Biotech Daily

Thursday January 31, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 11%, PHARMAXIS DOWN 46%**

*** FDA COMMITTEE BLOCKS PHARMAXIS; COMMENT; $38m FACILITY**

*** JANSSEN EXTENDS PHYLOGICA COLLABORATION**

*** NEUREN APPOINTS DR RICHARD TREAGUS EXECUTIVE CHAIRMAN**

*** ATCOR H1 SALES UP 43% TO $5.4m; TURN-AROUND PROFIT**

*** ELLEX H1 PROFIT WARNING**

*** BAYCREST $3m AGENIX FACILITY**

*** PROGEN EARNS $723k FEDERAL R&D TAX REFUND**

*** BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**

*** BENITEC, MEDICAL AUST, BIOPROSPECT, BIOXYNE CASH-STRAPPED**

*** CONSEGNA BOARD, MANAGEMENT TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.37 percent on Thursday January 31, 2013, with the S&P ASX 200 down 17.9 points to 4,878.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and two were untraded. All three Big Caps fell.

Impedimed was the best, up one cent or 10.5 percent to 10.5 cents with 430,500 shares traded. Phylogica climbed 8.0 percent; Anteo, Clinuvel and Neuren were up more than six percent; QRX, Reva and Uscom were up more than five percent; Avita climbed 4.2 percent; Circadian and Mesoblast were up more than three percent; with Bionomics and Medical Developments up more than one percent.

Pharmaxis led the falls, down as much as 64 cents or 51.2 percent to 61 cents before closing down 57 cents or 45.6 percent to 68 cents with 19.3 million shares traded, followed by Ellex down 27.7 percent to 17 cents with 202,365 shares traded and Antisense down 12.5 percent to 1.4 cents with 27.9 million shares traded. Resmed lost 7.7 percent; Benitec was down 6.25 percent; Allied Health, Cellmid, Optiscan and Prima fell more than four percent; Viralytics was down 3.3 percent; Alchemia shed 2.9 percent; Starpharma fell 1.2 percent; with Acrux, Cochlear, CSL, Nanosonics and Sirtex down by less than one percent.

PHARMAXIS

A US Food and Drug Administration advisory committee has overwhelmingly refused Pharmaxis market approval application for Bronchitol for cystic fibrosis.

The Pulmonary-Allergy Drugs Advisory Committee voted by 11 votes to three against whether Bronchitol was safe and demonstrated efficacy, criticized the phase III trial data and unanimously opposed marketing approval for patients aged six years and over.

In a media release, Pharmaxis chief executive officer Dr Alan Robertson said the vote was "disappointing, however, we are aware that these recommendations are not binding on the FDA and we will continue the process of working with the FDA to bring Bronchitol to patients in the US".

"It is important to remember that we are in a process and that opportunities remain to discuss the issues that were raised by the committee before the FDA makes its final decision on March 18, 2013," Dr Robertson said.

Pharmaxis said the FDA previously granted Bronchitol orphan drug designation for cystic fibrosis and it was approved for patients aged six years and over in Australia and for patients aged 18 years and over throughout the European Union.

Pharmaxis said that it was in an ongoing process with the FDA, and did "not intend to comment further … until the FDA announces its decision on March 18, 2013".

Lodge Partners analyst Marc Sinatra said the FDA briefing documents made it clear that Bronchitol faced an uphill battle at the Committee meeting.

"Comments made by the committee throughout the meeting were generally of a critical nature, both on the efficacy and safety side of the equation," Mr Sinatra said.

"There was some suggestion that some members may have voted 'Yes' had the questions been centred on adult patients only," Mr Sinatra said.

"Based on the comments made by [Committee] members and the strength of the votes on safety, efficacy and overall, it seems highly likely that Pharmaxis will have to provide a new trial to win FDA approval," Mr Sinatra said.

"In particular, they will probably need to provide at least one year's worth of solid safety data - that is, a fresh application is possibly up to two years away," Mr Sinatra said.

"Pharmaxis could seek a restricted label claim to patients 18 years or older in an effort to gain FDA approval, but we believe the chances of this succeeding are slim," Mr Sinatra said.

Separately, Pharmaxis said it had signed a $US40 million ($A38.4 million) financing agreement with Novaquest Pharma Opportunities Fund III to support the development, manufacturing and commercialization of Bronchitol for cystic fibrosis in the EU and US".

Pharmaxis said the minimum investment of $US20 million would be received within 30 days and an additional $US20 million could be invested from January 30, 2014, at Pharmaxis option and subject to it meeting commercial and regulatory criteria.

In its recent Appendix 4c quarterly statement, Pharmaxis said it had $64,863,000 in cash at December 31, 2012 (BD: Jan 24, 2013).

The company said Novaquest would receive payments based on US and EU revenue from Bronchitol for cystic fibrosis for eight years in the EU and seven years from the US launch, with average payments expected to range from low single digit to low double digit percentages, depending on the amount invested and sales, among other factors.

Dr Robertson said it was "prudent to ensure we have the necessary resources to fulfil our strategic objectives for the business and we look forward to continued success in bringing an innovative new pharmaceutical to markets around the world".

Pharmaxis fell as much as 64 cents or 51.2 percent to 61 cents before closing down 57 cents or 45.6 percent to 68 cents with 19.3 million shares traded.

PHYLOGICA

Phylogica says its collaboration with Janssen Biotech to discover, develop and commercialize new classes of peptide-drug conjugates has been extended.
Phylogica said it had received an undisclosed payment for additional research associated with the extension, established in 2012 (BD: Jan 22, 2012).
The company said that in the previous 12 months it had constructed novel libraries comprising more than 100 billion unique Phylomer peptides conjugated to Janssen proprietary therapeutic cargo.
Phylogica said it would screen the libraries against a disease cell type of interest to Janssen to identify cell-specific and cell-penetrating Phylomer peptide conjugates as potential drug candidates.
The company said that under the agreement, Janssen could develop multiple Phylomer-based drug candidates and had the option to expand the collaboration to include additional cell-specific Phylomer conjugates for the development of a further 10 drug candidates.
Phylogica said it was eligible for additional research funding and could potentially receive licence fees, milestone payments and royalties on worldwide sales of any product resulting from the collaboration.
Phylogica chief executive officer Dr Paul Watt said the “encouraging progress of our cell penetrating peptide discovery program suggests that our Phylomer peptides can be used to target specific cell types and deliver large biological payloads across cell membranes”.
“This application has broad potential in many disease areas such as cancer and other indications with a high unmet medical need,” Dr Watt said.
Phylogica was up 0.2 cents or eight percent to 2.7 cents.

NEUREN PHARMACEUTICALS

Neuren says that former Acrux chief executive officer Dr Richard Treagus has been appointed a director and executive chairman.
Neuren said that founding chairman Dr Robin Congreve would continue as a director.
The company said that Dr Treagus would be engaged in an executive capacity to review its business, financial and commercial strategy and work with chief executive officer Larry Glass in executing the business plan to realize shareholder value.
Neuren said that Dr Treagus was “an experienced and highly regarded pharmaceutical leader … [with] an extensive global network and a strong track record of being able to deliver exceptional outcomes and shareholder returns in a complex business environment”.
The company said that Dr Treagus had more than 20 years experience across the pharmaceutical industry and had held senior roles in South Africa and Australia.
Neuren said that at Acrux, Dr Treagus “concluded the largest product licensing deal in the history of the Australian biotech industry, a transaction with Eli Lilly worth $US335 million plus royalties”.
Neuren was up 0.2 cents or 6.1 percent to 3.5 cents with 3.3 million shares traded.

ATCOR MEDICAL

Atcor says unaudited sales for the six months to December 31, 2012 are expected to be $5.4million, a 43 percent increase over the prior corresponding period of $3.8 million.
Atcor said it expected to report a turn-around half year profit in February.
Atcor was up 1.5 cents or 21.4 percent to 8.5 cents with 1.1 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it expects profit before tax of $50,000 to $100,000 for the six months to December 31, 2012 compared to $949,246 for the half year to December 31, 2011.
Ellex said that despite a four percent improvement in group revenue compared to the period to June 30, 2012, revenue was expected to be 16 percent lower than the prior comparable period, which saw record sales in the US.
Ellex chief executive officer Tom Spurling said that “despite the expected fall in revenue compared to the prior comparable period, we are pleased with the revenue growth achieved over the past six months compared with the period ended June 30, 2012”.
Ellex fell 6.5 cents or 27.7 percent to 17 cents.

AGENIX

Agenix says it has a $3 million three-year investment agreement with Baycrest Capital.
Late last year, Agenix said that Fortrend Securities had failed to provide funding under a draw down equity facility (BD: Jan 20, 2013).
Today, Agenix said that the Boston Massachusetts-based Baycrest Capital was a specialist fund investing in high-growth Australian public companies.
The company said that it had full control over the timing, price and number of shares Baycrest purchased and executive chairman Nick Weston said the agreement “provides a solid base of funding for Agenix”.
Agenix was untraded at 2.6 cents.

PROGEN PHARMACEUTICALS

Progen says it has received $723,278 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Progen said the funds related to research and development expenditure for the year to June 30, 2012.
Progen was unchanged at 21 cents.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all the significant announcements to the ASX.
Biotechnology companies bleeding money is not news, unless the company involved has less than two quarters of cash.
When companies clearly explain that they have equity draw-down facilities or loans or are about to have a capital raising, Biotech Daily will not report their Appendix 4C statement.
Where there is no explanation or it is not clear and the company has less than six months of cash reserves, it will be reported, as will maiden revenues or profits.
Companies reporting after the close of business will be reported in the following edition.

David Langsam
Editor

BENITEC

Benitec says its net operating cash burn for the three months to December 31, 2012 was $902,000, with cash at the end of the quarter of $1,219,000.
Benitec said that with the Tacere hepatitis C acquisition it expected “increasing institutional interest in the company”.
Benitec fell 0.1 cents or 6.25 percent to 1.5 cents.

MEDICAL AUSTRALIA

Medical Australia says its net operating cash burn for the three months to December 31, 2012 was $371,000, with cash at the end of the quarter of $314,000.
Medical Australia said that it had $297,000 in credit standby arrangements.
Medical Australia was unchanged at 1.1 cents.

BIOPROSPECT

Bioprospect says its net operating cash burn for the three months to December 31, 2012 was $406,000, with cash at the end of the quarter of $578,000.
Bioprospect was unchanged at 0.1 cents

BIOXYNE

Bioxyne says its net operating cash burn for the three months to December 31, 2012 was $727,000, with cash at the end of the quarter of $508,000.
Bioxyne chief executive officer Dr Phillip Comans said that December quarter payments included final payments for clinical trials, the costs of shareholder meetings and planning for a further clinical trial.
Dr Commans said the company would require further funding to mitigate risks and broaden activities.
Bioxyne fell 0.4 cents or 14.3 percent to 2.4 cents.

CONSEGNA GROUP

Consegna has requested a trading halt “pending an announcement in relation to Board and management changes”.
Trading will resume on February 4, 2013 or on an earlier announcement.
Consegna last traded at 0.4 cents.