Biotech Daily

Tuesday November 26, 2013

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: ANTISENSE UP 7%, VIRALYTICS DOWN 10%**

*** QRX RESUBMITS MOXDUO FDA APPLICATION, AGAIN**

*** DAGMAR DOLBY TAKES 8% OF COGSTATE**

*** NOVOGEN FILES US ANTI-TROPOMYOSIN DRUG PATENT FAMILY**

*** BANK OF AMERICA, MERRILL LYNCH TAKE 5.5% OF SUDA**

*** MAYNE AGM 8% OPPOSE EXECUTIVE OPTION CHANGE**

*** IM MEDICAL PLEADS TECHNOLOGY NEWS TO ASX 200% QUERY**

*** ACTINOGEN TO LOSE EXECUTIVE DIRECTOR DAVID ZOHAR**

*** SOLAGRAN APPOINTS DR DARREN SCHLIEBS CEO**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Tuesday November 26, 2013 with the S&P ASX 200 up 4.2 points to 5,357.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and two were untraded.

Antisense was the best, up one cent or 6.9 percent to 15.5 cents with 227,867 shares traded.

Cellmid and Optiscan climbed five percent or more; Genetic Technologies and Mesoblast were up more than four percent; Admedus (Allied Health) was up 3.2 percent; Bionomics, Psivida and Sirtex were up more than one percent; with Acrux, Cochlear, CSL, Prana and QRX up by less than one percent.

Viralytics led the falls, down 3.5 cents or 9.6 percent to 33 cents with 169,476 shares traded, followed by Anteo down 9.1 percent to 15 cents with 21.7 million shares traded.

Medical Developments, Neuren and Uscom lost more than six percent; Reva fell 5.5 percent; Compumedics, Living Cell, Patrys, Pharmaxis and Universal Biosensors fell more than four percent; Benitec, Clinuvel and Starpharma were down more than three percent; percent; Atcor, GI Dynamics, Nanosonics, Prima and Tissue Therapies shed more than two percent; with Alchemia and Resmed down more than one percent.

QRX PHARMA

QRX says it has resubmitted its dual opioid Moxduo combination or morphine and oxycodone new drug application to the US Food and Drug Administration.

QRX chief executive officer Dr John Holaday said the company was “confident that our refiled NDA will confirm the validity of the data defining the product’s respiratory safety advantages and we are hopeful that the FDA will view them favorably in their consideration of the benefits of immediate release Moxduo as a therapeutic option for the millions of patients who suffer from acute pain”.

“We were encouraged by our candid dialogue with the FDA throughout this process, and will continue to liaise closely with the Agency to bring Moxduo to market,” Dr Holaday said.

QRX said that the FDA previously confirmed that the combination rule trial, Study 008, satisfied efficacy requirements and that there were no efficacy or safety issues identified in any of the studies submitted in the original NDA.

QRX said that it completed an audit of the more than 30 million data points for oxygen desaturation from Study 022 which demonstrated a significant respiratory safety advantage for Moxduo over equi-analgesic doses of morphine or oxycodone.

The company said that Moxduo provided a lower starting dose and finer dose titration steps than acute pain opioids presently available, giving greater flexibility to physicians and patients as the need for pain relief is balanced with lower risks of side effects.

QRX said it expected the FDA to schedule an advisory committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following this submission, projected for late May, 2014.

Last year, the FDA rejected the Moxduo application saying it required further data comparing the combination drug’s 12mg morphine and 8mg oxycodone to equi-analgesic doses of its component parts, that is, either 24mg morphine alone or 16mg oxycodone alone, not just 12mg morphine alone or 8mg morphine alone (BD: Jun 27, 2012).

QRX previously said the FDA had advised to would accept the drug measured against its component parts as it was in Study 008.

The 375-patient phase III post-bunionectomy Study 022 compared Moxduo to equi-analgesic doses but that wasn’t originally filed to the FDA.

Following resubmission earlier this year, QRX discovered errors in time zones and daylight savings at one of the trial centres and requested further time to correct the data (BD: Feb 28, Jun 27, 2013).

In August, QRX received a second ‘complete response letter’ from the FDA and said it would provide more data to the FDA and expected to launch the combination drug in 2014 (BD: Aug 28, 2013).

QRX was up half a cent or 0.8 percent to 60 cents.

COGSTATE

The Dagmar Dolby Trust has become a substantial shareholder in Cogstate with 8,108,108 shares or 8.04 percent.

The substantial shareholder notice said that the San Francisco, California-based Dagmar Dolby Trust acquired the shares on November 22, 2013 in a placement at 37 cents a share (BD: Nov 19, 2013).

Cogstate was up 1.5 cents or 4.05 percent to 38.5 cents.

NOVOGEN

Novogen says it has filed a family of provisional patents in the US covering anti-tropomyosin drug technology.
Novogen said that the technology was “an entirely novel approach to anti-cancer therapy, blocking the ability of cancer cells to divide and doing so in a highly cancer-specific way”.
The company said that based on their action, anti-tropomyosins belonged to a class of anti-cancer drugs known as anti-mitotics.
Novogen said that current anti-mitotic drugs were taxanes and vinca alkaloids and were among the most widely prescribed anticancer drugs after 40 years of use.
Novogen chief executive officer Dr Graham Kelly said that filing the patents was “a critical step for the company in protecting such a potentially valuable piece of intellectual property”.
“Taxanes continue to dominate anti-cancer therapy even though they recently came off-patent,” Dr Kelly said.
“We believe that [anti-tropomyosin] drugs have the ability to replace taxanes and to become the next generation of anti-mitotic drugs,” Dr Kelly said.
Novogen said that tropomyosin was a protein found in actin filaments, a key component of the cytoskeleton of a cell and actin filaments provided a cell with the ability to contract.
The company said that during cell division the separation of the two daughter cells occurred through the formation of a ring known as the contraction ring and when it tightened, the two cells effectively separated.
Novogen said that anti-tropomyosin drugs targeted a particular isoform of tropomyosin known as Tm5NM1 on which cancer cells were highly dependent and targeting this particular tropomyosin isoform prevented formation of the contraction ring and the ability of the cancer cells to divide.
“The current generation of anti-mitotic drugs, despite their widespread use, comes with two key negatives,” Dr Kelly said.
“The first of those is a serious side-effect profile,” Dr Kelly said.
“The second is that many types of cancer are inherently insensitive to them,” Dr Kelly said.
“[Anti-tropomyosin drugs to date are showing an apparent lack of serious toxicity as well as an ability to kill cancer cells that are insensitive to taxanes,” Dr Kelly said.
Novogen said its anti-tropomyosin program was focused on prostate cancer, melanoma and children’s cancers where it would be used as a monotherapy, as well as adjuvant therapy in combination with the company’s super-benzopyran drug technology.
Novogen fell 1.5 cents or 5.9 percent to 24 cents with 3.4 million shares traded.

SUDA

The Bank of America Corp and related bodies say they have become substantial shareholders in Suda with 48,723,480 shares or 5.46 percent of the company.
The Charlotte, North Carolina-based Bank of America substantial shareholder notice said that the Sydney-based Merrill Lynch (Australia) Futures and London-based Merrill Lynch International were the holders of the shares as beneficial owner and as the borrower of securities in a prime brokerage agreement, respectively.
The notice said that on November 12, 2013 Merrill Lynch (Australia) Futures bought 24,444,080 shares for $806,655 or 3.3 cents a share and Merrill Lynch International acquired 24,279,400 on November 21, 2013 but did not state any payment.
Suda was up one cent or 16.95 percent to 6.9 cents with 30.4 million shares traded.

MAYNE PHARMA

Mayne Pharma's annual general meeting passed all resolutions, but with up to 8.2 percent opposition to changes to executive option schemes.

The strongest dissent was against the amendment of option terms for holders of unvested options with 21,639,545 votes (8.2%) against and 242,076,705 votes (91.8%) in favor.

Mayne said that under ASX Listing Rules, if a company had a pro-rata issue the exercise price of any existing options could be reduced, but under the terms of the employee share option plan, the formula did not apply to unvested options which it said was "unreasonable and unfair" and sought shareholder approval to adjust the unvested options.

Last year, Mayne Pharma raised $65 million to fund the Metric acquisition with a rights issue raising $24.7 million at 20 cents a share (BD: Oct 8, Nov 1, 2012).

Resolutions five and six related to 1,500,000 options to chief financial officer Mark Cansdale exercisable at 33 cents and 26,300,000 options for other executives with exercise prices of 25 cents, 33 cents, 41 cents and 43 cents.

The amendment to Mr Cansdale's options was carried overwhelmingly but there were 18.3 million votes against amendments to chief executive officer Scott Richards' option terms with 246.2 million votes in favor.

The remuneration report and the re-election of director Ian Scholes were carried overwhelmingly but the re-election of director Bruce Mathieson was opposed by 19.25 million votes and supported by 247.1 million votes.

The company's most recent Appendix 3B said that Mayne had 563,459,968 shares on issue meaning the strongest opposition came from 3.8 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

Mayne was up 6.5 cents or 8.8 percent to 80 cents with 12.6 million shares traded.

IM MEDICAL

IM Medical 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 climbed from 0.1 cents on November 22 to 0.3 cents, a 200 percent increase, on November 25, 2013 and noted an increase in trading volumes.

IM Medical said it had been pursuing resources opportunities but had shifted strategy to the technology sector, which was mentioned in chairman Nigel Blaze's address to the annual general meeting posted to the ASX on November 22 about the time the share price and volumes increased.

IM Medical said the opportunity was at an advanced stage of discussions but was not finalized, was incomplete and confidential.

IM Medical was up 0.1 cents or 50 percent to 0.3 cents with 29.1 million shares traded.

ACTINOGEN

Actinogen says that executive director David Zohar will resign as a director, effective from the close of business on December 16, 2013 and a would be announced prior to that time.

Actinogen had been developing actinomycetes from Western Australian soils to produce antibiotics, but had difficulty raising funds (BD: Dec 13, 2010; Jul 25, 2012; Aug 2, 2013).

In September, the company said that directors Prof Alan Morton, Dr David Keast, Simon England and chairman Dr Zhukov Pervan had all resigned along with Shoshanna Zohar resigning as company secretary (BD: Sep 24, 2013) ,

Actinogen was untraded at 1.5 cents.

SOLAGRAN

Solagran says it has appointed Dr Darren Schliebs as its chief executive officer.
Solagran describes itself as a “healthcare and wellness company” based in South Melbourne.
The company was developing a treatment for liver cancer and a raft of other indications based on its pine needle extract Ropren (BD: Feb 25, 2009; Feb 5, 2010).
Solagran had an agreement with Bioprospect which was terminated with Bioprospect alleging it could source the same pine needle extract cheaper elsewhere and the two companies were involved in litigation (BD: Jun 28, Aug 5, Sep 20, Oct 27, 2010).
Despite claims of expected large contracts and the building of a manufacturing plant in Russia, Solagran was suspended by the ASX for failing to lodge accounts for the six months to December 31, 2010 (BD: Mar 1, 2011).
The company was reinstated but was again suspended on March 1, 2012, following the failure to lodge half-year statutory accounts to December 31, 2012 (BD: Mar 9, 2012).
In February 2012, Solagran said it would form a joint venture with Russia’s Art Life to develop and manufacture food additive products using its conifer needle extract ‘Bioeffectives’ and quoted Art Life founder and owner Prof Alexander Avstrievskih “forecasting revenues in the order of $US100 million [$A93.6 million] for 2012”.
Today, Solagran said that Dr Schliebs was “an experienced senior executive in the biotechnology and health sectors who has developed a unique blend of expertise and experience in technology and research management, business development, strategy, stakeholder relations and team leadership”.
The company said that Dr Schliebs had published several articles in the scientific and popular science literature and was the author on a granted patent.
Solagran said that Dr Schliebs had senior management experience from start-up companies Alchemia and Progen Pharmaceuticals to billion-dollar revenue enterprises such as CSR “and most recently reported to the board and [chief executive officer] of leading Australian complementary medicine and dietary supplement company Integria Healthcare in a business transformation role”.
Dr Schliebs’ Linkedin page said that he worked at Progen from 2003 to 2005 and Alchemia from 2000 to 2003.
Solagran said that Dr Schliebs held a Doctorate of Philosophy from the Australian National University and a Masters in Business Administration from the Australian Graduate School of Management.
Solagran remained suspended at 3.9 cents.