Biotech Daily

Friday March 28, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 12%, REVA DOWN 8%**

*** IMPEDIMED RAISES $8.8m, PLAN FOR $3m MORE**

*** MIELE TO DISTRIBUTE NANOSONICS TROPHON IN GERMANY**

*** CYCLOPHARM SAYS UNFAIR ANSTO COMPETITION CLOSES CYCLOTRON**

*** INVION RIGHTS RAISE $889k OF HOPED-FOR $2m, TOTAL $5.9m SO FAR**

*** ALIMERA REFILES PSIVIDA ILUVIEN NDA TO FDA**

*** REVA TO LOSE 40 STAFF, RAISE UP TO $27m**

*** INVION FOUNDER DR WILLIAM GARNER REDUCES TO 11.24%**

*** AVEXA HALTS SHARE FACILITY; ATC, ALABAMA COAL MINE UPDATE**

MARKET REPORT

The Australian stock market was up 0.31 percent on Friday March 28, 2014 with the S&P ASX 200 up 16.8 points to 5,366.9 points.

Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and four were untraded.

Universal Biosensors was the best, up four cents or 12.1 percent to 37 cents with 83,788 shares traded, followed by Antisense up 10 percent to 22 cents with 2.1 million shares traded.

Impedimed climbed 9.1 percent; Compumedics and Prima were up more than five percent; Atcor was up 4.2 percent; Clinuvel and Phosphagenics rose more than two percent; with Alchemia, Cochlear, Mesoblast and Nanosonics up less than one percent.

Reva led the falls on last night's news (see below), down 17 cents or 43.6 percent to 22 cents with 800,647 shares traded.

Prana lost 9.2 percent; Psivida fell 8.1 percent; Genetic Technologies was down 6.8 percent; IDT fell 5.9 percent; Avita, Neuren and Tissue Therapies fell four percent or more; QRX was down 3.1 percent; Benitec, Bionomics, Ellex and Patrys shed more than two percent; Acrux, Anteo, CSL, Pharmaxis, Sirtex and Viralytics were down one percent or more; with GI Dynamics and Resmed down by less than one percent.

IMPEDIMED

Impedimed says it has raised $8.8 million through the placement of 45.3 million shares at 19.5 cents a share and has announced a share plan to raise a further $3 million.
Impedimed said that the placement was at a 13.5 percent discount to the five-day volume weighted average price to March 25, 2014 and that shareholders at the record date of March 27, 2014 would be able to buy up to $15,000 in shares at the same price.
The company said that share plan would open on April 4, and close on April 24, 2014.
Impedimed said that proceeds from the placement and the share plan would be used primarily for sales and marketing activities in the US leading up to, and following, the expected publication of a current procedural terminology (CPT) category I reimbursement code on January 1, 2015 for the company's L-Dex system.
The company said it also intended to use the proceeds for sponsoring post-clearance clinical trials, including previously announced trials, new product development and general working capital.
Impedimed chief executive officer Richard Carreon said the company was "particularly excited to have the opportunity to now accelerate the sales and marketing of our L-Dex system in the US lymphoedema market following the recent acceptance of the CPT category I code submission by the American Medical Association".
The company said that Canaccord Genuity (Australia) acted as the sole lead manager and book-runner to the placement
Impedimed was up two cents or 9.1 percent to 24 cents with 1.2 million shares traded.

NANOSONICS

Nanosonics says that Miele Professional will distribute and advocate the adoption of its Trophon EPR ultrasound probe cleaner in Germany.
Nanosonics said that it had "a strategic partnership" with Miele Professional which was "a world leading authority and provider of medical disinfection and sterilization equipment" and had been at the forefront of development in the field of washer-disinfectors for hospitals and surgeries.
Nanosonics chief financial officer McGregor Grant told Biotech Daily that the company was pleased that Miele would advocate the adoption of the Trophon EPR in Germany.
The company said that Miele was a market leader due to development work with hygiene specialists, scientists, instrument manufacturers and end-users.
Nanosonics chief executive officer Michael Kavanagh said the "strategic partnership brings together two world leading authorities in the field of medical equipment disinfection".
"Partnering with Miele provides a great opportunity to establish the Trophon EPR as the new standard of care for the high level disinfection of ultrasound probes in the important German market," Mr Kavanagh said.
Miele Professional head Andreas Barduna said that the Trophon EPR was "a great example of innovation that not only strategically fits well with our disinfection and sterilization portfolio of products.
"It is clear the German market requires a new solution for the effective disinfection of ultrasound probes and Trophon EPR meets the necessary criteria to become established over time as the new standard-of-care," Mr Barduna said.
Nanosonics said that Miele would conduct a national launch of Trophon EPR at the DGKH-congress (German Society of Hospital Hygiene) in Berlin on March 30, 2014 and then begin Trophon EPR market awareness and education programs across Germany.
Nanosonics was up half a cent or 0.6 percent to 85.5 cents.

CYCLOPHARM

Cyclopharm says it will cease commercial production at its Macquarie University-based cyclotron facility for molecular imaging at the end of April 2014.

Cyclopharm managing director James McBrayer told Biotech Daily that wholly-owned subsidiary Cyclopet operated the cyclotron, manufacturing fluorodeoxyglucose (FDG) for positron emission tomography, which was completely separate from Cyclopharm's Technegas and the concentrated Technegas Ultralute business.

Mr McBrayer said that despite winning a Productivity Commission finding that the Federal Government-owned Australian Nuclear Science and Technology Organisation had breached competitive neutrality rules in order to gain an unfair advantage over the privately-owned Cyclopharm, ANSTO had continued selling fluorodeoxyglucose into the New South Wales market at prices that were not commercially viable (BD: Apr 4, Jun 28, 2012).

Mr McBrayer said the company was involved in legal proceedings against ANSTO and its subsidiary Petnet in the Federal Court of Australia with the next hearing due on September 1, 2014, pending mediation.

In a media release to the ASX Cyclopharm said that the decision to shut down the cyclotron operation was forced on the company when it became known that Petnet was entering into new contracts at prices considerably lower than those already raised in its claim as predatory.

The company said that despite a growth in sales volumes and being one of Australia's lowest cost producers of nuclear medicine isotopes, the failure by ANSTO to apply competitive neutrality principles and of the Commonwealth Government to take action following the Productive Commission's findings, created a market environment in which the Cyclopet business was unlikely to generate satisfactory returns in the near term.

Mr McBrayer said the company would continue to operate the facility for research purposes and had a joint venture with Macquarie Medical Imaging, which would buy its fluorodeoxyglucose from suppliers other than ANSTO.

Cyclopharm said that Cyclopet had a 2013 full year operating net loss before tax of about $2.93 million excluding the impairment charge of $8.86 million and closure of the cyclotron facility would enable Cyclopharm to focus its resources on its highly profitable and cash-generating Technegas business in international markets and continuing the development of its Ultralute technology.

The company said that as a result of the Cyclopet decision, it had recorded a non-cash asset write down of $8.86 million in its 2013 accounts and expected to make a provision for closure-related expenses, including redundancy costs, of about $110,000 after tax in 2014.

Cyclopharm said it would continue to pursue the claim against ANSTO in the Federal Court, before Justice Michael Wigney.

The company said that previously it had intended to establish a cyclotron facility in Brisbane, but as a result of the uneconomic market conditions established by the actions of ANSTO, the Brisbane cyclotron was deemed financially unviable and the company would not continue with the project at this time.

Cyclopharm said that in parallel with the litigation against ANSTO, it would continue to use the facility at Macquarie University Hospital to progress some of its research and development activities until a longer term use for the facility was ascertained to include the potential sale of the asset.

Cyclopharm was unchanged at 21 cents.

INVION

Invion says its one-for-20 rights offer at 7.5 cents a share has raised $888,673 of a hoped for $1,985,218 through acceptances for 11,848,977 shares (BD: Feb 21, 2014).
Invion said that the shortfall was 14,620,595 shares worth $1,096,545, which could be placed for up to three months after the close of the offer, that is, June 24, 2014.
Invion chief executive officer Dr Greg Collier said the company was “focused on the collaboration with 3M Drug Delivery Systems to develop Invion’s inhaled respiratory drugs franchise and to the continuing development of Invion’s three drug assets”.
The company said that Patersons Securities and Morgans Corporate acted as joint lead managers to the placement and rights issue.
Invion was up 0.1 cents or 1.4 percent to 7.4 cents.

PSIVIDA

Psivida says that licencee Alimera Sciences has resubmitted the new drug application for Iluvien for chronic diabetic macular oedema to the US Food and Drug Administration.
Psivida said that Alimera responded to questions raised in the FDA’s October 2013 complete response letter and provided a safety update, which included commercial experience with Iluvien in Europe (BD: Oct 21, 2013).
The company said that Alimera was awaiting the FDA’s acceptance of the resubmission and a Prescription Drug User Fee Act (PDUFA) date.
Psivida chief executive officer Dr Paul Ashton said his company was “pleased with the resubmission of the NDA for Iluvien, which brings us one step closer to potential approval in the United States”.
Psivida fell 39 cents or 8.1 percent to $4.41.

REVA MEDICAL

Reva says that it will lose about 40 staff in closing the Rezolve program and need to raise up to $US25 million ($A27 million) for the replacement Fantom coronary stent scaffold.
Yesterday, Reva said that it would cease spending on Rezolve, other than to follow patients in the European trial and that the Fantom scaffold was easier to manufacture, had thinner struts and was stronger than the Rezolve platform (BD: Mar 27, 2014).
Today, investor relations director Cheryl Liberatore told Biotech Daily that about 40 staff or 45 percent of the company’s workforce had been laid-off.
Ms Liberatore said that the company had about $US20 million in the bank at December 31, 2013 and would hope to raise $US20 million to $US25 million to take the Fantom product through trials beginning this year to commercialization by mid-2016.
Reva fell 17 cents or 43.6 percent to 22 cents.

INVION

Invion founder Dr William Garner has again reduced his substantial holding, this time from 61,585,000 shares (11.63%) to 59,505,774 shares (11.24%).
On Wednesday, Dr Garner said that between March 20 and 25, 2014, he sold 1,345,193 shares for $103,785 or an average price of 7.715 cents a share (BD: Mar 26, 2014).
Today, Dr Garner said he sold 2,079,221 shares on market for $157,493 or 7.57 cents a share.
Last year, Dr Garner was replaced as chief executive officer by Dr Greg Collier and was described at the time as Invion’s largest shareholder (BD: May 6, 2013).

AVEXA

Avexa says its plans to establish a facility for the sale of unmarketable parcels of shares will not proceed as planned (BD: Nov 14, 2013).

Avexa said that “certain provisions contained in the company’s constitution specifying, for example, the dates for the 5-day volume weighted average price calculation and then rounding to the nearest half cent ... created pricing anomalies which make it very difficult to efficiently build a book of prospective purchasers and then effectively execute on market sales for these shares”.

The company said that the directors would continue “to explore opportunities to execute these plans in the future and review changes that should be made to certain clauses in the company’s constitution which reflect more normal practice for such transactions”.

Avexa said that activities to make Apricitabine (ATC) available to HIV patients through a named patient scheme were underway (BD: Dec 12, 2013).

The company said that ATC batches were being shipped to the manufacturer and raw materials had been sourced with expected delivery date by October 2014.

Avexa said the North Pratt coal mine investment was “on schedule” with an expected production start-up by the beginning of the fourth quarter of 2014 (BD: Nov 5, 2012).

Avexa traded between 1.9 cents and 2.3 cents, closing down unchanged at two cents with four million shares traded.