Biotech Daily

Thursday September 9, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: STARPHARMA UP 6%; BENITEC DOWN 8%**

*** NOVOGEN SELLS ISOFLAVONE CANCER IP TO MARSHALL EDWARDS**

*** BIOGUIDE BRIEF: NOVOGEN TO BE CASH FLOW POSITIVE – DUH, WUH?**

*** ATCOR: 'US FDA BACKS CENTRAL BLOOD PRESSURE IN DRUG TRIALS'**

*** UNIVERSAL BIOSENSORS LOSES CEO MARK MORRISSON**

*** BIODIEM WINS FDA ORPHAN STATUS FOR NEW BDM-E INDICATION**

*** HEALTHLINX ADDS MORE UK CENTRES TO OVPLEX TRIAL**

*** UBS AG TAKES 13% OF CATHRX; PRIME BROKER, MARGIN CALLS**

*** NUSEP ESTABLISHES SCIENTIFIC ADVISORY COMMITTEE**

MARKET REPORT

The Australian stock market climbed 0.99 percent on Thursday September 9, 2010, with the ASX200 up 45 points to 4582.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and 10 were untraded.

Starpharma was best, up three cents or 6.1 percent to 52 cents with 95,935 shares traded, followed by Phosphagenics up half a cent or 5.5 percent to 9.6 cents with 155,000 shares traded.

Prana was up four percent; Novogen and Prima climbed more than three percent; Acrux, Pharmaxis and Tissue Therapies rose more than two percent; with Alchemia and Biota up more than one percent.

Benitec led the falls, down 0.2 cents or 8.3 percent to 2.2 cents with 1.7 million shares traded.

Patrys, Phylogica, Viralytics and Virax lost more than three percent; Clinuvel shed 2.2 percent; with Cellestis and Chemgenex down more than one percent.

NOVOGEN

Novogen expects to sell its isoflavone-related intellectual property to 71.3 percent US subsidiary Marshall Edwards for “several million dollars” in stock.

Novogen said it had reached agreement in principle with Marshall Edwards to sell the portfolio of isoflavone intellectual property, primarily developed for cancer indications.

The company said the specific terms of the proposed agreement were not disclosed but Novogen chairman Philip Johnston told Biotech Daily that the stock-based transaction was worth “several million dollars”.

Mr Johnston said the percentage ownership of Marshall Edwards would increase initially, but when Marshall Edwards had a capital raising, the percentage would fall back.

Mr Johnston said Novogen would focus on its consumer products, Promensil for menopause and the Trinovin dietary supplement for prostate health.

The consumer assets brought $8 million to Novogen in the last financial year (see below).

Mr Johnston said Novogen would try to find investors or partners for the glucan program through 80.7 percent subsidiary Glycotex Inc.

Novogen has previously said GLYC-101 was intended to stimulate and modulate the natural cascade of wound healing activities in several cell populations, with GLYC-101 a topical gel applied directly to the wound surface.

Mr Johnston said it made more sense to have the isoflavone technology with Marshall Edwards where the majority of research and development work was being conducted.

Marshall Edwards has licenced the rights from Novogen for isoflavone oncology drug candidates phenoxodiol, triphendiol, NV-143 and NV-128.

The closing of the transaction is subject to due diligence, the execution of a definitive agreement, an independent fairness opinion and shareholder approvals.

Novogen’s annual report said that gross revenue for the year to June 30, 2010 was $9.9 million with consumer health sales worth $8.0 million, a decrease of $300,000 or 3.6 percent. The report said that the chief executive officer of Glycotex Dr Reinhard Koenig had a base salary of $US315,000 ($A342,000) per annum.

Novogen was up half a cent or 3.85 percent to 13.5 cents.

MARC SINATRA’S BIOGUIDE BRIEF: NOVOGEN

Push this here, move that there and.....bingo, we’re cash flow positive, hang on, we might even be in profit!

By entering into a deal to offload its Isoflavone drug development portfolio to its subsidiary company, Marshall Edwards, Novogen looks to have done just. While Novogen argues that strategic rationale is behind the deal, why wasn’t the deal done sooner, a lot sooner?

There are several reasons for the existence of Novogen’s Nasdaq-listed subsidiary Marshall Edwards, such as access to US capital. Another is that it allowed Novogen to announce licencing deals, even if those deals were to a related party. Very few endorsements beat a licencing deal to justify the worth of your technology.

This one last deal with Marshal Edwards appears to be a move by Novogen to distance itself from the failure of its lead compound phenoxodiol a few months back and provide the appearance that it is ridding itself of its troubled Isoflavone technology (Novogen gets Marshal Edwards shares in the deal, so it is still leveraged to the technology).

Both of these things should get investors somewhat excited, since based on Novogen’s 2010 annual report, without the drug development drag on funds, Novogen might has posted a $5-6 million gross profit.

Not bad for a company whose market cap has dwindled down to $13 million.

Marc Sinatra, Analyst

ATCOR MEDICAL

Atcor says the US Food and Drug Administration welcomes the use of its Sphygmocor central blood pressure measure for safety in pharmaceutical clinical trials.

Atcor said the clarification of the FDA position on the use of central blood pressure measurement, reported in the Journal of the American Society of Hypertension, was "a significant step forward in expanding its ability to penetrate the annual $US100 million pharmaceutical market".

An abstract of the article is at: http://www.ncbi.nlm.nih.gov/pubmed/20729159.

The company said the April 2010 meeting with the FDA was organized and sponsored by the Atcor-established North American Artery Society "to review the burgeoning evidence of the superiority of using central pressures as a biomarker and to gain a formal understanding of the FDA's current view on providing central pressures data in pharmaceutical trials".

A consensus outcome of the meeting was that "incorporating central blood pressure measurement for safety purposes is welcomed by the FDA," Atcor said.

The company said the Journal of the American Society of Hypertension summarized the meeting between representatives of academia, medical device and pharmaceutical companies, including Merck & Co, and the FDA.

Atcor chief executive officer Duncan Ross said his company was "delighted that the FDA has taken this position, as it will strengthen the pharmaceutical trial industry's confidence that central blood pressure data should be formally included in their drug applications and safety reporting".

"Lack of clarity to date has limited the number of pharmaceutical companies incorporating central pressures in their drug trials and the use of central pressure measurement within trials," Mr Ross said.

"We now expect use of central blood pressure measurement to increase," Mr Ross said.

Atcor was untraded at 12 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says chief executive officer Mark Morrisson will retire effective from today but will assist in corporate development efforts for a transitional period.

In a media release to the ASX, Mr Morrisson said that the launch of the Johnson & Johnson Lifescan One Touch Verio glucose diagnostic in the Netherlands in January 2010 and the launch last month in Australia (BD: Aug 9, 2010), Universal Biosensors had "completed a transformational step in its development".

Mr Morrison said the company was "at an inflection point and that as the company transitions to a substantial operating business, a different set of skills was now more appropriate to facilitate the further growth".

"I have thoroughly enjoyed leading Universal Biosensors through the development stage to where it is now and would like to find a similar opportunity to do it again," Mr Morrisson said.

The company said an executive search had begun and until a new chief executive officer was appointed, chairman Andrew Denver would assume the role of executive chairman and interim chief executive officer.

Mr Denver has a BSc in chemistry from the University of Manchester and a Harvard MBA. He worked for Baxter Healthcare for 12 years in roles including director of manufacturing engineering and president of medical devices and is a director of Cochlear and Cathrx.

Universal Biosensors fell one cent or 0.7 percent to $1.51.

BIODIEM

Biodiem says the US Food and Drug Administration has granted orphan drug designation for its BDM-E compound for the treatment of retinitis pigmentosa.

Biodiem began a phase I/II clinical trial for its peptide BDM-E for diabetic macula oedema in December 2005 and completed the 192-patient enrolment in August 2007 (BD: Aug 13, 2007).

Further studies were initiated for the wet form of age-related macular degeneration and diabetic retinopathy (BD: Aug 31, 2007).

In October 2007 Biodiem said BDM-E did not meet its endpoints for diabetic macular oedema but BDM-E was safe and well tolerated with no significant adverse events (BD: Oct 9, 2007).

Today, Biodiem said it would undertake an early stage clinical trial to establish proof-of-concept in retinitis pigmentosa and was seeking partners and funding.

Biodiem said preclinical work had demonstrated BDM-E's potential for the treatment of retinitis pigmentosa and mouse, rat and rabbit studies showed that BDM-E was able to reduce the degree of retinal damage of the retinal cell layers and that it could "exert a degree of protection of the retina in models of this disease".

The company said that in another research model of light damage, it prevented photoreceptor apoptosis (programmed cell death) when high doses were administered.

Biodiem said Russian use of BDM-E and results of an earlier clinical trial showed it had a good safety profile.

The company said retinitis pigmentosa was a rare but serious eye disease which caused progressive degeneration of the light receptor cells in the retina, which, over time, diminishes night and peripheral vision and eventually led to blindness.

Biodiem said the condition affected about one in 4,000 people, equivalent to 88,000 people in the US and there was no therapy that stops the evolution of the disease or restores vision.

The company said FDA orphan drug program was intended to support the development of new drugs in rare diseases affecting fewer than 200,000 people in the US with incentives including study design assistance, exemption from application filing fees, grant funding for clinical trials, tax credits for clinical research and seven years of US market exclusivity after marketing approval.

Biodiem chief executive officer Julie Phillips the company wanted "to co-develop or out-licence the product, initially for the US market and then consider expansion into other indications".

Biodiem was untraded at 15 cents.

HEALTHLINX

Healthlinx says it has increased the number of UK sites in its second study of its Ovplex ovarian cancer diagnostic.

The company said the Liverpool Women's Hospital and Clatterbridge Centre for Oncology would also contribute samples for study.

Healthlinx said sample collection had begun with the UK expected to contribute up to 600 for the 1150 patient samples to be tested.

The company said it already had more than 500 samples of which 450 would be used for the first stage of the second study.

Healthlinx said the results were expected by the end of 2010.

Healthlinx was up 0.2 cents or 2.2 percent to 9.2 cents.

CATHRX

UBS AG and related bodies corporate have increased their substantial shareholding in Cathrx from 12,512,500 shares (8.83%) to 18,012,500 shares (12.57%).

The substantial shareholder notice said the holders of the interests in Cathrx were UBS AG's London and Sydney branches and the holdings were subject to 'prime broker' agreements, including margin call provisions.

Cathrx was untraded at 18 cents.

NUSEP

Nusep has establishment of a scientific advisory committee chaired by Prof John Aitken.

Nusep said the committee would help it direct development projects such as Spermsep and other biological separations, review developments in the Proteoiq software area and evaluate the alternative gel products that the company was considering developing.

Prof Aitken is at the University of Newcastle, New South Wales, graduated from the University of London in 1969 in physiology and holds a PhD in reproductive biology from the University of Cambridge.

Other committee members include the University of Georgia's Prof Ron Orlando, Dr Colin Wrigley and Nusep chief scientific officer Dr John Andrews.

Nusep was untraded at 21.5 cents.