

# **Biotech Daily**

### Wednesday December 5, 2018

## Daily news on ASX-listed biotechnology companies

\* ASX, BIOTECH DOWN: AIRXPANDERS UP 10%; IMPEDIMED DOWN 8%

- \* CSL R&D SPEND UP, APPROVALS, 'FLU VACCINES, PIPELINE
- \* BIOTRON OPTIONS RAISE \$4.7m
- \* RHYTHM COMPLETES COLORECTAL CANCER TEST REAGENTS
- \* CHAIR ALLAN TRIBE, AUSTRALIAN LAND TAKE 23% OF PHYLOGICA
- \* PRANA REGISTERS 1m ADRs
- \* STEMCELL: 'ASX OK MARIJUANA COSMETICS; DRAGON'S BLOOD'

#### MARKET REPORT

The Australian stock market fell 0.78 percent on Wednesday December 5, 2018 with the ASX200 down 44.7 points to 5,668.4 points.

Seven of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and four were untraded.

Airxpanders was the best, up 0.3 cents or 10 percent to 3.3 cents, with 1.3 million shares traded.

Actinogen was up seven percent; Compumedics climbed 6.6 percent; Oncosil rose 2.7 percent; Avita and Paradigm were up more than one percent; with Cochlear, Opthea and Resmed up by less than one percent.

Impedimed led the falls, down two cents or 7.7 percent to 24 cents, with 994,350 shares traded.

Imugene and Polynovo fell more than four percent; Dimerix and Starpharma lost more than three percent; Clinuvel, Cyclopharm, Cynata, Ellex, Immutep, Neuren and Telix shed two percent or more; CSL, Kazia, LBT and Pro Medicus were down more than one percent; with Genetic Signatures, Medical Developments, Nanosonics and Volpara down by less than one percent.

<u>CSL</u>

CSL's 2018 research and development briefing has focused on the company's influenza assets and its commitment to research and development spending.

CSL research and development director and chief scientist Prof Andrew Cuthbertson said that CSL had increased research and development spending from \$US667 million

(\$A912.1 million) in 2016-'17 to \$US702 million (\$A960.0 million) for 2017-'18, with a target spend of about 10 percent of the company's global revenue.

Prof Cuthbertson said CSL had "multiple shots on goal" and was balancing its risk-reward profile with some products lower risk and some higher risk with the potential for much greater reward.

"We have a good track record for delivering shareholder value from research and development," Prof Cuthbertson said.

The briefing presentations showed the CSL had 1,700 scientists employed at major centres across Australia, the US, Europe, China and Japan.

CSL head of research Dr Andrew Nash singled out the Melbourne Bio-21 facility associated with the University of Melbourne in the Parkville biotechnology precinct, whoch would house 170 scientists and was due to be opened officially "in a week or so". Dr Nash said that like Bio-21, the Switzerland facility was based on Bern University and Hospital campus providing access to translational medicine as well as clinical trials. Dr Nash described a range of immunoglobulin therapies, including a nebulized immunoglobulin for respiratory tract infections, and recombinant compounds in early to

mid-stage development for indications including auto-immune disease, hereditary angiooedema and thrombosis, and neutrophil-mediated inflammation.

Prof Cuthbertson said the Australian Therapeutic Goods Administration had approved Hizentra for chronic inflammatory demyelinating polyneuropathy (CIDP), along with a US Food and Drug Administration approval for the CSL Seqirus subsidiary's Flucelvax and a UK approval for Fluad.

He said that Privigen for CIDP had been approved in the US as had Hizentra, which had also been approved in the EU, with an application submitted for approval in Japan. Prof Cuthbertson said CSL used "stage gates" to decide which compounds to progress and although CSL626 had shown it could extend the half-life of Factor VIII, Roche had a competitor and in the absence of a market in a few years' time, development was stopped. He said that Haptoglobin and Hemopexin had similarities, but Hemopexin had shown promise for sickle cell anaemia and would continue while Haptoglobin would not.

Prof Cuthbertson said that CSL200, developed by the recently acquired Calimmune, was "our stem cell gene therapy to treat or even cure sickle cell disease" and was currently in pre-clinical development ahead of human trials.

"There's a lot of activity in our early stage portfolio," Prof Cuthbertson said. Seqirus head of research and development Dr Gregg Sylvester described the nature of the "hundreds" of circulating influenza viruses and how global authorities attempted to identify the four most predominant each year.

"But the virus is trickier than that," Dr Sylvester said. "The virus changes."

Dr Sylvester said that Seqirus was developing both traditional egg-based vaccines and cell-based vaccines as well as adjuvant compounds to broaden the ability of vaccines to impact the target viruses.

He said that the US FDA had approved Afluria for patients aged more than six months, Fluad for people aged 65 years, along with process changes for Flucelvax.

Dr Sylvester said Seqirus had completed its MF59 pre-pandemic vaccine clinical program with more than 130 million doses administered and showing "excellent" safety.

CSL fell \$2.03 or 1.1 percent to \$179.75 with 999,236 shares traded.

#### **BIOTRON**

Biotron says that it has raised \$4,707,598 from the exercise of BITOA six cent options, which expired on November 30, 2018.

Biotron said the 77,123,826 options exercised by investors amounted to 98.29 percent of all options available and the underwriters had subscribed for the remaining 1,336,137 options.

The company said it was "in a sound financial position".

Biotron was unchanged at 14 cents with 10.8 million shares traded.

#### RHYTHM BIOSCIENCES

Rhythm says it has completed development of the reagents required for the lead biomarkers for its Colostat colorectal cancer blood test.

Rhythm said that it would focus on manufacturing scale-up and assay optimization. Rhythm chief executive officer Glenn Gilbert said that completyion of the reagent development was "another key milestone".

"Next steps are to scale-up the manufacture, optimize these key reagents and integrate them into a robust, reproducible Colostat test," Mr Gilbert said.

Mr Gilbert said the scale-up and optimization would be verified in study "which is on-track for completion in 2019".

Rhythm fell half a cent or 3.3 percent to 14.5 cents.

#### **PHYLOGICA**

Phylogica chair Allan Tribe says that through his Australian Land company he has increased his holding from 425,766,247 shares (19.91%) to 559,266,247 shares (22.9%). In a substantial shareholder notice, the Perth, Western Australia based Australian Land said that on September 21 it bought 9,000,000 shares for \$256,500 or 2.85 cents and on November 16, 2018 was approved to acquire 124,500,000 shares for \$3,735,000 or three cents a share in the September placement which raised \$9.12 million (BD: Sep 12, 2018). In April, Phylogica said it had appointed Mr Tribe as its chairman and Mr Tribe with Australian Land said they had increased their substantial shareholding to 425,776,247 shares (19.91%) (BD: Apr 11, 2018).

Phylogica was unchanged at 2.9 cents.

#### PRANA BIOTECHNOLOGY

Prana says it has filed a US Securities and Exchange Commission registration to issue 1,000,000 American depository receipts for its US employee option plan.

The SEC form said that each American depository receipt was equivalent to 60 Australian shares and was valued at \$US1.60 (\$A2.18).

The company told Biotech Daily that the form registered its US employee share option plan approved at the annual general meeting, for 27,000,000 previously granted options and the potential future grant of 33,000,000 options.

Prana said that the 60,000,000 shares was the original approved pool, including already issued shares, and the pricing was used to calculate the SEC registration fee only. Prana was untraded at 3.9 cents.

#### STEMCELL UNITED

Stemcell says the ASX confirms that its acquisition of 51 percent of Yunnan Hua Fang Industrial Hemp for cosmetic marijuana "is not a change of nature of [its] activities". Stemcell said that the expansion into the cannabis beauty products sector for cosmetic purposes only was not considered to be a change to the nature of the company's activities for the purpose of Listing Rules 11.1.2 or 11.1.3.

The company said that Hua Fang Industrial Hemp had an industrial hemp licence in China and it would invest RMB3.8 million (\$A760,000) for a 51 percent interest in the coming months, subject to availability of funds.

In July, Stemcell said it had a \$US10 million (\$A13.5 million) five-year deal to supply Daemonorops draco blume resin, or "Dragon's Blood" to China's Zhejiang Forest Rainbow Medical (BD: Jul 13, 2018).

In its prospectus of June 29, 2015, Stemcell (then On Q Group) said it would extract Resina from Daemonorops draco blume or Dragon's Blood for traditional Chinese medicines, saying that "whether or not [traditional Chinese medicine] is believed, studies have shown that Chinese herbal medicine can be successful in treating a range of disorders" (BD: May 18, 2017).

Stemcell was up 0.4 cents or 17.4 percent to 2.7 cents with 5.4 million shares traded.