



Biotech Daily

Tuesday April 30, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: OPTISCAN UP 12.5%; PRESCIENT DOWN 7%**
- * **MEDIBIO DE-NOVO SUBMISSION WITHDRAWN, 510k DROPPED**
- * **VOLPARA RECEIPTS UP 83% TO \$5.3m**
- * **EU REGISTRATION FOR CELLMID ÉVOLIS HAIR CARE PRODUCTS**
- * **GI DYNAMICS HAS LESS THAN TWO QUARTERS CASH**
- * **RESPIRI HAS LESS THAN TWO QUARTERS CASH; \$1.4m LOAN**
- * **MEDIBIO HAS LESS THAN TWO QUARTERS CASH; RIGHTS PLACEMENT**
- * **AMPLIA LESS THAN TWO QUARTERS CASH; 'COSTS DOWN'**
- * **CRESO MARIJUANA IMPORT LICENCE; BURLEIGH HEADS DISTRIBUTOR**
- * **PHARMAUST RECEIVES \$672k FEDERAL R&D TAX INCENTIVE**
- * **BLACKCRANE TAKES 6.7% OF AVITA**
- * **YANHUA HUANG TAKES 13% OF STEMCELL**
- * **ALCHEMIA EXTENDS 'CHANGE IN ACTIVITIES' SUSPENSION**

MARKET REPORT

The Australian stock market fell 0.53 percent on Tuesday April 30, 2019, with the ASX200 down 34.0 points to 6,325.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and five were untraded.

Optiscan was the best for the second day in a row on no news, up 0.5 cents or 12.5 percent to 4.5 cents, with 278,501 shares traded. Uscom climbed 9.7 percent; Antisense and Pro Medicus were up more than seven percent; Cochlear, Compumedics and Polynovo rose more than two percent; Avita, Clinuvel, Kazia, Nanosonics, Oncosil and Proteomics were up more than one percent; with CSL, Cynata, Genetic Signatures and Mesoblast up by less than one percent.

Prescient led the falls for the second day in a row on no news, down 0.3 cents or 6.7 percent to 4.2 cents, with 1.3 million shares traded. Orthocell, Patrys and Volpara fell more than four percent; Impedimed, Paradigm, Pharmaxis and Telix lost more than three percent; LBT shed 2.5 percent; Neuren, Osprey and Starpharma were down more than one percent; with Medical Developments, Opthea and Resmed down by less than one percent.

MEDIBIO

Medibio says it has withdrawn its de-novo submission for its heart rhythm test for mental illnesses to the US Food and Drug Administration filed last year.

In March, Medibio said that the de-novo submission had “shortcomings” and was under review (BD: Mar 21, 2019).

Today, the company said the de novo submission “was flawed in many ways” and the decision to withdraw was made after input from the FDA and the newly engaged regulatory counsel, the Minneapolis, Minnesota-based Duval and Associates.

The company said it had a long-term regulatory strategy allowing for more efficient use of staffing and cash resources, leading to more commercialization opportunities.

Medibio said that analysis of the 510(k) submission showed “limited commercialization opportunity ... due to the limited indications for use that would be obtained”.

The company said that “these limited indications did not fit with the company’s strategy and it would be better served by building a longer-term FDA strategy for a sustainable commercial pathway in the US, which includes a more attractive indications-for-use statement only obtainable through the de-novo path”.

The company said it would have the resources to pursue opportunities in Australia and the US and revise their current Conformité Européenne (CE) mark for commercialization opportunities in Europe.

Medibio executive chairman David Kaysen said that the “changes in our regulatory strategy come after extensive review and analysis of all pathways currently available to us”.

Medibio fell 0.1 cents or 5.9 percent to 1.6 cents, with 1.4 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says receipts from customers for the 12 months to March 31, 2019 were up 82.6 percent to \$NZ5,608,000 (\$A5,304,060).

Volpara said its annual recurring revenue from its breast imaging software for early cancer detection was “one of the strongest quarters in its history” taking the total for the year to \$NZ6.63 million (\$A6.27 million).

Volpara chief executive officer Dr Ralph Highnam said the company expected annual recurring revenue to increase between 50 percent to 80 percent and “the percentage of US women screened using a Volpara service to exceed 10 percent and a strong gross margin to remain above 80 percent”.

Volpara fell 9.5 cents or 4.9 percent to \$1.85, with 1.3 million shares traded.

CELLMID

Cellmid says its Évolis Professional anti-aging hair care products have been registered for sale in the European Union.

Cellmid said the registration was the final step in a comprehensive regulatory compliance assessment of the Évolis Professional products before they could be freely sold in the UK and EU.

The company said that “key treatment and efficacy claims have been retained on the product labels during the review process, which provides for strong market positioning as efficacious products that are derived from natural plant extracts”.

Cellmid said it had a partnership with an unnamed European cosmetics retailer and it expected electronic commerce sales would begin by January 2020.

Cellmid fell half a cent or 2.5 percent to 19.5 cents.

GI DYNAMICS

GI Dynamics says its cash burn for the three months to March 31, 2019 was \$US3,424,000 (\$A4,859,160) with cash at March 31 of \$US1,286,000 (\$A1,824,812). GI Dynamics said its net operating cash burn for the three months to June 30, 2019 was expected to be \$US852,000 (\$A1,208,973). The company did not provide any further information. GI Dynamics was up 0.1 cents or 4.55 percent to 2.3 cents.

RESPIRI

Respiri says its expected cash burn for the three months to June 30, 2019 will be \$2,007,000, with cash at March 31 of \$1,591,000. Yesterday, Respiri said it expected to start a six-week pilot trial of its Wheezo asthma and chronic obstructive pulmonary disease wheeze detector with an undefined number of patients (BD: Apr 29, 2019). Today, the company said that it had no receipts from customers and its net operating cash burn for the three months to March 31, 2019 was \$2,162,000. Respiri said it had a "borrowing facility of up to \$1.4 million which anticipates the forecasted 2019 R&D Tax Incentive claim". The company said the Tax Incentive was expected by November 2019 and "the company anticipates being in revenue generating mode at the same time". Respiri, formerly Karmelsonix and Isona, has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006). Respiri fell 0.1 cents or one percent to 9.6 cents.

MEDIBIO

Medibio says it expects a cash outflow for the three months to June 30, 2019 will be \$1,849,000 with cash at the March 31 of \$2,932,000. Medibio said that it had receipts from customers for the three months to March 31 of \$69,000 with a net operating cash burn of \$1,883,000. Medibio said it expected to raise \$3,129,100 from sale of 156,455,043 rights offer shortfall shares (BD: Mar 12, 2019).

AMPLIA THERAPEUTICS

Amplia says its expected cash outflow for the three months to June 30, 2019 will be \$895,000 with cash at March 31, 2019 of \$1,241,000. Amplia said its net operating cash burn for the three months to March 31, 2019 was \$340,000. Amplia chief executive officer Simon Wilkinson told Biotech Daily that \$612,000 of the expected expenditure to June 30 was for projects that would be completed during the quarter and the three months to September quarter cash burn was expected to be about \$250,000. Mr Wilkinson said the company was reviewing capital raising strategies to complete a phase I healthy volunteer study of its anti-cancer compounds in early 2020. Amplia was untraded at 13.5 cents.

CRESO PHARMA

Creso says it has an Australian import permit for its first shipment of Cannaqix to be distributed by the Southern Queensland-based Burleigh Heads Cannabis.

Creso said the first shipment would arrive by October 2019 to be sold as a therapeutic product through approved channels.

The company said that Cannaqix 50 was a buccal, or cheek-delivered, lozenge for chronic pain, containing 50mg of cannabidiol along with niacin, vitamins B6, B12, C, and zinc.

Creso fell half a cent or 1.1 percent to 44.5 cents.

PHARMAUST

Pharmaust says it has received \$672,250 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Pharmaust said the rebate related to research and development activities for its monepantel for cancer in dogs and humans for the year to June 30, 2018.

Pharmaust was unchanged at 3.5 cents.

AVITA MEDICAL

Blackcrane Capital says it has increased its holding in Avita from the equivalent of 105,443,712 shares (5.6%) to 124,345,592 shares (6.7%).

The Bellview, Washington-based Blackcrane said it had 59,445,952 Australian shares and increased from 2,299,888 American depository receipts (ADRs), equivalent to 45,997,760 Australian shares, to 64,899,640 ADRs, equivalent to 3,244,982 Australian shares.

The company said that it acquired the shares between April 10 and April 25, 2019, with the single largest purchase of 242,850 ADRs equivalent to 4,857,000 Australian shares for \$US1,391,895 (\$A1,944,605) or 40.0 cents a share.

Avita was up half a cent or 1.3 percent to 38.5 cents, with 10.7 million shares traded.

STEMCELL UNITED

The Hong Kong-based Yanhua Huang says he has become a substantial shareholder in Stemcell United with 78,947,368 shares or 12.7 percent of the company.

Mr Huang said that on April 24, 2019, he bought 78,947,368 shares for \$1,500,000 or 1.9 cents a share.

Stemcell United was unchanged at 1.7 cents.

ALCHEMIA

Alchemia has requested an extension to the suspension requested on March 29, pending a proposed change to the nature and scale of its activities (BD: Mar 29, 2019).

Earlier in March, Alchemia said that chief financial officer and company secretary Melanie Leydin and Lynden Polonsky replaced chairman Simon Gennari and director Darren Book as directors effective, with director Cameron Petricevic appointed chairman and Michael Sapountzis appointed joint company secretary (BD: Mar 5, 2019).

Today, the company said the announcement was expected by June 3, 2019.

Alchemia last traded at 1.1 cents.