Biotech Daily

Wednesday May 3, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: FACTOR THERA UP 9%, DIMERIX DOWN 8%**

*** ASCEND CLAIMS 89% ASN-002 NBCC COMPLETE RESPONSES**

*** SIMAVITA PLACEMENT, RIGHTS ISSUE FOR $2.9m**

*** APPLICATIONS OPEN FOR $8m MTP CONNECT PROJECT FUND**

*** GI DYNAMICS HOPES TO LIST ON LONDON'S AIM**

*** GI DYNAMICS 3.9m MORE DIRECTORS OPTIONS 'IN THE MONEY' AGM**

*** OVENTUS: 'TRIAL SHOWS O2 VENT IMPROVES SNORING; 2 NEW TRIALS'**

*** CHALLENGER BELOW 5% OF MAYNE PHARMA**

*** WASHINGTON H SOUL PATTINSON, HUNTER HALL HAS 14% OF AVITA**

*** RHINOMED 10-FOR-1 CONSOLIDATION UNDERWAY**

*** ONCOSIL: DR CHRIS ROBERTS CHAIR, DR ROGER ASTON DIRECTOR**

*** VISIONEERING APPOINTS TOM DOOLEY DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.98 percent on Wednesday May 3, 2017 with the ASX200 down 6.1 points to 5,950.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and two were untraded. All three Big Caps were up.

Factor Therapeutics was the best, up 0.5 cents or 8.8 percent to 6.2 cents, with 29.1 million shares traded. Actinogen climbed 3.8 percent; Avita, Starpharma and Universal Biosensors rose more than two percent; Acrux, Opthea, Resmed and Viralytics improved one percent or more; with Clinuvel, Cochlear, CSL, Pro Medicus and Sirtex up by less than one percent.

Yesterday's best, Dimerix led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 524,780 shares traded. Prana lost 9.4 percent; Psivida shed 7.5 percent; Atcor was down 6.8 percent; Compumedics fell 5.75 percent; both Living Cell and Oncosil fell 4.2 percent; IDT was down 3.7 percent; Osprey shed 2.3 percent; Admedus, Cyclopharm, Impedimed and Pharmaxis were down more than one percent; with Ellex, Medical Developments, Mesoblast and Nanosonics down by less than one percent.

ASCEND BIOPHARMACEUTICALS

Ascend says that eight of nine patients in the medium and high dose cohorts of its phase I/IIa trial of ASN-002 for nodular basal cell carcinoma have had complete responses.

Ascend said that 12 patients in its up to18-patient phase I/IIa clinical trial had completed the study, evaluating the safety and clinical activity of the ASN-002 immunotherapy in nodular basal cell carcinoma (NBCC), and the treatment was well-tolerated, with favorable clinical signals supporting efficacy.

The company said that all three patients in the high dose cohort (3×10^{11} viral particles per lesion) had a complete response of histological clearance, while five of six patients in the intermediate dose cohort (1.5×10^{11} viral particles per lesion) had a compete response and one had a partial response.

Ascend said that the "overall objective response rate" observed for the nine patients in the medium and high doses was 100 percent and, at the lowest dose administered (5×10^{10} viral particles per lesion), one of three patients achieved a complete response.

The company said that the high dose cohort was fully recruited and the remaining patients were expected to complete the study by October, 2017.

Ascend chief executive officer Dr Clement Leong told Biotech Daily that nodular basal cell carcinomas appeared predominantly on the face and/or upper torso.

Dr Leong said that the alternative treatment was surgery and patients could have lesions numbering in the hundreds.

Dr Leong said that the trial had observed that some non-proximal, non-injected lesions also responded to treatment with ASN-002.

In 2015, Ascend recruited the first patient in the study of the injectable immunotherapy and said at that time that basal cell carcinoma was a non-melanoma skin cancer diagnosed in an estimated two million people worldwide every year and was the most prevalent form of cancer in Australia, the US and Europe.

Today, the company said that the trial was designed to assess the safety, tolerability and clinical response of ASN-002 administered intra-tumorally in up to 18 adult patients, with up to six patients per cohort in three cohorts and assessing the three escalating doses of one injection per week for three weeks.

Ascend said that the primary endpoints for all cohorts were clinical and histological clearance and overall safety.

The company said it was planning confirmatory studies of the intermediate and high dose in basal cell nevus syndrome, an orphan disease with a high incidence of basal cell carcinoma, to be conducted in the US and Australia.

Ascend said it had recruited US dermatologists Dr Jeffrey Dover and Prof Anna Bar to its clinical advisory board to assist with plans for late stage studies in the US.

Ascend is a public unlisted company.

SIMAVITA

Simavita says it hopes to raise $2.93 million in a placement to institutional and sophisticated investors and a one-for-seven rights issue at four cents a share.

Simavita said it hoped to raise $1.5 million in the placement with a further $1.43 million to be raised in the non-renounceable rights issue.

The company said Lodge Partners was lead manager to the placement, with Lodge Corporate underwriting the rights issue to $700,000, with rights record date May 8, the offer opening on May 11 and closing on May 22, 2017.

The company said that funds would be used for working capital.

Simavita was unchanged at six cents.

MEDICAL TECHNOLOGIES AND PHARMACEUTICALS INDUSTRY GROWTH CENTRE

MTP Connect says that applications have opened for up to $8.2 million over two years through its Project Fund Program.

The Federal Government-funded MTP Connect said it was looking for “applicants with big, bold ideas that aim to improve the productivity, competitiveness and innovative capacity of Australia [medical technologies and pharmaceuticals] sector”.

MTP Connect said applications would need to demonstrate their proposal was collaborative and industry-led, would deliver results on a national scale, have a sector-wide impact and were aligned with its sector growth priorities, with funding to be matched at least dollar-for-dollar by the sector.

MTP Connect chief executive officer Sue MacLeman said the first-round last year had 38 applications from industry, research organisations and universities, offering up to $90 million in matched funding to address the, barriers and opportunities for the sector.

For more information, go to: www.mtpconnect.org.au.

GI DYNAMICS

GI Dynamics says it is investigating listing on the London Stock Exchange’s Alternative Investment Market and has appointed broker Allenby Capital as its adviser.

GI Dynamics said it was commercializing its Endobarrier in Europe, the Middle East and South America for patients with obesity and type 2 diabetes.

In March, GI Dynamics said it hoped to confirm a new study design and begin a new US Endobarrier for obesity and diabetes trial this year, following the termination of its proposed pivotal 500-patient US trial, which ended with 325 patients enrolled, following seven cases of bacterial liver infection, with the trial failing to meet its primary and secondary endpoints (BD: Mar 15, 2016; Mar 30, 2017).

GI Dynamics chief executive officer Scott Schorer said in March 2017 that Endobarrier was “safe and effective” and that with increasing rates of type 2 diabetes, none of the therapies were without risk, but the rate of liver abscesses had been identified as primarily relating to the use of proton pump inhibitor drugs in the US trial.

Mr Schorer said that gastric bypass and insulin had greater risks than the Endobarrier.

Last week, GI Dynamics said its net operating cash burn for the three months to March 31, 2017 was $US2,964,000 with cash at the end of the quarter of $US5,365,000 and did not provide any further information, other than it expected a cash burn for the coming three months of $US3,000,000 (BD: Apr 28, 2017).

The company said that a US Securities and Exchange Commission Form 10-Q to be filed on or before May 15, 2017 would include “management’s discussion and analysis of financial condition and results of operations”.

Today, Mr Schorer said that he looked forward “to working with Allenby Capital to explore options for listing GI Dynamics shares on the AIM market”.

“We also view AIM as a method of increasing GI Dynamics profile in our key European markets, which is synchronized with our commercial focus,” Mr Schorer said.

According to AIM data there did not appear to be any Australian biotechnology stocks on its lists, although it had about 60 pharmaceutical and biotechnology companies and several Australian incorporated mining companies.

The last Australian biotechnology company which intended to list on AIM was Stirling Products (BD: Jun 7, 2011).

On Monday, the London and Guernsey Island-based Crystal Amber Fund said it had increased its holding in GI Dynamics to 227,544,113 shares (40.79%) (BD: May 1, 2017).

GI Dynamics was up 0.3 cents or 4.8 percent to 6.5 cents with two million shares traded.

GI DYNAMICS

GI Dynamics annual general meeting will vote to grant six directors options over 78,000 US shares, equivalent to 3,900,000 Chess depository instruments (CDIs).
GI Dynamics said it proposed to issue director Dr Oern Stuge 30,000 “initial” options over US shares, vesting over three years and exercisable at 76 US cents, equivalent to 1,500,000 options exercisable at 2.025 Australian cents over CDIs, within 10 years.
The company said it proposed to issue each of the six named directors 8,000 “annual” options over US shares exercisable at $US2.33 each, equivalent to 400,000 Australian options each, exercisable at 6.2 cents, vesting in 12 months and expiring in 10 years.
GI Dynamics said the six directors were Dr Stuge, Timothy Barberich, Graham Bradley, Michael Carusi, Anne Keating and Daniel Moore.
The company said that other resolutions to the meeting were the election of directors Dr Stuge and Mr Moore, the approval of an increase in US shares from 13,000,000 to 50,000,000 and the elimination of class B shares, the ratification of placement and broker shares, renewal of the 10 percent placement capacity and the transfer of securities under the Employee, Director and Consultant Equity Incentive Plan.
In 2015, GI Dynamics annual general meeting saw up to 19.2 percent opposition to the grant of stock and options equivalent to 50,000 Chess depositary interests and options to directors Ms Keating, Mr Carusi, Mr Barberich, Mr Bradley, Mr Myer and Mr Moore as well as shares equivalent to 1,343,500 CDIs and 1,568,150 options to then chief executive officer Michael Dale (BD: May 1, Jun 9, 2015).
At that time, the votes against the directors’ stock issue amounted to 11.2 percent of the company, sufficient to requisition extraordinary general meetings.
The 2017 annual general meeting will be held at the offices of law firm Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, 1 Financial Center, Boston, Massachusetts on May 22, 2017 at 6pm (USEDT), May 23, 2017 at 8am (AEST).

OVENTUS MEDICAL

Oventus says a pilot clinical study has progressed the clinical validation of its O2Vent anti-snoring mouth guards including validation of the benefit of the device’s airway.
Oventus said the 29-patients study of the O2Vent Monoblock appliance showed it was effective for mild to moderate sleep apnoea, moderate to severe sleep apnoea, reduced time below 90 percent oxygen saturation for moderate to severe patients and had been accepted as an article in the Journal of Dental Sleep Medicine.
The company said that all 29 patients in the trial had “a significant improvement in snoring” and with 24 patients, or 82 percent, snoring was eliminated completely.
The company said the study showed the O2Vent Mono could treat self-reported nasal obstructers as effectively as those with no nasal obstruction, an unmet market need.
Oventus said that a Brisbane trial assessing the value of mandibular advancement alone, versus mandibular advancement with the addition of the proprietary airway technology, was fully recruited and expected to be completed by July 2017 and a trial at Perth’s Sir Charles Gairdner Hospital focused on pressure and flow measurements in the patient’s airway at various levels of advancement, with results expect in the next six months.
Oventus clinical director Dr Chris Hart said that having the company’s original trial published was “a significant achievement”.
“The subsequent trials have been designed to prove that the Oventus airway technology is specifically the reason our initial clinical results were so promising and facilitates a change in the paradigm of care for patients with [obstructive sleep apnoea],” Dr Hart said.
Oventus was unchanged at 44 cents.

MAYNE PHARMA GROUP

Challenger Limited and its entities say they have reduced their holding in Mayne Pharma below the five percent substantial shareholder mark.
Last week, the Sydney-based Challenger became substantial in Mayne with 77,797,626 shares or 5.16 percent.
Today, Challenger said that between April 28 and May 1, 2017 it sold 5,029,856 shares with the single largest sale 1,378,886 shares for $1,679,897 or $1.22 a share.
With 72,767,770 shares, Biotech Daily calculates that Challenger holds 4.8 percent of Mayne Pharma fell 5.5 cents or 4.4 percent to $1.205 with 16.6 million shares traded.

AVITA MEDICAL

Washington H Soul Pattinson and WHSP Hunter Hall say they have reduced their holding from 113,111,698 shares (16.81%) to 96,364,398 shares (14.32%).
The Sydney-based Washington H Soul Pattinson said it sold shares between March 21 and April 28, 2017 with the single largest sale 3,922,325 shares for $361,690 or 9.2 cents a share.
Avita was up 0.2 cents or 2.3 percent to nine cents.

RHINOMED

Rhinomed says it expects its 10-for-one consolidation to be completed on May 12, 2017.
Rhinomed said that the record date for the consolidation would be May 4, 2017 with shares traded as RNODC from today until May 12.
Rhinomed was unchanged at a post-consolidation 17 cents.

ONCOSIL MEDICAL

Oncosil says it has confirmed former Cochlear chief executive officer Dr Chris Roberts as non-executive chairman effective from May 8, 2017.
Oncosil said that founding chairman and co-inventor of the Brachysil radiation therapy Dr Roger Aston would continue as a non-executive director.
The company said that Dr Roberts was appointed as a director in 2016, following his retirement from Cochlear after 11 years with the company (BD: Jan 25, Sep 14, 2016).
Oncosil said that Dr Roberts had more than 40 years' experience in medical innovation as a director and executive of companies, research institutions and government entities and in January 2017 was appointed an Officer in the Order of Australia.
The company said that prior to Cochlear, Dr Roberts was the chairman of Sirtex Medical and executive vice-president of Resmed and continues as a non-executive director of Resmed.
Oncosil said that Dr Roberts held a Bachelor of Engineering from the University of New South Wales, a Masters of Business Administration from Macquarie University, a Doctorate of Philosophy from the University of New South Wales and honorary Doctor of Sciences degrees from Macquarie University and the University of New South Wales.
The company said that Dr Roberts was a member of the Centenary Institute of Cancer Medicine and Cell Biology board.
Oncosil fell half a cent or 4.2 percent to 11.5 cents with 1.3 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Tom Dooley as a non-executive director, effective from today, May 3, 2017.

Visioneering said that Mr Dooley was most recently Alcon Japan president, responsible for 1,300 employees and more than $US1 billion in annual sales of medical devices, pharmaceuticals and contact lens care products.

The company said that prior to moving to Japan, Mr Dooley was Alcon's Australia and New Zealand manager.

Visioneering said that Mr Dooley had 27 years' experience as a healthcare and ophthalmology executive.

The company said that Mr Dooley held a Bachelor of Science from the West Lafayette, Indiana-based Purdue University.

Visioneering fell 2.5 cents or six percent to 39 cents.