Biotech Daily

Friday May 31, 2013

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: PATRYS UP 12%, PHARMAXIS DOWN 14%**

*** FDA 'BREAKTHROUGH DESIGNATION' EXPLAINED**

*** SUDA EXPECTS ARTIMIST LICENCING TALKS BY OCTOBER**

*** BIOTRON EARNS $892k FEDERAL R&D TAX REFUND**

*** CORRECTION: REVA**

MARKET REPORT

The Australian stock slipped 0.08 percent on Friday May 31, 2013, with the S&P ASX 200 down 4.1 points to 4,926.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and four were untraded.

Patrys was the best, up 0.3 cents or 12.0 percent to 2.8 cents with five million shares traded, followed by Medical Developments up 11.1 percent to $1.30 with 15,622 shares traded and Phylogica up 10 percent to 2.2 cents with 239,116 shares traded.

Benitec and Sirtex climbed more than six percent; Psivida and Tissue Therapies were up four percent or more; Nanosonics, Optiscan, Osprey and Prana rose more than two percent; Acrux, Alchemia, Clinuvel and Resmed were up more than one percent; with Mesoblast up 0.5 percent.

Pharmaxis led the falls, down 2.5 cents or 13.9 percent to 15.5 cents with 13.3 million shares traded.

Genetic Technologies lost 9.5 percent; Neuren and Reva were down more than five percent; Avita and Universal Biosensors fell more than four percent; Cochlear and Impedimed shed more than two percent; with Bionomics, CSL, Heartware and QRX down by less than one percent.

US FOOD AND DRUG ADMINISTRATION

The US Food and Drug Administration has granted eight requests for 'Breakthrough Designation' since the program began on July 9, 2012.

The FDA's website said that 24 requests for Breakthrough Designation had been made between inception and March 31, 2013, with eight granted and nine denied.

The FDA's Center for Drug Evaluation and Research told Biotech Daily that Breakthrough Designation was one of a number of programs "intended to expedite drug development and review" including fast track designation, accelerated approval, and priority review.

The Center said the breakthrough therapy program was for "a drug that treats a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies".

"In contrast, a fast track program is for a drug that treats a serious condition and non-clinical or clinical data demonstrate the potential to address unmet medical need," the Centre said.

"Although breakthrough and fast track have similarities as they both are intended to expedite the development and review of drugs for serious conditions, there are differences in what needs to be demonstrated to qualify for the program," the Centre said. "In addition, there are differences in the features of the two programs - a breakthrough therapy program will have important features in addition to all the fast track program features."

The FDA said it would provide more intensive guidance on an efficient drug development program and had a commitment to involve senior management in guidance for drugs designated as breakthrough therapies.

The Centre said that Section 902 of FDA Safety and innovation Act (FDASIA) required the following actions, as appropriate: meeting the sponsor and the review team throughout the development of the drug; providing timely advice to, and communication with, the sponsor regarding the development of the drug to ensure that the program to gather the non-clinical and clinical data necessary was as efficient as practicable; involving senior managers and experienced review staff in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and serve as a scientific liaison between the review team and the sponsor; taking steps to ensure that the design of the clinical trial(s) was as efficient as practicable, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

The Centre said that a drug designated as a breakthrough therapy could be eligible for the accelerated approval pathway if the relevant criteria were met and could be granted priority review if supported by clinical data at the time of application.

Asked for guidelines for minimal data the Centre said: "Preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints is evaluated by the FDA on a case by case basis as Breakthrough Therapy Designation requests are received."

"FDA will strive to ensure that products that are designated as a breakthrough therapy receive special attention so that the development program is patient-focused, leading to streamlined evidence development," the Centre said.

The Centre said the FDA or sponsor could propose alternative clinical trial designs such as adaptive design, enrichment strategy, use of historical controls, that might result in smaller trials or more efficient trials that require less time to complete.

The Centre said that the FDA had experience approving drugs for serious diseases, including rare diseases, based on small datasets provided the data meet the statutory standard for approval and there appears to be a favorable benefit risk profile for the drug in the indicated population.

SUDA (FORMERLY EASTLAND MEDICAL SYSTEMS)

Suda executive chairman Stephen Carter hopes to begin Artimist licencing talks in October when the full phase III data package has been completed.

On a road-show to meet investors and potential investors in Melbourne, Sydney and Perth, Mr Carter told Biotech Daily that the sublingual Artimist spray used six times in two days had proven superior to 22 doses of intra-venous quinine in reducing and/or eradicating malaria parasites from children.

In April, Suda said the 151-paediatric subject, phase III trial of sub-lingual Artimist had shown significant superiority to intravenous quinine in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications (BD: Apr 30).

Suda said at that time that 95.6 percent of Artimist patients had reduced parasite counts by more than 90 percent in the first 24 hours, compared with 40.6 percent using intravenous quinine ($p < 0.005$).

Suda said in April that it clearly met both primary efficacy endpoints, but under secondary endpoints, there was no significant difference in complete cure rates.

Today, Mr Carter said that from onset of malaria-related fever most children under the age of five years would die without treatment in 24 hours.

He said that a small 7ml bottle of Artimist which was “not expensive to make” contained 70 sprays of the 6mg dose.

Mr Carter said the value of Artimist was its ability to stabilize a sick child, quickly and easily so that further treatment could be better managed.

Mr Carter said that in Africa, charities, governments and multinational corporations each had about one third of the malaria treatment market.

Mr Carter said that at the same time as completing the commercialization of Artimist, he expected to close the $2 million acquisition of Novodel and its medication spray technology platform by early July (BD: Apr 8, 2013).

He said that the platform could be used with a wide range of drugs, extending their patent life through a spray delivery system.

Mr Carter said that the first four drugs to be proposed for registration were sumatriptan for migraine, sildenafil (Viagra) for erectile dysfunction, odansetron for chemotherapy induced nausea and midazolam for pre-operation anxiety.

Mr Carter said that the wholly owned subsidiary Westcoast Surgical and Medical Supplies had improved its sales of hospital and medical supplies, was averaging monthly revenues of about $320,000 and had reached a break even point.

He said that Suda had $1.3 million in cash at March 31, 2013, and with the Artimist trial completed, was burning about $100,000 a month.

Mr Carter said he would continue the road-show to Adelaide and Brisbane later this year.

Suda was up 0.2 cents or 7.1 percent to three cents.

BIOTRON

Biotron says it has received $891,951 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Biotron said that the rebate related to research and development expenditure in 2011-’12 for its HIV and hepatitis C programs.

Biotron chief executive officer Dr Michelle Miller said the cash rebate “strengthens Biotron's cash position and is an important source of funds for the company's research and development activities”.

Biotron fell half a cent or five percent to 9.5 cents.

REVA MEDICAL

Last night's edition reported that all resolutions to the Reva annual general meeting including director stock issues were passed overwhelmingly, except the change of auditors with the resolution to appoint Ernst & Young opposed by 5,234,246 US common stock votes (23.49%) with 17,057,556 votes (76.51%) in favor.

Today, executive chairman Robert Stockman told Biotech Daily that the opposing votes were "an error" and Ernst and Young received 100 percent support with the votes entered incorrectly.

No sub-editors were injured in making this correction, but that butterfly over California is eying China very carefully.

Reva fell three cents or 5.3 percent to 54 cents.