Biotech Daily

Monday January 24, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BENITEC UP 21%; ANTISENSE DOWN 12.5%**

*** QRX MOXDUO TRIAL v EQUAL STRENGTH MORPHINE, OXYCODONE**

*** NOVOGEN PLEADS SCHULTZ TO ASX 70% PRICE QUERY; UP 50%**

*** TRIDENT REVIVES SAFETY MEDICAL; RETURNS TO ASX TOMORROW**

*** AVITA PLACEMENT RAISES $722k**

*** CLINUVEL MAY FILE IN 2011, STAYS FOCUSED, CONSIDERS NEW DRUGS**

*** LBT APPOINTS DR MIKE HIRSHORN DIRECTOR**

*** PHYLOGICA WINS FROST & SULLIVAN GONG**

MARKET REPORT

The Australian stock market climbed 0.64 percent on Monday January 24, 2011 with the S&P ASX 200 up 30.3 points to 4786.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and four were untraded.

Benitec was the best, up 0.7 cents or 21.2 percent to four cents with 16.9 million shares traded, followed by LBT up 14.7 percent to 7.8 cents with 12,800 shares traded.

Genetic Technologies climbed 8.7 percent; Prana and Virax were up more than seven percent; Cellmid was up 6.1 percent; Phylogica was up 5.9 percent; with Alchemia, Clinuvel, Nanosonics and Pharmaxis up more than one percent.

Antisense led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 100,000 shares traded, followed by Compumedics down 8.6 percent to 16 cents with 70,618 shares traded.

Bionomics, Immuron and Phosphagenics lost more than three percent; Chemgenex, Prima, Tissue Therapies and Viralytics shed more than two percent; with Cochlear, Heartware, Impedimed, Patrys, Sirtex and Starpharma down more than one percent.

QRX PHARMA

QRX has begun its phase III trial comparing the tolerability and safety profile of Moxduo IR (immediate release) to equi-analgesic doses of either morphine or oxycodone given alone.
QRX said the study (Study 022) would compare the incidence level of the opioid-related adverse events of moderate to severe nausea, vomiting and dizziness and changes in respiratory function in patients with moderate to severe postoperative pain following bunionectomy surgery.
The company said it expected to complete dosing by July 2011 and the results would form part of a marketing authorization application to European regulators later this year and once published in medical literature, might be a component of the promotional package following projected commercial launch of Moxduo IR in the US and in Europe in 2012, along with other trial data.
QRX chief executive officer Dr John Holaday said that “every trial conducted to date has demonstrated the benefits of Moxduo, achieving as good or better pain relief with fewer incidences of moderate to severe side effects when compared with morphine, oxycodone or Percocet”.
“We expect this head-to-head comparison of Moxduo IR versus equi-analgesic doses of morphine and oxycodone will provide data confirming the competitive advantages of our product over current standards of care,” Dr Holaday said.
QRX said the randomized, double-blind, fixed-dose phase III trial of about 375 patients would compare Moxduo IR (12mg morphine and 8mg oxycodone) with morphine equivalent doses of morphine (24 mg) and oxycodone (16 mg) given once every six hours. Safety will be measured by recording adverse events, changes in vital signs and respiratory function as well as other endpoints.
QRX said the results were expected to confirm the significant tolerability and safety advantages of Moxduo IR.
The company said that a prior study with postoperative bunionectomy pain patients demonstrated the potential side effect and safety benefits of a lower dose of Moxduo IR (6mg and 4mg) when compared to equi-analgesic doses of morphine (12 mg) or oxycodone (8 mg).
QRX said the occurrence rate of moderate to severe adverse events including nausea, vomiting and dizziness was reduced by 50-75 percent in Moxduo IR treated subjects compared to patients receiving morphine or oxycodone alone at the same 12 mg morphine-equivalent dose (MED).
The company said the phase III (022) study announced today was similarly designed, but compared Moxduo (12mg and 8mg) with 24mg MEDs of morphine and oxycodone.
QRX was unchanged at $1.45.

NOVOGEN

Novogen has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose from 11.5 cents on January 17, 2011 to 19.5 cents, a 69.6 percent increase, today and noted an increase in trading volume.
Novogen last traded up 53.45 percent to $US1.12 on the Nasdaq on January 21, 2011 having fallen from more than $2.80 a year ago, to a low of 41 cents on November 18, 2010.
Novogen’s 70 percent subsidiary Marshall Edwards was up 59.3 percent to $2.90 on January 21, 2011.
Novogen was up six cents or 50 percent to 18 cents with 1.4 million shares traded.

SAFETY MEDICAL PRODUCTS

The ASX says Safety Medical will return to trading tomorrow.
Last year, Safety Medical went into voluntary administration having been suspended for failing to lodge full year accounts (BD: Mar 1, Apr 16, 2010).
Trident Capital was appointed by the administrators and the company's three directors Simon Lill, Peter Christie and Stephen Hewitt-Dutton are all associated with Trident, which is also involved in reviving Narhex Life Sciences.
In a series of announcements today Safety Medical said it had raised $2.2 million and detailed a program of expenditure over two years to revive the company.
Safety Medical said that former chief executive officer John Riemelmoser had been retained as a technical consultant for an initial term of 12 months.
Safety Medical said it had registered trademarks in Australia including Safetymed, Securetouch and Syringesafe and had registered Securetouch in New Zealand.
The company said it listed on the ASX to finalize commercialize and produce its range of safety syringes and had Australian Therapeutic Goods Administration certification.
Safety Medical said it was not able to develop the machining capability to produce the full range of safety syringes and had limited sales of a 1 ml syringe, with failure to break through into more substantial markets as it was unable to offer a range of products to successfully compete against rivals with a full range of syringes (1ml, 2ml, 5ml and 10ml).
Safety Medical said that before investing in new facilities it would "undergo a detailed evaluation of the technology in order to then consider how best to commercialize it".
Options include acquisition of assembly machine technology capable of producing all sizes and sole manufacture in new premises; partnering with other medical technology companies to use the company's technology, share facilities and equipment and access their medical distribution network; technology licencing or sales on an exclusive basis to key regions around the globe; and enhancement of existing technology and development of ancillary technology, using the existing skills base, the company said.
Safety Medical said a detailed review process could take up to 12 months.
The company said its business plan included the retention of existing intellectual property rights including all patents and trademarks relating to its medical product business; reviewing the syringe industry as a precursor to deciding the best path forward to further develop its asset base of intellectual property rights; and identify investment opportunities.
Safety Medical said its focus was to continue development of its Securetouch syringe and associated technologies, but a portion of the Company's assets would be in cash.
The company said its directors had commercial and public company experience as well as experience in project development, finance and corporate transactions.
Safety Medical last traded at 3.7 cents but has since had a one-for-five consolidation.

AVITA MEDICAL

Avita says it has raised $US722,000 through the placement of 6,077,441 shares at 12 cents a share with one attaching option for every two new shares.
Avita said the shares were placed through a US investment group and the options were exercisable at 20 cents by January 31, 2014.
The company said the funds would assist in the further development of its Recell wound treatment and assist in paying for the acquisition of unmarketable parcels of shares (BD: Jan 16, 2011).
Avita said an Australian investor had bought 2,000,000 of the 3,930,869 shares from 3,312 shareholders.
Avita fell one cent or 7.1 percent to 13 cents.

CLINUVEL

Clinuvel chief executive officer Dr Philippe Wolgen says the company will stay focused on its lead drugs and hopes to file regulatory applications this year

In a letter to shareholders released to the ASX Dr Wolgen said results were due from the Scenesse or afamelanotide trials including a US phase II trial and a European phase III trial for eythropoietic protoporphyria as well as results from the phase III polymorphic light eruption trials and the first study in vitiligo.

“Additionally, we expect further regulatory meetings with the [US Food and Drug Administration and European Medicines Agency] which will to lead to the company’s first filing for marketing authorization,” Dr Wolgen said.

“At this critical stage the preparation of our European filing dominates our efforts,” Dr Wolgen said. “Writing the proper dossier with the required modules – according to industry guidelines – is an enormous challenge.”

Dr Wolgen said a question often posed was whether the company should not be diversifying its efforts and adding more products to its pipeline.

“My view has always been that one or two products (CUV9900) is on the thin side for Clinuvel,” Dr Wolgen said. “However, a valuable managerial lesson to be learned is that of focus. Progress to date would not have been conceivable without the rigor and concentration of effort.”

“Nevertheless, management has not ceased to look for opportunities which may be synergistic and which may add value to the company,” Dr Wolgen said.

“With more certainty of regulatory filing and the commercialization of Scenesse in sight, diversification can no longer be rejected,” he said.

Clinuvel was up four cents or 1.85 percent to $2.20.

LBT INNOVATIONS

LBT has appointed Dr Mike Hirshorn as a non-executive director.

LBT said Dr Hirshorn had more than 30 years experience in technology companies and was a founder and chief executive officer of Cochlear and a founding director of Resmed.

LBT said Dr Hirshorn had about 10 years of private equity experience, invested in several technology companies and worked with them on the development and implementation of their growth strategies and had expertise in commercializing medical diagnostic and therapeutic devices including in the microbiology field.

Dr Hirshorn resigned form the board of ITL last year (BD: Aug 11, 2010) and continues as a director of Biotron and Cathrx

LBT was up one cent or .14.7 percent to 7.8 cents.

PHYLOGICA

Phylogica says it has won the 2011 Asia-Pacific Frost & Sullivan new product innovation award for peptide screening technologies for its Phylomer platform.

Phylogica said the award demonstrated its leadership “in realizing the untapped potential of nature’s vast biodiversity to discover novel peptide-based drugs”

Phylogica was up 0.4 cents or 5.9 percent to 7.2 cents.