Biotech Daily

Wednesday July 5, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PSIVIDA UP 20%, ORTHOCELL DOWN 6%**

*** TEVA TO PAY SUDA $2.7m FOR ZOLPIMIST INSOMNIA SPRAY**

*** CYNATA: FDA CYP-001 GVHD PRE-IND MEETING 'VERY POSITIVE'**

*** BARD1 RAISES $1.1m, PLAN FOR $1m MORE**

*** SLATER AND GORDON $25k MEDICAL RESEARCH GRANTS**

*** RHINOMED UNMARKETABLE PARCELS FACILITY**

*** CVC, STINOC TAKE 13.8% IN CYCLOPHARM**

*** TDM TAKES 14% OF SOMNOMED**

MARKET REPORT

The Australian stock market fell 0.35 percent on Wednesday July 5, 2017 with the ASX200 down 20.5 points to 5,763.3 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded.

Psivida was the best, up 46 cents or 19.5 percent to $2.82 with 4,507 shares traded, followed by Bionomics up 12.35 percent to 45.5 cents with 2.2 million shares traded.

Compumedics climbed 6.8 percent; Oncosil and Prana climbed five percent or more; Benitec, Cellmid, Living Cell and Pharmaxis were up four percent or more; Cyclopharm was up 3.05 percent; Admedus, Airxpanders, ITL and Sirtex rose more than one percent; Medical Developments, Pro Medicus, Resmed and Viralytics were up by less than one percent.

Orthocell led the falls, down two cents or 5.6 percent to 34 cents with 2,539 shares traded.

Factor Therapeutics, Opthea and Starpharma lost more than three percent; Clinuvel, Ellex, Polynovo and Universal Biosensors shed more than two percent; Actinogen, Avita, CSL, LBT, Mesoblast, Neuren and Reva were down more than one percent; with Cochlear and Nanosonics down by less than one percent.

SUDA

Suda says Teva Pharmaceuticals will pay up-front $US300,000 ($A394,002) and milestones of up to $US1,750,000 for a licence to its Zolpimist for insomnia

Suda said the licence, through Teva International GmbH for its oral zolpidem tartrate spray covered Brazil, Mexico and Chile, with an 18-month option to licence the product in Argentina, Israel and Australia.

The company said that once Zolpimist was registered for sale it would receive a double-digit royalty on net sales less the supply price.

Suda said that Teva would assume responsibility for development, regulatory and commercialisation activities for Zolpimist in the territory and it would supply the product to Teva at cost plus an agreed handling fee.

Suda chief executive officer Stephen Carter said his company was “committed to its strategy of partnering with leading companies to commercialize its pipeline of novel oral sprays”.

“We are proud to be partnering with Teva, a major pharmaceutical company, to bring Zolpimist to market in Latin America, Israel and Australia,” Mr Carter said.

“Teva has the commercial capabilities to take advantage of Zolpimist’s unique profile within the insomnia market,” Mr Crater said.

“This agreement is another step towards our goal of bringing this new treatment option to patients in countries beyond the US and Canada,” Mr Carter said.

Suda fell 0.2 cents or 10.5 percent to 1.7 cents with 7.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says the US Food and Drug Administration has provided advice on the regulatory path for its Cymerus mesenchymal stem cell products in the US.

Cynata said that the FDA confirmed that the scope and substance of its chemistry, manufacturing and controls dossier was “commensurate with its expectations, which indicates that Cymerus [mesenchymal stem cell] products are expected to be of suitable quality for clinical trial use in the US”.

The company said that the FDA provided “clarification on the design of pre-clinical studies” required to support an investigational new drug application (IND) and expects to conduct those studies in parallel with the ongoing clinical trial of CYP-001 for the treatment of graft-versus-host disease in the UK and Australia.

Cynata said the FDA provided advice regarding the protocol for a planned US graft-versus-host disease trial.

The company said that the FDA clarified that it could submit a request for regenerative medicine advanced therapy designation for CYP-001 for graft-versus-host disease, pending preliminary results of the first trial.

Cynata said the designation was an initiative from the US 21st Century Cures Act, allowing companies with designated products additional and earlier interactions with the FDA and to seek priority review and accelerated approval.

Cynata product development head Dr Kilian Kelly said the pre-IND meeting was “an enormously valuable exercise for Cynata”.

“The outcome of the meeting was very positive and we are optimistic that we will be able to open an IND and include clinical centres in the US in future trials,” Dr Kelly said.

“This will be an important step in the commercial development of CYP-001 in the world’s largest market for pharmaceutical products,” Dr Kelly said.

Cynata was up four cents or 6.7 percent to 64 cents.

BARD1 LIFE SCIENCES

Bard1 says it has commitments to raise $1,097,325 through the issue of 137,165,811 shares at 0.8 cents a share, with a share plan to raise a further $1 million.
Bard1 said that the 0.8 cents issue price was 19.1 percent discount to the 5-day volume-weighted average price to June 30, 2017, the last trading day prior to the announcement of the share plan.
The company said that the funds would be used to fund ongoing research and development programs, commercial initiatives and for general working capital purposes.
Bard1 said that CPS Securities was the lead manager for the placement.
Bard1 fell 0.1 cents or 10 percent to 0.9 cents with 2.3 million shares traded.

SLATER AND GORDON

Slater and Gordon says medical and healthcare professionals can apply for grants up to $25,000 to facilitate projects that make a positive difference for health and wellbeing.
The law firm said that in the past three years, the Slater and Gordon Health Projects and Research Fund had donated about $300,000 to 12 not-for-profit groups, health organisations and research bodies.
Slater and Gordon personal injury head Janine Gregory said the fund was established “to ensure people with asbestos-related illness, occupation-caused cancer or significant disabilities caused by a catastrophic injury are able to access ongoing, high- quality care and treatment”.
“We regularly hear from everyday Australians whose lives have been turned upside down following an unexpected accident or workplace injury or illness,” Ms Gregory said.
“While a positive legal outcome often paves the way towards a brighter future, we want to also be able to improve the long term quality of life for our clients and other members of the community who share similar experiences,” Ms Gregory said .
Ms Gregory said that the Fund was “an important way for the firm to give back by providing support to medical and healthcare professionals in their invaluable work to help rebuild the lives of people who are suffering from significant health setbacks”.
Slater and Gordon said that grants from $3,000 to $25,000 were available to support innovation and research projects and educational initiatives of medical and allied health professionals.
For a copy of the application guidelines, email: researchfund@slatergordon.com.au or go to: www.slatergordon.com.au/researchfund.
Applications close on August 11, 2017.

RHINOMED

Rhinomed says it will provide an unmarketable parcel sale facility for shareholders with less than $500 of shares or fewer than 2,702 shares at the record date of July 3, 2017.
Rhinomed said that 539 shareholders held unmarketable parcels totalling 550,841 shares.
The company said it valued all of its shareholders, but it incurred significant administrative costs maintaining such a large number of less than marketable parcels and the sale was expected to reduce the administrative costs and provide an opportunity to investors with small holdings, who may find it difficult or expensive to dispose of those shares through normal means, to dispose of their small holdings in a cost-effective manner.
Rhinomed said that it would cover all costs, including brokerage and stamp duty, related to the sales under this program.
Rhinomed was untraded at 18.8 cents (following a 10-for-one consolidation).

CYCLOPHARM

CVC says that it has increased its substantial shareholding in Cyclopharm from 7,633,242 shares (12.78%) to 9,470,393 (13.80%).
The Sydney-based CVC said that between April 20 and May 12, 2017 Stinoc bought 622,999 shares on-market for $473,793 or 76.05 cents a share and acquired 1,214,152 shares for $971,322 or 80 cents a share in an entitlement offer which raised $6,947,814 (BD: Jun 28, 2017).
CVC director Alexander 'Sandy' Beard is a former director of Cyclopharm appointed in April 2011 and resigning in July 2011 and (BD: Apr 29, 2011).
Cyclopharm was up 2.5 cents or 3.05 percent to 84.5 cents.

SOMNOMED

TDM Asset Management says it has increased its holding in Somnomed from 6,917,454 shares (11.95%) to 8,129,563 shares (14.05%).
The New York-based TDM said it bought 1,212,109 shares at "market prices" but did not disclose the price paid for the shares as required under the Corporations Act 2001.
The TDM substantial shareholder notice was signed by company secretary Jason Sandler and said that associated entities included TDMAM Pty Ltd, Madleowill Investments Pty Ltd, Zoolander Investments Pty Ltd, Thomas Cowan, Rebecca Cowan, Hamish Corlett and Benjamin Gisz.
Somnomed was untraded at $3.11.