# Biotech Daily

Monday June 17, 2013

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: ALLIED HEALTH UP 9%, PHYLOGICA DOWN 14%**

*** MAYNE SUBACAP US TRIALS, EU APPROVAL, TGA APPLICATION**

*** UNILIFE 'IMMINENT' CONTRACT DELAYED**

*** UK NICE RECOMMENDS PSIVIDA'S ILUVIEN FOR DME SUB-GROUP**

*** US GRANTS CIRCADIAN VEGFR-3 DIAGNOSTIC PATENT**

*** ALCHEMIA PLEADS SCHULTZ TO ASX 14% FALL QUERY**

*** ALLIED HEALTH LOSES CARDIOCEL CEO BOB ATWILL**

## MARKET REPORT

The Australian stock market was up 0.71 percent on Monday June 17, 2013 with the S&P ASX 200 up 34.1 points to 4,825.9 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and three were untraded. All three Big Caps were up.

Allied Health was the best, up half a cent or 9.3 percent to 5.9 cents with 19.4 million shares traded.

Both Cellmid and Impedimed climbed four percent; Alchemia and Neuren were up more than three percent; Bionomics, Cochlear and Prana rose more than two percent; Mesoblast was up 1.2 percent; with CSL, QRX and Resmed up by less than one percent.

Phylogica led the falls, down 0.3 cents or 13.6 percent to 1.9 cents, with 973,729 shares traded, followed by Patrys down 12.5 percent to 2.8 cents with two million shares traded.

Antisense lost 8.3 percent; Avita, Prima and Reva fell more than four percent; both Phosphagenics and Tissue Therapies lost 3.6 percent; Anteo, Living Cell and Psivida shed more than two percent; Acrux, Genetic Technologies, Heartware and Sirtex were down one percent or more; with GI Dynamics, Medical Developments, Nanosonics and Starpharma down by less than one percent.

## MAYNE PHARMA

Mayne Pharma says the first of two US pivotal studies of Subacap (formerly Suba-itraconazole) for fungal infections has begun.

Mayne Pharma investment relations manger Lisa Pendelbury told Biotech Daily that the company had recruited all 52 healthy volunteers for the pharmacokinetic study.

In 2010, Mayne Pharma (the Halcygen) completed a 175-patient, phase II US study comparing Suba-itraconazole with itraconazole and described it as successful in demonstrating superiority over itraconazole (BD: Apr 13, 2010; Dec 15, 2011).

Mayne said in its half-yearly report in February 2013, that Subacap had received UK marketing authorization for Subacap for the treatment of superficial and systemic fungal infections in January 2013.

The company said that the approval followed completion of the decentralized procedure in which the UK, as the reference member state, delivered a positive outcome, along with the three concerned member states of Germany, Spain and Sweden.

Mayne said that German, Spanish and Swedish authorizations were expected to be issued later in 2013 and it would begin the 'repeat use procedure' for marketing approval in Italy, the largest itraconazole market in Europe.

The company said that approval in the five European countries would give access to more than half the European itraconazole market, valued at more than $US90 million a year, placing the company in a position to secure marketing and distribution partners in Europe.

Mayne said it had applied to the Australian Therapeutic Goods Administration for regulatory approval of Subacap and expected authorization within 12 months.

Mayne was unchanged at 43 cents with 981,598 shares traded.

## UNILIFE

Unilife says that a major contract with a global pharmaceutical company, that was being "routed for signatures" more than a month ago, could be delayed for days or weeks.

Pre-filled syringe manufacturer Unilife climbed 138.7 percent from 31 cents to 74 cents, after announcing the supply contract on May 10, before retreating as much as 21.6 percent on clarification on May 13 (BD: May 14, 2013).

On May 10 and 13, Unilife published its third quarter report and a conference call transcript in which chief executive officer Alan Shortall said the company was "getting ready to announce our first major long-term supply contract for the Unifill syringe".

"Negotiations for this agreement are complete and all terms have been agreed upon, with the execution copy now being routed for signature by both parties," Mr Shortall said at that time. "I expect this agreement will establish Unilife as one of the leading suppliers of pre-filled syringes in our industry."

Today, Mr Shortall said the company had "successfully completed negotiations with a global pharmaceutical company for a major long-term supply contract for the Unifill syringe as referred to during our last earnings call".

"I can advise that this contract is finalized with all terms having been agreed upon by both parties," Mr Shortall said.

"The formal process of having the execution copy of the contract signed is now taking place, and we have been advised by the customer that it may require an additional few days or weeks to complete," Mr Shortall said.

"While this process is taking slightly longer than both parties originally anticipated, it is understandable given the size of the company and the number of steps involved," Mr Shortall said.

Unilife was up eight cents or 15.2 percent to 60.5 cents with 1.9 million shares traded.

## PSIVIDA

Psivida says the UK National Institute for Health and Care Excellence has recommended Iluvien for diabetic macular oedema patients who have prior cataract surgery.
Psivida said that National Institute for Health and Care Excellence (Nice) reversed its previous decision not to recommend Iluvien for the treatment of diabetic macular oedema and issued draft guidance recommending the drug delivery system for patients who had undergone prior cataract surgery, known as pseudophakic patients, with diabetic macular oedema considered insufficiently responsive to available therapies.
The company said that more than half the control patients in the 1,000 patient phase III study of Iluvien with diabetic macular oedema had previously undergone cataract surgery and diabetic macular oedema patients had a far higher incidence of cataracts than the general population.
Psivida said that following a review, the Nice recommendation proposed a change to the guidance issued by in January 2013 and took into consideration a patient access scheme submitted by licencee, Alimera Sciences.
Psivida said that if the recommendation became final, Iluvien would be available to pseudaphakic as well as for private pay and privately insured patients in the UK.
The company said that Iluvien sales in the UK and Germany began in April with sales expected begin soon France, Austria, Spain, and Portugal.
Psivida said the Nice committee confirmed the conclusions that Iluvien was clinically effective in the treatment of vision impairment associated with chronic diabetic macular oedema considered insufficiently responsive to available therapies as well as in the subgroup of pseudophakic chronic diabetic macular oedema patients and concluded that the cost-effectiveness threshold had been met for the subgroup of chronic patients who were pseudophakic.
Psivida fell eight cents or 2.2 percent to $3.54.

## CIRCADIAN TECHNOLOGIES

Circadian says the US Patent and Trademark Office has granted a patent covering diagnostic uses of vascular endothelial growth factor receptor-3 (VEGFR-3).
Circadian said the patent, entitled ‘Methods of screening for neoplastic disease states’was granted to its subsidiary Vegenics Pty Ltd and covered the measurement of VEGFR-3 in human tissue samples to assist in disease detection and added to the intellectual property portfolio covering the VEGF-C, VEGF-D and VEGFR-3 molecules and their therapeutic and diagnostic uses.
The abstract provided by the USPTO said “the present invention provide purified Flt4 receptor tyrosine kinase polypeptides and fragments thereof, polynucleotides encoding such polypeptides, antibodies that specifically bind such polypeptides, and uses therefore”.
Circadian said that “a very large number of scientific publications have been published showing the diagnostic potential of measuring VEGFR-3 levels to identify patients at risk of a very wide array of different cancer types as well as to monitor the ongoing effectiveness of a range of different cancer therapies”.
Circadian chief executive officer Robert Klupacs said “the grant of this patent greatly assists our ongoing partnering and licensing discussions with companies who are actively developing VEGFR-3 diagnostics using a range of biological tissue types and diagnostic platforms, and further enhances our dominant intellectual property position around VEGFR-3 and its use”.
Circadian was unchanged at 30 cents.

## ALCHEMIA

Alchemia 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 fell 14.3 percent from 35 cents on June 11 to 30 cents on June 14, 2013, but did not note an increase in trading volume.
Alchemia was up one cent or 3.3 percent to 31 cents.

## ALLIED HEALTHCARE GROUP

Allied Health says that the chief executive officer of its Cardiocel division Bob Atwill resigned from the company effective on June 7, 2013.
The Cardiocel division has developed bovine cardiac tissue for tissue replacement and has Australian Therapeutic Goods Administration pre-market approval and has applied for US Food and Drug Administration regulatory approval (BD: Apr 2, 8, 2013).
Allied chief executive officer Lee Rodne told Biotech Daily that the Cardiocel division had become sales focused and Mr Atwill would not be replaced.
Allied climbed half a cent or 9.3 percent to 5.9 cents with 19.4 million shares traded.