



Biotech Daily

Tuesday September 11, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: IMMUTEP UP 15%; OPTISCAN DOWN 8%**
- * **TELIX \$14m CASH, SCRIP FOR ATLAB, BZL PROSTATE CANCER IP**
- * **FEDERAL GOVERNMENT: \$10m FOR SIX RARE DISEASE TRIALS**
- * **IMUGENE PHASE Ib HER-VAXX CANCER TRIAL RECRUITED**
- * **GOODBYE INNATE, WELCOME AMPLIA**
- * **SIRTEX DEPARTS ASX ON THURSDAY**
- * **FISHER & PAYKEL SEEKS RESMED US EXCLUSION ORDER**
- * **MEDLAB WINS MARIJUANA PRODUCT EXPORT LICENCE**
- * **SUDA REQUESTS UNSPECIFIED TRADING HALT**
- * **PHYLOGICA TAKES 3¢ CAPITAL RAISING HALT TO SUSPENSION**
- * **INBRIDGE BELOW 5% OF INVITROCUE**
- * **CREDIT SUISSE BELOW 5% OF BARD1**
- * **DR GÖRAN ANDO REPLACES EYEPOINT CHAIR DR DAVID MAZZO**
- * **NUHEARA APPOINTS PHILIP NEWTON 'CHIEF SALES OFFICER'**

MARKET REPORT

The Australian stock market was up 0.62 percent on Tuesday September 11, 2018 with the ASX200 up 38.0 points to 6,179.7 points. Nine of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and three were untraded.

Immutep was the best, up 0.6 cents or 15.4 percent to 4.5 cents with 40.5 million shares traded. Imugene climbed 9.1 percent; Cynata improved 4.4 percent; Benitec, Compumedics and Starpharma rose more than two percent; Genetic Signatures was up 1.75 percent; with Cochlear, Pro Medicus and Sirtex up by less than one percent.

Optiscan led the falls, down 0.4 cents or 7.55 percent to 4.9 cents, with 236,347 shares traded. Impedimed lost 6.1 percent; Bionomics, Dimerix, LBT, Osprey, Prescient and Universal Biosensors fell more than four percent; Avita, Factor and Pharmaxis were down more than three percent; Clinuvel, Neuren, Oncosil and Telix shed more than two percent; Actinogen, Medical Developments, Opthea, Orthocell, Polynovo and Volpara were down one percent or more; with CSL and Resmed down by less than one percent.

TELEX PHARMACEUTICALS

Telex says it has acquired the Nantes, France-based Atlab Pharma SAS for \$US10 million (\$A14.1 million) in cash or shares as disclosed in its initial public offer prospectus.

Telex said that as part of the acquisition, it renegotiated Atlab's material background intellectual property licences, including with the Chappaqua, New York-based BZL Biologics LLC, the holder of a portfolio of patents originating from Prof Neil Bander's laboratory at New York City's Weill Cornell Medical Centre.

Telex said the Atlab BZL patent portfolio supported potential indication expansion for TLX591, notably the combination use of anti-prostate specific membrane antigen (PSMA) therapeutics in conjunction with anti-androgen drugs, further increasing the value and relevance of its TLX591 program for prostate cancer.

The company said that Atlab had the rights to a clinical data set from about 200 patients that would inform the development of TLX591, including unpublished data around dose optimization schemes for antibody-based PSMA radio-pharmaceuticals.

Telex said the data might accelerate and further de-risk the development of TLX591.

The company said that Atlab's Prof Jean-François Chatal and BZL's Prof Bander would continue as members of its scientific advisory board.

Telex said that Atlab held the rights and materials necessary to develop HuJ591, "the most widely clinically-studied anti-PSMA antibody".

The company said it would keep HuJ591 as a back-up clinical drug candidate and "support several high-value academic collaborations around the use of this antibody that may also be informative to the future development of TLX591, including in non-prostate cancer indications".

Telex chief executive officer Dr Christian Behrenbruch said the company had built on the Atlab and BZL experience to develop TLX591, an engineered and optimized form of 177Lu-labelled HuJ591.

"The result is a best-in-class anti-PSMA therapeutic that clearly rivals the performance of small molecule anti-PSMA agents such as PSMA-I&T and PSMA-617," Dr Behrenbruch said. "We believe that this transaction has the potential to give Telex a significant commercial advantage in the combination use of anti-PSMA therapeutics with androgen-targeting drugs such as Zytiga and Xtandi."

Atlab president, Dr Jean-Marc Le Doussal said his company was "delighted to become part of Telex and to contribute to the future success of TLX591".

"Together with our colleagues at BZL, we bring a considerable depth of knowledge around antibody-based PSMA therapeutics, built on a decade of clinical collaboration with the University of Nantes and [Weill Cornell]," Prof Le Doussal said.

Telex said it would provide \$US9 million in shares to Atlab shareholders at 89 cents a share, with 41 percent of the allocated shares classed as management shares and escrowed for two years, with the remaining 59 percent classified as investor shares, with 25 percent escrowed for three months and 75 percent escrowed for 12 months.

Telex said the \$US9 million was a reduced consideration for Atlab, reflecting diverted consideration to BZL for reduced royalties as well as the assumption of responsibility for a repayable research and development loan facility of EUR258,000 (\$A420,254) owed to a French public investment bank (with partial repayment obligations out to 2021), along with \$US500,000 in Telex shares to BZL at 89 cents a share, escrowed for two years, with \$US500,000 in warrants, exercisable at \$1.34 a share within four years.

The company said it had a limited back-licence with BZL for certain intellectual property rights to support ongoing commercial research activities outside the scope of the product development focus for Telex.

Telex fell 2.5 cents or 2.9 percent to 84.5 cents.

FEDERAL GOVERNMENT

The Minister for Health Greg Hunt says the Federal Government's Medical Research Future Fund will invest \$10 million for six rare cancer and rare disease clinical trials.

A media release from Mr Hunt's office said the six trials, to be conducted at the University of Melbourne, the University of Sydney, Melbourne's Monash University and Melbourne's La Trobe University, would target pancreatic cancer, traumatic brain injury, rare skin tumors, myeloma, myelofibrosis and high mortality cancers such as glioblastoma.

The media release said a pancreatic cancer trial would test advances in radiotherapy to safely increase low level radiation to kill more tumor cells and a traumatic brain injury trial would test the effectiveness of precision medicine neuro-intensive care.

The Government said that a combination of radiotherapy and a new drug would be trialled for merkel cell carcinoma, with an aim to improve the five-year survival rate from its low of 18 percent.

The media release said researchers at Monash University would investigate treatments for senior Australians with multiple myeloma.

Mr Hunt said that low-cost genomic profiling would track the result of precision medicine in patients with the rare and incurable blood-cancer myelofibrosis.

Mr Hunt's media release said researchers at La Trobe University were developing an antibody drug to target specific tumors, with a trial led by Prof Hui Gan to test patients with one of nine cancers, including glioblastoma.

The media release said that more information about the trials was available at:

<https://beta.health.gov.au/initiatives-and-programs/medical-research-future-fund>.

IMUGENE

Imugene says it has completed recruitment for its phase Ib combination with chemotherapy trial of its HER-Vaxx cancer vaccine for gastric cancer patients.

In 2016, Imugene said it had begun its phase Ib/II trial of HER-Vaxx for gastric cancer at eight sites in Asia, including Hong Kong, Thailand and Taiwan (BD: Nov 7, 2016).

Last year, the company said it had begun dosing the first of up to 18 patients in the phase Ib trial (BD: Aug 31, 2017).

Today, Imugene said it had recruited 18 patients, which would test three doses of HER-Vaxx in combination with standard of care chemotherapy drug cisplatin and either fluorouracil or capecitabine.

The company said that HER-Vaxx was designed to produce an antibody response against cancer growth signal receptor protein human epidermal growth factor receptor 2 (HER2), with the phase Ib study to evaluate the safety, tolerability, immunology and clinical activity of HER-Vaxx in combination with chemotherapy and establish the optimal dose for a larger phase II study that would test HER-Vaxx in 68 patients with metastatic gastric cancer.

Imugene said a cohort review committee would determine the recommended phase II study dose.

Imugene was up 0.2 cents or 9.1 percent to 2.4 cents with 31.5 million shares traded.

AMPLIA THERAPEUTICS (FORMERLY INNATE IMMUNOTHERAPEUTICS)

Amplia, formerly Innate, has begun trading under the ASX code of ATX from today.

Amplia fell one cent or 2.8 percent to 35 cents.

SIRTEX MEDICAL

Sirtex says that pending approvals it will be removed from the ASX on September 13 and from the S&P ASX200 on September 14, 2018.

Sirtex said that Standard and Poors (S&P) Dow Jones Indices would remove it from the ASX200 at the opening of trading on September 14, 2018, subject to final court approval of the Grand Pharma Sphere scheme of arrangement.

A Sirtex spokesman told Biotech Daily the last trading day would be September 13, 2018. Yesterday, Sirtex said that shareholders overwhelmingly approved the CDH Genetech and China Grand Pharmaceutical and Healthcare \$1.9 billion bid (BD: Sep 10, 2018). Sirtex was up 18 cents or 0.55 percent to \$33.08 with 585,207 shares traded.

FISHER & PAYKEL HEALTHCARE, RESMED

Fisher & Paykel says it has filed a complaint with the US International Trade Commission to stop Resmed importing and selling nasal pillow masks in the US.

Last week, Fisher & Paykel said it would contest patent allegations that had been made against it by Resmed in the US International Trade Commission (ITC) and the US Southern California district court (BD: Sep 3, 2018).

Today, the company said that Resmed's Airfit P10 range of nasal pillow masks for obstructive sleep apnoea infringed five Fisher & Paykel patents, and as such said it was seeking a permanent exclusion order and cease and desist order from the ITC to prevent the sale and importation of the Airfit P10 masks in the US.

Fisher & Paykel was up 24 cents or 1.8 percent to \$13.84 with 315,815 shares traded. Resmed fell 12 cents or 0.8 percent to \$15.61 with 2.2 million shares traded.

MEDLAB CLINICAL

Medlab says it has received an export licence from the Australian Office of Drug Control for its marijuana-based products Nanabis and Nanabidial.

Medlab said the export licence would facilitate formalized trade conversations "with confidence in the knowledge that the company can supply legally overseas".

The company said the licence was renewable annually.

Medlab chief executive officer Dr Sean Hall said that the licence was "a welcome addition to our other approvals, allowing Medlab to research, manufacture, conduct research trials, supply within Australia, and now, pending the right partner, foreign markets".

Medlab said that Nanabis and Nanabidial delivered nano-particles of pharmaceutical ingredients extracted from the cannabis plant into the patient's cheek.

In July, the company said it had begun a 30-patient phase I/IIa trial of Nanbis for cancer pain (BD: Jul 4, 2018).

Medlab was up 3.5 cents or 7.8 percent to 48.5 cents.

SUDA PHARMACEUTICALS

Suda has requested a trading halt, but at the time of publication had not disclosed a reason to the public.

Trading will resume on September 13, 2018 or on an earlier announcement.

Suda last traded at 0.4 cents.

PHYLOGICA

Phylogica has requested a voluntary suspension to follow the trading halt requested on September 7, pending an “announcement to the market regarding a proposed capital raising transaction” (BD: Sep 7, 2018).

Phylogica said the capital raising was being conducted at three cents a share “available to professional investors only and will introduce new sophisticated and institutional investors to Phylogica’s register”.

The company said the fund raising was supported by existing major shareholders and would provide funding to complete screening of its drug libraries for second generation cell penetrating peptides, to reach a read-out on the ability of the peptides to deliver cargoes in therapeutic settings, ex-vivo or in-vivo; and to advance its flagship program to an investigational new drug filing for first-in-human studies.

Phylogica said it expected to finalize the raising and resume normal trading prior to the end of this week, September 14, 2018.

Phylogica last traded at three cents.

INVITROCUE

The Singapore-based Inbridge Ventures says it has ceased its substantial holding in Invitrocue.

Inbridge said it sold 5,225,000 shares off-market for \$377,000, or 7.2 cents a share. Previously, the company said it held 28,049,000 shares implying that it retained 22,824,000 shares (BD: Aug 28, 2018).

According to Invitrocue’s most recent Appendix 3B new share announcement, it had 513,624,180 shares, implying that Inbridge retained 4.4 percent of the company. Invitrocue was untraded at 9.5 cents.

BARD1 LIFE SCIENCES

The Sydney and Zurich-based Credit Suisse Group says it has ceased its substantial shareholding in Bard1.

Credit Suisse said that between April 16 and September 4, 2018, it bought and sold shares with the single largest acquisition on May 2 of 2,744,626 million shares for \$51,599 or 1.88 cents a share, with the single largest sale on May 22 of 3,396,190 shares for \$71,320 or 2.1 cents a share.

Bard1 was unchanged at 1.2 cents.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA)

Eyepoint says Dr Göran Ando has been elected as its chairman, with Dr David Mazzo to resign but remain a director.

Earlier this year, Eyepoint said it had appointed former Novo Nordisk AS chairman Dr Ando as a director (BD: Jun 27, 2018).

On the Nasdaq, Eyepoint was unchanged at \$US2.22 (\$A3.12) with 174,614 shares traded.

[NUHEARA](#)

Nuheara says it has appointed Philip Newton as its first chief sales officer for its Iqbuds sound filtering and hearing devices.

Nuheara said that co-founder David Cannington previously was responsible for sales and marketing and would continue as chief marketing officer.

The company said that Mr Newton was formerly Samsung Australia's head of corporate and previously worked for Mitsubishi Electric Australia as a director and group general-manager, as well as managing-director of digital monitoring company Benq Australia.

Nuheara was up 0.3 cents or 3.75 percent to 8.3 cents with 1.5 million shares traded.