Biotech Daily

Wednesday May 11, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 7%, COMPUMEDICS DOWN 8%**

*** DRAXIMAGE DEAL OFF, CYCLOPHARM FUNDS US TECHNEGAS TRIAL**

*** CELLMID SYMPOSIUM LEADS TO 'ADAPTIVE PATHWAY'**

*** MEDICAL DEVELOPMENTS: 'FDA WORKLOAD DELAYS PENTHROX'**

*** CYCLOPHARM AVOIDS 2nd STRIKE, 6% OPPOSE CHAIR VANDA GOULD**

*** DICKS SPORTING GOODS TO TRIAL RHINOMED TURBINE PLUGS**

*** EUROPE APPROVES MGC CANNABINOID COSMETICS**

*** M&G REDUCES TO 10% OF GI DYNAMICS, TAKES $3m-$6m LOSS**

*** VOLPARA DIRECTORS HOLD 36%**

*** UNITED OVERSEAS VENTURE TAKES 5% OF MACH7**

MARKET REPORT

The Australian stock market was up 0.55 percent on Wednesday May 11, 2016 with the ASX200 up 29.5 points to 5,372.3 points. Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and four were untraded.

Antisense was the best for the second day in a row, up 0.3 cents or 6.7 percent to 4.8 cents with 50,000 shares traded, followed by Prana up 6.3 percent to 8.4 cents with 131,747 shares traded.

Genetic Technologies climbed 5.3 percent; Starpharma was up 4.6 percent; Atcor improved 3.2 percent; Factor rose 2.8 percent; Admedus, Clinuvel, Ellex, IDT, Nanosonics, Pro Medicus, Reva and Sirtex were up more than one percent; with Cochlear, CSL, Medical Developments, Polynovo and Viralytics up less than one percent.

Compumedics led the falls, down three cents or 7.9 percent to 35 cents with 200,779 shares traded.

Pharmaxis fell 5.7 percent; Bionomics, Mesoblast, Oncosil and Osprey lost three percent or more; Actinogen, Airxpanders, Anteo and Prima shed more than two percent; Acrux, Impedimed, Living Cell and Neuren were down more than one percent; with Resmed down 0.4 percent.

CYCLOPHARM

Cyclopharm says its agreement for Jubilant Draximage to fund a pivotal US Technegas trial has been terminated and it will complete the trial alone.

Cyclopharm said that it would fund the remainder of the US Food and Drug Administration trials “from cash on the balance sheet and strong on-going Technegas revenues” and the trial program was on-track for approval in mid-2018.

Last year, Cyclopharm said it had a term sheet with the Kirkland, Quebec-based Jubilant Draximage, to provide up to $6.3 million for US trials and take an exclusive licence to market and distribute Technegas in the US (BD: Sep 14, 2015).

Cyclopharm managing director James McBrayer told Biotech Daily at that time that in 2014, 600,000 US citizens had nuclear imaging for pulmonary embolisms worth $US90 million and it would be reasonable to expect that, when approved, Technegas could be used in 80 percent of that market, and earn a 17.5 percent royalty from Draximage, in addition to an agreed margin above the cost of goods sold.

Cyclopharm said that Draximage was a subsidiary of the Uttar Pradesh, India-based Jubilant Life Sciences and would assist it in the development and financing of phase III Technegas trials and other steps required to file and obtain US Food and Drug Administration approval, with the agreement expected to be completed within 60 to 90 days, subject to due diligence and approvals.

Cyclopharm said that Draximage would provide a non-refundable up to $US4.5 million ($A6.3 million) for the FDA clinical trial currently under development with any additional costs to be funded by both parties equally and on successful completion of the US trial, Draximage would be able to convert the trial costs into up to 15 percent of Cyclopharm shares.

Cyclopharm managing-director James McBrayer told Biotech Daily that the term sheet with Draximage never reached full agreement.

Mr McBrayer said that consequently Draximage did not pay the non-refundable deposit and did not receive any shares in the company.

Today Cyclopharm said that “despite several months of negotiations the two companies have not been able to reach agreement on the final terms” and as a result, Cyclopharm notified Draximage of its decision continue its US trial program independently, but the two companies agreed to continue to discuss potential commercial opportunities once FDA approval for Technegas was achieved.

Cyclopharm said that it expected to finalize the US trial program design by July 2016, with the FDA trial program completed by the end of 2017 and FDA approval targeted for mid-2018.

The company said that the total cost was expected to be less than $US7 million, which would be “fully funded from existing cash reserves and on-going profits from Technegas sales”.

Cyclopharm said that Technegas sales underpinned record sales revenue of $12.6 million and record net profit after tax of $4.8 million for the year to December 31, 2015 (BD: Feb 24, 2016).

The company said that the decision to fully fund the FDA trial program would not impact the company’s dividend policy and it was also working to expand the clinical uses of Technegas beyond its primary purpose of diagnosing pulmonary embolism.

Cyclopharm said that it recently received positive early clinical trial results from China, where Technegas was being tested for its efficacy in diagnosing and managing chronic obstructive pulmonary disease, a leading cause of death worldwide.

Cyclopharm was unchanged at 64.5 percent.

CELLMID

Cellmid says its Budapest Midkine Symposium reached a consensus for “an adaptive pathway for clinical validation” for midkine antibodies.

Cellmid said that following presentations of new data by 20 scientists from nine countries on the therapeutic potential of midkine and midkine inhibitors, the clinical validation pathway would be developed from a “clear understanding of [midkine’s] role in disease mechanisms, collaborations with academia and major [pharmaceutical companies] and via the development of surrogate markers for efficacy”.

The company said that the presentations and discussions at the Symposium were made under confidentiality, but further evidence emerged that midkine was “an important molecule in inter-organ signalling in a number of diseases”.

Cellmid said that midkine was “one of the few novel approaches in the management of complex metabolic and cardiovascular diseases including chronic kidney disease and vascular calcification” and studies on its biology, mechanism of action and clinical utility were presented, with promising data on the therapeutic potential of drug candidates.

The company said it had two separate midkine antibodies binding to opposite ends of a protein, the C-terminus-binding and N-terminus-binding midkine antibodies.

Cellmid said that both were assessed for disease attenuation in a mouse model of myocarditis, or heart muscle inflammation, by the Munich-based Ludwig Maximilians University which found that N-terminus binding midkine antibodies “showed marked efficacy in the model not only pointing to a novel potential clinical application but also demonstrating the difference in efficacy between the two midkine antibodies”.

The company said that information on midkine biology was instructive for future studies and further collaboration was expected.

Cellmid said that two midkine antibodies showed tumor supressing ability in glioblastoma cell lines resistant to cannabinoid treatment in studies at the Madrid-based, Complutense University, with work on C-terminus and N-terminus-binding antibodies in animal models of the disease to assess efficacy.

The company said that its N-terminus-binding midkine antibody enhanced bone fracture healing in ovariectomized mice and studies by Germany’s University of Ulm in which the mouse model mimicked the biology of osteoporosis in post-menopausal women and the related delayed bone-healing, with further in-vivo work expected to show the mechanism by which midkine contributed to delayed bone healing.

The company said that data on the structure of midkine binding with glycos-amino-glycans and how it might affect biological function were presented by Arizona State University’s Prof Xu Wang and Spain’s University of Seville’s Dr Pedro Nieto and a further collaboration was expected to ascertain the binding characteristics of midkine in biological systems.

Cellmid said that diagnostic work by three separate groups included further understanding of urinary midkine in prostate and bladder cancers, as well as in patients with acute and chronic kidney disease.

Cellmid clinical adviser Dr Victoria Campbell presented early evidence that midkine might be an important marker of chronic kidney disease.

The company said that clinical development plans over two and five years were discussed with “outcomes around uncovering mechanism of action in disease states, additional academic and commercial collaborations, engaging with key opinion leaders overseas and surrogate markers of efficacy identified as key milestones in an adaptive plan, in addition to the traditional drug development milestones of manufacture, pharmacodynamics, pharmacokinetics, safety and efficacy”.

Cellmid was unchanged at 2.1 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the US Food and Drug Administration's work load has delayed its inhaled analgesic methoxyflurane Penthrox application.
Medical Developments said the FDA had been "delayed in its responses to nearly all submissions as a result of Division of Anesthesia, Analgesia, and Addiction Products work load".
The company said the FDA estimated the delay until the end of June 2016 and "confirmed the delay is not related to Penthrox" and Medical Developments was "well placed", as many other responses were being delayed to September 2016.
Medical Developments chief executive officer John Sharman said the "feedback from the FDA is not unexpected given the epidemic of narcotic addiction in the US and the political pressure this is generating".
"We are encouraged by the informal feedback that the review of our non-narcotic Penthrox is towards the top of the list," Mr Sharman.
Medical Developments was up six cents or 0.9 percent to $6.43.

CYCLOPHARM

Cyclopharm says its annual general meeting overwhelmingly passed the remuneration report but there was some dissent against chairman Vanda Gould.
Last year, Cyclopharm earned a remuneration report first strike, with 10,984,944 votes (25.8%) against the report and 31,662,895 votes (74.2%) in favor (BD: May 26, 2015).
Today, the company said that the remuneration report was supported by 46,274,021 votes with just 1,865 votes against and the spill motion was withdrawn.
Cyclopharm said that prior to the withdrawal, the spill motion was opposed by 46,337,734 votes and supported by 24,188 votes.
The company said that the re-election of Mr Gould was supported by 43,597,848 votes (94.02%) and was opposed by 2,772,633 votes (5.98%)
In its most recent Appendix 3B and 3C announcements, Cyclopharm said that it had 59,588,733 shares on offer, meaning that the votes opposed to Mr Gould amounted to 4.65 percent of the company, not sufficient to request extraordinary general meetings.
Cyclopharm said that director Henry Townsing "did not seek re-election" at the meeting and thanked him for his contribution.

RHINOMED

Rhinomed says that US sporting goods retailer Dicks Sporting Goods will launch a trial of the Turbine nasal plugs in 20 shops across eight states in June.
Rhinomed said that the Findlay, Pennsylvania-based Dicks had 610 shops in 47 states and was a retail destination for American sporting and exercise enthusiasts and athletes.
Rhinomed was unchanged at 2.1 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says that 16 of its cannabinoid cosmetic products have been approved in Europe.
MGC said that the European Commission's Cosmetic Products Notification Portal approved the distribution of its 16 initial cannabinoid-based cosmetics in its MGC Derma Ananda product line.
MGC was up 0.3 cents or 6.7 percent to 4.8 cents with 22.8 million shares traded.

GI DYNAMICS

M&G Investment Funds says it has further reduced its holding in GI Dynamics from 52,560,345 Chess depository instruments (11.05%) to 46,030,187 CDIs (9.68%).
The London-based M&G group began reducing its GI Dynamics holding in April, first selling 4,946,301 CDIs for $106,067 or 2.1 cents a share and later selling 5,683,392 CDIs for $111,800 or 1.97 cents a share (BD: Apr 7, 19, 2016).
In 2014, the London-based M&G group said it acquired 2,000,000 shares in a placement at 52 cents as well as 7,411,464 shares for an average of 54.2 cents a share between August 8, 2013 and April 8, 2014 (BD: May 2, 12, 2014).
Today, M&G said that between April 19 and May 9, 2016 it sold 5,683,392 CDIs for $112,735 or an average of 1.73 cents a share.
In 2011, GI Dynamics raised $80 million of a hoped-for $95 million in an initial public offer at $1.10 per CDI, implying that M&G lost between $2.96 million and $6.15 million in the recent sale (BD: Aug 30, 2011).
GI Dynamics fell 0.1 cents or 5.6 percent to 1.7 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara chairman Roger Allen, chief executive officer Dr Ralph Highnam and director John Michael Brady say they collectively hold 35.9 percent of the company.
As Patagorang Pty Ltd director the Sydney-based Mr Allen said he held 20,467,848 shares or 16.71 percent, the Wellington, New Zealand-based Dr Highnam said he held 15,632,298 shares or 12.76 percent and the Oxford, England-based Mr Brady said he held 7,919,075 shares or 6.47 percent, with Naomi Brady.
Volpara was unchanged at 45 cents.

MACH7 TECHNOLOGIES (FORMERLY 3D MEDICAL)

The Kuala Lumpur, Malaysia-based United Overseas Venture Sdn Bhd says it has become substantial in Mach7 with the acquisition of 46,741,623 shares (5.23%).
The substantial shareholder notice, signed by Dato' Ling Keak Ming said the shares were acquired on April 8, 2016 as consideration for the acquisition of Mach7 Technologies Pte Ltd from his company at a deemed price of 10 cents a share.
Mach7 fell 0.2 cents or 3.5 percent to 5.5 cents.