Biotech Daily

Thursday February 19, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL UP 10%, POLARTECH DOWN 10%**

*** BIOMD: JUST $860k FROM A REVOLUTIONARY COW PATCH**

*** TG4010 WITH VIRAX CO-X-GENE SHOWS LUNG CANCER BENEFIT**

*** FDA OKAYS VET USE OF MEDICAL DEVELOPMENTS' METHOXYFLURANE**

*** ARANA AXES PMX53 FOR EYE DISEASE**

*** QRX BEGINS 2nd DUAL OPIOD TRIAL FOR SEVERE POST-OP PAIN**

*** CYTOPIA RESPONDS TO PROGEN MEETINGS; PROGEN HAS $73m CASH**

*** ATCOR POSTS $181k MAIDEN H1 PROFIT; SALES UP 76% TO $5.4m**

*** PETER VASSILEFF INCREASES TO 17% OF PHARMAUST**

*** RMIT OFFERS TWO NEW LIFE SCIENCE GRAD CERT PROGRAMS**

MARKET REPORT

The Australian stock market climbed 1.05 percent on Thursday February 19, 2009 with the S&P ASX 200 up 35.7 points to 3,448.9 points.

Nine of the Biotech Daily Top 40 stocks were up, 13 fell, 14 traded unchanged and four were untraded.

Universal Biosensors was best, up five cents or 10.4 percent to 53 cents with 5,500 shares traded, followed by Peplin up 9.52 percent to 46 cents.

Antisense climbed 6.1 percent; Novogen was up 4.84 percent; Alchemia, Cellestis and Heartware were up more than three percent; Bionomics rose 2.5 percent; with Avexa up 1.45 percent; and CSL and Cochlear up by less than one percent.

Polartechnics led the falls, down 1.5 cents or 10.34 percent to 13 cents with 111,000 shares traded.

Optiscan and Prana lost more than six percent; Benitec fell 4.76 percent; Resmed was down 3.07 percent; Biota, Circadian, Clinuvel, Progen and Starpharma shed more than two percent; with Chemgenex and Mesoblast down more than one percent.

BIOMD

Biomd's executive director Robert Towner and managing director Michael Bennett have been wearing out shoe leather to bring their revolutionary bovine cardiac patch to market.

In Melbourne and Sydney to see investors, potential partners and media, the pair are absolutely committed to the Freemantle Heart Institute technology invented by the company's chief scientific officer Prof William (Leon) Neethling.

Mr Towner says raising the $860,000 through the one-for-two rights issue at two cents has not been easy and he's talking to high net worth friends, but is almost dismissive of the problem. "I'll get the $860,000," he says with determination.

Mr Bennett partly explains the secret to Biomd's Adapt tissue engineering process as removing all cells, RNA and DNA and effectively leaving a clean collagen scaffolding, but he won't give away the "eleven different herbs and spices" that are central to the process.

He does say that the process "manipulates the collagen helix structure".

The material goes through a two week "time, temperature and chemical" process making the end product sterile, but it is then put through a further terminal sterilization step.

The product is "like wet silk" and can be freeze dried returning to 97 percent efficiency.

Mr Bennett says it is pliable, elastic, durable and strong and has a wealth of preclinical data to support the South African phase II trial, which has enrolled 20 of its 50 patients, with four already passed the six month observation point.

When 12 month monitoring is completed the next step is a US Food and Drug Administration 510k application as an equivalent device for market registration.

He says his patch has significant advantages over both synthetic and other bovine and equine based pericardial patches.

He says the synthetics develop problems relating to their rigidity and need to be replaced, sometimes requiring greater surgical intervention than the original medical problem.

The animal-based tissues can be consumed by the host body or develop calcification, which his doesn't.

"It is a totally and utterly benign collagen scaffold."

The material is intended for use in hole-in-the-heart operations, Sanvenero-Rosselli procedures for cleft palate, ventral and septal defects as well as pelvic floor repair and heart valve replacement.

He said Biomd would "derisk products with our technology".

"Plastic mesh for pelvic floor reconstruction doesn't work in the long term," Mr Bennett said. "It becomes fibrotic, it shrinks, causes adhesions and pain and can erode back into the vagina or rectum and has a 15-20 percent occurrence rate."

"We can overcome the problems with synthetics and it's not a xeno-transplant because it is not living tissue."

"It is a scaffold that allows the patients own tissue to regrow," Mr Bennett said.

He is hoping for approval to conduct a pilot trial at a leading Sydney public hospital by the middle of 2009.

Other uses of the Adapt process include catheter introduction of replacement heart valves, which is being trialed in sheep, but it can also be used to create kangaroo patches which are thinner and stronger than bovine tissue.

Finally, he says researchers "have grown mesenchymal stem cells on our patch and we have the evidence that the mesenchymal cells have infiltrated the full thickness of the patch".

"This is world class technology," Mr Bennett says.

He says he has been talking to the two or three major players in the sector and "all are on a watching brief" for his results.

Biomd was untraded at 4.2 cents.

VIRAX

Virax says Transgene SA has shown further phase IIb efficacy with its cancer vaccine TG4010 as an adjunct to first line chemotherapy for advanced non-small cell lung cancer
Virax said TG4010 uses its Co-X-Gene technology which is licenced to the France-based Transgene.
The 21 month data confirms a statistically significant six-month increase in median survival in patients who have a normal level of a biomarker prior to treatment.
Virax receives milestone and royalty payments on Transgene achieving relevant development milestones and sale of product.
Virax chief executive officer Dr Larry Ward said the phase IIb data was "a very exciting value adding event for TG4010 as the demonstration of a statistically significant survival benefit will be required to gain regulatory approval for a [non-small cell lung cancer] treatment".
"Similarly this survival data is a major step forward for Transgene towards securing a collaborative partnership with global pharmaceutical companies to further develop TG4010," Dr Ward said.
Virax said Transgene was planning multi-national phase III clinical testing of TG4010 and intended to have meetings with the major international regulators the US Food and Drug Administration and the European Medicines Agency in the second quarter of 2009.
Transgene's chief executive officer Dr Phillipe Achinard said his company was "pleased by the continued efficacy of our vaccine on such an important sub-population of patients … and by the progress made in our partnership discussions with potential pharmaceutical companies".
The 21 months data confirmed a statistically-significant six-month increase in median survival (17.1 months in the experimental arm versus 11.3 months in the control arm) in patients with normal levels of activated natural killer cells at baseline (75 percent of the patients in the trial), a sub-population identified by Transgene's biomarker program.
Virax climbed 0.4 cents or 15.38 percent to three cents.

MEDICAL DEVELOPMENTS

Medical Developments says the US Food and Drug Administration has approved methoxyflurane for use as a veterinary anaesthetic
Methoxyflurane is known as Penthrox in Australia and is used as an analgesic by Australian ambulance services.
Medical Developments said the product would be supplied under the trade name Anafane in the US.
Medical Developments chief executive officer Chris Rossidis said the FDA veterinary registration was "the culmination of significant work by the company to support the launch of methoxyflurane for veterinary use in the US".
"The company now has a gateway to the US veterinary market," Mr Rossidis said.
The company said it had been supplying methoxyflurane in the US on special access for veterinary use in research institutions but had been unable to actively promote the product.
Medical Developments said methoxyflurane had "some distinct advantages for veterinary medicine including the slowness with which animals emerge from anaesthesia and therefore the ability to manage animal welfare post-anaesthesia".
The company said it had been developing delivery methods that would include the management of post-operative pain to be incorporated following regulatory approval.
Medical Developments was up 1.5 cents or 8.33 percent to 19.5 cents.

ARANA

Arana has discontinued PMX53 for ocular indications despite showing activity in age-related macular degeneration animal models.
Arana said the level of activity “was not sufficient to warrant further development expenditure”.
Arana had expected to begin a clinical trial of PMX53 in age-related macular degeneration by June 30, 2009.
The company said all ongoing pre-clinical PMX53 studies would be completed including an osteoarthritis study which was expected to be finished by September 30, 2009 and a data package would be assembled for out-licencing.
Acting chief executive officer Dr Steffen Nock said PMX53 was “a small cyclic peptide rather than a recombinant protein and thereby falls outside our core technology focus”.
“Arana has a deep product pipeline and has an active ongoing evaluation process to ensure resources are focussed on the highest priority projects,” Dr Nock said.
“PMX53 is a potent molecule with demonstrated activity in various non-ocular disease models,” Dr Nock said. “A number of companies have expressed interest in evaluating PMX53 and we will continue to progress all discussions with an aim of maximizing the value of this asset.”
Arana said PMX53 was an inhibitor of the human C5a ‘complement’ factor receptor.
PMX53 is a cyclic hexapeptide compound and behaves as an insurmountable antagonist with nanomolar affinity for the human C5a receptor
Arana fell half a cent or 0.6 percent to 83.5 cents.

QRX PHARMA

QRX Pharma has begun a three-arm pilot study to evaluate the analgesic efficacy and safety of Moxduo IR capsules in patients following total knee replacement surgery.
QRX said data from the study would be used to further establish the optimal dose regimen for Moxduo IR (immediate release) capsules, select an appropriate control group, and design a pivotal phase III trial in patients following total knee replacement surgery.
QRX expects to complete dosing in April 2009 and launch Moxduo IR in the US in 2011.
QRX said Moxduo IR targeted acute pain, a $2.5 billion segment of the $7 billion spent annually on prescription opioids in the US.
QRX chief executive officer Dr John Holaday said the study was “an important step forward as the data collected will not only provide critical insights for structuring phase III trials leading to product approval, but also serve as an important indicator of the clinical and commercial value Moxduo IR offers”.
Dr Holaday said Moxduo IR was expected to “greatly improve patient care by providing equal or better analgesia with fewer and less intense side effects”.
Each group of patients experiencing moderate to severe postoperative pain following total knee replacement will be treated every four to six hours over a 48-hour period.
The study will enroll a total of 45 patients at three US clinical research sites.
The study’s primary objectives include comparing the analgesic efficacy and safety profile of Moxduo IR against control groups of patients receiving Percocet, a frequently used opioid for the treatment of pain; and comparing Moxduo IR against the present standard use of intravenous morphine in patients who self-control their pain relief using “patient controlled analgesia”.
Moxduo IR is the first patented analgesic product that consists of two opioid drugs in a fixed ratio of morphine and oxycodone.
QRX was unchanged at 25 cents.

PROGEN, AVEXA, CYTOPIA

Cytopia has responded to yesterday's Progen announcement that it would block a single shareholder meeting to vote on the two merger proposals.

Cytopia said that Progen had accepts the "legitimate call" by shareholders to a general meeting; would not allow shareholders to vote on a full share buy-back; denied shareholders a single meeting refusing to align meeting dates; and persisted with a "high risk, high funding, Avexa merger proposal".

Cytopia said the director candidates for the Progen board were well qualified and their biographies were summarized in the request for the meeting (BD: Jan 28, 2009).

Cytopia said the Progen board denied shareholders the choice being sought since the termination of the PI-88 trial.

Cytopia said the shareholder resolutions it proposed on January 28 allowed all shareholders the option of remaining as investors in a cancer-focused biotechnology company, having their shares bought back by the company at $1.10 per share or some combination of the two.

The merger proposal with Avexa only allows for up to a $20 million capital return to shareholders and possibly more than half the shareholders would choose the full share buy-back, facing a significant scale back, Cytopia said.

"The current Progen board has denied shareholders the opportunity to vote on all resolutions at the one meeting, as requested. Although it clearly would be in the best interests of shareholders to delay by two weeks the meeting scheduled for 11 March 2009, shareholders will now have to endure the avoidable inconvenience and cost of two shareholder meetings," Cytopia said.

Cytopia said Progen material on the Avexa Merger (BD: Feb 5, 2009) "details the high risk, high funding strategy that is being proposed under the merger with Avexa".

"This strategy is in stark contrast to the strategic recommendations arising from the company-commissioned Beerworth report and presented to Progen shareholders on November 13, 2008," Cytopia said.

Cytopia said Progen shareholders were advised of partnering interest in PI-88 over a number of years, but the took it into phase III trials and no partnering deal eventuated.

The Avexa merger proposes to focus investment in the phase III trials of apricitabine which has also not been partnered and the total estimated cost of completion of phase III trials is $155 million.

In the absence of either substantial new capital or partnering and assuming trial success, a further $95 million is likely to be needed to achieve product registration.

Cytopia said that despite the failure of PI-88 development, the Progen board proposed a continuation of the same high risk business model under an Avexa merger.

The Avexa merger proposal concentrates on HIV, not oncology. The Avexa assets are not complementary with the Progen assets, Cytopia said.

Cytopia said all Progen shareholders should vote against the merger with Avexa on March 11 and vote for a new board on March 27, 2009.

Separately, Progen said its loss in the six months to December 31, 2008 fell by 88.0 percent to $1,726,000 on revenue down 25.1 percent to $2,217,000.

The half-year result year included a foreign exchange gain of $7.1 million and the accrual of $4 million in milestone payments relating to the termination of the agreement with Medigen executed on January 16, 2008.

Progen had $72,912,000 in cash at December 31, 2008.

Progen fell two cents or 2.38 percent to 82 cents.

Cytopia was untraded at 9.5 cents.

Avexa climbed 0.1 cents or 1.45 percent to 7.0 cents.

ATCOR

Atcor has reported its first full-year net profit after tax for the 12 months to December 31, 2008 of $180,477 compared to the previous year's $1,678,798 loss.
Atcor said sales revenue climbed 75.9 percent to $5,377,038, with total revenue up 78.4 percent to $6,506,836.
Atcor reported diluted earnings per share of 0.18 cents compared to the previous year's loss of 1.68 cents a share.
The company had $2,924,484 in cash at December 31, 2008, but no dividend will be paid.
Atcor was up one cent or 6.06 percent to 17.5 cents.

PHARMAUST

Peter Vassileff of Mosman Park Western Australia has increased his substantial shareholding in Pharmaust from 20,654,569 shares (8.7%) to 39,454,569 shares (16.7%).
The shares were bought through Silktree Investments, Pinebrook Nominees, Peter Vassileff ATF Pitch Investments and Ashwild.
Pharmaust was unchanged at two cents.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY UNIVERSITY

The Royal Melbourne Institute of Technology University is offering two life science graduate certificate courses next month.
RMIT's School of Life and Physical Sciences says the two post-graduate programs are the Graduate Certificate in Biotechnology Industry and the Graduate Certificate in Laboratory Health, Safety and Environmental Management Systems.
The courses cost $560 each and begin on March 28, 2009
The School of Life and Physical Sciences said the courses were accredited professional qualifications for graduates from various disciplines, needing to enhance their knowledge in specific areas.
Both programs are offered by a combination of online and face to face classes after hours.
The School said the courses incorporate work-based projects and laboratory based exercises.
The Graduate Certificate can be completed in about 12 months.
The School said the entrance requirements were a related degree or diploma, or extensive relevant work experience.
The fees for 2009 are government assisted places
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