



Biotech Daily

Thursday May 9, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PATRYS UP 19%; ORTHOCELL DOWN 21%**
- * **FDA COMMITTEE BACKS PHARMAXIS BRONCHITOL FOR CYSTIC FIBROSIS**
- * **PARADIGM COMPLETES \$78m CAPITAL RAISING**
- * **ZELDA RECEIVES \$769k R&D TAX INCENTIVE**
- * **ADMEDUS TAKES \$1m SIO LOAN AT 12%, \$125k FEE**
- * **GI DYNAMICS \$4.3m CRYSTAL AMBER NOTE**
- * **OSPREY DIRECTOR OPTIONS FACE 13% DISSENT**
- * **AIRXPANDERS HIRES COWEN FOR FINANCIAL ADVICE**
- * **LBT RECEIVES FIRST \$1m OF \$4m SA GOVERNMENT LOAN**
- * **AUSTRALIAN ETHICAL TAKES LOSS ON ACTINOGEN**
- * **AUSTRALIAN ETHICAL TAKES 8.4% OF ELLEX**
- * **ROBERT LEDERER, RTL GROUP TAKE 10% OF ANATARA**
- * **OCH-ZIFF REDUCES TO 6% OF TOTAL BRAIN**
- * **FACTOR LOSES DIRECTOR TIM HUGHES; DIRECTORS FEES BACK**
- * **GENERA LOSES DIRECTOR JIM KALOKERINOS**

MARKET REPORT

The Australian stock market was up 0.42 percent on Thursday May 9, 2019, with the ASX200 up 26.2 points to 6,295.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and four were untraded.

Patrys was the best on no news, up 0.4 cents or 19.05 percent to 2.5 cents with 5.2 million shares traded. Osprey climbed 17.4 percent on an AGM; Pharmaxis was up 10.0 percent; Actinogen and Impedimed recovered more than seven percent; Genetic Signatures was up 4.5 percent; Benitec, Clinuvel, Compumedics, Immutep and Opthea were up more than three percent; Mesoblast rose 2.3 percent; Polynovo and Pro Medicus were up one percent or more; with Cochlear up 0.9 percent.

Yesterday's 377.3 percent best, Orthocell, led the falls, retreating 11 cents or 20.95 percent to 41.5 cents with 87.3 million shares traded. Oncosil lost 7.7 percent; Prescient retreated 6.8 percent; Antisense, Avita and Cyclopharm fell more than four percent; Cynata, Kazia, Medical Developments and Optiscan shed more than two percent; Ellex, Nanosonics, Starpharma and Volpara were down more than one percent; with CSL, Neuren, Paradigm, Resmed and Telix down by less than one percent.

PHARMAXIS

Pharmaxis says a US Food and Drug Administration committee has given a positive recommendation for Bronchitol for adult cystic fibrosis.

Pharmaxis said that nine of the 16-person pulmonary-allergy drugs advisory committee (Padac) voted yes to the question “is the benefit-risk profile adequate to support approval of [dry powder mannitol or Bronchitol] for the proposed indication of the management of cystic fibrosis to improve pulmonary function in patients 18 years of age and older in conjunction with standard therapies”?

Pharmaxis said the committee reviewed and evaluated available data on the safety and effectiveness of new products to treat pulmonary disease and conditions with allergic or immunologic mechanisms.

The company said its licensee, the Parma, Italy-based Chiesi, was responsible for regulatory approval and commercialization of Bronchitol in the US.

Pharmaxis said if approved by the FDA, it would receive a \$US10 million (\$A14.3 million) milestone payment on the launch of Bronchitol in the US and mid to high teen percentage royalties on in-market net sales.

The company said it would manufacture and exclusively supply Bronchitol for the US market.

Pharmaxis said Bronchitol had been subject to three large-scale global clinical trials and was approved and marketed in Europe, Russia, Australia and several other countries.

Pharmaxis chief executive officer Gary Phillips said the committee vote was “very encouraging, however, we are aware that these recommendations are not binding and Pharmaxis will continue to support Chiesi to work with the FDA to bring Bronchitol to patients in the US”.

“We expect the FDA to make its final decision by mid-year,” Mr Phillips said.

Pharmaxis was up 2.5 cents or 10.0 percent to 27.5 cents with 2.5 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it had applications for \$9.1 million in its up-to \$16.6 million underwritten retail rights issue at \$1.50 a share, taking the total raised to \$77.9 million.

Paradigm said that Bell Potter Securities had fully underwritten the one-for-eight non-renounceable retail entitlement offer and would place the shortfall of 4.98 million shares, worth \$7.47 million,

In April, Paradigm said it had raised \$51.55 million in a placement and \$9.8 million in an institutional rights issue placement, with a further \$16.6 million to be raised in the retail rights offer (BD: Apr 17, 2019).

Last month, the company said it expected to raise \$77.9 million, following positive data from its 112-patient, phase IIb trial of pentosane polysulfate sodium for knee osteoarthritis pain (BD: Apr 15, 2019).

Paradigm fell one cent or 0.7 percent to \$1.50.

ZELDA THERAPEUTICS

Zelda says it has received \$769,030 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Zelda said the funds related to expenditure for the year to June 30, 2018.

Zelda was unchanged at 4.4 cents.

ADMEDUS

Admedus says it has a \$1 million, 18-month loan from New York hedge fund SIO Partners at 12 percent compounding monthly and carrying a \$125,000 "facility fee".

Admedus said the interest and facility fee would be "capitalized to the loan balance and repayable at maturity".

The company said that if it held a rights issue while the loan was outstanding, SIO might elect to offset all or part of the outstanding balance against its entitlement and any underwriting commitment.

Admedus said that if shareholder approval was obtained, the outstanding balance might, at SIO's election no later than three months prior to maturity, be converted to shares at the lesser of 2.0 cents a share or 80 percent of the 5-day volume weighted average market price to the date on which the shares would be issued.

The company said the loan was secured to \$1 million and the funds would be used for general working capital and operational costs.

Admedus said it was continuing with a restructure "to reduce certain overhead costs, and a proposed divestment of the infusion business so as to capitalize on its growing Adapt business.

In an Appendix 4C in April, Admedus said it had receipts of \$5,973,000 for the three months to March 31, 2019, cash of \$4,626,000 and an expected three months burn to June 30 of \$12,591,000 (BD: Apr 29, 2019).

The company said at that time that it had a cash burn of \$6,351,000 to March 31, comprising \$788,000 on research and development, \$6,948,000 on staff costs, \$2,380,000 on administration and corporate costs and \$2,014,000 on product manufacturing and operating costs.

Combining the revenue for the quarter to March 31, with cash and cash equivalents implies \$10,599,000 compared to projected spend of \$12,591,000 for the coming quarter. Earlier in April, the company said it had an agreement to sell Admedus Vaccines, formerly Coridon, to Hong Kong's Star Bright and Constellation but said the sale had been terminated and it remained suspended for funding (BD: Apr 10, 23, 2019).

Last year, Admedus said Star Bright Holding intended to take 60 percent of Admedus Vaccines for \$18 million, with Admedus retaining 29.1 percent and chief executive officer Wayne Paterson to be its chairman for five years (BD: Apr 27, Jun 27, 2018).

In December, the company said that it had raised \$18,964,198 of a hoped-for \$20 million with applications for \$5,374,530 shares at eight cents a share and underwriters taking \$13,589,668 of the shortfall shares (BD: Dec 14, 2018).

In November, Admedus said it hoped to raise a minimum of \$12 million after the payment of underwriter fees and repayment of a \$5 million loan to major shareholder Star Bright through the rights issue (BD: Nov 28, 2018).

The company said at that time that the New York hedge fund SIO Partners LP would underwrite up to \$6 million with Star Bright underwriting \$1 million and taking its full entitlement of about \$4 million.

Admedus said that SIO would provide "up to a further \$6.3 million in underwriting" if the offer did not raise a minimum net cash amount after underwriting fees and repayment of the Star Bright loan of about \$12 million, with SIO to be paid 3.0 percent for the initial \$6 million underwriting, but if SIO was required to provide more than \$6 million because the offer did not raise a net \$12 million, it would be paid 12.5 percent on the initial underwriting instead of the 3.0 percent and 25 percent on any amount SIO takes up over \$6 million.

Admedus is in an extended voluntary suspension and last traded at six cents.

GI DYNAMICS

GI Dynamics says it has a \$US3 million (\$A4,302,780) convertible note and warrant financing with 47.5 percent shareholder Crystal Amber for general working capital.

GI Dynamics said the new convertible note would be provided in two tranches of \$US500,000 no later than May 10 and May 25 and two tranches of \$US1,000,000 no later than June 11 and July 11, 2019.

The company said the funds would satisfy its working capital requirements until the end of July and it would work to extend the July 1, 2019 maturity date of its 2017 convertible note.

The company said Crystal Amber would not be permitted to convert the note into common stock or Chess depository interests (CDIs) until it had shareholder approval, which would be sought at an annual general meeting.

GI Dynamics was up 0.1 cents or 4.55 percent to 2.3 cents.

OSPREY MEDICAL

Osprey's annual general meeting passed all resolutions but with up to 12.6 percent opposition to the issue of exchange options to chairman John Erb and director Neville Mitchell.

Last month, Osprey said it would vote to grant 920,000 replacement options and 160,000 options to Mr Erb, 430,000 replacement options and 100,000 options to Mr Mitchell, 80,000 options to director Sandra Lesenfants and 7,080,000 replacement options and 4,740,000 options to chief executive officer Michael McCormick (BD: Apr 11, 2019).

The company said at that time that there had been "a sharp decline in the price of its CDIs ... [and] the board believes that the stock option exchange offer will serve as a means of motivating and retaining individuals with out-of-the-money stock options" with the previous options exercisable at 30 cents per CDI and the new options exercisable at the closing price on the date of grant.

Today, the company said it faced up to 16,520,180 votes (12.64%) against the issue of exchange options to Mr Erb and Mitchell with 114,183,709 votes (87.35%) in favor.

Osprey said there was up to 7.7 percent opposition to the issue of options to Mr Erb, Mr Mitchell, Mr McCormick and Ms Lesenfants.

The company said that other resolutions were passed by wider margins with Ms Lesenfants and McCormick re-elected unopposed.

Osprey's most recent Appendix 3B new issue announcement said it had 431,797,370 shares on issue, meaning the vote against Mr Erb and Mr Mitchell's exchange options represented 3.8 percent of the company, not sufficient to requisition extraordinary general meetings.

Osprey was up two cents or 17.4 percent to 13.5 cents.

AIRXPANDERS

Airxpanders says it has engaged the New York-based Cowen Inc as an independent financial advisor to explore "financial and strategic alternatives".

Last week, Airxpanders requested an extension for its voluntary suspension "until it can finalize its negotiations and provide the market with an accurate update on its future plans", following a voluntary suspension request and March 29, 2019 "debt agreement" trading halt (BD: Mar 29, Apr 2, May 3, 2019).

Airxpanders was in a suspension and last traded at 3.5 cents.

LBT INNOVATIONS

LBT says it has received the first \$1 million instalment of a \$4 million loan from the South Australian Government.

Last year, LBT said the South Australian Government had approved drawdowns of \$1 million and a further two drawdowns of \$1.5 million each by December 2019, to be repaid over five years (BD: Aug 28, 2018).

The company said it would use the funding to insource core capability in artificial intelligence, science and software engineering.

LBT was unchanged at 8.3 cents.

ACTINOGEN MEDICAL, AUSTRALIAN ETHICAL INVESTMENT

Australian Ethical Investment says it has ceased its substantial holding in Actinogen, selling all 80,323,117 shares for \$1,565,836 or 1.95 cents a share.

Australian Ethical said that on March 18 it sold 7,554,307 shares for \$425,879.35 or 5.6 cents per share; and on Tuesday May 7 it sold 72,768,810 shares for \$1,139,956.89 or 1.57 cents a share.

On Tuesday, Actinogen said that its 186-patient, phase II trial of Xanamem for Alzheimer's disease "did not achieve statistical significance" and the company fell as much as 70.8 percent on the day (BD: May 7, 2019).

Last year, Australian Ethical said it became a substantial shareholder of Actinogen, with 80,323,117 shares or 7.37 percent of the company and said that it had bought 37,323,117 shares for \$1,517,163 or 4.06 cents a share (BD: Oct 16, 2018).

In 2014, Actinogen acquired its assets for Alzheimer's disease from the University of Edinburgh (BD: Aug 27, 2014).

Actinogen was up 0.1 cents or 7.1 percent to 1.5 cents with 89.7 million shares traded.

ELLEX MEDICAL LASERS

Australian Ethical Investment says it has increased its holding in Ellex from 7,736,389 shares (6.39%) to 12,087,186 shares (8.42%).

Australian Ethical said it bought shares between September 28, 2017 and May 8, 2019, with the largest and most recent purchase 1,593,034 shares for \$941,958 or 59.1 cents a share.

Ellex fell one cent or 1.7 percent to 59 cents.

ANATARA LIFESCIENCES

The Sydney-based Robert Anthony Lederer says he has increased his substantial shareholding in Anantara from 4,477,000 shares (9.06%) to 4,977,000 (10.07%).

Mr Lederer said the shares were held by RTL Group Investments Pty Ltd and his superannuation fund, with 500,000 shares acquired on-market between December 12, 2018 and May 7, 2019 as "on market purchases".

Mr Lederer yet again failed to state the price paid for the shares, as required under the Corporations Act 2001 (BD: Nov 14, 2017; May 16, Dec 12, 2018).

Anantara was unchanged at 40 cents.

TOTAL BRAIN

Och-Ziff Holding Corp says it has reduced its substantial shareholding in Total Brain from 47,136,884 shares (7.10%) to 47,100,794 (6.06%).

The Wilmington, Delaware-based Och-Ziff said that on March 29, 2019, OZ Enhanced Master Fund sold 36,090 shares for \$975 or 2.7 cents a share and it was diluted on May 7, 2019 in an issue of 55,470,747 shares.

Total Brain was up 0.1 cents or 4.0 percent to 2.6 cents.

FACTOR THERAPEUTICS

Factor says director Tim Hughes will retire, effective from May 15, 2019.

Factor said following its commitment to forego director fees in November 2018, it would reintroduce fees for non-executive directors from June 1 at 50 percent of the previous level with the chair receiving \$40,000 a year and non-executive directors earning \$30,000 a year, during the transition period (BD: Nov 14, 2018).

Factor was unchanged at 0.4 cents.

GENERA BIOSYSTEMS

Genera says non-executive director Jim Kalokerinos has resigned, effective from today.

Genera said that Mr Kalokerinos was appointed a director in October 2010.

The company said it would make "additional appointments to the board in the short term".

Genera was in a suspension and last traded at 16 cents.