Biotech Daily

Thursday April 6, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTHEA UP 5.5%, BENITEC DOWN 19%**

*** PARADIGM PPS FOR HAY FEVER 'TO EARN $1b PA'; 4 PHASE II TRIALS**

*** PRESCIENT PTX-200, PACLITAXEL SAFE FOR BREAST CANCER**

*** IMMURON COMPLETES IMM-124 NASH ENROLMENT**

*** MESOBLAST RECEIVES $3.7m FEDERAL R&D TAX INCENTIVE**

*** IMUGENE OPTIONS RAISE $3m, 10m OPTIONS FOR DR AXEL HOOS**

*** REDHILL LICENCES ENTERAGAM FOR DIARRHOEA**

*** NOVOGEN KILLS ATM-3507, ANSINA; OTHER PROGRAMS CONTINUE**

*** ANTEO SECURES $1m INVESTOR, CEO, DIRECTOR LOANS**

*** MEMPHASYS COMPLETES $130k GEL SALE TO DYCENT, CLARIFICATIONS**

*** TUMBLING 10c AVIRAGEN (BIOTA) 1m EXECUTIVE OPTIONS**

*** RHINOMED SIGNS GNC FOR US MUTE SALES**

*** OCH-ZIFF INCREASES, DILUTED TO 17% OF BRAIN RESOURCE**

MARKET REPORT

The Australian stock market fell 0.34 percent on Thursday April 6, 2017 with the ASX200 down 19.9 points to 5,856.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and four were untraded.

Opthea was the best for the second day in a row, up six cents or 5.5 percent to $1.15 with 913,644 shares traded. Prana and Reva climbed more than four percent; Factor Therapeutics improved three percent; Impedimed and Universal Biosensors rose more than two percent; with Acrux, Avita, Cochlear, CSL, Ellex, Mesoblast and Nanosonics up by one percent or more.

Yesterday's 32.5 percent second best, Benitec, led the falls, down five cents or 18.9 percent to 21.5 cents with 764,858 shares traded. Cellmid fell 8.8 percent; Viralytics lost 7.7 percent; Neuren was down 5.5 percent; ITL, Oncosil and Psivida fell four percent or more; IDT and Pharmaxis were down more than three percent; Genetic Signatures and Pro Medicus shed more than two percent; with Actinogen, Airxpanders, Bionomics, Compumedics, Orthocell, Polynovo, Resmed and Starpharma down one percent or more.

PARADIGM BIOPHARMACEUTICALS

Paradigm says that once launched it expects its Rhinosul pentosan polysulfate sodium (PPS) for allergic rhinitis, or hay fever, to earn more than $1 billion a year.

Paradigm chief executive officer Paul Rennie told a Melbourne investor conference hosted by Adelaide-based stockbrokers Baker Young that the company expected results from the 40-patient, phase IIa, double-blind, placebo- controlled, cross-over allergen challenge trial in June, having completed enrolment in January (BD: Jan 25, 2017).

Mr Rennie said that competitor drugs for hay fever included the anti-histamine Zyrtec, the Astrazeneca-developed and Johnson & Johnson owned cortico-steroid Rhinocort and Meda AB's combination anti-histamine and cortico-steroid Dymist.

Mr Rennie said that hay fever market was worth more than $US11 billion and Dymist took 10 percent of that market in its first year.

He said that given that pentosan polysulfate sodium was a non-steroidal alternative "we would be disappointed if we got less than $I billion a year" from Rhinosul for hay fever.

Mr Rennie said the Rhinosul trial was conducted at the Lund, Sweden-based Skane University Hospital, which was the same place which trialled Rhinocort.

He said that pre-clinical data on guinea pigs was expected to be published soon and the pre-clinical studies compared Rhinosul to Rhinocort as well as to placebo.

Mr Rennie said that the phase IIa human trial compared Rhinosul to placebo but not against Rhinocort.

In January, Paradigm said that market surveys highlighted patient dissatisfaction with the existing drugs and Rhinosul had "unique properties consisting of both histamine stabilizing and non-steroidal anti-inflammatory properties without the known side effects of anti-histamines and steroids".

Mr Rennie, said that as a repurposed drug on the market for more than 60 years and sold by Johnson & Johnson as the oral drug Elmiron for interstitial cystitis, as well as an injectable drug for deep vein thrombosis, the pathway to regulatory clearance was much faster and cheaper than for a completely new drug.

Mr Rennie said that intellectual property protection for each indication was the same as for a new molecule at 20 years, but there were regulatory exclusivity periods preventing generic manufacturing, as well as the difficulty of copying the "complex molecule".

He said that Paradigm had an exclusive deal with the Munich, Germany-based Bene Pharmachem GmbH for the manufacture of pentosan polysulfate sodium and would pay a two percent royalty to the manufacturer.

Mr Rennie said that Paradigm would also have the advantage of being the "first to market" with a new drug for hay fever.

Mr Rennie said that the company was currently conducting a 40-patient, open-label, phase II trial of pentosan polysulfate sodium, as Zilosul, for bone marrow oedema lesions, or bone bruising, from sporting or accidental injuries to the knee, such as a ruptured anterior cruciate ligament, which was expected to be completed by July with results by October 2017 (BD: Feb 23, Mar 2, 2016).

He said the company expected to begin related bone marrow oedema osteoarthritis and rheumatoid arthritis trials by October 2017 which would take 12 to 24 months to complete.

Mr Rennie said that the company also hoped to begin two phase II trials of pentosan polysulfate sodium for viral arthritis caused by Ross River virus and chikungunya in 2017.

He said that the company had a cash burn of $350,000 a month, of which 80 percent went to clinical programs, thereby earning significant funds from the Federal Government Research and Development Tax Incentive system and the company had $6.3 million in cash at December 31, 2016.

Paradigm was up one cent or 1.85 percent to 55 cents.

PRESCIENT THERAPEUTICS

Prescient says its phase Ib trial of PTX-200 in combination with paclitaxel for breast cancer was safe and had shown signals of efficacy.

Prescient said the trial evaluated PTX-200 in women with HER2- negative breast cancer, including patients with metastatic breast cancer and other cancers, at New York's the Montefiore Medical Center and the Tampa, Florida-based H Lee Moffitt Cancer Center.

The company said that the study comprised a 17-patients dose escalation cohort, followed by a 12-patient expansion cohort, with the recommended phase II dose determined to be 35mg/m2 of PTX-200, with 80mg/m2 per week of paclitaxel.

Prescient said the study would continue to the phase II trial in locally advanced breast cancer.

The company said that eight patients had been evaluated for clinical response to date and one patient had a complete response, four had partial responses, two exhibited stable disease and one had progressive disease.

Prescient said that five of the 12 patients enrolled in the expansion cohort had locally advanced breast cancer and their responses would be included in the phase II study analysis.

The company said that of the five, three patients had gone on to surgery, with one patient with stage III breast cancer exhibiting a pathologic complete response.

Montefiore Cancer Center principal investigator Prof Joseph Sparano said that "only about 15 percent of patients with … [oestrogen receptor positive] HER2-negative breast cancer achieve a pathologic response to neoadjuvant chemotherapy".

"We are therefore very encouraged to see that one of the two patients with [oestrogen receptor positive] disease treated thus far have had a pathologic response," Prof Sparano said.

Prescient chief executive officer Steven Yatomi-Clarke said the results were "an important clinical milestone".

"We are very pleased with the results from the phase Ib study and are cautiously confident that the early signals of activity of PTX-200 will continue into the phase II study," Mr Yatomi-Clarke said.

Prescient was up 0.1 cents or one percent to 9.9 cents.

IMMURON

Immuron says it has completed enrolment of 134 patients in its phase II clinical trial of IMM-124E for non-alcoholic steato-hepatitis, or fatty liver disease.

Immuron said it expected to report an interim analysis of the first 80 subjects by October 2017 and results by the end of the year.

Immuron medical director Dr Dan Peres said the company was "receiving excellent feedback from our principal investigators … and we have already begun to establish a small working group to design the next phase of our clinical study".

Immuron fell half a cent or 1.25 percent to 39.5 cents.

MESOBLAST

Mesoblast says it has received $3,722,330 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Mesoblast said the rebate related to research and development expenditure for the year to June 30, 2016.

Mesoblast was up three cents or 1.2 percent to $2.53 with 803,428 shares traded.

IMUGENE

Imugene says it has $3,001,054 through the exercise of options at 1.5 cents each as part of its option plan which expired on March 31, 2017.
Imugene said 171,107,121 options which were not exercised had lapsed.
Imugene chief executive officer Leslie Chong said the funding “further places Imugene in a solid position to continue the development of our Her-2 focused clinical candidate, HER-Vaxx, plus our broader mimotope platform and arginine modulator program”.
Ms Chong said that Private Portfolio Managers, Platinum Asset Management and Celtic Capital increased their investment as underwriters to the plan.
Imugene said it would issue 10,000,000 unlisted options to director Dr Axel Hoos, exercisable at two cents each within three years from issue, subject to shareholder approval, in recognition of additional services he has performed.
Imugene was up 0.1 cents or 6.7 percent to 1.6 cents with 2.1 million shares traded.

REDHILL BIOPHARMA

Redhill says it has an exclusive licence with Entera Health Inc for the rights to Enteragam medical food intended for chronic diarrhoea and loose stools.
Redhill said that Enteragam must be administered under medical supervision and had net US sales in 2016 of more than $US5 million.
The company said it would pay the Cary, North Carolina-based Entera Health royalties on sales of Enteragam and was not required to make any upfront or milestone payments.
Redhill said that Entera would grant it certain US rights to its US Food and Drug Administration-approved dicyclomine hydrochloride5 oral solution (10 mg/5 ml), an antispasmodic and anti-cholinergic (anti-muscarinic) agent indicated for the treatment of functional bowel/irritable bowel syndrome.
The company said that Enteragam was “a serum-derived bovine immunoglobulin protein isolate (SBI) with a unique mechanism of action to restore gut balance and had been studied for diarrhoea-predominant irritable bowel syndrome, inflammatory bowel disease and human immunodeficiency virus-associated enteropathy.
Redhill chief business officer Guy Goldberg said the company was building its US commercial operations and was “excited to complement our product portfolio with a second commercial product geared towards gastroenterologists”.
Mr Goldberg said that the promotion of Donnatal and Enteragam would begin in mid-2017.
In January, Redhill said it had an exclusive co-promotion agreement with a subsidiary of the Oakville, Ontario-based Concordia International for US promotional rights for Donnatal, a prescription oral drug used with other drugs for irritable bowel syndrome, including irritable colon, spastic colon, mucous colitis, and acute entero-colitis or inflammation of the small bowel.
Redhill’s head of business development and licencing Adi Frish said the licence was “another important step in implementing our strategic plan of becoming a revenue-generating, gastrointestinal-focused, specialty pharmaceutical company in the US”.
“We continue to pursue additional commercial product opportunities in the specialty [gastro-intestinal] area to further expand our commercial operations,” Mr Frish said. “In parallel, we continue to advance the development of our three phase III [gastro-intestinal] products, which, if approved by the FDA, we intend to commercialize.”
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, Redhill fell one US cent or 0.1 percent to $US9.72 ($A12.86) with 97,859 shares traded.

NOVOGEN

Novogen says it has terminated further development of its ATM-3507, or Anisina, pre-clinical program, but retains its anti-tropomyosin program.

Novogen said the decision followed a review by the internal scientific committee, which concluded that “the balance of available pre-clinical data did not support a transition into clinical trials, and that the future commercial potential of the asset was likely to be low”.

The company said that “in particular, a level of toxicity was observed that raised significant concern around the ability to safely dose patients to a therapeutic level”.

Novogne said that changes in treatment of the kinds of cancer in which Anisina might be tested suggested “there would likely be regulatory and commercial barriers to success”.

In 2014, Novogen said ATM-3507 was its lead anti-tropomyosin compound to boost the anti-cancer activity of existing chemotherapies (BD: Nov 21, 2014).

Throughout 2015, the company’s then executive chairman Dr Graham Kelly said that ATM-3507 destroyed cancer cytoskeletons and killed melanoma as an oral monotherapy in mice as well as boosting chemotherapy for neuroblastomas in mice, and had no toxicities (BD: Mar 18, Apr 9, May 15, Jul 14, 2015).

Dr Kelly left Novogen in July 2015, to found Noxopharm (BD: Jul 2015; Aug 11, 2016).

In December 2015, Novogen appointed Sanofi executive Dr James Garner as its chief executive officer (BD: Dec 19, 2015).

Today, Dr Garner said that “the work that has been done on the Anisina program has been first-class and it is important to acknowledge the efforts of the many dedicated scientists that have been involved”.

“However, our responsibility to patients and to shareholders lies in taking forward only those development programs which are likely to provide benefit in the treatment of cancer,” Dr Garner said.

“Our view is that the data that has been collected for Anisina does not, in aggregate, make it an appropriate candidate for clinical development,” Dr Garmer said.

Dr Garner said that a “considerable quantum of funds” would have been devoted to a clinical trial of Anisina but could be reallocated to activities that were “more likely to benefit patients and drive economic value for the company”.

Dr Garner said the company had a strong pipeline and was focused on the clinical programs of GDC-0084 for glioblastoma multiforme and Cantrixil of TRXE-002-01 for ovarian cancer.

“These are entirely independent of Anisina in scientific terms,” Dr Garner said.

Novogen said that under the 2013 licence with Genscreen Pty Ltd it was expected that the intellectual property associated with the program would revert to Genscreen.

The company said it expected significant savings from the termination and a staff reduction would be implemented, with other employees reallocated to new responsibilities.

Novogen said that Prof Peter Gunning, who discovered the anti-tropomyosin technology and was named as an inventor on the patent that covers ATM-3507, would remain a member of the scientific advisory board.

Prof Gunning said that Novogen was “fundamentally confident that targeting tropomyosin is a sound approach to the development of new cancer therapies”.

“While this program has ultimately yielded mixed results, much has been learned that will no doubt help enormously to advance both the development of new [anti-tropomyosin] drugs and the basic science in this field,” Prof Gunning said.

Novogen said terminating ATM-3507 did not affect the next-generation anti-tropomyosin program that was the subject of a $3 million Federal Government co-operative research centre grant (BD: Feb 9, 2017).

Novogen fell 0.7 cents or 10.45 percent to six cents with 3.7 million shares traded.

ANTEO DIAGNOSTICS

Anteo says it has secured $1,005,000 in short term loans from shareholders, directors and chief executive officer Dr Jef Vangenechten and secured an extension of the earn out liability to the Diasource vendors to June 2017.

The company said that shareholders had loaned the company $805,000 for working capital to be repaid by September 30, 2017 at an interest rate of 15 percent a year, with the issue of 32,200,000 unlisted options exercisable at three cents each within 18 months from draw down of the loan.

Anteo said that the director and chief executive officer loans $200,000 on the same terms.

Last year, the company said that Diasource Immunoassays SA chief executive officer Dr Vangenechten had been appointed as chief executive officer starting on a base salary of EUR350,000 ($A534,140) and would be entitled to up to EUR150,000 ($A228,917) in short term incentives and a further EUR150,000 in long term incentives.

Anteo was up 0.1 cents or three percent to 3.4 cents with 1.05 million shares traded.

MEMPHASYS

Memphasys says it has completed the sale of its gels business to China's Dycent Biotech (Shanghai) Co for $US130,000 (BD: April 12, 2016).

Memphasys said that on March 2 it said that JP Asia Prime Capital (Pte) Ltd was assisting the parties in their negotiations to reach a commercial settlement, but JP Asia was not and had not been part of the negotiation process and that a loan from Crescendas Projects was provided on an arms-length basis.

Memphasys was unchanged at 0.4 cents with 1.5 million shares traded.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says chief executive officer Dr Joseph Patti and chief financial officer Mark Colonnese have been awarded 1,050,000 options.

Aviragen said that the options were exercisable at 65.6 US cents (86.7 Australian cents) by April 3, 2027.

In a filing to the US Securities and Exchange Commission, Aviragen said that Dr Patti would receive 650,000 options and Mr Colonnese 400,000 options, with 33 percent of their options vesting on October 3, 2017 and the remainder in equal monthly instalments from November 3, 2017 to April 3, 2018.

Yesterday, Aviragen said 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 (BD: Apr 5, 2017).

Last night on the Nasdaq, Aviragen closed down 1.8 US cents or 2.91 percent to 60 US cents (79.3 Australian cents, equivalent to 9.9 cents prior to the Nabi merger, when it was trading around $A1.00), with 44,099 shares traded.

RHINOMED

Rhinomed says the Pittsburgh, Pennsylvania GNC Holdings will sell Mute anti-snoring nasal plugs in its 811 North American shops, including 140 shops on military bases.

Rhinomed was up 0.2 cents or 11.8 percent to 1.9 cents with 1.4 million shares traded.

BRAIN RESOURCE

Och-Ziff Holding Corp has increased its holding in Brain Resource from 25,072,526 shares to 27,785,377 shares but has been diluted from 18.72 percent 17.27 percent.
The New York-based Och-Ziff became substantial in 2013, saying it represented associated companies in New York, Delaware, the Cayman Islands and the British Virgin Islands acquiring 6,734,185 shares at 30 cents a share (BD: Aug 19, 2013).
Today, Och-Ziff said that between September 16, 2015 and April 4, 2017 it bought and sold shares at a range of prices and was diluted in a placement that raised 41 million at eight cents share (BD: Mar 30, 2017).
Brain was unchanged at nine cents.