Biotech Daily

Friday September 28, 2012

Daily news on ASX-listed biotechnology companies

VALE DR HELMER (HANK) AGERSBORG

*** ASX FLAT, BIOTECH UP: BENITEC UP 14%, CIRCADIAN DOWN 8%**

*** US DEFENCE GRANTS AVITA $841k FOR SLOW RECRUITMENT**

*** CLINUVEL CSO DR HELMER AGERSBORG DIES**

*** BIODIEM 1-FOR-2 RIGHTS ISSUE FOR $2.55m**

*** CORRECTION: PROGEN**

*** MEDIVAC, REPUBLICA MERGER**

*** PATRYS AGM FOR 375k CEO OPTIONS, LOAN SHARE PLAN**

MARKET REPORT

The Australian stock market was up 0.06 percent on Friday September 28, 2012 with the S&P ASX 200 up 2.8 points to 4,387.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and seven were untraded.

Benitec was the best, up 0.2 cents or 14.3 percent to 1.6 cents, with 120,006 shares traded, followed by Patrys up 11.8 percent to 3.8 cents with 444,127 shares traded.

Impedimed climbed 9.7 percent; Avita was up eight percent; Prana rose 7.1 percent; Pharmaxis, Prima and Sunshine Heart were up by more than five percent; Phylogica and QRX rose more than three percent, Anteo and Reva were up more than one percent; with Biota and Starpharma up by less then one percent.

Circadian led the falls, down three cents or 7.7 percent to 36 cents with 7,731 shares traded.

Cellmid lost 6.25 percent; Antisense and Optiscan were down five percent or more; Allied Health fell 4.2 percent; Living Cell and Universal Biosensors were down more than three percent; Bionomics shed 2.6 percent; Mesoblast fell 1.2 percent; with Alchemia and Cochlear down by less than one percent.

AVITA MEDICAL

Avita says it has received a further US Defence grant of $US880,000 to cover recruitment delays in its trial of Recell for burns injuries (BD: May 27, 2009; Jan 28, Jun 10, 2010).

Avita said the additional $US880,000 ($A840,619) supplemented the $US1.75 million provided in prior funding for the pivotal trial and "underscores the commitment by the US Department of Defence, the US Army and the US Armed Forces Institute for Regenerative Medicine to bringing the Recell technology through the [US Food and Drug Administration] approval process and cleared for sales in the US, thereby having it available for the military and civilian population".

Avita said the study design required similarity across patients and within patients, two comparable wounds for treatment, necessary for a randomized controlled clinical trial, but imposing tight inclusion and exclusion criteria, constraining use to a particular and small subset of burns patients.

The company said that about 75 percent of the expected 106 patients had been enrolled in the trial, in which each patient received both the standard-of-care graft treatment and the Recell treatment of sprayed autologous cell suspension.

The company said that the patients with partial-thickness thermal injuries were assessed for healing and pain on a weekly basis during the initial four weeks post-treatment.

Avita said that the treatment site would be assessed at weeks eight, 12, 16, 24 and 52 for healing and aesthetic outcomes.

The company said that clinical data at the 16 week follow-up would be reported to the FDA in support of an application to market Recell in the US.

Avita chief executive officer Dr William Dolphin said the company was "grateful for the continued support of the US Department of Defense and AFIRM program".

"As a first-of-its-kind study the patient selection criteria and protocol for the FDA study are stringent, requiring significant commitment from the participating surgeon and their team," Dr Dolphin said.

"AFIRM has recognized the difficulty of the protocol - reflected in the slower than hoped for enrolment - and, following close scrutiny and careful review, have provided additional funding in support of the study - further indication of the importance of this innovative technology," Dr Dolphin said.

"Recell has shown the potential to provide significant benefits over current options in the treatment of burns and other acute and chronic wounds and for a wide range of skin defects," Dr Dolphin said.

AFIRM program leader Dr James Holmes said his organization viewed the Recell FDA study "as a high priority project and recognizes Recell as a potential game-changer in the treatment of burns and acute wounds".

"The AFIRM program managers have acknowledged that this is an extremely difficult study and are backing their assessment of the importance of the Recell technology with additional funding at a time of tight budgetary constraints," Dr Holmes said.

The company said that the US Armed Forces Institute for Regenerative Medicine (AFIRM) program was established in March 2008 to bring transformational technologies in regenerative medicine to wounded soldiers by developing clinical therapies and advanced treatment options.

Avita said the program had a special interest in using the most advanced regenerative medicine for its wounded soldiers and recognized that the company's treatment for burns and other skin injuries had the benefits of using the patient's own skin, yielded improved healing, reduced scar formation and reintroduced pigmentation to the skin.

Avita was up one cent or eight percent to 13.5 cents.

DR HELMER (HANK) AGERSBORG

Clinuvel says that executive director and chief scientific officer Dr Helmer (Hank) Agersborg has died suddenly.
Clinuvel chief executive officer Dr Philippe Wolgen said that Dr Agersborg's daily involvement as chief scientific officer was "instrumental to the progress of the company and his contribution as a board member at all stages has been of great importance to influencing the company's strategic direction".
Dr Wolgen said Dr Agersborg was a renowned toxicologist and a man of great integrity, broad knowledge and unforgettable wit.
Throughout his career, including a period where he served as president of Wyeth-Ayerst Research, Dr Agersborg oversaw the successful filing of 53 new drug applications, Dr Wolgen said.
He said that Dr Agersborg was well-known within the drug development industry in the US and in the years following his departure from Wyeth he was a sought-after member of company boards.
Dr Wolgen said that Dr Agersborg was involved in the final stages of the European Medicine Agency's review of the marketing authorization application of Scenesse (afamelanotide) for erythropoietic protoporphyria.
Dr Wolgen said that Dr Agersborg joined Clinuvel's board in 2001 and had been unwavering in his support of the strategy to develop Scenesse for medical use.
Dr Agersborg's funeral service will be in Philadelphia, Pennsylvania on October 4, 2012.
Clinuvel said that Dr Dennis Wright had been appointed acting chief scientific officer.
"On behalf of my fellow directors and staff I extend our deepest sympathy to Dr Agersborg's wife Marcella and their family," Dr Wolgen said.

BIODIEM

Biodiem expects to raise $2.55 million through a partly underwritten one-for-two, plus attaching option, renounceable rights issue at five cents a share.
Biodiem said the attaching options were exercisable at eight cents by December 31, 2014.
Biodiem said the funds raised would be used "to continue development of the company's extensive portfolio of vaccine and antimicrobial therapies targeting infectious diseases and to pursue additional business development opportunities, and for general working capital".
The company said the issue was underwritten to $2.0 million by Patersons Securities, the record date for the issue was October 11 and the closing date was November 2, 2012.
The company said its three largest shareholders, Brezzo Enterprises, David Li and Hugh Morgan had indicated they would take up their rights in full.
Biodiem was up 0.7 cents or 13.0 percent to 6.1 cents with 1.8 million shares traded.
Biodiem was unchanged at 6.2 cents.

PROGEN PHARMACEUTICALS

Last night's Progen headline and lead sentence said that Medigen had enrolled the first patient in its phase III trial of PI-88 for liver cancer.
The patient was the first enrolled in China and, as reported, more than 150 patients have been enrolled in Taiwan and South Korea.
The mistake was made by the sub-editor, who is no longer enrolled at Biotech Daily. We appreciate that that's two in three days, but they are cheap and plentiful and it's hard to find good hired help these days.
Progen was up 0.5 cents or 2.0 percent to 26 cents.

MEDIVAC

Medivac says it has executed an agreement to acquire all of Republica Capital's issued shares.

Medivac said the transaction would bring income-producing assets, provide for a pay down of the La Jolla Cove facility and lead to an injection of cash and ensure future funding for the merged businesses.

The company said that the proposed transaction was subject to shareholder approval.

Medivac announced the proposed transaction in June saying that "delays in achieving critical regulatory decisions across both the Metamizer and Sunnywipes businesses has resulted in a significant drain in cash resources, and at the same time seen low share market liquidity and led to some uncertainty regarding our ability to rely on the La Jolla funding facility" (BD: Jun 22, 2012).

The company said at that time that the transaction provided for an immediate injection of $154,572 at 0.6 cents a share and a loan of about $300,000 on terms to be agreed and it would undertake a strategic review of its businesses to reduce costs.

Medivac said Republica Capital was an investment manager investing in businesses with the aim of adding value for all parties.

Today, Medivac said Republica had five convertible note and loan assets, excluding the funds invested in and loaned to Medivac, of $2.258 million and forecast it would earn significant interest and capital gains on these assets.

Medivac said Republica had made a commitment to provide a further $400,000 in October and support the raise of capital of up to $5 million for the merged businesses, with up to $2 million to be raised shortly after the proposed merger is approved.

Medivac said that payment for the merger would be the issue of 660 million shares at 0.6 cent each, over five payments with the first payment of 450 million shares on execution.

Medivac said it would focus on its core Metamizer business and the soon-to-be acquired Republica investments.

The company said that Republica would expand its portfolio of high-return convertible note facilities where opportunities were presented and the narrower focus would enable it to operate on a lower cost base.

Medivac was up 0.2 cents or 50 percent to 0.6 cents.

PATRYS

Patrys shareholders will vote to issue chief executive officer Dr Marie Roskrow 375,000 options exercisable at the five-day volume weighted average price to the date of issue.

Patrys said the options would vest in three tranches over three years.

The company said the loan share plan was an employee incentive plan for directors executives and employees and the company would continue to use both the plan to issue shares as well as the employee share option plan for eligible participants.

Patrys said shareholders would also vote on the re-election of directors Michael Stork and Suzy Jones.

The meeting will be held at the offices of accountants BDO (Binder Dijker Otte), Level 10, 1 Margaret Street, Sydney on October 31, 2012 at 11am (AEDT).

Patrys was up 0.4 cents or 11.8 percent to 3.8 cents.