Biotech Daily

Monday May 14, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AVITA UP 8%; MEDICAL DEVELOPMENTS DOWN 13%**

*** PLANET INNOVATION $400k TAKES LBT RAISING TO $7.9m**

*** CLINUVEL 5100 SCENESSE IMPLANTS SAFE; US NDA BY JULY**

*** FEDERAL $6m FOR MELBOURNE ACADEMIC HEALTH RESEARCH CENTRE**

*** ONCOSIL FILES CE MARK DATA TO BRITISH STANDARDS INSTITUTE**

*** FACTOR ON-TRACK TO COMPLETE ENROLMENT IN JUNE**

*** MEDICAL DEVELOPMENTS 'FLAT REVENUE EXPECTED'**

*** RHYTHM REAGENTS FOR COLORECTAL CANCER TEST ON-TIME, BUDGET**

*** LIFESPOT FINGERPRINT MARIJUANA VAPORIZER FOR ISRAEL TRIALS**

*** ANTISENSE PLEADS SCHULTZ, $5m TO ASX 7% QUERY**

*** PATRYS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ANATARA REQUESTS 'DETACH DEAL' TRADING HALT**

*** CRESO REQUESTS 'ISRAELI ACQUISITION' TRADING HALT**

*** BARD1 TAKES 'ASX PRICE QUERY' TRADING HALT TO SUSPENSION**

*** OPTHEA (CIRCADIAN) BELOW 5% OF ANTISENSE**

*** MARK, TIFFANY DEVLIN, 34th AVENUE TAKE 5% OF INNATE**

MARKET REPORT

The Australian stock market was up 0.31 percent on Monday May 14, 2018 with the ASX200 up 19.1 points to 6,135.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell, three traded unchanged and two were untraded. All three Big Caps were up.

Avita was the best, up 0.4 cents or eight percent to 5.4 cents, with 799,101 shares traded. Cynata, LBT and Polynovo climbed four percent or more; Admedus, Pharmaxis and Reva were up more than three percent; Actinogen and Volpara rose more than two percent; with Nanosonics and Sirtex up more than one percent.

Medical Developments led the falls, down 93 cents or 13 percent to $6.22 with 689,421 shares traded. Airxpanders lost 11.5 percent; Prescient fell 7.7 percent; Oncosil was down 6.1 percent; Osprey and Telix shed more than five percent; Dimerix and Optiscan fell more than four percent; Clinuvel, Ellex, Genetic Signatures and Starpharma were down more than three percent; Benitec, Compumedics, Opthea, Prana and Universal Biosensors shed two percent or more; with Bionomics, Neuren, Orthocell and Pro Medicus down more than one percent.

LBT INNOVATIONS

LBT says that it has completed its placement and share plan 15 cents a share with the issue of $400,000 in shares to Planet Innovation (BD: Mar 6, Apr 6, 2018).
In March, when the company announced the share plan it was “in negotiations with [an unnamed] strategic investor to subscribe for up to an additional $400,000 under the placement”.
Today, LBT said the investor was the Melbourne-based Planet innovation and the shares had been issued as part of the second tranche of the placement.
LBT was up half a cent or four percent to 13 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has implanted more than 4,000 Scenesse devices for erythropoietic protoporphyria (EPP) and expects to file a US new drug application by July, 2018.
Clinuvel said it had implanted more than 5,100 Scenesse (afamelanotide 16mg) devices and reported a greater than 99 percent treatment compliance rate in European EPP patients.
The company said more than 85 percent of European patients consented to inclusion in a disease registry, with “confirmation that no off-label use of Scenesse has taken place”.
When Clinuvel changed its name from Epitan and before it appointed Dr Philippe Wolgen as chief executive officer, it was believed by some biotechnology industry specialists that Scenesse, then known as EPT1647 and later as CUV1647, the treatment would be used off-label as an injectable sun tan.
In 2007, Dr Wolgen told Biotech Daily: “This will not be a cosmetic drug. I oppose systemic treatment for cosmetics” (BD: Apr 18, 2007).
Today, the company said that individual Swiss patients received more than 50 Scenesse implants over 12 years of treatment.
Today, Clinuvel said that the European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) had issued a favorable opinion on the risk-benefit profile of Scenesse following its review of the third post-authorization annual report.
The company said it had submitted six-monthly periodic safety update reports to the CHMP to provide an overview of the ongoing safety profile of the product and implementation of risk minimisation measures.
Clinuvel said that the sixth review, covering the six months to December 31, 2017 provided “a comprehensive overview of the safety profile from the use of Scenesse, with no new safety concerns identified and excellent ongoing compliance with [risk minimisation measures] across Europe … [and] confirmed that no off-label use of Scenesse had occurred for the period, an indication of the success of the control of the distribution program”.
The company said it had incorporated the analyses into its new drug application to the US Food and Drug Administration with a final submission expected by July 1, 2018.
Clinuvel said that several therapeutic products were in development by its Vallaurix Singapore operation focussed on complementary non-prescriptive products.
The company said that follow-on products to address unmet medical needs in severe and genetic disorders were in developments, with the first product line expected to be announced in July 2018.
Clinuvel said that it was developing a paediatric formulation of Scenesse, Scenesse Enfance, as well as progressing scientific work on the novel molecules CUV9900 and VLRX001.
Clinuvel fell 43 cents or 3.3 percent to $12.47.

FEDERAL GOVERNMENT, MELBOURNE ACADEMIC CENTRE FOR HEALTH

The Federal Government says it will provide $6.1 million to the Melbourne Academic Centre for Health consortium to support health and medical research.

A media release from Federal Health Minister Greg Hunt said the funds from the Medical Research Future Fund built on an earlier $2.22 million grant and would enable the Centre "to build on research work it has undertaken in relation to asthma, retinal photography and artificial intelligence, the degeneration of muscles, and precision medicine for epilepsy".

The media release said that the Melbourne Academic Centre for Health was one of seven Advanced Health Research and Translation Centres.

According to its website, the Centre was a consortium including the University of Melbourne, the Florey Institute, Melbourne Health, the Peter MacCallum Cancer Centre, the Walter and Eliza Hall Institute, Austin Health, the Bionics Institute, Eye Research Australia, the Murdoch Children's Research Institute, Mercy Health, Northern Health, the Olivia Newton John Cancer Research Institute, St Vincent's Institute, the Royal Melbourne Hospital, the Royal Women's Hospital, the Royal Children's Hospital, St Vincent's Hospital, the Eye and Ear Hospital and Western Health.

ONCOSIL MEDICAL

Oncosil says it has submitted a clinical report on "emerging performance and safety data" for its Brachysil pancreatic cancer treatment to the British Standards Institute.

Oncosil said the British Standards Institute was the regulatory body overseeing its Conformité Européenne (CE) mark application and the report provided safety data on the 46 patients enrolled to date, along with efficacy data for 25 patients implanted with the device and had reached the eight-week and 16-week radiological assessments.

The company previously said that the Australian and European trials would be part of a 300-patient US regulatory-directed trial, but more recently has been describing its 45-patient Panco trial in Australia and Europe and a 20-patient Oncopac-1 trial in the US "to inform future trials" (BD: Sep 14, 2016).

Oncosil fell one cent or 6.1 percent to 15.5 cents with 1.4 million shares traded.

FACTOR THERAPEUTICS

Factor says it has reduced the number of patients required for its phase IIb trial of VF001 for venous leg ulcers with enrolment expected to be completed by July 2018.

Factor said that with more than 90 patients having completed treatment it consulted with external statistical experts to finalize the trial's analysis plan, "leading to a modest reduction in the number of patients that need to be recruited whilst maintaining the overall robustness of the analysis".

Factor chief executive officer Dr Ros Wilson said that progress in the last few weeks was "excellent".

"The low withdrawal rate we have seen throughout [the trial] is a very encouraging sign that our patients and investigators have a positive perception of the study," Dr Wilson said.

Factor said the study had enrolled 124 patients and a further 10 were being screened.

The company said that recruitment was expected to complete at the end of June and with 12-weeks of follow up results would be expected by July.

"This final phase of recruitment is important to not only achieve readout of all the study endpoints, including changes in pain and quality of life scores, but also deliver the additional patients required for re-submission of the CE mark dossier in Europe".

Factor was unchanged at four cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that despite 15 additional European approvals for its Penthrox methoxyflurane inhaled analgesic, revenue is likely to be “flat or slightly down”.
Medical Developments chief executive officer John Sharman said that “the upside from this global expansion will not be seen until [June 30, 2019]”.
The company said that underlying profit for the year to June 30, 2018 was expected to be $300,000 due to investment in infrastructure for the roll-out of Penthrox across Europe, Mexico, Canada and the Middle East.
“We are confident of another 15 new country marketing authorizations in the next 12 months including Italy, Spain, Switzerland, Saudi Arabia, Hong Kong and South Korea,” Mr Sharman said.
“However, sales into these new markets are not expected until the second half of [the 2018-’19 financial year], Mr Sharman said.
Mr Sharman said that sales revenue for the year to June 30, 2018 was “lower than market expectation mainly because of lower device sales in Australia and lower than expected sales growth rates for devices in the US and Europe”.
“Both the US and Europe respiratory device businesses will still deliver good sales growth, but some delays in key contracts and partnership agreements have impacted our initial growth rate expectations,” Mr Sharman said.
Medical Developments fell 93 cents or 13 percent to $6.22 with 689,421 shares traded.

RHYTHM BIOSCIENCES

Rhythm says that the first phase in the development of two antibody reagents for its Colostat blood test for colorectal cancer has been completed.
Rhythm said that four independent mixed monoclonal antibody preparations had been identified passing all three preliminary screening tests, completed as part of its research contract with Commonwealth Scientific and Industrial Research Organisation “on-time and on-budget”.
The company said that completion of preliminary screening triggered the next phase of reagent development, the cloning of cells that produce the desired antibody specificities, separating them from other cells producing other products.
Rhythm said the success of the cloning step was “critical to ensuring that the company has a reliable, long-term source of these key reagents”.
Rhythm was unchanged at 18 cents with one million shares traded.

LIFESPOT HEALTH

Lifespot says it has begun discussions with potential clients in Israel to include its marijuana vaporizer in clinical trials for the commercialization of medical cannabis.
Lifespot said the Seng-Vital vaporizer was activated by a patient fingerprint, allowing marijuana to be taken as a vapor extracted from oils or herbs.
The company said the vaporizer embedded in the medically certified software infrastructure of Bodytel allowed patients and physicians to retrieve and evaluate the readings and data collected on the Bodytel data monitoring and collection platform.
Lifespot was up one cent or 7.7 percent to 14 cents.

ANTISENSE THERAPEUTICS

Antisense has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 7.1 percent from 2.8 cents on May 10 to 3.0 cents on May 11, 2018 and noted a significant increase in trading volume.
Antisense said it recently raised $5 million "with prominent institutional investor Australian Ethical … becoming [its] largest shareholder with a 19 percent holding and Platinum Asset Management a substantial shareholder with a 5.7 percent" (BD: May 3, 2018).
Antisense fell 0.2 cents or 7.4 percent to 2.5 cents with 1.4 million shares traded.

PATRYS

Patrys has requested a trading halt "pending an announcement by the company to the market regarding an institutional capital raising".
Trading will resume on May 16, 2018 or on an earlier announcement.
Patrys last traded at 3.8 cents

ANATARA LIFESCIENCES

Anatara has requested a trading halt "pending an announcement regarding the outcome of negotiations for an international commercial agreement for Detach".
Anatara has been developing the pineapple-stem bromelain-based Detach for pig diarrhoea and has said it intended to develop a human version.
Trading will resume on May 16, 2018 or on an earlier announcement.
Anatara last traded at $1.445.

CRESO PHARMA

Creso has requested a trading halt ""pending an announcement regarding a significant Israeli acquisition"
Trading will resume on May 16, 2018, or on an earlier announcement.
Creso last traded at 72.5 cents.

BARD1 LIFE SCIENCES

Bard1 has requested a voluntary suspension to follow the trading halt requested on May 10, pending "a response to an ASX price query". (BD: May 10, 2018).
Bard1 last traded at two cents.

ANTISENSE, OPTHEA (FORMERLY CIRCADIAN TECHNOLOGIES)

Opthea says it has been diluted below the five percent substantial shareholder mark in Antisense following the latter company's $5 million capital raise (BD: May 3, 2018).
Opthea said it retained 10,190,649 Antisense shares (2.74%) at May 9, 2018.
The then Circadian, previously had subsidiaries that held Antisense shares, and in the past was an "incubator" investing in a range of other biotechnology companies, including Avexa, (now Novita), Metabolic (now Polynovo) and Optiscan as well as Antisense (BD: May 16, 2016; Apr 7, 2017).
Opthea fell one cent or two percent to 49 cents.

INNATE IMMUNOTHERAPEUTICS

Mark and Tiffany Devlin and 34th Avenue Pty Ltd say they have become substantial shareholders in Innate with 2,215,237 shares or 5.40 percent of the company.

The Melbourne-based Mr and Ms Devlin and 34th Avenue for the Devlin Family Account said they acquired the shares on May 4, 2018 at a deemed price of 2.1 cents a share as consideration for shares in Amplia Therapeutics, acquired by Innate.

Innate was up six cents or 15.4 percent to 45 cents.