Biotech Daily

Tuesday March 22, 2011

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: PRANA UP 48.5%; GENERA DOWN 7%**

*** NOVOGEN'S 19% PHASE II PHENOXODIOL OVARIAN CANCER RESPONSE**

*** BENITEC'S US GRAHAM PATENT SETTLED**

*** PRANA FLIES 75% (84% ON NASDAQ) ON MHRI DATA**

*** KARMELSONIX, HEALTHY SLEEP PARTNER FOR CHEST TESTS**

*** CITIGROUP TAKES 5% OF PATRYS**

*** IAN MACPHERSON, FATS TAKE 6% OF AVITA**

*** BAHEN & BAHEN TAKE 7% OF NARHEX**

*** SOLAGRAN EARNS $179k IN 3 MONTHS; FDA WANTS DATA CLARIFIED**

MARKET REPORT

The Australian stock market edged up 0.01 percent on Tuesday March 22, 2011, with the S&P ASX 200 up 0.6 points to 4643.4 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, five traded unchanged and eight were untraded. All three Big Caps were up.

Prana was best for the second day in a row, up eight cents or 48.5 percent to 24.5 cents with 3.6 million shares, followed by Antisense up 11.1 percent to one cent with nine million shares traded.

Advanced Surgical climbed 10 percent; Benitec was up 7.4 percent; Phylogica, Prima and Sunshine Heart were up more than six percent; Pharmaxis and Phosphagenics climbed more than three percent; Heartware rose two percent; with Bionomics, Biota, Clinuvel and Resmed up more than one percent.

Genera led the falls, down two cents or 7.1 percent to 26 cents, with 124,000 shares traded.

Cellmid and Genetic Technologies lost four percent or more; Chemgenex and Universal Biosensors fell more than three percent; Starpharma and Viralytics shed more than two percent; with Nanosonics down 1.1 percent.

NOVOGEN, MARSHALL EDWARDS

Novogen's 71 percent subsidiary Marshall Edwards says three of 16 (19%) platinum-resistant ovarian cancer patients responded to intravenous phenoxodiol with cisplatin.

Novogen said the phase II study, published in the International Journal of Gynecological Cancer, suggested phenoxodiol was active when administered intravenously in combination with the platinum-based chemotherapy for ovarian cancer.

The company said the study, conducted at Yale-New Haven Hospital, showed that the combination of intravenous phenoxodiol, a novel nicotinamide adenine dinucleotide with hydrogen (NADH) oxidase inhibitor, with cisplatin, a platinum-based chemotherapy, was well tolerated and resulted in an overall response rate of 19 percent or three of 16 ovarian cancer patients previously resistant to platinum.

Novogen said the response rate was defined as the percentage of patients whose tumor demonstrated a radiologically confirmed reduction or disappearance after treatment.

The study, entitled 'Evaluation of Phenoxodiol in Combination With Cisplatin or Paclitaxel in Women With Platinum/Taxane-Refractory/Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancers' was co-authored by former Novogen executive director Prof Alan Husband.

An abstract is at: http://www.ncbi.nlm.nih.gov/pubmed/21412168.

The abstract said that of the total 32 patients recruited to the trial there were no treatment-related deaths, one treatment-related hospitalization and two grade 4 toxicities.

In the cisplatin arm, there were three partial responses, nine patients (56%) achieved stable disease, four (25%) progressed and the overall best response rate was 19 percent, the abstract said.

The abstract said that in the paclitaxel arm, there was one complete response and two partial responses, eight patients (53%) achieved stable disease, four patients (27%) progressed and the overall best response rate was 20 percent.

Tufts Medical Center gynecologic oncologist and lead author Dr Michael G Kelly said the results suggested that the combination of intravenous phenoxodiol with cisplatin had a good safety profile "and may be capable of reversing resistance to platinum-based chemotherapy".

"This study provides early clinical proof-of-concept for the combination of NADH oxidase inhibitors with standard-of-care chemotherapy and lays the groundwork for the development of more potent next-generation compounds," Dr Kelly said.

Novogen said that phenoxodiol had been introduced into more than 400 patients in multiple clinical trials via oral or intravenous routes and has been well tolerated.

The company said that Marshall Edwards had identified NV-143 that in laboratory studies demonstrated significantly more activity than phenoxodiol against a broad range of tumor cell lines.

Novogen said that In addition to being more active as a single agent, NV-143 appeared to be superior in its ability to synergize with platinum-based chemotherapy in pre-clinical studies.

Novogen said Marshall Edwards planned to begin a phase I clinical trial of intravenous NV-143 later this year, followed immediately by randomized phase II trials in combination with chemotherapy.

Marshall Edwards acting chief medical officer Dr Robert Mass said the published results "combined with data from previous studies reinforce our conclusion that intravenous administration is the optimal route of delivery for this class of drugs and give us added confidence moving forward as we develop our next-generation compound NV-143 for the clinic".

Novogen was up four cents or 30.8 percent to 17 cents.

BENITEC

Benitec says the US Patent and Trademark Office has issued the re-examination certificate for the Graham '099 patent.

The patent, entitled 'Genetic Constructs for Delaying or Repressing the Expression of a Target Gene', has been the subject of a long-running legal action defended by Benitec and the Commonwealth Scientific and Industrial Research Organisation and the certificate finalizes the intellectual property dispute.

The patent covers the use of expressed RNA interference in human therapeutic applications (BD: May 5, 2009; Jan 29, Sep 30, 2010; Feb 17, 2011).

Benitec said today the finalization "effectively reinstates the patent which had been subject to challenge and provides Benitec with the exclusive US rights to ddRNAi technology for research use and as human therapeutics".

The company said substantial progress had been made with the Graham patent applications in Europe, where all outstanding objections to the pending claims by the European Patent Office had been overcome.

Benitec said allowance in Europe would result in allowance of the Graham patent applications in every major Western jurisdiction in which it was being pursued.

The company said a range of related patent applications were under consideration, had been accepted or had been granted in Australia, Canada, India, Japan, China, Hong Kong and Singapore.

Benitec chief executive officer Dr Peter French said the "significant progress made in the Graham patent family in a range of countries reinforces Benitec's dominant worldwide position in the field of ddRNAi and enables us to execute our strategy of building a pipeline of novel ddRNAi-based therapeutics whose commercial potential is protected by a robust intellectual property position".

Benitec was up 0.2 cents or 7.4 percent to 2.9 cents with 4.2 million shares traded.

PRANA BIOTECHNOLOGY

Last night on the Nasdaq, Prana shares climbed $US1.23 or 83.67 percent to $2.70 with 9,679,350 shares traded.

Yesterday, Prana announced anatomical data from Victoria's Mental Health Research Institute supporting clinical and preclinical observations on the efficacy of PBT2 for Alzheimer's disease (BD: Mar 21, 2011).

The company climbed 2.5 cents or 17.9 percent to 16.5 cents yesterday and today closed up eight cents or 48.5 percent to 24.5 cents with 3.6 million shares traded.

KARMELSONIX

Karmelsonix says it has a joint venture with Sydney's Healthy Sleep Solutions International to provide home testing of nocturnal wheeze, cough and asthma.

Karmelsonix said Healthy Sleep Solutions was "Australia's leading home sleep testing service provider" with 30 percent market share in Australia and with operations in India.

The company said the venture would use its Wholter medical device through Healthy Sleep's patient disease management and established networks systems.

Karmelsonix chief executive officer Ross Haghighat said the venture was "projected to provide up to over 24,000 tests annually" contributing significantly to revenue.

The company said the partnership could be "scalable beyond Australia and specifically applicable to the massive US [and] European markets".

Karmelsonix was unchanged at 1.8 cents with four million shares traded.

PATRYS

Citigroup Global Markets Australia has become a substantial shareholder in Patrys with the acquisition of 12,483,366 shares or 5.01 percent of the company.
The initial substantial shareholder notice said Citigroup bought the shares as prime broker for a number of related parties but did not disclose the cost of the shares.
Patrys was unchanged at 10 cents.

AVITA MEDICAL

Ian Macpherson and Fats Pty Ltd have become substantial shareholders in Avita with the acquisition of 6,649,997 shares or 5.64 percent of the company.
The initial substantial shareholder notice said Mr Macpherson and Susan Macpherson of Claremont, Western Australian were related parties to Macadam Pty Ltd and the Macib Family and on March 21, 2011, bought 1,000,000 shares for $105,000 or 10.5 cents a share.
Avita was up half a cent or five percent to 10.5 cents.

NARHEX LIFE SCIENCES

Mark and Margaret Bahen have become substantial shareholders in Narhex with the acquisition of 30,000,000 shares or 6.97 percent of the company.
The initial substantial shareholder notice said Mr and Ms Bahen bought the shares through their superannuation account for $90,000 or 0.3 cents a share.
Narhex was up 0.3 cents or 17.65 percent to two cents with 1.3 million shares traded.

SOLAGRAN

Solagran says it has sold 1079 bottles of its over-the-counter cure all Ropren in the three months to the end of February 2011.
The company said it reduced its charge from $US1150 to $US600 per course of six bottles of Ropren, in January 2011, implying revenue of about $US179,425 for the three months.
Solagran said it had sold a total of 3,602 bottles implying further revenue of $US483,575 since sales began or a total of about $US663,000.
Last year, Solagran said it was “confident of achieving the forecast previously provided of selling in excess of 13,000 courses [78,000 bottles] of Ropren by December 2010” (BD: Mar 12, 2010).
Today, Solagran said it spoke with representatives of the US Food and Drug Administration in mid-January 2011.
“The FDA has requested further clarification on some of the statistical data supplied in support of our application,” Solagran said.
“We are working with the trial coordinators to collate this data,” the company said.
“This data will then subject to an independent review by an appropriately certified specialist for conducting clinical trials prior to re-submission to the FDA,” Solagran said.
Solagran was up 0.7 cents or 7.8 percent to 9.7 cents.