILY EDITORIAL: YOUR R&D TAX INCENTIVE IS NOT REVENUE

In previous reporting periods, some companies have claimed the Federal Research and Development Tax Incentive as "revenue" when they have little or no revenue, at all.

The Tax Incentive is similar to a tax rebate and is not taxable, so it should not be called revenue; just as one's tax payment in one year is not an allowed tax-deductible expense in the following year.

Unless one goes to the fine detail (and some companies do not provide it) an investor could think the company has money from the sale of product when it doesn't.

Revenue does not include the Tax Incentive or grants. It does include: sales of product, licence fees, milestone payments, royalties and bank interest.

All these sub-units of revenue should be made clear and investors should not need to go searching for the truth, buried deep in the notes, or have to call the company to find out what they have not announced.

Claiming the RDTI as revenue is deliberately misleading the industry and investors.

While the ASX and ASIC refuse to act on this practice, apparently allowed by accountants and auditors, for the companies we cover (with real revenue of more than $1 million a year), we shall strip out the misinformation wherever we find it.

David Langsam, Editor

NUHEARA

Nuheara says revenue for the year to June 30, 2021 was up 373.8 percent to $10,746,831, with net loss after tax down 38.4 percent to $7,200,681.
Nuheara said the revenue was primarily from the direct-to-consumer sales of its sound filtering Iqbuds Max through as well as original equipment manufacture sales and service.
In May, the company said it had shipped its first batch of Elite wireless earbuds under a three-year supply agreement to Hewlett-Packard Inc (BD: May 10, 2021).
Today, Nuheara said diluted loss per share fell 58.7 percent to 0.45 cents, net tangible asset backing per share was up from 0.1 cents to 0.4 cents and it had cash and cash equivalents of $7,276,355 at June 30, 2021 compared to $4,430,710 at June 30, 2020.
Nuheara was unchanged at 3.4 cents with 2.3 million shares traded.

PHARMAUST

Pharmaust says revenue for the year to June 30, 2021 was down 33.0 percent to $2,140,320 with net loss after tax down 1.8 percent to $1,337,310.
Pharmaust said revenue was primarily from its Epichem medicinal chemistry operations.
The company said net tangible asset backing per share was up 1.1 percent to 1.81 cents, diluted loss per share fell 8.7 percent to 0.42 cents and it had cash and cash equivalents of $3,020,268 at June 30, 2021 compared to $2,880,496 at June 30, 2020.
Pharmaust fell 0.3 cents or 3.3 percent to 8.9 cents.

TOTAL BRAIN

Total Brain says it had applications for $1.9 million of $4 million in its fully-underwritten one-for-seven rights issue at 26 cents a share, taking the total raised to $6.5 million.
Total Brain said that the take-up rate was 48 percent and the 8.1 million shares not taken up under the offer would be allotted to the sub-underwriters.
In July, the company said it would issue one option for every two new shares, exercisable at 36 cents within 12 months from issue (BD: Jul 21, 2021).
Total Brain was unchanged at 23.5 cents.

ISLAND PHARMACEUTICALS

Island says it has been granted a “key Australian patent” relating to its ISLA-101 lead program for dengue fever and other mosquito borne viruses.
Island said that the patent, titled ‘Method of Viral Inhibition’ would provide intellectual property protection until April 16, 2034.
The company said the patent covered a method of treating or preventing dengue virus or other mosquito borne virus infections with ISLA-101, and it had licenced the patent portfolio, which was generated by Melbourne’s Monash University.
The company said it was the third patent granted in the last 12 months, adding to patents granted for the same coverage in the US, Singapore and Brazil.
Island chief executive officer Dr David Foster said the Australian patent “adds to Island’s growing intellectual property portfolio and supports the broad applicability of ISLA-101 for different mosquito bone viruses”.
The company said that dengue fever was “often seen as predominantly a disease of developing countries … [but] global warming has meant that mosquitoes carrying dengue are travelling further” with rising case numbers in Florida and North Queensland”.
Island was up half a cent or 1.5 percent to 34.5 cents.

TELIX PHARMACEUTICALS

Telix says it has a pan-cancer clinical collaboration with Merck KGaA, combining a Merck DNA damage response inhibitor with TLX591 and TLX250.

Telix said the collaboration with the Darmstadt, Germany-based Merck followed previous work with undisclosed Merck molecules (BD: Aug 1, 2019).

Today, the company said that TLX591 and TLX250 were late-stage products in development for prostate and renal cancer therapy, respectively.

Telix said that based on encouraging pre-clinical data from the initial collaboration, the companies agreed to investigate the synergy of TLX591 and TLX250 with Merck's DNA damage response inhibitor (DDRI) across a variety of cancers in the clinic.

Telix chief executive officer Dr Christian Behrenbruch said the collaboration was "the vanguard of nuclear medicine and oncology, and we are excited by the level of new data and intellectual property already generated".

"Pre-clinical studies provide evidence that the combined effect of Merck's DDRI compound with Telix's [molecularly targeted radiation] candidates has potential to significantly impact cancer by improving efficacy and reducing the required radiation dose for tumor reduction and remission, compared to [molecularly targeted radiation] only," Dr Behrenbruch said.

Separately, Telix said that two investigator-led studies would evaluate the use of its late-stage imaging portfolio, initially in two subtypes of breast cancer.

Telix said that TLX591-CDx and TLX250-CDx had "potential utility in breast cancer imaging, particularly for specific phenotypes that are not consistently well-imaged using existing techniques".

The company said that the first of 20 patients had been dosed in a US National Institutes of Health-sponsored phase I trial of TLX591-CDx for the detection of occult metastases of lobular breast cancer, also called invasive lobular carcinoma at the Atlanta, Georgia-based Emory University.

Telix said that TLX591-CDx targeted glutamate carboxypeptidase II, more generally known as prostate specific membrane antigen (PSMA), a protein that is highly expressed in many cancers, including invasive lobular carcinoma.

The company said it had filed for regulatory approval of TLX591-CDx in prostate cancer imaging but this study was the first formal clinical investigation of TLX591-CDx in another indication of interest.

Telix said that invasive lobular carcinoma was the second most common form of breast cancer, affecting about 10 percent of people with invasive breast cancer, with no accurate imaging techniques for staging the cancer, adversely impacting clinicians' ability to inform decisions about optimal treatment and management of the disease.

The company said that the 12-patient, phase II, 'Opalescence' study would evaluate the feasibility of using TLX250-CDx positron emission tomography (PET) and computed tomography (CT) to detect CA9 expression as the basis of a potential future therapeutic strategy for triple negative breast cancer, a subtype of breast cancer that had a poorer prognosis than other breast cancer subtypes.

Telix said the study would be at the St Herblain, France-based Institut de Cancérologie de l'Ouest and be led by Dr Caroline Rousseau.

The company said the study would evaluate CA9 expression in cancers other than clear cell renal cell carcinoma, currently the focus of the Zircon imaging and Starlite therapy studies.

Telix said the aim of the studies was to evaluate how CA9 imaging could be used in cancer diagnosis and staging and to develop a deeper understanding of the use of CA9 as a therapeutic target.

Telix was up 41 cents or 6.7 percent to $6.50 with 652,139 shares traded.

TALI DIGITAL

Tali says it has an up-to $51 million licence agreement with Boston's Akili Interactive Labs to commercialize its paediatric cognition products in the US.
Tali said that the attention deficit hyperactivity disorder ADHD therapeutics market in the US was estimated at $US10 billion a year.
The company said that more than six million children aged eight to 18 years in the US had been diagnosed with ADHD.
Tali said its platform built on Akili's portfolio and complemented its flagship product Endeavorrx.
The company said that payments and royalties were contingent on achievement of milestones, with the first milestone of US$2 million pending US Food and Drug Administration clearance, expected by July 2023, and on commercialization, Akili would pay royalties on sales, above the milestone payments.
Tali said it would lead the clinical and regulatory clearance and Akili would be responsible for commercialisation of paediatric cognition digital products in the US.
The company said its technology targeted attention in children aged three to eight years, through its evidence and video game-based Detect screening and Train training product.
Tali fell 0.1 cents or 2.2 percent to 4.5 cents with 83.7 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has filed a registration statement with the US Securities and Exchange Commission for a proposed US offer of American depositary shares (ADSs).
Incannex said there would be 50 Australian shares for each ADS, but the number of securities to be sold and the price per ADS had not been determined.
The company said that it had applied to list the ADSs on the Nasdaq under the symbol IXHL and would call an extraordinary general meeting for shareholder approval.
Incannex said it had appointed Rimon Law as its legal counsel and Withum Smith and Brown to undertake the accounting due diligence process, with Roth Capital Partners the sole bookrunning manager for the offer, and EAS Advisors LLC as US corporate advisors.
Incannex was up 1.5 cents or 5.45 percent to 29 cents with 6.6 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says its annual general meeting had more than 32 percent dissent against the issue of options to director Roger Allen and increasing the director fee pool 40 percent.
Volpara said the vote to grant Mr Allen 150,000 options exercisable at $1.33 each by 1 October 1, 2027 was opposed by 21,281,673 votes (32.03%) and supported by 45,166,852 votes (67.97%), with the increase in the directors' fee poll from $NZ500,000 to $NZ700,000 opposed by 21,012,904 votes (32.20%) and supported by 44,248,103 votes (67.80%).
Volpara said that director Paul Reid faced 8.40 percent opposition with the employee share plan and the auditor fees passed overwhelmingly.
According to the company's most recent Appendix 2A application for quotation of securities announcement Volpara had 251,315,081 shares on issue, meaning that the votes against Mr Allen's options amounted to 8.5 percent of the company, sufficient to requisition extraordinary general meetings.
In its notice of meeting, Volpara said that director Dr Monica Saini would retire at the meeting and today she filed an Appendix 3Z final director's interest notice.
Volpara was up half a cent or 0.45 percent to $1.115.

LIFESPOT HEALTH

Lifespot says an extraordinary general meeting will vote to change its name to Inhalerx and elect three directors.

Lifespot said the name change to Inhalerx reflected a focus on developing, inhaled pharmaceuticals for unmet medical needs, and the ASX code would change to IRX, subject to ASX confirmation.

In its Appendix 4C quarterly activities and cash flow report Lifespot said it had “break-through first sales of cannabidiol e-liquid using Medihale inhaler system in Australia”.

The company said that in partnership with EC Pharma Medihale Pods using its proprietary cannabinoid e-liquid were dispensed through its compounding pharmacy partner.

In 2017, Lifespot said that with Germany’s Seng Vital it would form Seng Vital Australia to integrate the Cannamed vaporizer into its Bodytel platform (BD: May 1, 2017)

Lifespot said that shareholders would vote to elect Darryl Davies, Dr Andrew Saich and Sean Williams as directors.

The virtual meeting will be held on September 15, 2021 at 11am (AEST).

Lifespot was untraded at 9.5 cents.