



Biotech Daily

Monday March 8, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMPEDIMED UP 10%; COMPUMEDICS DOWN 9%**

- * **AMA REIMBURSEMENT CODE FOR IMPEDIMED TEST**

- * **CHINESE PATENT FOR ALCHEMIA'S FONDAPARINUX**

- * **EUROPEAN SPERM SEPARATION PATENT FOR NUSEP**

MARKET REPORT

The Australian stock market climbed 0.85 percent on Monday March 8, 2010 with the S&P ASX 200 up 40.7 points to 4807.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and six were untraded.

Impedimed was best, up seven cents or 9.6 percent to 80 cents with 242,854 shares traded, followed by Novogen up 3.5 cents or 7.95 percent to 47.5 cents with 21,448 shares traded.

Sirtex climbed 6.1 percent; Avexa and Phylogica were up more than four percent; Cellmid and Prana were up more than three percent; Antisense, Circadian, Mesoblast and Pharmaxis rose more than two percent; with Bionomics, Biota and Psivida up more than one percent.

Compumedics led the falls, down 1.5 cents or 9.1 percent to 15 cents with 60,100 shares traded, followed by Living Cell down 8.8 percent to 15.5 cents with 75,400 shares traded.

Viralytics lost 5.45 percent; Benitec and Phosphagenics fell more than four percent; Cathrx was down 3.7 percent; Heartware and Nanosonics shed more than two percent; with Cellestis, Chemgenex, Clinuvel, Resmed and Starpharma down one percent or more.

IMPEDIMED

Impedimed says the American Medical Association has approved a unique reimbursement code for its lymphoedema detection diagnostic for both arms and legs.

Impedimed said the category III 'current procedural terminology' (CPT) code, designated for emerging technologies, was expected to be published by July 1, 2010, for use from January 1, 2011.

Impedimed chief executive officer Greg Brown told Biotech Daily that the application was submitted by Dallas-based general surgeon AMA Dr Peter Beitsch and was supported by the American Society of Breast Surgeons.

Mr Brown said the code was a critical first step to receiving insurance reimbursement and he was pleased the code included both arms and legs as the company's next generation diagnostic device, the L-Dex UB500, was capable of detecting lymphoedema in both arms and legs. He said lymphoedema of the legs was 80 percent of the market.

Mr Brown said the AMA code would enable him to hold talks with US health insurers for reimbursement.

Mr Brown said the unique code, specific to Impedimed's bio-impedance spectroscopy (BIS) meant that the insurance reimbursement was specific to his company.

"BIS will allow payers in the US to distinguish procedures that are otherwise grouped under a miscellaneous code," Dr Beitsch said.

"As a growing number of my colleagues are adopting L-Dex technology in the management of their patients with breast cancer, a category specific code will facilitate clearer tracking of utilization and outcomes," Dr Beitsch said.

"Using this new code supports the AMA's ruling to now allow clinicians and payers to track and to better understand the utilization and value of bio-impedance spectroscopy," he said.

Impedimed said CPT codes described medical services performed in the US and were used to communicate to payers for billing purposes. Prior to the establishment of this category III CPT code, physicians and hospitals using Impedimed's L-Dex technology had to use a non-specific, miscellaneous code.

The miscellaneous CPT code could be used for billing many different medical procedures associated with the lymphatic system and was not specific to lymphoedema detection. Due to the multiplicity of the miscellaneous code, additional documentation regarding the medical necessity of L-Dex readings was required to accompany each and every claim.

This, with a manual claims review process by insurance companies, often led to payment decisions that have taken months to approve or decline, Impedimed said.

Dr Beitsch said physicians needed an accurate and objective tool to assess and monitor the early changes in the limbs that lead to the development of lymphoedema.

"Today, we can institute preventative and more cost effective measures by detecting and treating lymphoedema at its earliest stages," Dr Beitsch said.

"Simply, BIS provides better outcomes for patients, while delivering better cost effectiveness for payers," Dr Beitsch said.

"This new code will provide a pathway for greater physician and patient access to this advanced BIS technology. In addition, I see the use of BIS expanding to help prevent lymphoedema in melanoma patients," he said.

Impedimed said that unlike a category I CPT code, the new code would have the benefit of not having a specific payment amount associated with it and payers would continue to make individual decisions regarding payment values and protocols based on the health economic data available to demonstrate the benefits of pre-emptive care.

Impedimed was up seven cents or 9.6 percent to 80 cents.

ALCHEMIA

Alchemia says the Chinese State Intellectual Property Office has granted a patent entitled 'Synthetic heparin pentasaccharides' relating to its fondaparinux process.

Alchemia said fondaparinux was a generic version of Glaxosmithkline's Arixtra a synthetic anticoagulant mainly used for the prevention of deep vein thrombosis

The company's head of intellectual property and technology transfer Mike West said he was "exceptionally pleased with the grant of this patent and the extent of protection it gives us in China".

"China has a rapidly developing market for pharmaceuticals and the addition of patent protection will greatly assist our partnering efforts in the territory," Mr West said.

Alchemia said the Chinese patent formed part of a broader family, with granted patents in Australia and the US and further applications pending in Europe, Japan, and the US.

"Whilst most attention is focused on the pending approval for the US market, we are actively seeking to maximize the total value of generic fondaparinux through partnerships in other territories," Dr West said.

Alchemia said it continued to accrue data for market approval outside the US, which required stability data from a single exhibit batch of finished product. Other jurisdictions including Europe, required data from three batches which was available and would allow approvals to be sought in many countries.

Alchemia said fondaparinux could not be sold in the EU until the 10-year data exclusivity period expired in 2012, but an application could be submitted in December 2010.

Alchemia was unchanged at 64 cents.

NUSEP

Nusep says the European Patent Office has granted a patent entitled 'Gamete separation' for its Spermsep sperm separation technology.

Nusep said the patent was "an important step in the commercial development of the Spermsep" as it gave exclusive rights to manufacture and sell the Spermsep in Europe".

Nusep said the Spermsep electrical process had granted patents in Australia and Europe, with a pending patent application in the US.

The company said sperm separation was required for assisted reproductive technology treatments (ART), a market worth \$170 million in Australia and a \$3 billion in the US.

Nusep said its Spermsep instrument addressed one to two percent of these markets.

Nusep said the 2006 report estimated a total of one million ART cycles in the world per year, providing a Spermsep consumables market at \$45 million a year.

Nusep said its electrical process was superior to the density gradient centrifugation process demonstrated in a phase I trial at the Westmead Fertility Clinic in 2008 including separation time reduced from 45 minutes to five minutes; lower DNA damage; lower sample cross-contamination; and a higher rate of pregnancies and live births.

Nusep executive chairman John Manusu told Biotech Daily that of nine couples in each cohort, none became pregnant in the existing density gradient centrifugation process, while three did in the Nusep process, resulting in three live births.

Mr Manusu said he expected the company to undertake a larger pivotal trial of about 100 semen samples this year with first commercial sales expected by the end of 2010.

Nusep was up 4.5 cents or 18.4 percent to 29 cents.