



# Biotech Daily

Monday September 7, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: STARPHARMA UP 21%; AVITA DOWN 14%**
- \* **STARPHARMA, ASTRAZENECA DEP DEAL \$180m-PLUS POTENTIAL**
- \* **3D QUALITY AUDIT, PRINTER COMMISSIONED, 333D AGREEMENT**
- \* **IMUGENE REQUESTS CAPITAL RAISING TRADING HALT**
- \* **ACRUX, GEDEON RICHTER LENZETTO EURO APPROVAL, \$3m PAYMENT**
- \* **INVION CANCELS SHAREHOLDER ENTITLEMENT ISSUE**
- \* **BVF PARTNERS, MARK LAMPERT TAKE 18% OF CIRCADIAN**
- \* **TREAGUS FAMILY INCREASE, DILUTED TO 17% OF BIOTECH CAPITAL**

## MARKET REPORT

The Australian stock market fell 0.2 percent on Monday September 7, 2015 with the ASX200 down 10.2 points to 5,030.4 points.

Seven of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and four were untraded.

Starpharma was the best, up 13 cents or 21.3 percent to 74 cents with 2.6 million shares traded. Anteo and Cellmid climbed more than three percent; Bionomics, Nanosonics and Pharmaxis rose two percent or more; Prima was up 1.7 percent; with Cochlear and CSL up by less than one percent.

Avita led the falls, down one cent or 14.3 percent to six cents with 74,133 shares traded, followed by Compumedics down 12.5 percent to 21 cents with 164,855 shares traded and Optiscan down 10 percent to 4.5 cents with 399,436 shares traded.

Both Circadian and Genetic Technologies lost 9.1 percent; Benitec fell 6.9 percent; Neuren and Oncosil were down five percent or more; Orthocell fell 4.6 percent; Biotron, Impedimed and Osprey were down more than three percent; Admedus shed 2.9 percent; Actinogen, Clinuvel, IDT, Medical Developments, Tissue Therapies and Viralytics were down more than one percent; with Acrux, Mesoblast, Resmed, Reva and Sirtex down by less than one percent.

## STARPHARMA

Starpharma says it has licenced its dendrimer drug delivery technology to Astrazeneca for potentially more than \$US126 million (\$A180 million), with \$US2 million up-front.

Starpharma said that beyond the \$180 million deal it could be entitled to \$US93.3 million (\$A133 million) in milestone payments for each product developed under the agreement. The company said that licence allowed Astrazeneca to develop and commercialize compounds directed at a defined family of targets using its dendrimer enhanced product (DEP) drug delivery technology.

Starpharma said that platform used its proprietary dendrimers, with the aim of enhancing the dosing and efficacy characteristics of pharmaceuticals.

The company said that it would be eligible to receive signature and milestone payments on one or more Astrazeneca DEP products if they progress through the development pipeline and milestone and royalty payments on any net sales of the resultant products. Starpharma said that Astrazeneca would fund all development and commercialization costs under the agreement, including on-going and future collaborative work.

The company said that its other programs, including the DEP docetaxel product were not negatively impacted by the arrangement.

Starpharma said that a signature payment of \$US2 million (\$A2.9 million) became payable on execution of the agreement and that for the initial product, "development and launch milestones could total up to \$US64 million (\$A91 million) and sales milestones based on specified annual sales levels could total up to \$US60 million (\$A86 million).

The company said that the licence agreement allowed for additional products to be incorporated, with development and regulatory milestone payments of up to \$US53.3 million (\$A76 million) and potential sales milestones based on specified annual sales levels for qualifying additional products could total up to \$US40 million (\$A57 million).

Starpharma said that any Astrazeneca DEP products would also attract tiered royalties on net sales.

Starpharma chief executive officer Dr Jackie Fairley said that the agreement was "an exciting development for Starpharma and its DEP platform".

"It follows a successful collaboration in which Starpharma's DEP drug delivery technology has been applied to an important Astrazeneca oncology candidate," Dr Fairley said.

"The agreement clearly illustrates both the commercial potential and platform nature of Starpharma's DEP drug delivery technology," Dr Fairley said.

"We estimate that each qualifying product successfully commercialised under this agreement could be worth over its life around \$US450 million (\$A643 million) to Starpharma and depending on the range of indications and degree of commercial success in the market potentially significantly more," Dr Fairley added.

"The fact that this deal is structured for multiple products underlines the real potential for additional upside for both companies," Dr Fairley said.

"It is worth noting that Starpharma retains all rights outside of a well-defined and narrow area of application, meaning that its platform remains unencumbered and available for licensing in the vast majority of oncology and other applications for future deals with other partners," Dr Fairley said.

Astrazeneca's head of the oncology innovative medicines unit Susan Galbraith said the company had a "a long-standing and successful working relationship with Starpharma [and] this licence agreement will enable us to further harness the DEP technology and evaluate its potential across novel molecules within our oncology portfolio".

Starpharma climbed 13 cents or 21.3 percent to 74 cents with 2.6 million shares traded.

### 3D MEDICAL

3D Medical says it has completed the first stage audit of its quality management system. 3D said the audit was to meet International Organization for Standardization (ISO) standards ISO 13485 Medical devices, quality management systems and ISO 9001 quality management systems.

The company said that the second stage audit would examine the implementation of the quality management system and assess the conformity against certification requirements and was scheduled for December 2015 at the Port Melbourne facility.

3D said that ISO accreditation was necessary for building commercial scale as a supply chain partner in delivering custom made and mass customised medical devices.

The company said the Stamford, Connecticut-based research company Gartner Inc had analyzed the technological trends in medical three-dimensional (3-D) printing and identified specialist applications allowing for personalization of design, such as hearing aids and dental devices, were viable and had already become the norm in medical care.

3D Medical said that Gartner predicted that 3-D printed orthopaedic devices, such as those used in the \$US15 billion market for hip and knee replacements, as well as other common internal and external medical devices, would be in mainstream use within two to five years.

The company said that its selective laser melting (SLM) printer had been installed commissioned, providing medium to high volume metal part production with a build envelope of about 27 litres.

3D Medical chairman Dr Nigel Finch told Biotech Daily that the capacity was 280mm by 280mm by 350mm.

The company said that the printer had been configured to print in grade 5 titanium alloy suitable for the prototyping and production of custom patient-specific implants, such as orthopaedic devices and jaws, standard size medical implants, medical instruments and other medical consumables.

3D Medical said it had a service level agreement with 333D Pty Ltd to provide three-dimensional printing services.

Dr Finch said that Frank Pertile was a director of both 3D and 333D, with the latter having a sub-lease agreement to share a proportion of the office and commercial space at 3D Medical's Port Melbourne facility.

The company said that 333D was focused on opportunities associated with additive manufacturing and had designed and manufactured "the largest fused filament fabrication printer in Australia".

3D Medical said that the Agreement provided the company with access to a broad range of 3-D printing hardware technologies and services that further extended its prototyping and production capacity and capability.

Dr Finch said that "the co-location of 333D within the company's premises provides synergistic benefits to [3D Medical] including the sharing of intellectual capital, knowledge transfer and access to dedicated facilities for the rapid prototyping and production of 3-D printed medical devices and consumables".

3D Medical was up 1.6 cents or 23.5 percent to 8.4 cents.

### IMUGENE

Imugene has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on September 9, 2015 or on an earlier announcement.

Imugene last traded at 0.9 cents.

### ACRUX

Acrux says its Lenzetto estradiol spray for menopause symptoms has had multiple approvals in Europe, triggering milestone payments of \$US2 million (\$A2.9 million). Acrux says that Lenzetto was licenced exclusively in Europe to the Budapest, Hungary-based Gedeon Richter Plc and the approvals were granted after the European decentralised procedure was completed, with the first country approval triggering a milestone payment of \$US1 million and the second and third approvals triggering milestone payments of \$US500,000 each, with launches planned by July 2016, following pricing and reimbursement approvals.

Acrux said that its estradiol product was branded Lenzetto in Europe and Evamist in the US where it had been on sale since 2009.

The company said that in Europe, including Russia, the oestrogen-only hormone replacement market had annual sales of more than EUR85 million (\$A136.5 million).

Acrux fell half a cent or 0.85 percent to 58 cents.

### INVION

Invion says it has cancelled a secondary capital raising that would have enabled existing shareholders to acquire shares at about 1.4 cents each.

Last week, Invion said it would raise \$1,001,000 from an unnamed US institutional investor at 1.4 cents a share, with 12-months options exercisable at 1.4 cents each and five-year options exercisable at 1.75 cents each (BD: Sep 1, 2015).

The company said at that time it was "reviewing other secondary capital raising options to enable existing shareholders to participate on similar terms".

Invion fell 0.1 cents or 6.7 percent to 1.4 cents with 2.7 million shares traded.

### CIRCADIAN

BVF Partners and Mark Lampert say they have increased their substantial holding in Circadian from 26,005,102 shares (17.32%) to 26,998,691 shares (17.98%).

The San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert said that between June 24 and September 3, 2015 they acquired the shares in 24 separate trades with the largest single purchase on June 29 of 139,181 shares for \$27,753 or an average price of 19.9 cents a share.

Circadian fell two cents or 9.1 percent to 20 cents.

### BIOTECH CAPITAL

Dr Richard and Karen Treagus say they have increased their holding in Biotech Capital from 16,261,781 shares to 17,000,000 shares, but have been diluted to 17.24 percent.

Biotech Capital chairman Dr Treagus said that with Karen Treagus and between March 13 and May 25, 2015 he bought 738,219 shares on-market for \$78,204 or 10.6 cents a share.

Last week, Biotech Capital said it had raised \$1,028,847 through the issue of 12,860,583 shares at eight cents each to the Auckland Trust Co (BD: Sep 1, 2015).

Biotech Capital fell half a cent or four percent to 12 cents.