

Biotech Daily

Wednesday March 28, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: OPTISCAN UP 9%; ONCOSIL DOWN 7%
- * OPTISCAN: 'BUSINESS CONTINUES DESPITE LOSING 6 SENIOR STAFF'
- * G MEDICAL RESPONDS TO ASX MISSED MILESTONES QUERY
- * INNATE \$4m AMPLIA ACQUISITION, DIRECTORS, CONSOLIDATION EGM
- * MICRO-X CONVERTIBLE NOTES RAISE \$5m
- * FIRST SWISS IMPLANT OF REVA FANTOM ENCORE
- * US ORPHAN STATUS FOR CYNATA CYP-001 FOR GVHD
- * ITL BIOMEDICAL LAUNCHES SAFETY SUB CULTURE UNIT 2
- * AUSCANN: CHILE MARIJUANA SPECIAL ACCESS SCHEME
- * ANTISENSE REQUESTS CAPITAL RAISING TRADING HALT
- * RECCE EXPECTS \$853k R&D TAX INCENTIVE, PAUSES LIND FACILITY
- * CVC TAKES 5.2% OF IDT
- * CHAIRMAN DAVID WILLIAMS TAKES 2.2% OF POLYNOVO
- * IMUGENE PROMOTES CEO LESLIE CHONG TO M-D
- * JIM HALLAM REPLACES MMJ CFO LISA DEA

MARKET REPORT

The Australian stock market fell 0.73 percent on Wednesday March 28, 2018, with the ASX200 down 42.8 points to 5,789.5 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Optiscan was the best, up 0.6 cents 8.7 percent to 7.5 cents with 404,680 shares traded. Genetic Signatures climbed four percent; Factor and Volpara rose more than two percent; Airxpanders, Pharmaxis and Telix were up more than one percent; with Impedimed, Sirtex and Viralytics up by less than one percent.

Oncosil led the falls, down one cent or 7.4 percent to 12.5 cents with 1.5 million shares traded. Both Actinogen and Dimerix fell four percent; Acrux, LBT and Mesoblast were down more than three percent; Benitec, Clinuvel, Prana and Starpharma shed two percent or more; Avita, Cochlear, Compumedics, Ellex, Nanosonics, Orthocell, Osprey, Polynovo, Pro Medicus and Resmed were down more than one percent; with CSL, Medical Developments, Neuren and Opthea down by less than one percent.

OPTISCAN

Optiscan says it that despite losing six of its most senior staff it has "sufficient skilled management resources to continue the operations of the business".

Optiscan said it had received two shareholder requisition notices requesting board spill extraordinary general meetings.

Optiscan said attempts were continuing to negotiate "an outcome to avoid the company holding a general meeting of shareholders".

Earlier this month, shareholders associated with director Ian Mann, founder and inventor Peter Delaney and former chief executive officer Archie Fraser called for the removal of chairman Alan Hoffman and directors Peter Francis, Dr Ian Griffiths and Dr Philip Currie, to be replaced by Mr Fraser and Ron Grey (BD: Mar 16, 19, 2018).

On Monday, a second group of shareholders called for the removal of Mr Mann and the election of Darren Lurie and Graeme Mutton as directors (BD: Mar 27, 2018).

It was not clear whether the second spill resolution implied the retention of the remaining directors other than Mr Mann.

Today, Optiscan said it was "focussed on ensuring the day to day running of the business continues".

"To highlight this, the company has received advice from our [quality assurance] auditors that they will be recommending that Optiscan be given an ISO 13485:2016 certificate ... and the process of appointing a new [chief executive officer] is well advanced".

Optiscan said that two staff members had resigned "having previously linked their tenure to the outcomes of the general meeting".

The company said that founder, inventor, former director and chief technology officer Peter Delaney had worked with the company since 1994 and would remain with the company until mid-June 2018.

"The company thanks Peter for his 24 years of service," Optiscan said.

The company did not name the second employee, but chief executive officer Archie Fraser resigned in January (BD: Jan 22, 2018).

Optiscan said that three "contractors" indicated they were withdrawing their services with two indicating a dependence on the outcome of the extraordinary general meeting.

The company said that the requisition notice from Mr Mann, Mr Fraser and Mr Delaney was "co-signed by a small minority of shareholders and seeks the removal of four current board members".

That requisition was signed by investors holding 13.41 percent of Optiscan, the second requisition was signed by investors with 14.21 percent and the combined holding of the directors except Mr Mann amounted to 4.09 percent.

"In closing, the board can assure investors that the company's regular business operations are continuing," Optiscan said.

"The board is confident that the company has sufficient skilled management resources to continue the operations of the business and has succession and recruitment plans in place to ensure this continues to be the case," the company said.

A source told Biotech Daily that the other staff member was the head of regulatory affairs and quality assurance Peter Pavlicek, and the three "contractors" were the head of research and development Rob Pattie, the general manager of pre-clinical products Andrew Froude and the company accountant Tony Dobson.

Including former chief executive officer Mr Fraser, six staff with 59 years' experience in Optiscan have resigned from the company.

The dissenting executives, director and shareholders have established a website titled www.saveoptiscan.com which was expected to be launched this afternoon.

Optiscan was up 0.6 cents 8.7 percent to 7.5 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical has responded to an ASX query saying that it has not achieved a number of milestones it expected to reach in previous announcements.

Last year, G Medical raised \$12 million to list on the ASX and commercialize its mobile telephone electronic health devices (BD: May 10, 2017).

G Medical said that a trial of its smartphone case with vital sign sensors announced in May last year would not go ahead following agreement with Beijing Silverlake that "the trial was no longer required [and a number of G Medical partners, including Silverlake, have received the first released units for internal assessment purposes".

The ASX asked G Medical whether Silverlake had purchased any units in accordance with the distribution and co-operation agreement which cited 100,000 in the first year and reaching a total of 4,050,000 units in five years.

The ASX also noted that in July, G Medical said that the Shandong Boletong Information S&T Co would distribute a minimum of \$US67,500,000 of its products and services in China within the first year on the granting of certification (BD: Jul 27, 2017).

G Medical said that to supply its devices to Silverlake it required China Food and Drug Administration approvals, expected by July 2018, with Silverlake to begin buying "within a few weeks of ... approvals".

The ASX asked whether the company had received any payments from Medtel. Last year, G Medical said it had appointed the Nikosia, Cyprus-based Medtl [as it was named sat that time] Medical Technologies as its Prizma smartphone case distributor for Greece and Cyprus, which would provide \$US500,000 for a 24 hours a day, seven days a week medical call centre service and agreed to buy a minimum number of cases in the first year worth \$US10.5 million, with the minimum increasing at 25 percent a year (BD: Oct 2, 2017).

G Medical told the ASX it had received \$US15,000 from Medtel following its receipt of the first commercially-ready Prizma cases.

The ASX asked whether First Channel had purchased any units under the memorandum of understanding which expected minimum commitments of \$US90 million in the first year rising to \$US135 million in the second year and \$US180 million in the third year for distribution in India and Taiwan (BD: Nov 10, 2017)

The company told the ASX that the British Virgin Islands-registered First Channel had "not purchased any units".

G Medical said in November that First Channel was in discussion with partners including Vodafone India, Reliance Communications and BSNL Mobile with agreements to be finalized, providing support for the distribution and financial commitments to G Medical. "On this basis, the company cannot categorically state that the full anticipated revenues under this agreement ... can be achieved.

The ASX said that the company had been granted "green channel" approval by the China FDA and asked whether or when it expected regulatory approval for the Prizma medical smartphone case.

G Medical said it had not been granted approval, with clinical trials to be finalized within the next few weeks and a submission lodged for approval, expected by July 2018.

The ASX asked whether the Prizma smartphone cases were commercially ready and G Medical confirmed they were.

The ASX asked for a breakdown of the receipts received from customers totalling \$US22,000 and the company responded that it "related to receipts from services provided by G Medical Diagnostic Services, previously Cardiostaff, in the US and does not reflect any sales related to our Prizma product.

G Medical fell half a cent or 1.8 percent to 27 cents with 1.5 million shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate says investors will vote on the election of new directors, the issue of \$3,876,665 in shares to Amplia shareholders and a 10-to-one consolidation.

Innate said that the proposed new directors were Dr Christian Behrenbruch, Dr Christopher Burns, Dr Warwick Tong and Andrew Cooke.

The company said that the 18,460,308 share issue would be post consolidation and last week said that it would comprise 45 percent of the company (BD: Mar 23, 2018). Innate said that shareholders would vote on the acquisition of Amplia Therapeutics.

The company said that the extraordinary general meeting would be held at Level 17, 383 Kent Street, Sydney on April 26, 2018 at 11am (AEST).

Innate fell 0.1 cents or 1.4 percent to 7.1 cents with 6.5 million shares traded.

MICRO-X

Micro-X says it has raised \$5,000,000 through the private placement of unsecured mandatorily \$100 notes convertible at 40 cents a share, pending capital raisings. Micro-X said that pending a qualifying capital raising by September 30, 2018 the notes would convert at the lesser of 40 cents a share or a 20 percent discount to the issue price in the capital raising with a minimum conversion price of 23 cents a share.

The company said that a qualifying capital raising would be either a single placement or a placement and rights issue for at least \$10 million, excluding the notes or any issue of shares or securities under an employee incentive scheme.

Micro-X said that noteholders could convert their notes at any time after April 19, 2018. The company said that its directors would subscribe for \$450,000 in convertible notes, subject to shareholder approval at a meeting expected to be held in May 2018. The company said that the funds would provide working capital to support manufacturing and increased inventory for first customer shipments of the DRX Revolution Nano x-ray system and the expansion of the internal engineering capability, including the ramp-up of design and development work on the Mobile Backscatter Imager. Micro-X fell two cents or five percent to 38 cents.

REVA MEDICAL

Reva says the first implant of the Fantom Encore bioresorbable coronary scaffold has been conducted in Switzerland.

Reva said the procedure was conducted by Dr Gregor Leibundgut at Medizinische Universitätsklinik, Kantonsspital Baselland in Liestal.

"Reva's Tyrocore polymer makes Fantom Encore the most advanced bioresorbable scaffold with x-ray visibility and the thinnest strut profile in the 2.5 mm diameter size," Dr Leibundgut said. "During the procedure, I experienced the flexibility and ease-of-use provided by a thinner strut profile as well as excellent scaffolding."

"A thinner strut profile, without compromising strength, as well as the excellent visibility of the scaffold are some of the most important improvements over first generation bioresorbable scaffolds," Dr Leibundgut said.

Reva said that first generation bioresorbable scaffolds were made from polylactic acid and a magnesium alloy, which were not x-ray visible and were limited by their thick strut profiles about 150 microns, while its Fantom Encore was x-ray visible and had a 95 micron strut profile in the 2.5mm diameter size, "features associated with improved ease-of-use, vessel healing and long-term clinical performance".

Reva was unchanged at 39 cents.

CYNATA THERAPEUTICS

Cynata says the US Food and Drug Administration has granted orphan drug designation for CYP-001 for acute graft versus host disease.

Cynata said that the designation meant that CYP-001 was eligible for incentives, including an extended period of marketing exclusivity, tax credits and FDA fee waivers.

The company said the designation was for a therapeutic agent used for the prevention, diagnosis or treatment of a rare disease, defined as a disease or condition that affected fewer than 200,000 people in the US.

Cynata was up 9.5 cents or seven percent to \$1.445.

ITL HEALTH GROUP

ITL says its Biomedical division has launched the safety sub-culture unit 2 (SCU2) for the microbiology laboratory blood culture testing process.

ITL said it had sold the original sub-culture unit (SCU) for more than eight years and the SCU2 was designed and developed with laboratory technologists who used the products. The company said that the SCU2 was a safety oriented, needleless device used to transfer positive blood culture samples from the reagent bottle for further testing and it was compatible with most manufacturers blood culture reagent bottles.

ITL said that the SCU2 was the fifth new product it had launched to build its presence in the blood culture testing market, which was worth \$US3.3 billion in 2016. ITL was untraded at 30 cents.

AUSCANN GROUP

Auscann says that Chilean partner Fundación Daya has established a special access scheme to provide patients with locally produced medicinal cannabis.

Auscann said that Fundación Daya worked with the Chilean National Institute of Public Health to allow the use of its medicinal marijuana in a scheme similar to one used in Australia, enabling doctors to prescribe medicines prior to registration.

The company said that doctors typically used this mechanism to prescribe imported pharmaceutical products when there were no alternatives in the local market, but medical cannabis was being locally produced at Knop Laboratories from cannabis supplied by the Auscann and Fundación Daya joint venture Dayacann.

Auscann said that the special access scheme allowed patients to access the products while clinical trials for registration were being completed.

The company said that phase I trials had been completed and a phase II trial was underway for pain management in cancer patients.

Auscann said the drug would be mainly accessed by patients of 15 municipalities who participated in the funding of earlier plantings by Fundación Daya and a number of residents would receive free access to a year's treatment, while patients outside the municipalities would be able to buy the products in pharmacies with an official permit. Auscann fell 1.5 cents or 0.9 percent to \$1.605.

ANTISENSE

Antisense has requested a trading halt "pending an institutional placement and entitlement issue".

Trading will resume on April 3, 2018 or on an earlier announcement.

Antisense last traded at 3.7 cents.

RECCE PHARMACEUTICALS

Recce says an expected Federal Government Research and Development Tax Incentive has allowed it to defer the next \$50,000 Lind Partners draw-down instalment.

Recce said that "in view of the company's current liquidity and the imminent receipt of a further \$853,000 from the Federal Government" it had sufficient funds to meet its nearterm objectives as it maintained a prudent and cautious approach to its finances.

The company said it deferred the next \$50,000 payment from the New York-based Lind Partners' Australian Special Opportunity Fund under its \$6.05 million funding agreement (BD: Jun 16, 2017).

Recce said that the agreement allowed it "to pause investment or terminate the agreement without penalty at any time and was structured to provide capital in advance on a monthly basis, minimizing shareholder dilution".

Recce was unchanged at 15 cents.

IDT AUSTRALIA

CVC has become a substantial shareholder in IDT with 12,372,781 shares or 5.05 percent of the company.

The Sydney-based CVC said it bought the shares between June 29, and November 21, 2017 for \$1,041,996 or 8.4 cents a share.

Earlier this month, Sandon Capital became a 5.3 percent substantial shareholder in IDT (BD: Mar 8, 2018).

Both companies have previously taken positions in companies and requested board spill extraordinary general meetings, resulting in changes to the boards of Alchemia and Alchemia (BD: May 20, Jun 18, 2015; Feb 4, Mar 16, Aug 9, 31, 2016) IDT was unchanged at 7.9 cents.

POLYNOVO

Polynovo chairman David Williams says he bought the 2,100,000 of the 10,500,000 shares sold by Merchant Funds Management yesterday.

Mr Williams filed an Appendix 3Y director's interest statement yesterday saying he bought the shares for \$1,029,601 or 49 cents a share

The Perth-based Merchant Funds said it sold a total of 10,500,000 shares for \$4,591,808 or 43.7 cents a share (BD: Mar 27, 2018).

Mr Williams said that he held a total of 14,100,000 shares or 2.16 percent of the company, through Moggs Creek Pty Ltd Superannuation Fund and Amore Foods Pty Ltd. Polynovo fell one cent or 1.9 percent to 52 cents.

IMUGENE

Imugene says that chief executive officer Leslie Chong has been appointed managingdirector, effective immediately.

Imugene executive chairman Paul Hopper said that "since her appointment as CEO, Leslie has led Imugene in an outstanding fashion".

"Through her leadership and tireless contribution, Imugene has successfully achieved various important milestones in both the clinical and corporate fronts," Mr Hopper said. "Her appointment as the company's managing-director recognizes the value of Leslie's strategic input," Mr Hopper said.

Imagene fell 0.1 cents or 2.9 percent to 3.4 cents with 56.5 million shares traded.

MMJ PHYTOTECH

MMJ says it has appointed Jim Hallam as chief financial officer, replacing Lisa Dea, effective form April 3, 2018.

MMJ said that Ms Dea would continue as the chief financial officer of Canadian investee company, Harvest One Cannabis Inc.

The company said that Mr Hallam was "an experienced senior finance executive".

MMJ fell two cents or 5.3 percent to 36 cents with 1.4 million shares traded.