Biotech Daily

Wednesday April 5, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: OPTHEA UP 35%, BENITEC 33%; PRANA DOWN 8%**

*** OPTHEA PLACEMENT, INSTO RIGHTS RAISE $42m, RETAIL FOR $3m MORE**

*** US ORPHAN STATUS FOR REDHILL'S YELIVA FOR BILE DUCT CANCER**

*** IM MEDICAL TO RAISE $500k TO BECOME BABYLON PUMP & POWER**

*** VIRALYTICS PRESENTS 22 MITCI PATIENT, 10 STORM B PATIENT DATA**

*** TUMBLING 10c AVIRAGEN (BIOTA) REVIEW LEADS TO 'CONSIDERING OPTIONS'**

*** UNILIFE HAS 3 DAYS CASH; STAFF TO GO, FACILITIES TO CLOSE**

*** BARD1, RESPIRATORY INSTITUTE EVALUATE CANCER VACCINE**

*** VOLPARA LAUNCHES ENTERPRISE 2.0 SOFTWARE**

*** BOTANIX RAISES $7.4m FOR CANNABIS-BASED DERMATOLOGY**

*** MGC COMPLETES EUROPEAN CANNABINOID EXTRACTION FACILITY**

*** MMJ FIRST MARIJUANA HARVEST NETS 60kg DRIED BUDS**

*** MEMPHASYS $500k PLATINUM LOAN FOR SPERM SEPARATION**

*** ALLAN GRAY REDUCES TO 8% OF PHARMAXIS**

*** SUDA REQUESTS CAPITAL RAISING TRADING HALT**

*** ZELDA TO RELEASE 10m ESCROW SHARES**

*** PROF CHRIS PORTER REPLACES MIPS DIRECTOR PROF BILL CHARMAN**

MARKET REPORT

The Australian stock market was up 0.33 percent on Wednesday April 5, 2017 with the ASX200 up 19.6 points to 5,876.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and 13 were untraded.

Opthea was the best, up 28 cents or 34.6 percent to $1.09 with 1.8 million shares traded, followed by Benitec up 32.5 percent to 26.5 cents with 1.5 million shares traded. Oncosil climbed 19.05 percent with 4.7 million shares traded, Reva and Uscom were up more than five percent; Actinogen, Avita and Living Cell improved more than three percent; with Admedus, Compumedics, Impedimed and Mesoblast up one percent or more.

Yesterday's best, Prana, led the falls, down 0.6 cents or 8.2 percent to 6.7 cents with 202,885 shares traded. Neuren lost 7.6 percent; Viralytics fell 3.7 percent; Cellmid and Factor Therapeutics shed more than two percent; with Acrux, Atcor, Orthocell and Sirtex down more than one percent.

OPTHEA

Opthea says its placement and institutional entitlement offer raised $42 million and the retail one-for-14 rights offer is expected to raise a further $3 million.
Opthea said the placement and institutional entitlement offer at 93 cents a share was to existing and new institutional and sophisticated investors.
The company said the funds were for its expanded clinical development of OPT-302 for wet age-related macular degeneration and diabetic macular oedema.
On Monday, Opthea said its first-in-human 51-patient, phase I/IIa trial of OPT-302 for wet age-related macular degeneration met its safety and efficacy endpoints, including biological activity at the low dose of 0.3mg of OPT-302 (BD: Apr 3, 2017).
Opthea jumped 28 cents or 34.6 percent to $1.09 with 1.8 million shares traded.

REDHILL BIOPHARMA

Israel's Redhill says it US Food and Drug Administration orphan drug designation for Yeliva (ABC294640) for cholangio-carcinoma, or bile duct cancer.
Redhill said the designation provided incentives, including tax credits, waiver of a fee on submission of a marketing application and marketing exclusivity.
The company said that Yeliva was a first-in-class, oral, sphingosine kinase-2 selective inhibitor with anti-cancer and anti-inflammatory activities, targeting multiple oncology, inflammatory and gastrointestinal indications.
Redhill said that a phase I study with Yeliva for solid tumors met its primary and secondary endpoints and, of the three cholangio-carcinoma patients in the study, one had a sustained partial response and the other two had prolonged stable disease.
The company said a phase IIa study of Yeliva in patients with advanced, unresectable, intra-hepatic and extra-hepatic cholangio-carcinoma was planned to start by October 2017
Redhill said that cholangio-carcinoma was a highly lethal malignancy, with a five-year relative survival rate ranging between two and 30 percent, depending on the tumor type and stage at diagnosis and about 8,000 people were diagnosed each year in the US.
The company said that surgery with complete resection was the only curative therapy.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Last night on the Nasdaq, was up 31.5 US cents or 3.31 percent to $US9.825 ($A12.99) with 281,739 shares traded.

IM MEDICAL

IM Medical says it hopes to raise $500,000 in a three-for-eight rights issue at 0.1 cents a share to become Babylon Pump & Power.
IM Medical said it had a six month option agreement to acquire the Perth, Western Australia-based Babylon Operations which was "a recently established provider" of equipment rental and diesel maintenance services to the resource maintenance sector.
The company said that if it exercised the option to acquire Babylon it would undertake a capital raising of up to $6 million, consolidate stock on a one-for-20 basis, change its name to Babylon Pump & Power and seek re-listing on the ASX following re-compliance with Chapters 1 and 2 of the ASX Listing Rules Rights.
In 2015, IM said its attempt to acquire data centre service provider Syncom Australia Pty Ltd through a reverse takeover had failed (BD: Jan 18, May 22, Jul 23, 2015).
Previously, IM Medical had been attempting to commercialize cardiac testing.
IM was untraded at 0.1 cents.

VIRALYTICS

Viralytics says a trial of Cavatak with Yervoy for melanoma continues to show positive results and a trial of Cavatak with Keytruda is in the dose escalation phase.

Viralytics said that of 22 patients in its phase Ib Yervoy combination study, entitled the melanoma intra-tumoral Cavatak and Ipilimumab, or Mitci, trial, showed that 11 had a best overall response rate with a disease control rate of 77 percent or 17 patients.

The company said the data was presented at the American Association for Cancer Research meeting in Washington. DC.

Viralytics said that of 11 patients who had progressed on prior checkpoint therapy, four had responses, with a best overall response rate of 36 percent, compared to published data where a rate of 10 to 13 percent was achieved in patients with advanced melanoma who received Yervoy alone following treatment failure with an anti-PD1 inhibitor.

The company said that nine of 11 prior checkpoint therapy Mitci patients had disease control or a rate of 82 percent.

Viralytics said the two responses were seen in patients with advanced stage IV metastatic melanoma who previously failed both ipilimumab and anti-PD-1 therapies.

The company said that seven of 11 patients who had not had prior checkpoint therapy responded giving a best overall response rate of 64 percent compared to 11 percent in melanoma patients that had not received prior checkpoint therapy when treated with Yervoy alone.

Viralytics said that positive outcomes were seen in non-injected visceral metastatic lesions including those in the lung and liver, with four patients having complete responses and two patients having complete responses continued for one year from the start of treatment and with no dose-limiting toxicities, and no Cavatak-related grade 39 or higher adverse events have been reported.

Viralytics said that among the first 10 of 80 patients in the phase Ib Keynote-200 or Storm part B, the combination of Cavatak and Keytruda (pembrolizumab) for systemic treatment of resistant metastatic disease, was generally well-tolerated with one grade 3 Cavatak-related and no grade 3 or higher pembrolizumab-related adverse events, with no dose limiting toxicities.

The company said that Merck Sharp and Dohme was a collaborative partner for the trial with results expected by the end of 2017.

Viralytics said that the combination of Cavatak and Keytruda in patients with advanced non-small cell lung or metastatic bladder cancer who had not been treated with checkpoint inhibitors as well as those who have progressed after checkpoint therapy.

The company said that the low rate and incidence of adverse events was “encouraging”.

Viralytics said that patients enrolled in the dose escalation phase of the study had very advanced disease, had been heavily pre-treated and included patients who had received prior checkpoint therapies.

The company said that all three patients in the third cohort assessing the highest dose of Cavatak in combination with pembrolizumab were continuing in the study.

Viralytics said that biopsies of tumor tissue from patients with melanoma, non-small cell lung cancer and metastatic bladder cancer confirmed successful tumor targeting by detecting Cavatak in these samples following three intravenous doses of the agent.

There was also evidence of potential tumor-specific secondary viral replication, which might lead to upregulation of PD-L1 expression, a target for pembrolizumab.

Viralytics managing-director Dr Malcolm McColl said that “based on the earlier pre-clinical combination studies and the results from Storm part A we are keen to assess the potential of the Cavatak Keytruda combination in these very important cancer indications”.

Viralytics fell 4.5 cents or 3.7 percent to $1.175.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says that following a review of its programs, resources and capabilities, it will "explore a wide range of strategic alternatives" and cut staff by a further 25 percent.

Aviragen said that alternatives included a business combination or strategic merger, in-licencing clinical stage programs, an acquisition, or other transaction.

The company said it had retained the St Louis, Missouri-based Stifel, Nicolaus & Co as its financial advisor in the process.

Aviragen said it did not have a timeline for the alternatives and was not confirming that the process would result in any alternative being announced or consummated.

The company said that it did "not intend to discuss or disclose further developments during this process unless and until its board of directors has approved a specific action or otherwise determined that further disclosure is appropriate".

Aviragen said that its phase II trial of its BTA074 topical antiviral treatment for condyloma caused by human papillomavirus was continuing with enrolment expected by the end of 2017 with top-line data by July 2018.

The company said that it was evaluating a potential clinical development path for Vapendavir based on the "consistent antiviral effect" in the phase IIb Spiritus trial, previous clinical studies and its favorable safety profile.

Aviragen said that based on the Spiritus trial, the previously planned phase II trial in haematopoietic stem cell transplant patients would not proceed.

The company said it would "progress activities" supporting its response to the US Food and Drug Administration clinical hold on its BTA585 investigational new drug application.

Aviragen said that development of the non-nucleoside inhibitor program for the treatment of respiratory syncytial virus infections was making "good progress with the identification of several compounds that demonstrate low nanomolar antiviral activity in vitro".

In February, Aviragen said its 455-patient, phase IIb trial of vapendavir in moderate to severe asthmatics with a rhinovirus infection failed to meet its endpoints.

In 2015, the then Biota began dosing the patients with laboratory-confirmed human rhinovirus, the cause of most incidents of the common cold, in its phase IIb Spiritus trial of vapendavir, expecting top-line data in mid-2016 (BD: Mar 4, 2015).

Prior to Biota departing Australia in a failed attempt to acquire $US54 million in cash held by Nabi Pharmaceuticals and settling for $US27 million, the company was earning multi-million dollar sales royalties from Glaxosmithkline for its Relenza anti-influenza drug, as well as multi-million dollar royalties from Daiichi Sankyo sales of Inavir in Japan (BD: Feb 1, 2011; Apr 23, Oct 30, 2012).

Following its move to the US, Biota lost its $US231 million contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA) to further develop its laninamivir anti-influenza drug with BARDA citing "concerns about the project with regard to the product manufacturing, clinical study enrolment pace, costs, and contractor performance" (BD: Apr 1, 2011; Apr 30, May 1, May 9, 2014).

Biota says that following the termination of its $US231 million US Government contract it planned "to reduce its workforce by approximately two-thirds over the next six to nine months and close its Melbourne, Australia facility by June 30, 2015" (BD: Jun 3, 2014).

In 2013, Biota sacked 30 percent of its workforce and closed its pre-clinical antibiotic programs (BD: Apr 17, Nov 22, 2014).

It is believed that about 10,000 Australian based Biota investors still hold shares in Aviragen with only several hundred establishing US accounts and selling their shares.

Last night on the Nasdaq, Aviragen closed down 3.8 US cents or 5.79 percent to 61.8 cents (81.6 Australian cents - equivalent to 10.2 cents prior to the Nabi merger, when it was trading around $A1.00), with 137,065 shares traded.

UNILIFE CORP

Unilife says it has does not have “sufficient liquidity to fund … operations past the week ending April 7, 2017” and is faced with sacking staff and closing its facilities.

Unilife said that at March 31, 2017, its unaudited cash balance was about $US6.3 million ($A8.3 million), including $US2.4 million of restricted cash, but by April 7 it would fall “below the minimum cash and restricted cash balance requirements of $US5.1 million under its debt facilities”.

In February, Unilife said its revenue for the six months to December 31, 2016 was $US4,053,000, with a loss of $US33,282,000 and $US9,309,000 in cash and equivalents (BD: Feb 10, 2017).

Last year, the company reported revenue for the year to June 30, 2016, of $US9,841,000 with net loss after tax of $US79,451,000 (BD: Sep 1, 2016).

The company has faced difficulties including legal action and the exit of executive director Alan Shortall departing with $1,980,584 in termination pay (BD: Mar 15, 2016).

In 2016, Unilife said it had a strategic collaboration with Amgen for its wearable injectable drug delivery systems worth up to $US75 million and Amgen had purchased a $US30 million “senior secured convertible note” with an option for a further $US25 million in convertible notes over the next two years (BD: Feb 23, 2016).

Today, Unilife said that if it fell below its minimum cash balance requirements “we would be in default under one or more of our debt obligations unless we are able to obtain waivers from our lenders”.

“A breach of any of the covenants related to our debt instruments could result in a higher rate of interest to be paid or the lenders could elect to declare all amounts outstanding under the applicable agreements to be immediately due and payable,” the company said.

“If the lenders were to make such a demand for repayment, we would be unable to pay the obligations as we do not have existing facilities or sufficient cash,” Unilife said.

“We also would be unable to pay our other obligations as they come due, which could prompt our creditors to pursue other remedies,” the company said.

Unilife said it was seeking financing with the assistance of a financial advisory firm but to date had not obtained any financing commitment and it received a notice on March 31 from a key customer for wearable injectors that the customer was putting a program on hold for reasons unrelated to the products and the delay might negatively impact its ability to obtain financing or the amount of financing it might be able to obtain.

Unilife said it was exploring bridge financing alternatives, possibly from Orbimed Advisors affiliate ROS Acquisition Offshore LP, likely to be in the form of debtor-in-possession financing in connection under Chapter 11 of the US Bankruptcy Code.

The company said it was possible it could obtain finance outside a Chapter 11 process, but the terms might not be favourable, and if it did not obtaining bridge financing or a commitment for other finance it would have to file a petition for relief under Chapter 7 of the Code and any reorganization, sale, or liquidation was unlikely to result in funds being available to investors or to creditors other than secured creditors.

The company said that on April 4 it issued a Worker Adjustment and Retraining Notification Act notice to employees and state and local government agencies, that if it did not obtain financing, it would permanently close both its York and King of Prussia, Pennsylvania facilities, that notice began the 60-day period prior to permanently closing operations under the Act and without finance the closure would be about June 4, 2017.

The company said that on April 4, it terminated the employment of 51 employees at its York and King of Prussia locations and expected to record a charge related to terminated employees of approximately $US600,000 in connection with the Notice.

Unilife fell 2.8 cents or 77.8 percent to 0.8 cents with 43.5 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says it has a collaboration with the Perth, Western Australia-based Institute for Respiratory Health to evaluate a vaccine for human cancer in animal models.
Bard1 said that the project would evaluate Bard1 formulations across several fully-characterized tumor cell lines to determine their effectiveness in preventing tumor growth or reducing tumor size in two tumor models in mice.
The company said that the project would determine the optimal dose and timing for vaccination and secondary outcomes.
Bard1 chief executive officer Dr Leearne Hinch said the agreement “gives us the opportunity to explore the therapeutic potential of our Bard1 Technology”.
“We have already demonstrated the utility of this technology in the diagnostic area, but therapeutic applications offer a large upside potential and, if the animal studies demonstrate effectiveness, this collaboration will enable us to advance our therapeutic program towards preclinical development,” Dr Hinch said.
The Institute for Respiratory Health director Prof Geoff Laurent said that the Bard1 technology “has much to offer in the field of therapeutic vaccines for lung cancer”.
Bard1 was unchanged at 3.9 cents with 8.3 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has launched its Enterprise 2.0 software, an enhanced version of its cloud-based breast imaging analytics platform.
Volpara said that the Enterprise 2.0 software delivered “real-time quality assurance and performance monitoring through dynamic, interactive dashboards that update over 100 key indicators and quality metrics with every mammography or tomosynthesis exam”.
The company said users could perform rapid quality control checks to optimize imaging resources, decreasing costs through the reduction of retakes, increase employee effectiveness and improve patient mammography experience.
Volpara said that the Enterprise 2.0 software had a redesigned user interface and a new technologist dashboard enabling radiographers to track their performance, to improve compression and positioning of women.
The company said that the US Food and Drug Administration had increased its compliance standards through its update to the Mammography Quality Standards Act inspections, the Enhancing Quality Using the Inspection Program initiative.
Volpara said its technology was the only product available that provided an assessment of image quality.
The company said that it had signed 14 breast imaging centres to Volpara Enterprise software, with five joining in the last month.
Volpara chief executive officer Dr Ralph Highnam said the release of the Enterprise 2.0 software was “a turning point” in the application of digital health products to clinical performance.
“The goal is always better patient outcomes, and Volpara Enterprise 2.0 software, by providing a wide array of easily accessible quality control features and data, helps breast imaging centres achieve them,” Dr Highnam said. “Furthermore, by quantifying common staff errors, it enables managers to focus on improving human performance.”
“Over time this will ensure more consistent and appropriate breast positioning and compression, and thus provide centres with the image quality needed for compliance with the more stringent requirements of the EQUIP initiative, as well as similar standards around the world,” Dr Highnam said.
Volpara fell two cents or 4.35 percent to 44 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has raised $7,386,309 in a placement at 5.5 cents a share for its cannabis-based dermatology products and to commercialize its Permetrex technology.
Botanix said it expected to begin its phase Ia trial of BTX-1503 for acne “in the coming weeks … [and] fast- the clinical development of BTX-1204 for moderate to severe atopic dermatitis, psoriasis.
Botanix fell half a cent or 7.35 percent to 6.3 cents with 11.6 million shares traded.

MGC PHARMACEUTICALS

MGC says it has completed construction of its European cannabinoid extraction facility on schedule and under budget.
MGC said that initial trial extraction operations would begin by July, with the first commercial extraction operations to produce cosmetic and dermatological products to begin commence in its active pharmaceutical ingredient facility by October 2017, pending good manufacturing practice certification.
MGC was up 0.2 cents or 2.6 percent to 7.9 cents with 25.1 million shares traded.

MMJ PHYTOTECH

MMJ says wholly-owned subsidiary United Greeneries has completed its first cannabis harvest at the Duncan Facility in Canada yielding 60kg of dried cannabis buds.
MMJ said the harvest passed strict internal quality control measures and the cannabis buds were expected to be ready for shipment by late April.
MMJ fell two cents or 2.9 percent to 68 cents with 7.7 million shares traded.

MEMPHASYS

Memphasys says it has a $500,000 loan to begin the next phase of development of its Spermsep technology.
Memphasys said it had engaged an unnamed “specialist medical device development partner” in Melbourne to undertake engineering design and development to produce two prototype sperm separation cartridges, which would be internally tested with the assistance of scientific collaborator the University of Newcastle.
The company said the miniaturized cartridges would have operating protocols and would contain the new membranes, buffers and flow configuration to be used in the final product, in preparation for in-vitro key opinion leader studies.
Memphasys said that the 12-month, $500,000 facility with the Richmond, Melbourne-based Platinum Road Pty Ltd carried a 10 percent per annum interest rate with an option to convert the loan plus interest to shares at the lower of 0.4 cents a share or a 15 percent discount to the 10-day lowest daily volume-weighted average price.
The company said that it would issue 25,000,000 free shares to Platinum and up to 5,000,000 performance options, exercisable at 0.6 cents a share by December 31, 2018, as a corporate advisory fee, with a further 20,000,000 performance options exercisable at 0.6 cents a share by December 31, 2018 pending shareholder approval.
Memphasys said that Platinum was also owed $30,000 to be satisfied through an additional bond issued on the same terms as the Platinum facility, converting into a maximum of 38,823,529 shares.
Memphasys fell 0.1 cents or 20 percent to 0.4 cents with 2.3 million shares traded.

PHARMAXIS

Allan Gray says it has reduced its shareholding in Pharmaxis from 46,953,709 shares (14.71%) to 26,033,162 shares (8.16%).
Allan Gray said it sold 20,920,547 shares on March 31, 2016, for $5,525,116 or 26.4 cents a share.
Pharmaxis was unchanged at 28 cents.

SUDA

Suda has requested a trading halt “pending the release of an announcement regarding a capital raising”.
Trading will resume on April 7, 2017 or on an earlier announcement.
Suda last traded at 2.3 cents.

ZELDA THERAPEUTICS

Zelda says it will release 10,000,000 shares from escrow on April 20, 2017.
The company said it had 754,841,934 shares, of which 418,841,934 shares would be available for trading following the release, with a further 336,000,000 shares held in escrow, of which 111,625,156 would be in escrow until November 17, 2017 and a further 224,374,844 would be in escrow until November 17, 2018.
Zelda was up 1.9 cents or 20.9 percent to 11 cents with 86.5 million shares traded.

MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

The Monash Institute of Pharmaceutical Sciences says that Prof Chris Porter has been appointed director replacing founding director Prof Bill Charman (BD: Mar 16, 2012).
MIPS said that Prof Charman was “stepping down … to focus on his continuing position as dean [of the] Faculty of Pharmacy and Pharmaceutical Sciences”.
The Institute said that as associate dean for research in the Faculty for the past 10 years, Prof Porter had “played an essential role” and brought much experience to the role of director as a research leader and had led many of the initiatives driving research quality.
MIPS said that Prof Porter’s research group was “one of the leading drug delivery groups”, specializing in oral drug absorption, lymphatic transport and nano-medicine.
The Institute said that Prof Porter had published more than 200 peer-reviewed papers and his work has been cited more than 10,000 times.