



# Biotech Daily

Tuesday October 30, 2012

*Daily news on ASX-listed biotechnology companies*

- \* ASX, BIOTECH FLAT: OPTISCAN UP 5%, TISSUE THERAPIES DOWN 17%
- \* EMA DELAYS TISSUE THERAPIES VITROGRO UP TO 210 DAYS
- \* OCTA PHILLIP BIOXYNE BOARD SPILL FAILS
- \* BYE-BYE BIOTA, HELLO NASDAQ
- \* FULL US APPROVAL FOR GI DYNAMICS ENDOBARRIER TRIAL
- \* PHOSPHAGENICS TPM INJECTABLE ANTIBIOTIC DEAL TO INDIA'S AGILA
- \* ALCHEMIA HAS ONE QUARTER CASH, \$60m IPO, \$2m TAX CREDIT, SALES
- \* ISONEA RAISES \$4m
- \* NUSEP PLACES \$1m
- \* JOHN LEAVER TAKES 6% OF BIONOMICS
- \* LANDON CLAY, EAST HILL TAKE 13% OF BIOTA
- \* CB CO, CURRAN SUPER FUND TAKES 13% OF ATCOR
- \* CONSEGNA 77m SHARES, 80m OPTIONS, 1m NOTES AGM
- \* BONE \$1,671,987 DIRECTORS, OTHERS SHARES AS FEES AGM
- \* PROF MAREE SMITH, DR JIM AYLWARD WIN LSQ GONGS

## MARKET REPORT

The Australian stock market edged up 0.2 percent on Tuesday October 30, 2012 with the S&P ASX 200 up 8.8 points to 4,485.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and eight were untraded.

Optiscan was the best, up 0.5 cents or 5.3 percent to 10 cents with 22,572 shares traded. Allied Health and Prima climbed more than four percent; Phosphagenics was up 3.3 percent; Acrux, Ellex and Universal Biosensors rose more than two percent; with Circadian and Nanosonics up more than one percent.

Tissue Therapies led the falls, down eight cents or 17.2 percent to 38.5 cents with 973,160 shares traded, followed by Viralytics down 12.9 percent to 40.5 cents with 222,944 shares traded and Neuren down 10.9 percent to 4.1 cents with 22.1 million shares traded. Prana lost 5.4 percent; Biota fell 4.2 percent; with Pharmaxis and Starpharma down more than one percent.

## TISSUE THERAPIES

Tissue Therapies says that a European Medicines and Healthcare Products Regulatory Agency reclassification of wound treatment Vitrogro has delayed sales by up to 210 days. Tissue Therapies said that the European Medicines and Healthcare Products Regulatory Agency confirmed classification as a medical device class three, but under Rule 13 instead of Rule 8, as was previously agreed and as a result, the Agency decided that a European Medicines Agency review of manufacturing and quality data was required, which would take up to 210 calendar days.

The company said it was yet to be advised of the review start date but the EMA review was a desk audit with no on-site inspections required.

Tissue Therapies said it was confident that the Vitrogro quality and manufacturing data would be submitted, particularly because (protein manufacturer Eurogentec and fill and finish and packaging company Catalent were fully certified and licenced.

The company said the further delay to sales in the EU was frustrating, but approval to sell in the European Union would be final with no further potential regulatory examination and it would provide a definitive regulatory approval for sale, signed off by all 27 EU member states, providing a regulatory package for approvals in other jurisdictions including.

Turkey, the Middle East, Russia, Taiwan, Latin America, Canada and Australia.

Tissue Therapies said it would use the review delay to prepare for earlier sales launches than were initially planned in the Nordic countries, the Middle East, Turkey, Latin America and Russia, while preparing to lodge applications for venous and diabetic ulcer trials with the US Food and Drug Administration.

Tissue Therapies said its net operating cash burn for the three months to September 30, 2012 was \$2,489,500 with cash at the end of the quarter of \$3,747,700.

The company said that it expected reduced expenditure in the coming two quarters and that sales were expected to begin as soon as European approval was granted.

Tissue Therapies fell eight cents or 17.2 percent to 38.5 cents.

## BIOXYNE

The Octa Phillip investment group attempt to replace the Bioxyne board has narrowly failed with investors supporting the previous Hunter immunology directors.

Bioxyne said that chairman Ian Mutton and chief executive officer David Radford were not removed as directors, while Octa Phillip executive Dr Jeremy Curnock Cook was removed and his colleague Dr Stewart James Washer failed to win election as a director.

Bioxyne said that Anthony Ho was elected a director and Glenn Crisp was defeated in his election as a director.

Dr Douglas Wilson resigned from the company before the vote (BD: Oct 25, 2012).

Bioxyne said that the resolution to remove Mr Mutton was defeated with 67,050,898 votes (54.04%) against and 57,028,753 votes (45.96%) in favor.

Bioxyne's meeting results notice said that Mr Radford's removal was opposed by 53.20 percent to 46.80 percent; Dr Washer's election was lost with 54.12 percent against and 45.88 percent in favor; Dr Curnock Cook was removed as director with a vote of 53.16 percent in favor and 46.84 percent against; Mr Crisp was removed by the narrowest margin, with 51.04 percent in favor of the resolution and 48.96 percent against; and Mr Ho was elected by the largest margin with 61.60 percent in favor and 38.40 percent against. Bioxyne was untraded at four cents.

## BIOTA

Biota shares have been suspended from trading, effective from the close of trading today, as the company prepares to list on the Nasdaq as Biota Biopharmaceuticals.

Biota said the Supreme Court of Victoria approval of the scheme of arrangement to merge with Nabi and delist from the ASX had been lodged with the Australia Securities and Investments Commission.

The company said the scheme was legally effective (BD: Oct 26, 2012).

Biota shareholders may have received correspondence from their brokers advising that an international account would be required to sell the shares once they have been transferred to the Nasdaq.

Biotech Daily contacted Commonwealth Securities (Commsec) and was initially advised of a laborious procedure, but subsequently was assured that all paperwork can be filed at the same time, once the Nasdaq share certificates have been received from Biota.

Biotech Daily is aware that different brokers charge different rates and the spread so far has been \$60 to \$75 per trade or 0.6 percent to 0.75 percent.

Biota closed down 2.5 cents or 4.2 percent at 57 cents with 6.5 million shares traded.

## GI DYNAMICS

GI Dynamics says it has full approval from the US Food and Drug Administration for its 500-patient, pivotal clinical trial of Endobarrier for obese type 2 diabetes patients.

In August the FDA provided conditional approval for the trial (BD: Aug 23, 2012).

Today, GI Dynamics said that data from the US study, named the Endo trial, would be used to support a pre-market application (PMA).

GI Dynamics said the trial was a randomized, multi-center, double-blind, sham-controlled trial that was expected to enroll about 500 people living with uncontrolled diabetes and obesity who meet the enrollment criteria at 25 sites in the US.

The company said that the trial was designed to assess improvements in diabetes over a treatment period of up to 12 months.

GI Dynamics said the primary endpoint was improvement in HbA1c, a key blood sugar measure for diabetes, with secondary measures including weight loss and improvements in cardiovascular risk factors, such as cholesterol.

GI Dynamics said that in 12 clinical studies outside the US and one in the US, with more than 500 patients, Endobarrier had been shown to achieve rapid reductions in blood sugar levels, improvement of cardiovascular risk factors including blood pressure, cholesterol and triglycerides, and weight loss of about 20 percent in 12 months.

The company said that Endobarrier received Conformité Européenne (CE) mark approval in 2010 and approval by the Australian Therapeutic Goods Administration in 2011 for the treatment of type 2 diabetes and/or obesity for up to 12 months.

GI Dynamics said the Endobarrier was commercially available in Germany, Austria, the United Kingdom and the Netherlands, as well as Australia and Chile.

GI Dynamics chief executive officer Stuart Randle said that the company had completed "extensive clinical studies and achieved several regulatory approvals outside the US and it has been extremely rewarding to see the benefits Endobarrier has brought to people living with type 2 diabetes".

"We are very pleased to now have full approval in the US to commence a pivotal trial of this novel therapy," Mr Randle said.

"We look forward to providing updates on the progress of the Endo trial and to submitting the results for PMA approval to sell Endobarrier in the United States," Mr Randle said.

GI Dynamics was up two cents or 3.7 percent to 56 cents.

## PHOSPHAGENICS

Phosphagenics says it has licenced an injectable antibiotic using its vitamin E-based tocopheryl phosphate mixture to India's Agila Specialties, a subsidiary of Strides Arcolab. Phosphagenics investor relations officer David Segal told Biotech Daily that the tocopheryl phosphate mixture or TPM technology acted as an excipient, increasing the speed of solubility in the injection solution.

In its media release, the company said that Agila had one of the largest steriles capacity in India and one of the largest lyophilization of freeze drying capacities in the world with nine manufacturing facilities across the globe and was developing and commercializing products targeting anti-infectives, oncology, central nervous system, gastro-intestinal, ophthalmics and peptides.

Phosphagenics said it would licence the TPM technology to Agila for its use in an antibiotic injectable product and Agila would be responsible for the development and pay the costs required to register and commercialize the product, including all necessary clinical studies.

The company said it would receive an upfront payment as well as undisclosed royalties based on net sales and the antibiotic injectables market was worth several billion dollars a year.

Phosphagenics chief executive officer Dr Esra Ogru said the agreement "demonstrates the versatility of the TPM platform technology, paving the way for further opportunities in the injectable market".

"Strides and its subsidiary, Agila, have state-of-the-art manufacturing capabilities and have had tremendous success in bringing new products to market," Dr Ogru said.

"This will be the first time TPM will be used in an injectable formulation," Dr Ogru said.

Phosphagenics rose half a cent or 3.3 percent to 15.5 cents with 2.1 million shares traded.

## ALCHEMIA

Alchemia says its net operating cash burn for the three months to September 30, 2012 was \$5,366,000 with cash at the end of the quarter of \$8,634,000.

Alchemia chief executive officer Dr Pete Smith told Biotech Daily that along with continuing revenues from the sale of Fondaparinux and an expected Federal Government research and development tax credit by the end of 2012, the company was conducting an initial public offer for up to \$60 million to demerge its oncology assets and list Audeo Oncology on the Nasdaq (BD: Jul 9, Oct 15, 2012).

Dr Smith said that about \$3 million of the expenditure was on its 390-patient phase III trial of HA-irinotecan for metastatic colorectal cancer (BD: Sep 25, 2012).

Dr Smith said that a large proportion of the \$846,000 "other including working capital" payments was for the demerger transaction.

Alchemia was up half a cent or 0.9 percent to 55 cents.

## ISONEA

Isona says its three-for-five rights issue at five cents a share has raised about \$4.0 million before expenses.

Isona said that it received entitlement acceptances for 42,068,925 shares raising \$2,103,446 and leaving a shortfall of 38,656,220 shares.

The company said that the rights issue was fully underwritten by Patersons Securities and a shortfall notice for those shares had been issued to raise a further \$1,932,811.

Isona was untraded at 5.5 cents.

### NUSEP

Nusep says it has raised \$1,167,091 through the issue of shares at seven cents a share. Nusep said the placement was taken up by a sophisticated investor based in Singapore. Nusep fell 0.8 cents or 9.1 percent to eight cents.

### BIONOMICS

John Leaver has increased his substantial shareholding in Bionomics from 17,875,590 shares (5.18%) to 21,216,735 shares (6.14%).

Mr Leaver said he acquired the 3,341,145 shares for \$1,244,926 or an average price of 37.3 cents a share, through the Sydney-based Balzac Investments, Wenola Pty Ltd, Leagou Funds Management and Planette Thoroughbred Trading, of which he was a director.

Bionomics was unchanged at 31.5 cents with three (3) shares traded.

### BIOTA HOLDINGS

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 22,520,767 shares (12.35%) to 24,485,284 shares (13.07%).

### ATCOR MEDICAL

CB Co Pty Ltd for the Curran Superannuation Fund has increased its substantial shareholding in Atcor from 10,000,000 shares (6.77%) to 19,000,000 shares (12.85%). The substantial shareholder notice said that the 9,000,000 shares were acquired for \$630,000 or seven cents a share.

In August, Capital Investment Group transferred part of its Atcor holding of 22,332,347 shares or 15.11 percent, in two tranches, saying it acted for the Curran Superannuation Fund, which was associated with Capital Investment director Charles Paul Curran, acquiring 10,000,000 shares (6.77%) for \$650,000 or 6.5 cents a share (BD: Aug 6, 2012). A Capital Investment executive told Biotech Daily in August that the company retained the balance of 12,332,347 shares or 8.34 percent.

Atcor was untraded at seven cents.

### CONSEGNA

Consegna shareholders will vote on the previous issue of 76,767,370 shares and the issue of 80,000 options and one million \$1 convertible notes.

Consegna said that the one million convertible notes cost \$1 each and 50,000 notes converted into 3,333,333 shares or 66,666,666 shares in total.

The company said that 50,000,000 options exercisable at two cents each within three years of issue attached to the notes and it proposed to issue further 10 million options exercisable at 2.36 cents by July 17, 2015 to Lind Partners and 20 million options exercisable at three cents by February 28, 2015 to Exertus Capital Pty Ltd.

Consegna said shareholders would also vote on the remuneration report and the election of directors Brendan Fleiter, Simon Reading and Martin Rogers.

The meeting will be held at Level 29, Chifley Towers, 2 Chifley Square, Sydney on November 30, 2012 at 10am (AEDT).

Consegna fell 0.1 cents or 7.7 percent to 1.2 cents with 1.2 million shares traded.



## BONE MEDICAL

Bone shareholders will vote to issue shares to the value of \$1,671,987 in lieu of fees to its directors, executives and unrelated parties.

Bone said the shares would be issued at 0.3 cents each, implying that about 557,329,000 shares would be issued if the annual general meeting resolutions were approved.

Bone has proposed to issue shares at 0.3 cents a share to directors and unrelated parties with \$1,339,327 to Proxima Labs, \$70,559 to Proxima Concepts and \$42,505 to Bone and Proxima chairman Dr Roger New.

The company said it proposed to issue shares to the value of \$5,077 to chief executive officer Peter Young, \$32,775 to director Prof Peter Brooks, \$39,404 to director Leon Ivory, \$19,726 to Ivory and Co, \$15,914 to Dr Barry Walker, \$59,70 to Balion Pty Ltd, \$24,266 to Tim Earle and \$22,732 to Bill Ivory.

Bone said that shareholders would also vote on the remuneration report, the re-election of director Prof Brooks, approval for the issue of shares to La Jolla Cove on conversion of convertible notes and a \$2.5 million placement.

The meeting will be held at Ledger Corporate, Level 3, 46 Ord Street, West Perth Western Australia on November 29, 2012 at 6.30pm (AWST).

Bone was unchanged at 0.3 cents with 10.1 million shares traded.

## LIFE SCIENCES QUEENSLAND

Life Sciences Queensland says University of Queensland's Prof Maree Smith and Peplin founder Dr Jim Aylward are the joint winners of its Industry Excellence Award.

Life Sciences Queensland said that with Mccullough Robertson Lawyers the award was in its fourth year and acknowledged an individual that "made significant contributions to the performance and success of the Queensland life sciences industry and ... demonstrated a breadth of impact across the sector in Queensland".

The industry body said that for the first time two of the five candidates achieved the same number of votes.

Life Sciences Queensland said that Prof Maree Smith was the director of the Centre for Integrated Preclinical Drug Development and Tetraq, as well as a University of Queensland professor of pharmacy.

Life Sciences Queensland said that Prof Maree Smith had been involved in life sciences translational research at the University of Queensland for two decades and two of her analgesic inventions were being commercialized by University of Queensland spin-out companies, QRX Pharma and Spinifex Pharmaceuticals.

The industry organization said that Prof Smith co-founded the Centre for Integrated Preclinical Drug Development and Tetraq with three colleagues and had overseen establishment of its internationally recognized, accredited specialist preclinical drug development capabilities.

Life Sciences Queensland said that Dr Jim Aylward played a central role in the patenting and development of Australia's first US Food and Drug Administration-approved cancer chemotherapeutic drug, Picato for actinic.

The organization said that Dr Aylward founded Peplin obtained finance and guided the research and development program and in 2009, Peplin was sold to Leo Pharma for \$US287.5 million.

The other candidates were Prof Peter Andrews, Prof Julie Campbell and Prof James Dale.

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