



Biotech Daily

Monday May 4, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: LIVING CELL UP 11%, ATCOR DOWN 14%**
- * **CE MARK FOR ATCOR, SUNTECH OSCAR 2 WITH SPHYGMOCOR**
- * **STARPHARMA, ASTRAZENECA EXTEND DENDRIMER-ONCOLOGY WORK**
- * **BENITEC FILES US SEC DRAFT REGISTRATION STATEMENT**
- * **HEARTWARE Q1 REVENUE UP 5% TO \$89m**
- * **MEDICAL DEVELOPMENTS 9 MONTHS SALES REVENUE UP 24% TO \$8m**
- * **RHINOMED SALES 'RECOVER', SIGNS SIGMA FOR DISTRIBUTION**
- * **MAYNE TAKES CONTROL OF OXYCODONE, METHAMPHETAMINE, DORYX**
- * **INNATE JOINS US CONSORTIUM FOR MS TRIAL ASSESSMENT**
- * **ACORN BELOW 5% OF STARPHARMA**
- * **GENETIC TECHNOLOGIES REPAIRS NASDAQ DEFICIENCIES**
- * **ONCOSIL LOSES LAWRENCE GOZLAN**

MARKET REPORT

The Australian stock market was up 0.23 percent on Monday May 4, 2015 with the S&P ASX 200 up 13.1 points to 5,827.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and six were untraded. All three Big Caps rose.

Living Cell was best, up 0.6 cents or 11.1 percent to six cents with 3,100 shares traded, followed by Antisense up 10 percent to 16.5 cents with 1.3 million shares traded. Benitec climbed 9.6 percent; Genetic Technologies rose 8.1 percent; Biotron and Oncosil were up more than four percent; Anteo, Impedimed and Starpharma were up more than three percent; Admedus rose 2.7 percent; Acrux, CSL, IDT, Mesoblast and Resmed rose more than one percent; with Cochlear and Medical Developments up less than one percent.

Atcor led the falls, down 3.5 cents or 14.3 percent to 21 cents with 2.3 million shares traded, followed by Analytica down 10.0 percent to 1.8 cents with 1.7 million shares traded. Patrys lost 9.1 percent; Prima fell 8.3 percent; Actinogen, Cellmid, GI Dynamics, Optiscan and Tissue Therapies were down more than three percent; Compumedics, Neuren and Viralytics shed two percent or more; Universal Biosensors and Sirtex were down more than one percent; with Nanosonics down 0.6 percent.

ATCOR MEDICAL

Atcor says its 'Oscar 2 with Sphygmocor inside' blood pressure monitor system jointly developed with Suntech Medical has received Conformité Européenne (CE) mark. Last year, Atcor said that the Oscar 2 with Sphygmocor was a 24-hour ambulatory blood pressure monitor system jointly developed with the North Carolina-based Suntech Medical to enable periodic measurements to be captured over 24 hours (BD: Jun 18, 2014). Today Atcor said that the CE mark would enable commercial marketing and sales in Europe, Australia and selected Asian countries. The company said that the device would be jointly marketed, with Atcor taking the lead role in the pharmaceutical clinical trials market and Suntech in the clinical practice and research market and it would be the sole distributor in Australia. Atcor chief executive officer Duncan Ross said the CE mark was "a significant step forward which allows both Atcor and Suntech to actively sell Oscar 2 with Sphygmocor inside into major medical device markets". Atcor said that the companies had filed for US Food and Drug Administration 510k clearance and, assuming clearance was granted, Oscar 2 with Sphygmocor inside was expected to be available for sale in the US later in 2015. Atcor fell 3.5 cents or 14.3 percent to 21 cents with 2.3 million shares traded.

STARPHARMA HOLDINGS

Starpharma says that Astrazeneca has extended the collaboration to begin scale-up of a dendrimer enhanced oncology molecule for further development. Starpharma said that during 2014 the two companies conducted a series of studies in which the dendrimer enhanced or DEP technology was used to modify a development candidate from Astrazeneca's cancer pipeline (BD: Apr 7, 2014). The company said that the program had been successful with key enhancements for the DEP conjugate being demonstrated by Astrazeneca in animal models. Starpharma said that based on these results, Astrazeneca was conducting further pre-clinical studies with a view to clinical trials, if results continue to be positive. Starpharma chief executive officer Dr Jackie Fairley said that the company was "delighted that the DEP conjugate has performed so well in extensive testing by Astrazeneca over the last year or so". "The collaboration has been a very productive one and Astrazeneca has been a tremendous partner," Dr Fairley said. Astrazeneca pharmaceutical development project director Andrew Potts said that "combining the great science that's happening in our labs with the most innovative biotech science is an essential part of our plans to deliver the next generation of medicines ... [and] this collaboration will enable us to further harness the DEP technology supporting our plans to accelerate evaluation of a novel molecule within our oncology portfolio." Starpharma was up two cents or 3.3 percent to 62.5 cents.

BENITEC BIOPHARMA

Benitec says it has submitted a draft registration statement to the US Securities and Exchange Commission for a potential US initial public offering. Benitec said the registration statement was confidential and the timing, number of shares and price of the proposed offer had not been determined. The company said that should the US listing proceed, it intended to remain on the ASX. Benitec was up 7.5 cents or 9.6 percent to 85.5 cents.

HEARTWARE INTERNATIONAL

Heartware says cardiac pump revenue for the three months to March 31, 2015 was up five percent to \$US70.0 million (\$A89.4 million) compared to the same period of 2014.

Heartware said that currency fluctuations negatively impacted total revenue growth by about \$US5 million, or about eight percentage points.

Heartware chief executive officer Doug Godshall said that continued US expansion “drove the second-largest unit sales quarter for Heartware, although year-over-year US growth was offset by a decrease in international unit sales when compared to the exceptionally strong international sales we achieved in the first quarter of 2014”.

“We continue to see enthusiastic support of the Heartware System around the world, with the addition of six international and six US customers during the first quarter, which increases our global customer base to more than 280 hospitals,” Mr Godshall said.

Heartware said that for the three months to March 31, 2015, 713 Heartware ventricular assist systems were sold globally, a seven percent increase from 665 units sold in the first quarter of 2014, with US revenue from the sale of 381 units up 25 percent to \$US42.2 million and non-US revenue of \$US27.8 million.

On the Nasdaq on Friday May 1, 2015, Heartware fell 65 US cents or 0.86 percent to \$75.06 (\$A95.86, equivalent to \$2.74 per CDI prior to the company departing the ASX) with 480,642 shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that sales for the nine months to March 31, 2015 increased 24 percent to \$8.3 million compared to previous corresponding period.

Medical Developments said that Pentrox inhaled analgesic sales were 35 percent higher, than for the nine months to March 31, 2014, with respiratory device sales up 53 percent for the same comparative period.

The company said that earnings before interest, taxation, depreciation and amortization was up 300 percent to \$1.6 million and it expected to repay “all its banking facilities” by July 2015.

Medical Developments was up one cent or 0.5 percent to \$2.06.

RHINOMED

Rhinomed says its revenue has “recovered” in the three months to March 31, 2015 to \$159,000, compared to \$31,000 for the three months to December 31, 2014.

Rhinomed said that the sales were predominantly the Turbine sports nasal plugs, following “a substantial redesign resulting from feedback from customers and distributors”.

The company also announced an expansion of its Australian wholesale pharmacy distribution with Sigma Pharmaceuticals to wholesale its Mute nasal plugs snoring and sleep quality technology.

This agreement builds on Rhinomed’s announcement last month, that national pharmacy distributor Symbion was to support the entry of Mute™ into leading pharmacy chains.

Rhinomed was unchanged at 2.6 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has finalized an agreement with Mylan Inc to end its distribution of oxycodone and oxycodone combination tablets in the US from May 1, 2015.

Mayne said it had begun marketing and shipping the oxycodone products under its own label and would control the manufacture, marketing and distribution of the products, which competed in markets worth more than \$US1 billion.

The company said it had taken-back the methamphetamine tablet distribution rights in April 2015 from Mylan and had begun shipments.

Mayne chief executive officer Scott Richards said the oxycodone products were "the largest generic in-market opportunity for our business today and we are confident we can improve the performance of these products under our control".

Mayne said it had completed the establishment of its US specialty brands division responsible for the marketing and distribution of branded products in the US following the acquisition of the broad-spectrum anti-biotic Doryx assets in February 2015.

The company said that the transition period with Actavis had ended and the company had begun shipment of Doryx tablets and completed the recruitment and training of a field sales team of more than 60 staff, many of whom had previous Doryx promotion experience.

Mayne was up three cents or 2.7 percent to \$1.14 with 1.2 million shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate says it will join the US-based Multiple Sclerosis Outcome Assessments Consortium which was developing a clinical outcome assessment tool for clinical trials.

Innate said that the assessment tool could comprise a number of clinical tests and would improve and speed the evaluation of new therapies for progressive multiple sclerosis, in particular.

Innate has its drug candidate MIS416 in a phase II trial for secondary progressive multiple sclerosis with 23 of 90 patients enrolled (BD: Aug 19, Nov 11, 2014).

The company said that the Consortium was funded by the US National Multiple Sclerosis Society and was led by the US Critical Path Institute, a body which orchestrated the sharing of data and expertise among academia, industry, regulatory authorities and patient advocacy groups to generate evidence needed to improve the drug development pathway.

Innate said that the Consortium included clinicians and researchers at leading academic institutions in North America, the UK and Europe, pharmaceutical companies active in the development of multiple sclerosis-related therapies, regulators including the US Food and Drug Administration and the European Medicines Agency, as well as patient advocacy groups including the National Multiple Sclerosis Society and the Multiple Sclerosis Society of the UK.

Innate chief executive officer Simon Wilkinson said the invitation to join the Consortium was "an important event in the clinical development of our drug candidate for progressive [multiple sclerosis]".

"We are the first pre-market stage company to be invited to join this group," Mr Wilkinson said.

Innate chief scientific officer Dr Gill Webster said the company was "excited that the clinical assessments being used in our trial will provide valuable data which should help the Consortium's development of a much needed outcome assessment tool in progressive [multiple sclerosis]".

Innate was unchanged at 19.5 cents.

STARPHARMA

Melbourne's Acorn Capital has reduced further its holding in Starpharma from 18,714,254 shares (5.87%) to below the 5.0 percent substantial level.

Acorn began reducing its holding in Starpharma from 36,614,463 shares (13.05%) last year (BD: Aug 19, 2013).

Last Friday, May 1, 2015, Acorn said that between February 18 and April 30, 2015 it sold shares in a large number of modest trades, with the single largest and most recent sale of 480,000 shares for \$271,046 or an average price of 56.5 cents a share.

GENETIC TECHNOLOGIES

Genetic Technologies says it has remediated the second of two Nasdaq deficiencies.

Genetic Technologies said that in November 2014, it had received a letter from the Nasdaq Stock Market notifying that it was required to maintain a minimum of \$US2.5 million in stockholder equity for continued listing (BD: Nov 7, 2014; Feb 4, 2015).

The company said that in September 2014 it had raised \$2,150,000 through the issue of unlisted secured debt notes, in November 2014 it completed the sale of its heritage Australian genetics business for \$2,000,000 in cash, raised \$257,500 in December through a share plan, received \$1,844,500 since January 30 2015 from the exercise of options, received \$2,603,111 through a standby equity facility with the Kentgrove Capital Growth Fund and on March 6, 2015, raised about \$18.6 million from US investors, and at March 31, 2015 had \$20,176,450 in cash.

Genetic Technologies was up 0.3 cents or 8.1 percent to four cents with 3.6 million shares traded.

ONCOSIL MEDICAL

Oncosil says that non-executive director Lawrence Gozlan "has decided to step down ... effective from today".

Mr Gozlan was appointed a director in February 2014 and was elected as a director and provided with 11,038,464 loan shares in April 2014 (BD: Feb 27, Mar 21, 2014).

Today, Oncosil said that Mr Gozlan had resigned "in order for him to concentrate his focus more clearly on his considerable other business interests".

Mr Gozlan is also a director of Prana, Phosphagenics and Ausbiotech.

The company said it thanked Mr Gozlan "for his considerable input and contribution to the growth of Oncosil Medical to date, and wishes him all the best in his future endeavors".

Oncosil was up half a cent or 4.8 percent to 11 cents with 4.5 million shares traded.