# Biotech Daily

Thursday February 9, 2017

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: ORTHOCELL UP 8%, DIMERIX DOWN 12.5%**

*** NOVOGEN WINS $3m CRC GRANT**

*** PSIVIDA $26m FBR 'AT MARKET' FACILITY**

*** ONCOSIL EXPECTS DELAYED BRACHYSIL CE MARK 'THIS YEAR'**

*** FINAL ACTINOGEN XANAMEM ALZHEIMER'S TRIAL RESULTS PUBLISHED**

*** BPH REJECTS 'INVALID' BOARD SPILL MOTION**

*** SG HISCOCK TAKES 8% OF RESONANCE**

*** FIL TAKES 10% OF MEDIBIO**

*** CRESO TO RELEASE 5.7m ESCROW SHARES**

*** RESPIRI HIRES STEWART CORPORATE FOR PARTNER NEGOTIATIONS**

*** ASHLEY MORRIS REPLACES SCIGEN CEO DR JAMES KIM, $250k START**

## MARKET REPORT

The Australian stock market climbed 0.23 percent on Thursday February 9, 2017 with the ASX200 up 29.5 points to 5,651.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Othocell was the best on yesterday's FDA filing, up four cents or 8.3 percent to 52 cents with 792,482 shares traded.

Actinogen climbed 7.4 percent; Cellmid improved 6.45 percent; Cyclopharm was up 5.2 percent; Ellex climbed 3.7 percent; IDT, Impedimed, Mesoblast and Starpharma rose more than two percent; Atcor, Factor Therapeutics, Pro Medicus and Sirtex were up more than one percent; with Clinuvel, Cochlear, CSL, Opthea, Psivida and Resmed up by less than one percent.

Dimerix led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 3.5 million shares traded. Benitec lost five percent; Avita and Oncosil fell more than four percent; Bionomics, Medical Developments, Neuren and Osprey shed more than two percent; Acrux and Prana were down more than one percent; with Compumedics, Reva and Viralytics down by less than one percent.

## NOVOGEN

Novogen says it has been awarded a Federal Government co-operative research centre grant of up to $3 million over three years.
Novogen said the funds would be used for next-generation anti-tropomyosin program, intended to provide potential new therapies for cancer.
The company said the research was separate from its existing anti-tropomyosin development candidate ATM-3507, or Anisina.
Novogen said it was the lead partner in the collaboration with the University of New South Wales and the Sydney-based ICP Firefly Pty Ltd contract research organization.
The company said that it had committed to contributing $1 million over the three-year life of the project and the University of New South Wales would contribute up to $300,000 and the three parties would provide staff and other in-kind resources.
Novogen was unchanged at 8.4 cents.

## PSIVIDA

Psivida says it has a $US20,000,000 ($A26.2 million) “at market” draw-down facility with the Arlington, Virginia-based FBR Capital Markets.
Separately, Psivida lodged a “shelf registration” to raise up to $US75,000,000 with the US Securities and Exchange Commission.
The company said that it could offer and sell shares of its US common stock up to $US20,000,000 “from time to time, through FBR, acting as sales agent”.
Psivida said that FBR could sell shares by any method permitted by law deemed to be an “at the market offering” and would be entitled to a commission of up to 3.0 percent of the gross proceeds from each sale of shares.
The company said the funds would be used for “the continued research and clinical and pre-clinical development of our product candidates, commercialization of our product candidates, if approved, and for other general corporate purposes”.
Psivida was up one cent or 0.5 percent to $2.18.

## ONCOSIL MEDICAL

Oncosil says it expects conditional Conformité Européenne (CE) mark approval for its Brachysil localized radiation treatment for pancreatic and liver cancer by the end of 2017.
Last year, Oncosil moved the previous CE mark timeline from March 2016 to “the near term” (BD: Dec 14, 2015; Mar 1, Jun 30, Sep 14, 2016).
Oncosil said that the British Standards Institute advised that the conditions included the provision of supplemental data from 20 locally advanced pancreatic cancer patients supporting the existing safety and clinical performance data already reviewed, and agreement to undertake a post-marketing clinical follow-up program.
The company said that the 20-patient supplemental data request was “consistent with the request received from the US [Food and Drug Administration] prior to granting an investigational device exemption in July 2016”.
Oncosil said it was “well-positioned to provide the supplemental data” from its pancreatic clinical study program, which had 12 participating centres including Monash Health the MD Anderson Cancer Centre and Johns Hopkins University.
The company said that based on recruitment projections and data follow-up requirements it expected to provide the supplemental data by October 2017.
Oncosil said that CE mark review for primary liver cancer was “on-going”.
Oncosil fell 0.4 cents or 4.1 percent to 9.4 cents with 4.2 million shares traded.

## ACTINOGEN MEDICAL

Actinogen says the final results of its phase I trials of Xanamem for Alzheimer's disease have been published in British Journal of Pharmacology.

In 2015, Actinogen said its phase I trials of Xanamem showed it was safe and tolerable across the dose range of 10mg to 35mg twice daily, the drug crossed the blood-brain barrier and was effectively delivered to the brain (BD: May 12, Sep 29, 2015).

Today, the company said that the research article, entitled 'Selection and early clinical evaluation of the brain-penetrant 11-beta-hydroxysteroid dehydrogenase type 1 (11-beta-HSD1) inhibitor UE2343 (Xanamem)' was co-authored by chief executive officer Dr Bill Ketelbey, with scientific advisor board members Prof Alan Boyd, Prof Brian Walker and Dr Scott Webster as well as head of clinical research Vincent Ruffles.

The article is available at: http://onlinelibrary.wiley.com/doi/10.1111/bph.13699/pdf

Actinogen said the paper described the research underpinning the development of Xanamem at the University of Edinburgh over the last 10 years and summarized the results achieved from the early research studies that confirmed Xanamem to be the optimum candidate drug to take to clinical development in Alzheimer's disease and discussed in detail the ability of Xanamem to inhibit the 11-beta-HSD1 enzyme in the brain, blocking the production of excess cortisol in the brain.

The company said that raised cortisol was associated with Alzheimer's disease and lowering cortisol was "an important new target for treating Alzheimer's disease".

Actinogen said it expected to treat the first of the 174 patients in its phase II Xanadu trial by July 2017.

Actinogen was up 0.4 cents or 7.4 percent to 5.8 cents.

## BPH ENERGY

BPH says it has rejected a board spill notice under section 249D of the Corporations Act 2001 requisitioning a general meeting.

BPH executive chairman David Breeze said the request to remove the existing directors and appoint new directors had been determined to be "invalid on the grounds that it does not meet the requirements under section 249D of the Act".

"The board have resolved to reject the notice on the basis of the invalidity and does not intend to requisition a general meeting for the purposes of considering the resolutions in the notice," Mr Breeze said.

BPH has investments in Cortical Dynamics and Molecular Discovery Systems.

BPH fell 0.05 cents or 8.3 percent to 0.55 cents with 17.0 million shares traded

## RESONANCE HEALTH

SG Hiscock and Co says it has increased its substantial shareholding in Resonance from 25,868,854 shares (6.43%) to 30,889,686 shares (7.67%).

The Collins Street Melbourne-based SG Hiscock said the shares were held by HSBC Custody Nominees and gave its address as HSBC in Sydney.

The company said that it acquired 1,038,932 shares for $24,989 or 2.4 cents a share between February 2 and 6, 2017 but failed to disclose the cost of the other 3,981,900 shares as required under the Corporations Act.

Resonance was unchanged at 2.4 cents.

## MEDIBIO

The Hong Kong-based FIL Limited says it has increased its substantial shareholding in Medibio from 13,241,254 shares (8.92%) to 14,836,861 shares (9.99%).
FIL said it acquired the shares between January 5 and February 6, 2017 at prices ranging from 37 cents and 40 cents.
Medibio was up one cnet or 2.7 percent to 37.5 cents.

## CRESO PHARMA

Creso says it will release 5,700,000 shares from ASX escrow on February 22, 2017 and have 42,140,000 shares available for trading.
Creso said that it had a further 8,000,001 shares in escrow until October 20, 2018 and 6,329,500 shares to be released from escrow between April 13 and October 13, 2017.
Creso was unchanged at 23 cents.

## RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says it has engaged the Melbourne-based Stewart Corporate Advisory Pty Ltd to provide advice and assist the company in negotiations with strategic partners.
Respiri is attempting to commercialize its Sonosentry overnight asthma monitor and its Airsonea asthma wheeze diagnostic, based on technology invented by the Haifa, Israel-based Dr Noam Gavriely (BD: Nov 24, 2006; Jul 25, Dec 15, 2016).
Respiri was unchanged at 5.6 cents

## SCIGEN

Scigen says Ashley Morris will replace chief executive officer Dr James Kim who has tendered his resignation for personal reasons, effectively immediately.
Scigen said that Mr Morris would start on a base salary of $S270,000 ($A250,000) a year with an incentive scheme ranging from 10 to 50 percent of the base salary pending milestones, and a travel allowance of $S15,000 a year.
The company said that Mr Morris had more than 30 years' experience in the Asia Pacific pharmaceutical industry.
Scigen said that Mr Morris was previously Bausch & Lomb's ASEAN managing-director and before that was an executive with Schering-Plough in South Asia and later Malaysia and Singapore and had earlier worked for Pharmacia, Beecham, Farmitalia Carlo Erba, Pharmacia Asia and Pharmacia Philippines.
The company said that Mr Morris held a Bachelor of Arts from England's Nottingham University.
Scigen was untraded at two cents.