



# Biotech Daily

Friday June 30, 2017

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 1.66 percent on Friday June 30, 2017 with the ASX200 down 96.6 points to 5,721.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell and six traded unchanged. All three Big Caps fell.

Dimerix was the best for the second day in a row, up 0.1 cents or 11.1 percent to one cent with 16.2 million shares traded.

LBT climbed 6.25 percent; Clinuvel and Polynovo were up five percent or more; Compumedics and Living Cell improved more than four percent; Admedus, Bionomics and Osprey were all up 3.9 percent; Orthocell and Viralytics rose more than two percent; Actinogen, Avita and Factor Therapeutics were up more than one percent; with Mesoblast and Pro Medicus up by less than one percent.

Uscom led the falls, down two cents or 9.5 percent to 19 cents with 7,509 shares traded.

Atcor lost 5.4 percent; Cyclopharm and Neuren fell more than four percent; Benitec, Cellmid, Impedimed, Oncosil and Prima were down more than three percent; Acrux, Cochlear, CSL, Genetic Signatures, Nanosonics and Starpharma shed more than two percent; ITL, Medical Developments, Resmed and Sirtex were down one percent or more; with Airxpanders and Ellex down by less than one percent.

## DR BOREHAM'S CRUCIBLE: STARPHARMA

By TIM BOREHAM

**ASX Code:** SPL

**Market cap:** \$269.4 million; **Share price:** 73 cents; **Shares on issue:** 369.1 million

**Chief executive officer:** Dr Jacinth (Jackie) Fairley

**Board:** Rob Thomas (chairman), Dr Jackie Fairley, Richard Hazleton, Peter Turvey, Zita Peach

**Financials (March quarter):** revenue \$17,000 (\$641,000 year to date), cash used \$5.768 million (\$15.65 million year to date), cash on hand \$29.7 million\*, expected June quarter outflows \$5.9m

\* Does not include \$US2 million milestone payment from Astrazeneca and \$35 million proceeds from sale of agrichemical division

**Major shareholders:** Allan Gray 13.3%, M+G Investment Funds 13%, FIL Ltd 7.9%, Peter Colman 1%.

Sometimes an early-stage company is best judged on what it decides not to do, rather than what it decides to continue doing.

Hence the positive investor reaction to the sale of Starpharma's agrichemicals business to the global seed and crop protection giant Agrium, for \$35 million in cash.

The assets to be sold are based on Starpharma's Priostar (dendrimer) patents and know-how. The sale was accompanied by a prezo and investor dial-in that highlighted Agrium's \$US13 billion and how the Starpharma assets will suit the business. For Agrium, \$35 million is chickenfeed (which it sells through its local ag supplies business, Landmark).

Given Starpharma has banked the cash and there are no further ongoing links, we suspect most investors don't give a hoot about Agrium's prospects. But hats off to Starpharma for achieving four times book value for the asset.

According to Dr Fairley, the portfolio would have to generate revenue of \$1 billion for Starpharma to earn \$35 million in royalties.

The divestment tidies up the sprawling Starpharma portfolio, based on the use of its dendrimer intellectual property for cancer drug development coated condoms and as a topical microbicide for preventing bacterial vaginosis (BV).

Dendrimers are nanoscale polymers that have wide uses in the pharmaceutical sector. It's hoped that when combined with the magic molecule, existing cancer drugs will target tumors in a more patient-friendly manner.

Starpharma's drug delivery platform, dendrimer enhanced products, or DEP, unlike Johnny Depp's name, is always accompanied by a trademark logo so it can't be pirated.

In collaboration with drug giant Astrazeneca, Starpharma's early-stage program is based on three drugs: docetaxel for numerous indications including breast, head and gastric cancers, cabazitaxel for prostate cancer and irinotecan for colorectal cancer.

The company cites sales for docetaxel (brand name Taxotere) at \$US3.1 billion (\$A4.06 billion), cabazitaxel (Jevtana) at \$US426 million and irinotecan (Campostar) at \$US1.1 billion. (By the way, whoever invents these drug names should be kept away from the experimental pharmacy cabinet).

On June 6, Starpharma said DEP irinotecan "significantly outperformed [Campostar in] multiple human colon cancer models". Just to be clear, these did not involve real-life people but mice grafted with human cancer cells. But this is established practice and one has to start somewhere. The US Food and Drug Administration recently warned about irinotecan in relation to diarrhoea and immune suppression, so there's obviously room for improvement.

The Astrazeneca tie-up also covers Starpharma's antiviral Vivagel coating, which has been adopted by condom maker Ansell and Japan's Okamoto to prevent sexually transmitted nasties including HIV, genital herpes and human papillomavirus.

In May, Ansell said it would sell its 'sexual wellness' (condom) arm to China's Humanwell Healthcare and venture capital fund Citic for \$US600 million. Vivagel condoms were recently launched in Canada, the first North American jurisdiction. In July last year, Starpharma signed a deal with Shenyang Sky and Land Latex to provide condoms under a government program, with an annual requirement of three billion condoms. The company has also inked an Iranian deal.

"The strong Asian market presence of Humanwell will add additional strategic opportunities for the continued market penetration of the Vivagel condom in this fast growing region," Dr Fairley says.

Guffaws abounded after our Olympic athletes left for Rio last year armed with a generous supply of Dualprotect Vivagel dingers. The 15,000 extra condoms was over and above the 450,000 generally available at the village, which casts a new light on the ideals of stamina and performance. At least none of our bronzed athletes returned with the Zika virus.

Starpharma estimates the bacterial vaginosis treatment market at \$US750 million, the bacterial vaginosis preventative market at \$US1 billion and the global condom market at \$US51 billion. But so far, Starpharma has been unable to show statistical significance for Vivagel for bacterial vaginosis, while claiming clinical significance for both cure in 2012 and for recurrence in 2013, with further trials expected to report imminently.

### **What's next?**

There's a busy slate of news coming up, with Starpharma expected to release top-line data from its phase I docetaxel trial this year.

The company will also start a phase I clinical trial of DEP-cabazitaxel and is preparing for a phase II trial of DEP-docetaxel in the current half.

In the near future, Starpharma should also release the results of a phase III trial for Vivagel in preventing recurring bacterial vaginosis.

“The trials have completed and the extensive data set from the trials are currently undergoing data collection, routine blinded quality control review and bio-statistical programming,” Dr Fairley says.

Other events to watch for are further commercial deals for Vivagel BV and a new drug application to the FDA.

Dr Fairley says there are several term sheets under discussion for commercial rights to Vivagel, a process helped along by the FDA granting coveted Qualified Infectious Disease Product status.

“In fact, Starpharma is the only Australian company ever to have been granted the QIDP designation,” says a proud Dr Fairley.

While Starpharma funds its own trial candidates, Astrazeneca pays milestones and royalties for the use of DEP in its own portfolio, with three programs currently underway.

### **Dr Boreham’s diagnosis:**

Starpharma listed in 2000, having been spun off from the Biomolecular Research Institute in 1996 and its shares have traded between 61 cents and 86 cents in the last 12 months, having peaked at \$1.68 in late 2012.

Is there a statute of limitations for reaching the Promised Land?

While the condoms generate some revenue, meaningful returns remain elusive even though the company inked its first coated condom deal in 2008 (with Durex owner SSL, which was taken over by Reckitt Benckiser). The drug stuff is a wait-and-see proposition, although the company has enough cash to last four years.

Starpharma last month received a \$2.6 million milestone from Astrazeneca, in relation to a preclinical milestone relating to one of Astrazeneca’s “highly novel” oncology molecules and the company could receive up to \$US124 million in payments (as well as tiered royalties) if this secret drug is formalised.

More broadly, it’s hoped the Astrazeneca collaboration blossoms into big-ticket licencing deals.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He ponders whether Ansell and Starpharma would have won saturation headlines if they had provided free antiviral gloves to the athletes, rather than free condoms.***

## PRIMA BIOMED

Prima says it expects to raise \$US5.0 million (\$A6.5 million) through the issue of 2,631,268 American depository shares (ADSs) at \$US1.90 (\$A2.47) each.

Prima said that each ADS was equivalent to 100 Australian shares making the issue equivalent to 2.5 cents per Australian share, with the company trading between 2.8 cents and four cents in the month of June.

The company said that the registered direct offering included the issue of unregistered warrants to purchase up to 1,973,451 ADSs, exercisable at \$US2.50 per ADS within five years and six months from issue.

Prima said that the Maxim Group was the sole placement agent for the offer, which was expected to close on or about July 5, 2017.

The company said the funds would be used for clinical development of IMP321 in its phase IIb, 'active immunotherapy paclitaxel' (AIPAC) trial for metastatic breast cancer and its phase I 'two active immune-therapeutics in melanoma' or Tactimel trial for unresectable or metastatic melanoma, pre-clinical research on IMP761 and for other general corporate purposes, including the potential acquisition or investment in businesses, products and technologies.

Prima said the offer was only available in the US to US investors through a prospectus. Prima fell 0.1 cents or 3.45 percent to 2.8 cents with 2.9 million shares traded.

## PSIVIDA

Psivida's extraordinary general meeting passed the two resolutions, with up to 22.2 percent opposition to a 100 percent increase in shares on issue to 120,000,000.

Psivida said that 6,366,794 votes (22.2%) opposed the resolution to amend the company's certificate of incorporation to increase the number of authorized shares of common stock from 60,000,000 shares to 120,000,000 shares, with 22,312,009 votes (77.8%) in favor.

The company said that 1,838,123 votes (11.1%) opposed the issue of 5,100,000 shares under the \$US20 million (\$A26.0 million) "at market issuance sales agreement" with FBR Capital Markets, while 14,703,116 votes (88.9%) were favor, and there were 11,968,457 "broker non-votes" (BD: Feb 9, 2017).

The company's most recent Appendix 3B said that Psivida had 39,356,999 US shares and Chess depository interests on issue meaning that the opposition to the increase in the number of shares amounted to 16.2 percent of the company, sufficient to requisition extraordinary general meetings.

Psivida was unchanged at \$2.36.

## MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says that executive chairman Brett Mitchell and company secretary Rachel Kerr have exercised 5,375,000 unlisted options, increasing their holdings.

MGC said that Mr Mitchell exercised 2,500,000 options at 2.5 cents and 2,500,000 options at 4.0 cents.

The companies Appendix 3B said that a total of 2,875,000 were exercised at 4.0 cents each, implying Ms Kerr exercised 375,000 options.

MGC said that Mr Mitchell paid \$162,500 to increase his holding to 16,193,894 shares.

The company said that 4,000,000 unlisted options exercisable at 20c would expire today and would be cancelled.

MGC fell 0.1 cents or 2.1 percent to 4.6 cents with 7.2 million shares traded.

## BOTANIX

Botanix has requested a trading halt pending “an announcement regarding clinical trial results”.

In May, Botanix said it had begun a phase Ia study of its Permetrex-delivered synthetic cannabidiol BTX-1503 for acne (BD: May 8, 2017).

Trading will resume on July 4, 2017 or on an earlier announcement.

Botanix last traded at 4.3 cents.

## INNATE IMMUNOTHERAPEUTICS

Innate directors Michael Quinn and Andrew Sneddon say they sold shares following the phase II trial which showed that MIS416 did not work for multiple sclerosis.

On Tuesday, Innate fell 93 percent on news its 12-month, 93-patient, phase IIb trial of MIS416 for secondary progressive multiple sclerosis showed no “clinically meaningful or statistically significant” efficacy (BD: Jun 27, 2017).

Today, Mr Quinn said he held 462,963 shares directly, 656,445 shares through a superannuation fund and his wife Rosemary Quinn held 892,196 shares all of which were sold on June 29, 2017 at prices ranging from 5.4 cents to 5.5 cents a share.

Mr Quinn said he directly and indirectly held 2,525,000 options exercisable at prices ranging from 40 cents to 65 cents.

Mr Sneddon said he held 611,111 shares indirectly through a family superannuation fund and sold them on June 28, 2017 at 4.5 cents, retaining 364,893 shares held in a family trust as well as 1,725,000 options, exercisable at prices ranging from 40 cents to 65 cents. In 2013, Innate raised \$10 million at 20.1 cents a share to list on the ASX and hit a high of \$1.83 in January 2017 on news that Republicans close to US President Donald Trump including Health Secretary Dr Tom Price were shareholders, with New York Congressman Chris Collins a founding director (BD: Dec 18, 2013; Jan 22, 27, 31, Mar 31, 2017).

Innate fell 1.9 cents or 23.5 percent to 6.2 cents with 37.2 million shares traded.

## IMPEDIMED

The Sydney-based Macquarie Group says it has become a substantial shareholder in Impedimed with 20,647,529 shares (5.50%).

The Macquarie substantial shareholder notice filed more than 15 pages of information on “controlled bodies corporate” as well as two pages of purchases, sales, borrowings and returns and transfers, with individual trades ranging from 11 shares to 6,756,700 shares between March 1 and June 26, 2017 at prices ranging from 57 cents to 85 cents.

Impedimed fell three cents or 3.8 percent to 75.5 cents with one million shares traded.

## RESAPP HEALTH

Resapp says that 62,437,499 ordinary shares and 38,437,500 performance shares will be released from escrow on July 14, 2017.

Resapp said the performance shares would convert to ordinary shares on achieving an aggregated gross revenue of \$20 million in the five years to July 14, 2020.

Resapp most recent Appendix 3B new issue announcement said that it had 596,602,103 shares quoted on the ASX, implying that following the escrow release there would be 659,039,602 shares available for trading, with a further 55,312,500 unlisted performance shares pending the achievement of a milestone.

Resapp fell half a cent or 1.7 percent to 29.5 cents with 1.6 million shares traded.

## PRESCIENT THERAPEUTICS

Prescient says that executive director Paul Hopper will move to the role of non-executive director, effective from July 1, 2017.

Prescient non-executive chairman Steven Engle said that Mr Hopper's "contribution to the establishment of the Company has been exceptional".

"Prescient has built a high quality team to support our operations, including Paul's prior executive duties," Mr Engle said.

Mr Hopper said he was "firmly committed to Prescient as both a director and a large shareholder".

Prescient fell 0.1 cents or 1.9 percent 5.2 cents.