Biotech Daily

Monday November 7, 2011

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: IMPEDIMED UP 14%; CELLMID DOWN 11%**

*** ALCHEMIA DEMERGES MEDITECH ONCOLOGY; PLACES $15m; $5m PLAN**

*** FDA CLEARS IMPEDIMED L-DEX U400 FOR LEGS**

*** IMMURON FILES FDA IND FOR PHASE II IMM-124E FATTY LIVER TRIAL**

*** JAPAN PATENT FOR ANTISENSE ATL1103**

*** IM MEDICAL RAISES $3.3m**

*** NUSEP APPOINTS TOM ROWE COMPANY SECRETARY**

*** NOW WE ARE SIX!**

MARKET REPORT

The Australian stock market fell 0.18 percent on Monday November 7, 2011 with the S&P ASX 200 down 7.7 points to 4273.4 points.

Eleven of the Biotech Daily Top 40 stocks were up, nine fell, 12 traded unchanged and eight were untraded.

Impedimed was the best, up eight cents or 14.0 percent to 65 cents with 181,650 shares traded, followed by Antisense up 11.1 percent to one cent with 5.6 million shares traded and Alchemia up three cents or 10.9 percent to 30.5 cents with 5.2 million shares traded.

Phylogica climbed 5.4 percent; Avita rose 4.8 percent; Pharmaxis was up 3.4 percent; Mesoblast and Sirtex were up more than two percent; Clinuvel and CSL were up more than one percent; with QRX, Resmed and Starpharma up by less than one percent.

Cellmid led the falls, down 0.2 cents or 11.1 percent to 1.6 cents, with 32,000 shares traded.

Cathrx lost 8.3 percent; Neuren was down 6.9 percent; Sunshine Heart fell 4.8 percent; Cochlear, Phosphagenics and Prima shed more than two percent; with Acrux, Anteo and Biota down more than one percent.

ALCHEMIA

Alchemia will “demerge” the oncology assets acquired with Meditech in 2006, has raised $15 million in a placement at 24 cents a share and hopes to raise $5 million through a share plan at the same price.

Alchemia acquired Meditech in 2006 saying the merger would “create a substantial drug development company with an extensive pipeline of products, a strong financial position and an experienced management team” (BD: Mar 9, Aug 15, 2006).

Following US approval of fondaparinux in August, Glaxosmithkline announced it would distribute an authorized generic, knocking the Alchemia share price down 34.65 percent from 50.5 cents to 33 cents (BD: Aug 4, 9, 2011).

Today, Alchemia said it would demerge its “wholly owned subsidiary Alchemia Oncology … to create a stand-alone company containing all of the [hyaluronic acid (HA)] Hyact oncology assets including HA-irinotecan”, subject to evaluation and market conditions.

Alchemia said the subsidiary would be separately listed on a public exchange, in Australia or the US or both and expected the transaction would involve a pro-rata distribution of shares to existing shareholders, subject to market conditions, meeting legal and financial requirements and obtaining necessary shareholder approvals.

Alchemia said that at this time, it would continue to be listed on the ASX with its synthetic heparin fondaparinux the primary asset of the company.

Alchemia chief executive officer Dr Pete Smith told a teleconference that any merger and acquisition activity relating to Alchemia oncology was “unpredictable”.

The company said it would distribute the majority of profits from fondaparinux to shareholders by way of dividends or return of capital, as appropriate.

“After the demerger, the company would look to rationalize its cost structure, whilst effectively managing its ongoing relationship with its manufacturing and marketing partner Dr Reddy’s Laboratories,” Alchemia said.

Dr Smith said the changes would “provide a clear choice for investors as we recognize that the risk/return profile of each of these businesses is markedly different”.

“By separating the oncology business from Alchemia, we aim to allow the majority of profits arising from fondaparinux to fall to Alchemia’s bottom line,” Dr Smith said. “Equally, it will allow investors who want to participate in the upside potential of HA-Irinotecan and the Hyact platform to do so in a separate company with a clear identity and mission.”

“We anticipate initiating patient recruitment to our phase III trial and commencement of preparations to demerge as soon as possible after the fundraising,” Dr Smith said.

Alchemia said the $15 million will be settled in two tranches of $6.9 million on November 11 and $8.1 million on December 21, 2011, subject to shareholder approval at an extraordinary general meeting scheduled for December 19, 2011.

The company said Orbis Capital was its largest shareholder and had “the opportunity to maintain its shareholding at 19.1 percent subject to shareholder approval”.

Alchemia said the funds would go to its phase III trial of HA-irinotecan for colorectal cancer, a phase II trial in small cell lung cancer (BD: Sep 28, 2011), other research activities and working capital, including the spinning-out of Alchemia Oncology.

Alchemia said RBS Morgans acted as lead manager of the over-subscribed placement, with Ladenburg Thalmann the US placement agency and Blueprint Life Science Group as corporate adviser.

The company said the share plan record date was November 3, 2011 and shareholders would be able to apply for parcels of shares up to $15,000, the plan would open on November 23 and close on December 12, 2011.

Alchemia climbed three cents or 10.9 percent to 30.5 cents with 5.2 million shares traded.

IMPEDIMED

Impedimed says the US Food and Drug Administration has cleared the L- Dex U400 to assess unilateral lymphoedema of the arm in women and legs for both men and women.
Impedimed said the approval was “another major milestone”.
The company said the FDA had allowed the indication to be expanded to include patients who will have, or who have had lymph nodes from the axillary and pelvic regions removed, damaged or irradiated, “broadening the claim beyond just cancer and no longer links it to any one specific cancer”.
Impedimed said the clearance recognized the prospective model of care as it allowed for baseline and follow-up of patients at risk and better aligned the indication with US clinical standards and guidelines.
The company said its value came from prospective care for patients at risk of unilateral lymphoedema in both the arms and legs and the expanded claim covered this promotion.
Impedimed chief executive officer Greg Brown said “the FDA clearance paves the way for Impedimed to directly launch the device into the US market for limbs”.
“Impedimed will market the L-Dex U400 device directly with its US sales force and will initially target general surgeons who specialize in the breast and other cancers, for example melanoma, radiation oncologists and therapists”, Mr Brown said.
Mr Brown said that while the approval allowed a broader base of medical providers, the company “would not lose its current primary focus on breast cancer”.
“The FDA clearance of the L-Dex U400 device puts us in a strong position to build awareness in all of Impedimed’s target markets for lymphoedema and for driving adoption of the L-Dex technology” Mr Brown said. “The L-Dex U400 is considered the first product designed specifically to meet the needs of the routine clinical environment for surgeons (oncology and vascular), radiation oncologists and therapists.”
Impedimed was up eight cents or 14.0 percent to 65 cents.

IMMURON

Immuron says it has submitted its US Food and Drug Administration investigational new drug application for a phase II trial of IMM-124E for fatty liver disease.
Immuron said that IMM-124E was a potential new treatment of fatty liver disease and in particular non-alcoholic steato-hepatitis (NASH).
The company said that IMM-124E could enter a market with no existing approved competitors worth an estimated $US4.4 billion a year in the US alone.
Immuron said that based on the data generated to date IMM-124E had a high safety profile and an ability to elicit a response in many fatty liver and NASH parameters including insulin resistance and elevated serum cholesterol.
The company said the phase IIb clinical trial would further test the safety and efficacy of IMM-124E and was designed in conjunction with principal investigator Prof Arun Sanyal, the immediate past president of the American Association for the Study of Liver Diseases.
Immuron said the trial would be a dose-ranging, placebo-controlled, double blind multi-centre study in NASH patients receiving six months of active treatment involving sites in Australia, the US and Israel.
Immuron chief executive Joe Baini said the application was “key milestone for Immuron but is even more important for the millions of patients suffering from NASH as it remains one of few life threatening diseases without any approved treatment”.
“Along with the strong sales growth of Travelan, this further reinforces our strategy of accelerating to market more of our oral immuno-therapies,” Mr Baini said.
Immuron was unchanged at five cents.

ANTISENSE THERAPEUTICS

Antisense says the Japan Patent Office has granted a patent covering its growth hormone receptor-targeting drug ATL1103 and its use until February 2024.
Antisense said that the Japanese patent (No 4837555) entitled 'Modulation of Growth Hormone Receptor Expression and Insulin Like Growth Factor Expression' was part of its intellectual property portfolio protecting ATL1103 and its applications in the modulation of IGF-I in the treatment of acromegaly and other diseases, including patents granted in the US, States Australia and New Zealand, with applications pending in Europe and Canada.
Antisense said that ATL1103 was protected by other Isis proprietary antisense technology and manufacturing patents and applications to which it had a world-wide licence.
Antisense was up one cent or 11.1 percent to one cent with 5.6 million shares traded.

IM MEDICAL

IM medical says its one-for-six rights issue at half a cent per share was oversubscribed and raised $3.3 million.
IM said that each share came with an attached option exercisable at one cent by September 2016 and it would undertake a placement on the same terms to raise a further $272,500 for additional working capital.
The company said that Patersons Securities would be the lead manager for the placement.
IM was untraded at five cents.

NUSEP

Nusep says it has appointed Company Matters' principal Tom Rowe as company secretary.
Nusep said that Mr Rowe was a corporate and commercial lawyer with a specialty in listed company secretarial practice and held a Bachelor of Arts and Bachelor of Laws from the University of Adelaide.
Nusep said Company Matters provided of legal, governance and company secretarial services and Mr Rowe was previously legal counsel and company secretary at CSR.
Nusep was untraded at 10 cents.

BIOTECH DAILY

Now we are six!
Today marks Biotech Daily's sixth year of continuous publishing without missing a single major announcement or a single edition.
We have unfortunately lost an awful lot of sub-editors in this time, but they are, after all, expendable and no price is too high to ensure accuracy and veracity for our readers.
Again, none of this would be possible without our subscribers.
Thank you, all.

David Langsam
Editor

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