Biotech Daily

Monday July 22, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATCOR UP 44%, PATRYS DOWN 11%**

*** BIODIEM, CANBERRA UNI USE HEP D TO FIGHT LIVER DISEASE**

*** PHOSPHAGENICS CEO DR ESRA OGRU RESIGNS AS DIRECTOR**

*** ATCOR EXPECTS MAIDEN FULL-YEAR $2.8m PROFIT**

*** QRX, AESICA COLLABORATE ON 'STEALTH BEADLET' DETERRENT**

*** INVION BEGINS PHASE II TRIAL OF INV102 FOR SMOKING CESSATION**

*** PROGEN: 'MEDIGEN EXPECTS ENROLMENT BY END-OF-YEAR'**

*** PSIVIDA UNDERWRITTEN OFFER TO RAISE UP TO $12m**

*** AMP TAKES 7.7% OF ACRUX**

*** CONSTABLES TAKE 6% OF ANTISENSE**

*** CELLMID RELEASES 7,500,000 ESCROW SHARES**

*** SUDA REQUESTS ACQUISITION TRADING HALT**

*** BIO-MELBOURNE, SMALL TECHNOLOGIES CLUSTER US TOUR**

MARKET REPORT

The Australian stock market climbed 0.6 percent on Monday July 22, 2013 with the S&P ASX 200 up 29.8 points to 5,001.9 points. Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and six were untraded.

Atcor was the best, up 3.2 cents or 43.8 percent to 10.5 cents with 3.3 million shares traded, followed by Impedimed up 13.6 percent to 12.5 cents with 140,000 shares traded. Nanosonics climbed 9.4 percent; Viralytics was up 8.8 percent; Antisense rose 6.25 percent; Neuren and Phylogica were up more than five percent; Osprey climbed four percent; both Acrux and Alchemia were up three percent; Bionomics rose 2.8 percent; CSL, Heartware, QRX, Resmed, Reva, Sirtex and Starpharma were up one percent or more; with Clinuvel and Mesoblast up by less than one percent.

Patrys led the falls, down 0.3 cents or 11.1 percent to 2.4 cents with 391,000 shares traded. Cellmid lost 8.6 percent; Psivida and Universal Biosensors were down more than six percent; Phosphagenics fell 4.55 percent; Allied Health was down 3.9 percent; Prima shed 2.3 percent; Anteo, Ellex and Prana were down more than one percent; with Cochlear down 0.2 percent.

BIODIEM

Biodiem says it can engineer the hepatitis D virus to deliver a therapeutic payload to targeted liver cells, initially to treat hepatitis B.

Biodiem said that University of Canberra researchers had developed the system in which a vector is based on the hepatitis D virus.

The company said that the hepatitis D virus was a small, enveloped RNA virus requiring the envelope proteins of a helper virus, hepatitis B virus for further particle formation.

Biodiem said that hepatitis D could only infect liver cells and produce virus particles in cells that were also infected with hepatitis B and said that "based on this natural tropism for the liver and the successful generation of replication-competent recombinants this technologically has the potential to deliver biologically active therapies to the liver".

The company said that the technology would be relevant for hepatitis and liver cancer and due to the targeting, smaller dosages of currently used therapies could be given to liver disease patients, resulting in higher cure rates and/or fewer dose-related side effects.

Biodiem said the "groundbreaking work done recently has shown that the hepatitis D virus, which has been used as the basis for the technology, can be engineered into a stable and replication-competent virus, called a vector".

Biodiem said it had a global licence to the technology.

Biodiem chief executive officer Julie Phillips said the development "shows promise to support an array of new therapies targeting liver disease".

"We have filed international patents for this new vector technology and we envisage further development for specific treatments targeting viral hepatitis and liver cancer," Ms Phillips said. "This opens opportunities for vaccine manufacturers to design vaccines to target the liver selectively."

"The work conducted by the team at the University of Canberra has allowed us to file the patents necessary to protect the inventions associated with the development of this novel vector," Ms Phillips said.

The University of Canberra's Prof Ian Ramshaw said it was a significant development in the science supporting treatment of serious human disease affecting the liver.

Biodiem said that currently treatment was rarely curative and often associated with side effects which could cause patients to cease treatment and a targeted approach would open the possibility of better results for patients.

The company said that about 4.4 million Americans were living with chronic hepatitis and the global hepatitis market was estimated to be $3.2 billion in 2009 and expected to reach about $US5.9 billion by 2016, chiefly due to the large chronic carrier hepatitis population.

Biodiem was up 0.6 cents or 13.6 percent to five cents.

PHOSPHAGENICS

Phosphagenics says that suspended chief executive officer Dr Esra Ogru has resigned as a director of the company, effective from July 18, 2013.

Phosphagenics said it expected to receive the findings of its investigation into "irregular transactions in relation to its invoicing and accounting records" on July 23 and announce the key findings on July 24, 2013 (BD: Jul 1, 18, 2013).

Phosphagenics suspended Dr Ogru pending an investigation into the transactions on July 1, 2013 and said at that time that it believed that the amounts involved could be material, but did not affect the current cash balance of $14.1 million.

Biotech Daily understands that an unnamed major accounting firm is conducting the investigation and Dr Ogru has not returned to work since June 28, 2013.

Phosphagenics fell 0.5 cents or 4.55 percent to 10.5 cents.

ATCOR MEDICAL

Atcor says it expects to post its first full-year profit for the year to June 30, 2103 in the range of $2.7 million to $2.9 million when it publishes audited results on August 29, 2013.
Atcor said that unaudited sales of its Sphygmocor non-invasive measure of central blood pressures and arterial stiffness was up 40 percent to $9.0 million for the 12 months.
The company said that its cash balance at June 30, 2013 was $2.9 million compared to $1.1 million at June 30, 2012.
Atcor said sales to pharmaceutical companies sales was up 69 percent to a record $US6.1 million ($A6.6 million) with US non-pharmaceutical company sales up 21 percent to a record $US1.7 million.
The company said that sales in Australia and New Zealand were up 77 percent, but Asian and European sales declined.
Atcor chief executive officer Duncan Ross said the “focus on the global pharmaceutical and US market has increased sales substantially, supported by sales of our new Sphygmocor XCel system which greatly simplifies the ease of measuring central blood pressure in clinical practice”.
“This, together with effective cost management, has enabled Atcor to report its maiden full year profit this year,” Mr Ross said.
Atcor was up 3.2 cents or 43.8 percent to 10.5 cents with 3.3 million shares traded.

QRX PHARMA

QRX says it has a collaboration agreement with Aesica Pharmaceuticals for the wider use and promotion of its Stealth Beadlets abuse deterrence technology.
QRX said that Aesica Formulation Development supplied pharmaceutical contract development and manufacturing services from six sites in the UK, Germany and Italy.
The company said that Aesica had controlled drug services across the supply chain for which abuse or diversion might occur and was building relationships for supplying controlled drug active pharmaceutical ingredients and finished dose products to market.
QRX chief executive officer Dr John Holaday said that Aesica had extensive experience in formulation development and contract manufacturing and an established client base.
“A head-to-head comparison between Stealth Beadlets and a market leading abuse deterrent technology showed that Stealth Beadlets were more than twice as effective in reducing the percentage of oxycodone that could be extracted from a crushed controlled release tablet,” Dr Holaday said.
QRX said that Aesica would promote its Stealth Beadlets technology for inclusion in their clients’ formulations of controlled drugs and enter into fee-for-service contracts with third parties for the development of the new abuse deterrent formulations of specific drugs of interest, while QRX would negotiate licence terms directly with each party.
QRX said the Stealth Beadlets technology was developed for its Moxduo controlled release formulation of its dual opioid Moxduo for chronic pain and had shown that Stealth Beadlets for the delayed-release drug provided a potential once to twice-daily formulation.
QRX said that work was underway to assure that the abuse deterrent formulation technology conformed with US Food and Drug Administration guidelines.
QRX said that Stealth Beadlets could be incorporated “into almost any potentially abused drug … sold in solid dosage forms” such as tablet, capsule or sachet and had no effect on the active ingredient release profile, consisting of patient-safe, low cost, excipients that had generally regarded as safe FDA status, with patent applications were review at the US patent office, providing for product exclusivity until 2029.
QRX was up one cent or one percent to $1.01.

INVION (FORMERLY CBIO)

Invion says it has begun enrolment in its 136-patient, phase II clinical trial of INV102 in chronic bronchitis patients enrolled in a validated smoking cessation program.

Invion said the randomized trial was being conducted at two US and the primary objective was to evaluate the efficacy of INV102 in subjects with chronic bronchitis in improving rates of smoking cessation over a 10 to 12 week treatment period.

The company said that the primary outcome measure was the change from baseline in the average number of cigarettes smoked per day.

Invion said that the principal investigator was the former chair of the American Lung Association Dr Albert Rizzo.

Invion said that INV102, or nadolol, had been used in more than eight million people for the treatment of high blood pressure, migraine and chest pain and it was targeting the drug to the treatment of chronic inflammatory lung conditions, including asthma and chronic obstructive pulmonary disease.

Invion chief executive officer Dr Greg Collier said that the data from the trial would potentially advance a novel therapy for smoking cessation and would also add to the data package in the company's wider asthma and chronic obstructive pulmonary disease program.

Invion's chief medical officer Dr Mitchell Glass said that a therapy which could "reduce or eliminate smoker's cough, a common barrier to quitting smoking, could be life changing for patients".

Biotech Daily has asked Invion for evidence that smoker's cough was a barrier to quitting smoking but at the time of publication it was not available.

Invion said that earlier this year it began a trial of INV102 for asthma, which was funded by the US National Institutes of Health and a phase II trial of INV103, or chaperonin-10, for lupus was announced last week (BD: Jan 20, Jul 18, 2013).

Invion was up 0.1 cents or 2.9 percent to 3.5 cents with 3.2 million shares traded.

PROGEN PHARMACEUTICALS

Progen says that Taiwan licensee, Medigen Biotechnology expects to complete enrolment for its 500-patient phase III trial of PI-88 for liver cancer by the end of 2013.

Progen said that the trial was being conducted in Taiwan, South Korea and China and Medigen expected approval from the Taiwan Food and Drug Administration under the Cross-Strait Pharmaceuticals Research and Development Scheme for PI-88 to be marketed in Taiwan and China by the end of 2014, at the earliest.

The company said that the trial was designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection, with disease-free survival as the primary endpoint for efficacy assessment.

Progen said it was entitled to milestone payments based on various stages of clinical development and royalties on sales following marketing approval.

Progen fell three cents or 15.8 percent to 16 cents.

PSIVIDA CORP

Psivida says it expects to raise $US10.8 million ($A11.7 million) an underwritten public offer of 3,494,550 shares of its US common stock at $US3.10 ($A3.36) per share.

Psivida said the offer was expected to close on or about July 24, 2013 with Ladenburg Thalmann & Co as sole book-running manager and MLV & Co as co-manager.

Psivida fell 25 cents or 6.7 percent to $3.51.

ACRUX

AMP and related bodies have increased their shareholding in Acrux from 10,084,907 shares (6.06%) to 12,796,720 shares (7.68%).
The shares were acquired between May 30 and July 19, 2013 at a range of prices, with the single largest trade the purchase 372,513 shares for $1,257,384 or $3.375 a share.
Acrux was up 10 cents or three percent to $3.43 with 2.6 million shares traded.

ANTISENSE THERAPEUTICS

Jason and Catherine Constable have increased their substantial shareholding in Antisense from 72,000,000 shares (5.0%) to 87,920,107 shares (6.1%).
The shareholder notice said that Mr and Ms Constable acquired 15,920,107 shares for $200,593 or 1.26 cents a share.
Antisense was up 0.1 cents or 6.25 percent to 1.7 cents with 5.0 million shares traded.

CELLMID

Cellmid say that 7,500,000 shares issued on May 10, 2013 as part consideration for the Advangen acquisition will be released from voluntary escrow on August 10, 2013.
Cellmid chief executive officer Maria Halasz told Biotech Daily that a further 48,237,624 shares would be released from voluntary escrow between now and May 16, 2104.
Ms Halasz said that after all shares were released from escrow there would be 650,470,078 shares on issue and available for trading.
Cellmid fell 0.3 cents or 8.6 percent to 3.2 cents with 1.1 million shares traded.

BIO-MELBOURNE NETWORK, SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster and Bio-Melbourne Network want companies to join them for a Washington DC conference and tour of Boston and San Diego in September.
The Bio-Melbourne Network said that with the Small Technologies Cluster it would host a trade pavilion at the Advamed medical technologies conference in Washington September 23 to 25, 2103 and tour the major medical technology cities of Boston and San Diego from September 26 to Oct 2, 2013.
The Bio-Melbourne Network said it was seeking expressions of interest from Victorian biotechnology and medical technology companies to attend the trade mission and tour.
The Network said that Advamed was the leading medical technologies conference in North America, bringing companies together for business development, capital formation, technology showcasing, educational opportunities and networking.
The Network said that Boston was “Melbourne's oldest sister city relationship and one of the premier [medical technology] cities in the US”.
The Network said that San Diego was “equally as influential and connected [and] … the destination for BIO 2014” and had one of the largest information technology and venture capital clusters in the US.
The Network said that expressions of interest should be sent to chief executive officer Michelle Gallaher by email to mgallaher@biomelbourne.org by July 24, 2013.

SUDA
Suda has requested a trading halt “pending the release of an announcement concerning its proposed acquisition of the assets from Novadel Pharma”.
Trading will resume on July 24, 2013 or on an earlier announcement.
Suda last traded at 3.3 cents