Biotech Daily

Tuesday January 28, 2014

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: PRANA UP 10%, CLINUVEL DOWN 16%**

*** IDT OPTION ON PERRIGO'S HRT FDA APPLICATION**

*** NEUREN ON-TRACK FOR FOUR NNZ-2566 PHASE II TRIALS**

*** GOODBYE BIONICHE**

*** AUSTRALIAN CUSTOM PHARMACEUTICALS, CALZADA AOD9604 LICENCE**

*** BIOPROSPECT RAISES $1m FOR INVATEC DEPRESSION DIAGNOSTIC**

*** VIRALYTICS REQUESTS CAPITAL RAISING TRADING HALT**

*** BLUECHIIP CEO BRETT SCHWARZ, SALES HEAD BRETT ROBERTS GO**

*** ALLAN GRAY TAKES 13% OF STARPHARMA**

*** GLENEAGLES TAKES 27%, LSAF 7%, CHIFLEY 7% OF HEALTHLINX**

MARKET REPORT

The Australian stock market fell 1.26 percent on Tuesday January 28, 2014 with the S&P ASX 200 down 65.8 points to 5,175.1 points.

Eight of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and four were untraded.

Prana was the best, up 10 cents or 10 percent to $1.10, with 1.6 million shares traded.

Starpharma climbed 7.1 percent; QRX was up 5.7 percent; both Avita and Oncosil were up 3.6 percent; IDT rose 2.6 percent; with GI Dynamics and Optiscan up more than one percent.

Clinuvel led the falls, down 25 cents or 16.1 percent to $1.30 with 10,840 shares traded.

Psivida lost 8.5 percent; Medical Developments, Pharmaxis and Tissue Therapies all fell 7.7 percent; Universal Biosensors was down 6.6 percent; Anteo was down 5.6 percent; Neuren and Patrys fell more than four percent; Admedus, Cellmid, Genetic Technologies and Prima were down more than three percent; Alchemia, Bionomics, Ellex and Nanosonics shed more than two percent; Benitec, CSL and Mesoblast were down more than one percent; with Acrux and Cochlear down by less than one percent.

IDT AUSTRALIA

IDT says it has an option to acquire Perrigo Company's synthetic conjugated oestrogens abbreviated new drug application filing to the US Food and Drug Administration.

IDT said that Perrigo had previously commissioned it to manufacture the finished dose form of its synthetic conjugated oestrogens product in its high containment tableting facility as hormones, like cytotoxic oncology drugs, required specialist high containment manufacturing facilities.

The company said that Perrigo filed its abbreviated new drug application data package to the FDA but in 2013 Perrigo was notified by the FDA of a problem related to sourcing the bulk drug and the FDA was unable to further progress the review.

IDT managing director Dr Paul MacLeman told Biotech Daily that IDT previously made the tablet form of the product for Perrigo from bulk drug, but would either manufacture the bulk drug itself or buy it in.

IDT said that conjugated oestrogens were used as hormone replacement therapy in symptomatic menopausal patients.

The company said that sales were dominated by Premarin manufactured and marketed by Pfizer's Wyeth from equine conjugated oestrogens and sales for all conjugated oestrogens for the 12 months to March 31, 2013 were about $US1.2 billion, with synthetic conjugated oestrogens a synthetic version of Premarin.

IDT said that sales for synthetic conjugated oestrogens for the 12 months to March 31, 2013 were about $US25.2 million, but no major company was promoting them or expanding the label claims.

The company said that the option provides for Perrigo to exclusively market and distribute the product in the US on favorable terms if the FDA approves the abbreviated new drug application.

IDT managing director Dr Paul MacLeman said that acquiring Perrigo's synthetic conjugated oestrogens abbreviated new drug application "sits squarely within IDT's strategy to maximize the value of our existing assets via the growth of our own specialty generic drug portfolio, so expanding our revenue share of the products".

"In the event IDT proceeds with the transaction, Perrigo's role in marketing the product will maximize its success in the pharmacy channel where the product sits, due to Perrigo's dominance in this sector," Dr MacLeman said.

IDT said that during the four month option period it would undertake due diligence to assess whether the drug sourcing issue could be addressed through its specialist manufacturing capabilities and if so it would be able acquire a "turn-key" abbreviated new drug application package which had partly progressed through FDA review, potentially shortening the time to market.

The company said that it it was not satisfied that the issue was able to be addressed, it could terminate the option at any time or let it expire, with no further obligations.

IDT said that the commercial terms surrounding the option payment, the option extension payment, the consideration for IDT's acquisition of Perrigo's synthetic conjugated oestrogens abbreviated new drug application and the royalty split on product sales by Perrigo in the US were confidential.

IDT said that the Dublin, Ireland-based Perrigo developed, manufactured and distributed over-the-counter and generic prescription pharmaceuticals, infant formulas and nutritional products with sales in 2013 of $US3.26 billion.

IDT was up one cent or 2.6 percent to 40 cents.

NEUREN PHARMACEUTICALS

Neuren says it has begun its 60-patient, double-blind, placebo-controlled phase II trial of NNZ-2566 for Fragile X syndrome, with three other trials progressing on schedule.
Neuren said that the Fragile X trial was led by Chicago's Rush University Medical Center with subjects at six US sites and enrolment expected to be completed by the end of 2014, with top-line results announced by July 2015 (BD Oct 30, 2013).
Neuren said the trial was designed to assess the safety, tolerability and efficacy of NNZ-2566 in treating symptoms of Fragile X syndrome and the US Food and Drug Administration had granted orphan drug designation to NNZ-2566 for Fragile X syndrome, which also had FDA fast track designation.
Neuren said that its 48-patient phase II double-blind, placebo-controlled clinical trial of NNZ-2566 for Rett Syndrome began in April 2013 and the first group of subjects had received the lower dose or placebo.
The company said that the independent data and safety monitoring committee reviewed data from that group and gave approval for the trial to proceed to a second group of subjects who would receive the higher dose or placebo and the first subjects in the higher dose group had begun treatment.
Neuren said that 36 subjects were enrolled in the trial, 22 patients had completed the trial, with enrolment to be completed by July 2014 and top-line results by the end of 2014.
Last year, an on-line petition claiming anecdotal evidence called for the unblinding of the trial but Neuren opted to continue according to the protocol (BD: Aug 5, 2013).
Today, Neuren said the Rett syndrome program had FDA fast track designation and it intended to seek orphan drug designation after completing the current trial.
The company said that 131 subjects had been enrolled in its 260-patients phase II trial of intravenous NNZ-2566 for moderate to severe traumatic brain injury, which was a collaboration with the US Army which was reimbursing the majority of direct costs.
Neuren said that traumatic brain injury was a leading cause of death and disability in both civilian and military populations and the program had FDA fast track designation.
Neuren said it was in the process of increasing the number of US trauma centres participating in the trial and two large clinical studies that were directly competing for subjects at some of the trial sites had completed enrolment.
The company said that enrolment was forecast to be completed by the end of 2014 with top-line results reported by July 2015.
Neuren said that preparations were continuing for a 132-subject phase II clinical trial of the oral form of NNZ-2566 in concussion or mild traumatic brain injury in collaboration with the US Army at the Fort Bragg, North Carolina-based Womack Army Medical Centre.
The company said that the trial protocol was under review and arrangements with clinical service providers were being finalized for the trial to begin by July 2014, enrolment completed by July 2015 with results by the end of 2015.
Neuren said the US Patent and Trademark Office would issue a patent for NNZ-2566 claiming "a method for treating a cognitive disorder or a memory disorder" valid to 2026.
Neuren executive chairman Dr Richard Treagus said the company's clinical trials were "proceeding to plan and we remain on schedule and fully funded through to completion".
Neuren fell half a cent or 4.8 percent to 10 cents with 4.3 million shares traded.

BIONICHE LIFE SCIENCES

The ASX says Bioniche will be suspended from the close of trading today, January 28, 2014, pending removal from the Official List February 3, 2014 (BD: Dec 2,2013).
Bioniche last traded down three cents or 9.7 percent to 28 cents.

CALZADA

Calzada says that wholly-owned subsidiary, Metabolic Pharmaceuticals has licenced AOD9604 to Australian Custom Pharmaceuticals.
Calzada said that the Sydney-based Australian Custom Pharmaceuticals was Australia's largest compounding pharmacy and it would receive double-digit royalties on sales.
The company said that the licence was for the use, manufacture and sale of AOD9604 in compounded medicine preparations that comply with Australian regulations.
Calzada said that during the past 18 months "an increasing number of Australian registered medical practitioners have been prescribing AOD9604 products for use by their patients".
"Anecdotal evidence indicates that AOD9604 is being prescribed to reduce body fat and for muscle, tendon and cartilage repair," Calzada said.
In 2007, the then Metabolic demonstrated that AOD9604 did not reduce weight in a trial of 536 patients, and only those who did not conform to the US Food and Drug Administration diet and exercise regime lost weight (BD: Feb 21, 2007).
The drug has been at the centre of a controversy involving the Essendon Football Club and was initially included in Phosphagenics claimed fat-buster crème and later removed (BD: Jul 29, 2013).
Calzada said that doctor prescriptions filled by licenced compounding pharmacies, such as Australian Custom Pharmaceuticals, could be legally prepared under Australia's Therapeutic Goods Act.
Calzada said it was "exploring options by which it can derive revenue from the manufacture, use and sale of AOD9604 products infringing its patent portfolio by third parties".
The company said that the licence to Australian Custom Pharmaceuticals "opens the potential to strike similar licence agreements with other Australian compounding pharmacies".
Calzada said that in other jurisdictions such as the US compounding pharmacies operated under similar legislation and it intended to explore opportunities to licence AOD9604 outside Australia.
The company said that it did not manufacture, distribute or supply AOD9604.
Calzada was up 0.2 cents or 2.7 percent to 7.7 cents.

BIOPROSPECT

Bioprospect says it has raised $1,000,000 through the issue of convertible notes for its Invatec depression and mental illness diagnostic technology (BD: Jan 22, 2014).
Bioprospect said that each convertible note would have a face value of $25,000 for shares to convert at the lesser of 0.3 cents each or the five-day volume weighted average price immediately prior to conversion, until the maturity date of December 31, 2016.
The company said that notes would accrue interest at eight percent a year.
Bioprospect was unchanged at 0.3 cents with 1.6 million shares traded.

VIRALYTICS

Viralytics has requested a trading halt "pending an announcement in relation to a potential capital raising".
Trading will resume on January 30, 2014 or on an earlier announcement.
Viralytics last traded at 32 cents.

BLUECHIIP

Bluechiip says that chief executive officer Brett Schwarz has resigned and chief technical officer Dr Jason Chaffey has been appointed acting chief executive officer.
Bluechiip said that chairman Iain Kirkwood had been appointed as executive chairman and commercial director Brett Roberts had also left the company with all management changes effective immediately.
Mr Kirkwood said that Mr Schwarz co-founded the company with the inventor Dr Ron Zmood and helped oversee the company and its technology.
“However, the board has unanimously concluded that new leadership is required to implement the commercialization strategy and restore investor confidence in the company,” Mr Kirkwood said.
“A lot of hard work went into getting product ready for launch last year and it would be an understatement to say that the board is extremely disappointed with the sales performance in 2013,” Mr Kirkwood said.
“We are taking immediate action to redress this situation and are confident that Bluechiip is in a strong position to generate sales in 2014,” Mr Kirkwood said.
“We will focus urgently on securing sales and a meaningful presence in the domestic, Australian market where there are multiple opportunities in every state to introduce our product and reviewing our distributor arrangements in the US which have, to date, not produced the expected results,” Mr Kirkwood said.
Bluechiip fell 1.3 cents or 17.3 percent to 6.2 cents with 1.8 million shares traded.

STARPHARMA

Allan Gray Australia has increased its holding in Starpharma from 35,194,434 shares (12.41%) to 38,225,289 shares (13.43%).
Allan Gray said that it bought and sold Starpharma shares between June 18, 2013 and January 23, 2014 with the single largest transaction the acquisition of 1.794,899 shares for $1,712,609 or 95.4 cents a share and the most recent acquisition 30,119 shares for $22,804 or an average price of 75.7 cents a share.
Starpharma climbed five cents or 7.1 percent to 75.5 cents.

HEALTHLINX

Gleneagles Securities says it has become a substantial shareholder in Healthlinx with 3,367,401,500 shares or 26.68 percent.
Chifley Portfolios says it has become a substantial shareholder in Healthlinx with 905,000,000 shares or 7.17 percent
LSAF Holdings says it has become a substantial shareholder in Healthlinx with 905,000,000 shares or 7.17 percent.
The substantial shareholder notices said that shares were acquired as part of the deed of company arrangement annual general meeting (BD: Jan 21, 2014)
The St Leonards, Sydney-based LSAF notice, was signed by Les Ower for SGB Partners and the Chifley notice was signed by David Hannon.
Healthlinx was suspended ahead of a 500-to-one consolidation.