



# Biotech Daily

Friday October 26, 2012

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: NEUREN UP 13.5%, PRIMA DOWN 11.5%**
- \* **MIREVEN CLAIMS PRECLINICAL MIR-7 HEAD, NECK CANCER SUCCESS**
- \* **NICE RESULT: PHARMAXIS UK BRONCHITOL REIMBURSEMENT**
- \* **COURT APPROVES BIOTA MERGER, NABI CONSOLIDATES SHARES**
- \* **PARANTA CONTRACTS DSM FOR FOLLISTATIN MANUFACTURE**
- \* **MELBOURNE UNI, JANSSEN-CILAG WORK ON RESPIRATORY DRUG**
- \* **RESMED Q1 REVENUE UP 8% TO \$329m, PROFIT UP 41%**
- \* **BIOTRON PREPARES FOR 2<sup>nd</sup> STRIKE BOARD SPILL AGM**
- \* **BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**
- \* **PSIVIDA AGM FOR 314k CEO, DIRECTOR OPTIONS**
- \* **PRIMA APPOINTS MARC VOIGT CFO, DEANNE MILLER COUNSEL**

## MARKET REPORT

The Australian stock market fell 0.85 percent on Friday October 26, 2012 with the S&P ASX 200 down 38.1 points to 4,472.4 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and eight were untraded.

Neuren was the best, up half a cent or 13.5 percent to 4.2 cents with 24.1 million shares traded. Viralytics climbed 9.1 percent; Bionomics was up 6.6 percent; Pharmaxis and Tissue Therapies rose more than five percent; Circadian, Genetic Technologies and Phylogica were up more than four percent; Patrys rose 3.6 percent; Ellex was up 2.6 percent; Alchemia climbed 1.85 percent; with Acrux up 0.3 percent.

Prima led the falls, down 1.5 cents or 11.5 percent to 11.5 cents with 8.7 million shares traded. Allied Heath lost 8.3 percent; Anteo, Phosphagenics and Sunshine Heart fell more than six percent; Avita, Prana and Reva were down more than three percent; Biota, Sirtex and Starpharma shed more than two percent; Clinuvel, CSL, Mesoblast and Universal Biosensors were down more than one percent; with Cochlear down 0.3 percent.

## MIREVEN

Mireven says that its micro-RNA-7 (miR-7) reduces head and neck tumor growth in-vivo and sensitizes tumor cells to epidermal growth factor receptor(EGFR) inhibitors in vitro. Mireven said that research it was commercializing from the Western Australian Institute for Medical Research (WAIMR) on the anti-cancer potential of miR-7, showed promise in combination with the head and neck cancer treatment erlotinib hydrochloride (Tarceva). The company said that epidermal growth factor inhibitors were effective in up to 30 percent of patients with head and neck cancer, but the use of miR-7 alone or in combination could be a benefit to patients.

The study, entitled 'Regulation of epidermal growth factor receptor signaling and erlotinib sensitivity in head and neck cancer cells by miR-7' was published by the Public Library of Science and an abstract is at: <http://dx.plos.org/10.1371/journal.pone.0047067>.

The study, led by the WAIMR's Prof Peter Leedman, examined the capacity of miR-7 to regulate head and neck cancer growth in vivo and the combination of miR-7 with erlotinib in vitro, where it sensitized resistant cells to the tumor suppressive effects of erlotinib. Mireven said that a micro-array study found that miR-7 down-regulated multiple micro-RNAs associated with the EGFR protein kinase B (Akt) signaling pathway, which was strongly associated with the development, progression and treatment resistance of head and neck cancer.

Prof Leedman said that EGFR inhibitors like erlotinib had been developed to treat many cancers, but were "often not very effective, with responses typically short and tumors building up resistance quite quickly ... [but] when we combined erlotinib with the anti-cancer micro-RNA, miR-7, its effectiveness increased."

Mireven chairman Dr Stephen Thompson said that micro-RNA drugs like miR-7 were offering "a new direction for cancer therapeutic interventions in addition to monoclonal antibodies and small molecule inhibitors".

"These results demonstrate the potential for miR-7 to be a useful adjunctive therapy in the treatment of head and neck cancer," Dr Thompson said.

Mireven is a private company.

## PHARMAXIS

Pharmaxis says the UK National Institute for Health and Clinical Excellence (NICE) has recommended Bronchitol for cystic fibrosis, clearing the way for British reimbursement. Pharmaxis said the National Institute issued a positive recommendation in its final appraisal determination for Bronchitol, clearing the way for reimbursement by the National Health Service.

The company said that Bronchitol (mannitol dry powder for inhalation) was approved in the UK for the treatment of adult cystic fibrosis patients aged 18 years and above as an additional therapy to best standard of care.

Pharmaxis said the NICE decision was "an important milestone in marketing of the product".

The company said that the National Institute for Health and Clinical Excellence provided evidence-based guidance to help resolve uncertainty about which medicines were the best quality care and the best value for money for the UK's National Health Service.

Pharmaxis chief executive officer Dr Alan Robertson said this NICE decision "recognizes Bronchitol as a clinically and cost effective treatment option for [cystic fibrosis] patients with the most unmet medical need".

Pharmaxis was up seven cents or 5.6 percent to \$1.32 with 3.6 million shares traded.

### BIOTA HOLDINGS

Biota says the Supreme Court of Victoria has approved the merger with Nabi Pharmaceuticals, which has approved a six-to-one share consolidation.

Biota said that each Biota share would become 0.125 of a share in Biota Pharmaceuticals.

Biota said the record date for the merger share transfer was November 6, 2012.

The company said that the consolidation did not affect the ratio that Biota and Nabi shareholders would hold about 83 percent and 17 percent respectively of Biota Pharmaceuticals.

Biota said that shares in Biota Pharmaceuticals would be issued to Biota shareholders on November 9, 2012 and were expected to trade on the Nasdaq on November 9, 2012 in the US or November 10, 2012 in Australia.

Biota fell 1.5 cents or 2.4 percent to 61 cents with 1.4 million shares traded.

### PARANTA BIOSCIENCES

Melbourne's Paranta says DSM Pharmaceutical Products will conduct process development and manufacture of its lead recombinant human protein follistatin.

Paranta chief executive officer Ross Barrow told Biotech Daily that the Groningen Netherlands-based DSM Pharmaceutical Products was a subsidiary of Royal Dutch State Mines and the value of the contract was undisclosed.

In a media release, DSM said the contract covered the process development and manufacture at its Brisbane facility of follistatin for the treatment of respiratory diseases.

Paranta said follistatin was a therapeutic for inflammatory and fibrotic disorders that was a naturally occurring glycoprotein expressed by many cells in the body.

The company said that follistatin's primary function was to bind to and neutralize activins, which were a critical component of the immune response and in the development of fibrosis.

DSM chief executive officer Alexander Wessels said that "working with Paranta is an important milestone for DSM to support the local client base directly from our facility in Australia, expanding our presence in global regions".

Mr Wessels said the DSM collaboration with Biopharmaceuticals Australia, the Queensland and Australian Governments was bringing benefits to Australia by providing biopharmaceutical firms local support and manufacturing expertise.

Mr Barrow said that Follistatin had been shown "to have great potential in treating a wide range of inflammatory and fibrotic respiratory diseases, which affect over 300 million people worldwide".

Paranta is a public unlisted company.

### UNIVERSITY OF MELBOURNE, JANSSEN-CILAG

The University of Melbourne says it will collaborate with Johnson & Johnson company Janssen-Cilag Pty Ltd on an non-specified respiratory drug candidate.

The University said it would receive research funding to advance early stage drug candidates for the treatment of acute respiratory infections.

The University's research deputy vice-chancellor Prof James McCluskey said that acute respiratory infections were "the most common causes of both illness and mortality".

"This agreement reflects the desire for research at the University of Melbourne to be translated into impact, and recognizes the importance of collaboration with the pharmaceutical industry to achieve this goal," Prof McCluskey said.

The University was unable to provide further details on the collaboration.

## RESMED

Resmed has posted record revenue and profit for the three months to September 30, 2012, although the results were lower than the three months to June 30, 2012.

Resmed chief financial officer Brett Sandercock told Biotech Daily that with seasonal variation September was always the company's lowest quarter and compared to the previous corresponding period, the three months to September 30, 2012 was the company's best September quarter.

Resmed said that compared to the three months to September 30, 2011, revenue for the three months to September 30, 2012 was up 7.9 percent to \$US339,731,000 (\$A329,394,000) with net profit after tax up 41.1 percent to \$71,265,000.

Resmed said that revenue for the three months to June 30, 2012 was \$US371.9 million up nine percent compared to the same period in 2011, with net profit after tax up 31 percent to \$76.8 million.

Resmed was unchanged at \$3.99 with 7.2 million shares traded.

## BIOTRON

Biotron is preparing for a potential board spill at its annual general meeting, following last year's 'show of hands' first strike of 25 percent against the remuneration report.

In 2011, Biotron reported that 25 percent of the voters in the room at the annual general meeting voted against the remuneration report.

The company said at that time that 28,824,463 votes were for the report, 1,583,743 votes against, with 19,118,404 'open and undeclared'.

The meaning of 'open and undeclared' was unclear and did not appear to be votes against the resolution.

Biotron told Biotech Daily today that those votes were held as proxies by people in the room and although a majority were against the remuneration report, they were not counted, as a poll was not called, and the 'show of hands' was considered sufficient.

According to guidelines from Chartered Secretaries Australia, provided to Biotech Daily by the Australian Securities and Investments Commission, both a show of hands and a tally of votes are acceptable under the two strikes policy, with a count of votes preferred.

Biotron's notice of meeting said other resolutions to be considered at the meeting were the remuneration report and the re-election of directors Michael Hoy, Dr Susan Pond and Robert Thomas.

The meeting will be held at Level 33, 66 Hunter Street, Sydney, on November 28, 2012 at 11.30am (AEDT).

Biotron was unchanged at 12.5 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 statements. 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 dealt with in the following edition.

**David Langsam**  
Editor

### PSIVIDA

Psivida shareholders will vote to issue an option over 104,000 shares to chief executive officer Dr Paul Ashton exercisable at \$US2.14 vesting over four years and exercisable with 10 years.

Psivida said it proposed to issue options over 75,000 shares to director Douglas Godshall, an option over 45,000 shares to chairman Dr David Mazzo and options over 30,000 shares each to directors Paul Hopper, Michael Rogers, Peter Savas.

The company said that the options would vest on July 18, 2013 and would be exercisable at \$US2.14 within 10 years, except for 60,000 of Mr Godshall's option over shares which would vest on March 5, 2013, the anniversary of his appointment as a director, and would be exercisable at \$US2.10 with 10 years.

Psivida said that shareholders would also vote on the remuneration report, ratification of a prior issue of stock and warrants and the re-election of directors chairman Dr David Mazzo, Dr Ashton, Mr Hopper, Mr Rogers, Mr Savas and Mr Godshall.

The meeting will be held at the Waltham Westin Hotel, Cambridge Room, 70 Third Avenue, Waltham, Massachusetts on December 14, 2012 at 10am (USEST).

Psivida was untraded at \$1.50.

### PRIMA BIOMED

Prima says it has appointed chief business officer Marc Voigt as chief financial officer, and Deanne Miller has been appointed general counsel and co-company secretary.

The company said that Ms Miller's appointment as general counsel was effective immediately, and the two would replace chief financial officer and company secretary Ian Bangs effective from November 16, 2012.

Prima said the changes were intended to support the company's development, as the US and European operations increased in importance and to reduce administrative costs.

The company said that Mr Bangs would assist with a transition through to December 31, 2012.

Prima chief executive officer Matthew Lehman said that Mr Bang "significantly contributed to Prima's corporate development and played a crucial role in the previous capital raising and leading the preparations for our Nasdaq listing".

The company said that Ms Miller held a Bachelor of Laws and Bachelor of Commerce from the University of Sydney.

Prima said Ms Miller had experience in corporate law, tax and regulatory compliance, and had been previously employed by KPMG, Westfield Group, Australian Securities and Investments Commission, Macquarie Group and Westpac Group.

The company said that Ms Miller would be based in Sydney and Mr Voigt in Berlin, Germany.

Prima fell 1.5 cents or 11.5 percent to 11.5 cents with 8.7 million shares traded.