Biotech Daily

Wednesday October 25, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BENITEC UP 15%; CELLMID DOWN 17%**

*** STC ACTUATOR UP TO $75m FOR 40 MEDICAL TECHNOLOGY COMPANIES**

*** AUSBIOTECH ADELAIDE CONFERENCE; PROF JAN TENNENT DIRECTOR**

*** TGA APPROVES STARPHARMA VIVAGEL FOR BACTERIAL VAGINOSIS**

*** JAPARA ADOPTS DORSAVI MYVISAFE**

*** SIRTEX SIR-SPHERES, NIVOLUMAB LIVER CANCER TRIAL**

*** PERMITS EXPAND CANN MEDICAL MARIJUANA FACILITIES**

*** ACRUX, ELI LILLY AXIRON Q1 REVENUE DOWN 80%**

*** BRAIN RAISES $10m FOR 'AGGRESSIVE US GROWTH'**

*** PHOSPHAGENICS RAISES $3.4m OF HOPED-FOR $4.7m**

*** MEDIBIO RECEIVES $3.3m FEDERAL R&D TAX INCENTIVE**

*** BIOXYNE WINS MALAYSIA DIRECT SALES LICENCE**

*** TEVA SELLS 29m MESOBLAST SHARES, BELOW 5%**

*** REGAL FUNDS TAKE 6% OF MEDIBIO**

*** UBS 'RETURNS' 4m IDT SHARES TO 6%**

*** ANTHONY BARTON, ASSOCIATES TAKE 5% OF PHYLOGICA, AGAIN**

*** UP TO 30% OPPOSE MICRO-X DIRECTOR PATRICK O'BRIEN**

*** PHYLOGICA APPOINTS JUDY LIEBERMAN, STEPHEN DOBERSTEIN ADVISORS**

MARKET REPORT

The Australian stock market was up 0.14 percent on Wednesday October 25, 2017 with the ASX200 up 8.0 points to 5,905.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and four were untraded.

Benitec was the best, up 2.5 cents or 15.15 percent to 19 cents with 1.4 million shares traded. Dimerix and Prima climbed 10 percent or more; Cyclopharm was up 7.3 percent; Bionomics and Starpharma improved more than four percent; Medical Developments and Nanosonics were up more than three percent; Living Cell rose 2.1 percent; with Actinogen, Airxpanders, Avita and Polynovo up more than one percent.

Cellmid led the falls, down 0.4 cents or 17.4 percent to 1.9 cents with 9.9 million shares traded. Oncosil lost 13.3 percent; Mesoblast fell 10.4 percent; Impedimed lost 5.7 percent; Neuren and Prana fell more than four percent; Orthocell and Uscom were down more than three percent; Cochlear, Compumedics, Opthea and Volpara shed two percent or more; with Ellex, LBT, Pharmaxis and Universal Biosensors down more than one percent.

SMALL TECHNOLOGIES CLUSTER, ACTUATOR ACCELERATOR

The Small Technologies Cluster (STC) says subsidiary the Actuator Accelerator will provide up to $4 million each to up to 40 medical technology companies.

Actuator and STC chief executive officer Dr Buzz Palmer told Biotech Daily that with funding from the Federal Government through MTC Connect, the Victoria Government and the Sydney-based venture capital firm Artesian, the Actuator would have between $50 million and $75 million for the program.

Actuator said up to 40 medical technology start-ups would be accepted into its 15-month technology and entrepreneurial skill development program, which would provide training, $200,000 seed investment and up to $2.5 million, with matched funding from Artesian.

The media release said that with the 43.5 percent Federal Research and Development R&D Tax Incentive the funding would provide "nearly $4 million within 15 months, an unprecedented accelerated pathway to market in Australia".

Actuator said that applicants must have a functional prototype for a medical device at least technology readiness level 4 to apply.

Actuator chief technology officer Dr Laura Faulconer said that her organization "bridges a gap in the market".

"Even amazing seed-stage medical technologies companies were taking 12 to18 months to raise their first round of funding in Australia," Dr Faulconer said.

Actuator said the program was co-developed by medical technologies entrepreneurs, product development companies and early-stage investors.

Dr Palmer said the mission was "to support our home-grown talent within their local innovation ecosystems".

Artesian chief operating officer Tim Heasley said that the Actuator would "expedite technology transfer and research translation, stimulate the start-up ecosystem and bring together industry and stake-holder groups to pool efforts and increase impact".

For more information and to apply, go to: www.medicaltechnologiesactuator.com.

AUSBIOTECH

Ausbiotech says its Adelaide conference started today with Prof Jan Tennent elected as a director replacing Serina Cucuzza at its annual general meeting.

Ausbiotech deputy chief executive officer Lorraine Chiroiu told Biotech Daily that 985 delegates attended the first day of the Adelaide conference.

Ms Chiroiu said that delegates came from 18 countries with the largest numbers from South Korea, New Zealand, Singapore, the US, UK, Japan and China.

In a media release, Ausbiotech said that Prof Tennent brought "a strong industry-research conduit to the Ausbiotech board".

The organization said that Prof Tennent was a respected senior executive and business leader with experience in the pharmaceutical, agriculture and research sectors and was currently Biomedical Research Victoria chief executive officer.

Ausbiotech said that previously Prof Tennent was Pfizer Animal Health's business development and alliances director as well as a CSL Animal Health executive.

The organization said that Prof Tennent had been a director of the co-operative research centre (CRC) for Vaccine Technology and Commonwealth Scientific and Industrial Research Organisation Animal Health vaccines and immunology program manager.

Ausbiotech said that Prof Tennent was a University of Osaka collaborative professor and University of Melbourne fellow.

Ausbiotech chair Julie Phillips welcomed Prof Tennent and thanked Ms Cucuzza for her three years of service to Ausbiotech.

STARPHARMA HOLDINGS

Starpharma says the Australian Therapeutic Goods Administration has granted marketing approval for Vivagel BV for bacterial vaginosis.
Starpharma said that launch plans for Vivagel BV were advanced and the product was expected to be available in pharmacies in 2018.
The company said that Vivagel BV would be marketed in Australia by Aspen Pharmacare as Fleurstat BV gel, and would carry the Vivagel brand.
Starpharma said that Aspen would be responsible for all marketing, promotion and local distribution of the product to clinicians and pharmacies.
The company said that it would supply Aspen with the Vivagel BV product and receive royalties on net sales.
Starpharma said that TGA approval was significant for sales in many countries in Asia, the Middle East and South America where approval was based on home-country registration.
The company said that Vivagel BV's dendrimer active was not absorbed systemically, and acted locally to help restore the normal vaginal flora balance, resolving the associated signs and symptoms.
Starpharma chief executive Dr Jackie Fairley said the company was "delighted that Vivagel BV has been approved for sale in Australia".
"There's a significant need for new, clinically proven therapeutic options for this very common and persistent condition, which is associated with serious medical consequences and problematic symptoms if left untreated," Dr Fairley said. "Given the prevalence of antibiotic resistance worldwide, the fact that Vivagel BV is not a conventional antibiotic makes it a particularly appealing solution for patients and doctors alike."
Starpharma climbed six cents or 4.5 percent to $1.40 with 979,442 shares traded.

DORSAVI

Dorsavi says aged care provider Japara Healthcare will use its Myvisafe wearable sensor technology to improve workplace manual handling safety.
Dorsavi said that Myvisafe was an annuity product and its adoption by Japara followed an initial Visafe project this year, which identified potential exposure to injuries through repetitive movements by its staff involved in manual handling.
The company said that using its assessments, Japara planned interventions including administrative and equipment changes and the introduction of Myvisafe.
Dorsavi said Myvisafe comprised of a mobile telephone or computer tablet application and its movement sensors worn on the back and/or shoulders to measure movement, allowing Japara to show employees their own movements on the job, to alert employees when they were undergoing activities outside their safe zone, and to show safer ways to do the task.
Dorsavi said that Myvisafe would be used across all Japara residential aged care homes and five retirement complexes and would be used to assess hundreds of employees.
The company said that health and social care workers were at a higher risk of work-related musculo-skeletal disorders, with the main risk coming from patient handling and Japara expected "a significant reduction in manual handling workplace injuries".
Dorsavi chief executive officer Dr Andrew Ronchi said that low back and musculo-skeletal injuries were "a rapidly growing concern for workers in the health and aged care sector and nurses have one of the highest incidents of back injury".
"Japara's adoption of Myvisafe reflects how the wider industry is looking at innovative data-driven technologies to reduce occupational injuries and inform workplace safety decisions," Dr Ronchi said.
Dorsavi was unchanged at 29 cents.

SIRTEX MEDICAL

Sirtex says a 40-patient, investigator initiated trial will examine the efficacy of Opdivo, or nivolumab, following SIR-Spheres treatment for liver cancer.

Sirtex said that the 'Nasir-HCC' trial was a multi-centre, open label, single-arm study of the safety and anti-tumor efficacy of nivolumab "after SIR-Spheres microspheres for the treatment of patients with [non-resectable advanced hepatocellular carcinoma] that are candidates for loco-regional therapies".

The company said the primary endpoint was safety with secondary endpoints including overall survival, objective response rate, disease control rate, time to progression and progression-free survival.

Sirtex said the principal investigator was Spain's Clinica Universidad de Navarra liver unit director Prof Bruno Sangro and the company was a financial sponsor of the study.

The company said that by inducing tumor cell death SIR-Spheres might have a synergistic effect with immune checkpoint inhibitors by priming the immune system via the radiation-induced release of tumor antigens prior to treatment with nivolumab, taking the handbrake off immune system recognition of cancer cells.

Sirtex chief executive officer Andrew McLean said the Nasir-HCC study "forms part of our clinical strategy that seeks to add value to our core product through small, targeted [investigator initiated trials] using our therapy in combination with drug-based treatments like checkpoint inhibitors, which are in clinical development for a range of different cancer types, including [hepatocellular carcinoma]".

Sirtex fell four cents or 0.3 percent to $14.40 with 454,719 shares traded.

CANN GROUP

Cann says the Federal Office of Drug Control has expanded its medicinal cannabis licence and cannabis research licence for its two Victorian facilities.

Cann said it could expand capacity at its Southern facility and extend its cultivation, production and research activities at the Northern facility, subject to cultivation permits.

The company said the Northern facility had administration, research and development facilities and certified, climate-controlled and automated greenhouse cultivation areas, allowing the separation of different cannabis varieties during cultivation and harvest.

Cann chief executive officer Peter Crock said the licence variations would result in increased availability of high quality marijuana to manufacturers to produce medicinal cannabis products and extend its research and development programs.

"We are on track to be plant-ready at the Northern facility by the end of this year and aim to hold the necessary .., permits required to start cultivation at that time," Mr Crock said.

Cann was was up 12.5 cents or 8.4 percent to $1.62 with 1.1 million shares traded.

ACRUX

Acrux says that Eli Lilly's Axiron sales revenue fell 79.7 percent to $US7.9 million for the three months to September 30, 2017, compared to the previous corresponding period.

In Australian dollar terms, the three month fall was 78.4 percent from $46.4 million for the three months to June 30, 2017 to $10.2 million (BD: Jul 26, 2017).

In September, Acrux told Biotech Daily that a US Food and Drug Administration-required trial would have cost "hundreds of millions of dollars", sales had fallen since July 5, 2017, when generic versions of Axiron appeared on the market and it agreed with Eli Lilly to terminate the licencing agreement, effectively ending sales (BD: Sep 6, 2017).

Acrux was unchanged at 17 cents.

BRAIN RESOURCE

Brain says it has raised $10,013,351 at six cents a shares to fund “aggressive growth plans in the US”.
Brain said the placement was conditional on shareholder approval and a capital restructure, with each three placement shares coming with one attaching option, exercisable at eight cents within one year from the date of issue.
The company said that the option conversion would eliminate outstanding debt and remove the security interest held over the company’s assets.
Brain said that the conversion of $14,000,000 of convertible securities involved the issue of 175,000,000 shares at eight cents each, together with 50,000,000 options exercisable at 10 cents each within five years from the date of issue, subject to shareholder approval.
The company said that Bell Potter Securities and Gleneagle Securities were joint lead managers to the raising.
Brain was untraded at 6.2 cents.

PHOSPHAGENICS

Phosphagenics says it has raised $3.36 million of a hoped-for $4.7 million through its one-for-four non-renounceable rights offer at 1.5 cents a share (BD: Sep 26, 2017).
Phosphagenics said it had commitments for $567,000 from existing investors, along with underwriting agreements for $980,000 of shares, of which chief executive officer Dr Ross Murdoch, chairman Dr Greg Collier and director David Segal had committed $25,000, $30,000 and $30,000, respectively.
The company said the proceeds would fund the Mylan arbitration as well as continue the development and partnership of the tocopheryl phosphate mixture (TPM) opioid patches, the TPM injectable portfolio, the TPM animal health opportunities as well as cash for working capital and other purposes.
Dr Murdoch said the offer had the capacity to raise up to $4.7 million but was “targeting $3 million or better and I see $3.36 million as a very good result”.
Phosphagenics was unchanged at 1.6 cents.

MEDIBIO

Medibio says it has received $3,266,997 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Medibio said that the funds related to expenditure for the year to June 30, 2017.
Medibio was unchanged at 40.5 cents.

BIOXYNE

Bioxyne says Malaysia has granted a direct selling licence to its wholly-owned subsidiary Bioxyne International Malaysia Sdn Bhd.
Bioxyne said that new food additive, probiotec and cosmetic products sourced from New Zealand would be launched to underpin the commencement of business in Malaysia.
The company said that the New Zealand-sourced products would “suit the demographics and requirements of the discerning Malaysian consumers”.
Bioxyne said the Malaysian market was about $US4 billion.
The company said it had an office and showroom in Kuala Lumpur to be the regional office to support its business plans.
Bioxyne fell 0.1 cents or 2.2 percent to 4.4 cents with 1.9 million shares traded.

MESOBLAST

Mesoblast says that Teva Pharmaceuticals has sold 29,000,000 shares reducing its holding from 52,395,656 shares (11.14%) to 23,395,656 shares (4.75%).
At the time of publication neither Teva nor the as yet unnamed buyer had filed a substantial shareholder notice and Biotech Daily calculates that the acquired shares comprise 5.88 percent of the company.
Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that he was aware of the share transaction, but had no further details.
According to Commsec data the shares were sold in a single trade at $1.50 a share.
According to the Nasdaq, Teva's share price has fallen from more than $US30 for the past 10 years including a high of $US72 in July 2015 to $US14.28 last night.
On August 2, 2017, Teva fell from $US31.25 to $US20.60 overnight and to $15.86 at the end of the month.
In 2010, Mesoblast said that the Pennsylvania-based Cephalon would acquire 19.99 percent of the company in a deal worth up to $1.7 billion including $US100 million in up-front fees (BD: Dec 8, 2010).
In 2011, both Chemgenex, which was acquired by Cephalon in June 2011 for its Omapro for chronic myeloid leukaemia, and Mesoblast welcomed the acquisition of Cephalon by the Tel Aviv, Israel-based Teva (BD: Mar 29, May 3, Jun 1, 8, 2011).
Last year, Teva handed back the phase III stem cell cardiac program (BD: Jun 14, 2016).
Mesoblast fell 17 cents or 10.4 percent to $1.46 with 35.0 million shares traded.

MEDIBIO

Regal Funds Management says it has become a substantial holder in Medibio with 11,185,393 shares or 5.74 percent.
The Sydney-based Regal Funds substantial shareholder notice said the holders included UBS AG, Merrill Lynch International and Credit Suisse Securities Europe.
Regal said that 8,880,817 shares were acquired between July 4 and October 23, 2017 at prices ranging from 32 cents to 40 cents.

IDT AUSTRALIA

UBS AG says it has "returned" 4,000,000 IDT shares at no value, reducing its holding from 18,271,173 shares (7.35%) to 14,271,173 shares (5.75%).
The Singapore-based UBS Group AG and related bodies corporate said it returned the shares on October 20, 2017 and the registered holder was Brispot Nominees Pty Ltd.
IDT fell 0.1 cents or 1.3 percent to 7.6 cents with 1.7 million shares traded.

PHYLOGICA

The Perth-based Anthony Barton says that with associates he has become a substantial shareholder in Phylogica, again, with 107,000,000 shares (5.01%).
Last year, former Phylogica director Mr Barton said he became a substantial shareholder in Phylogica, again, with 100,500,000 shares or 5.01 percent and previously held as much as 7.73 percent (BD: Jul 14, 2010; Jun 20, 2011; Nov 17, 2016).
Today, Mr Barton said the associats were Harvey Springs Estate, AP and CH Barton Superfunds, Barton and Barton and Inglewood Lodge and the shares were acquired on-market but again failed to disclose the cost as required under the Corporations Act 2001.
Phylogica fell 0.1 cents or 2.6 percent to 3.8 cents with 3.1 million shares traded.

MICRO-X TECHNOLOGIES

Micro-X's annual general meeting passed all resolutions but with opposition to the re-election of director Patrick O'Brien.
Micro-X said that 8,522,468 votes (30.0%) opposed Mr O'Brien's re-election with 18,859,056 votes (66.4%) in favor and 1,034,360 votes (3.6%) at the proxy's discretion
All other resolutions were passed overwhelmingly.
The company's most recent Appendix 3B new share issue announcement said that Micro-X had 144,350,698 shares on issue meaning that the opposition to Mr O'Brien amounted to 5.9 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.
Micro-X fell one cent or 2.5 percent to 39 cents.

PHYLOGICA

Phylogica says it has appointed Prof Judy Lieberman and Dr Stephen Doberstein as the first members of its scientific advisory board.
Phylogica said that the board would be a strategic resource as the company continued "to develop its drug delivery platform technology, harnessing its ability to carry drug cargoes inside cells as new generation therapies for a range of diseases".
The company said that Prof Judy Lieberman was Boston Children's Hospital's chair of cellular and molecular medicine and Harvard Medical School's professor of paediatrics.
Phylogica said that Dr Doberstein was Nektar Therapeutics chief scientific officer.
Phylogica chief executive officer Stephanie Unwin said both appointments were "experts in intracellular delivery and disease biology … [and would] complement our internal research team".
"The background and experience these two members bring will be invaluable as we look to commercialize our platform and also work on delivering commercial products into the intracellular environment where important unexploited disease targets are located," Ms Unwin said.