Biotech Daily

Wednesday February 22, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: POLYNOVO UP 6%, BENITEC DOWN 8%**

*** SIRTEX NEW R&D AXED, H1 REVENUE UP 0.2%, PROFIT DOWN 26%**

*** FEDERAL GOVERNMENT APPROVES MEDICAL MARIJUANA IMPORTS**

*** MEDLAB WELCOMES CANNABIS IMPORT ANNOUNCEMENT**

*** AUSCANN, CRESO, MGC JOINT WELCOME FOR MEDICAL MARIJUANA**

*** CYCLOPHARM REVENUE UP 14% TO $14m, PROFIT DOWN 81% TO $891k**

*** CRYOSITE H1 REVENUE UP 4.5% TO $5.2m, PROFIT UP 23% TO $253k**

*** REGENEUS H1 REVENUE UP 830% TO $8m, LOSS TO $4m PROFIT**

*** ORTHOCELL 'EARLY DATA SHOWS CELGRO SAFE, TOLERABLE'**

*** BREASTFEEDING ASSOCIATION BACKS MEDICAL AUSTRALIA PUMPS**

*** JAPAN GRANTS ANALYTICA PERICOACH PATENT**

*** PROLOG DILUTED TO 8% IN AIRXPANDERS**

*** COMPUMEDICS APPOINTS ROB FERGUSON US GENERAL-MANAGER**

MARKET REPORT

The Australian stock market was up 0.24 percent on Wednesday February 22, 2017 with the ASX200 up 14.1 points to 5,805.1 points. Nine Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and four were untraded. All three Big Caps were up.

Polynovo was the best, up 1.5 cents or 5.9 percent to 27 cents with 780,956 shares traded. Bionomics, Ellex and Factor Therapeutics were up three percent or more; Cellmid and Sirtex rose more than two percent; Clinuvel, CSL, Mesoblast and Opthea were up more than one percent; with Cochlear and Resmed up less than one percent.

Benitec led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 295,898 shares traded, followed by Neuren down 7.7 percent to 7.2 cents with 2.25 million shares traded. Compumedics, Cyclopharm and IDT lost more than six percent; Living Cell fell 5.7 percent; Avita and Uscom both fell 4.55 percent; Oncosil was down 3.3 percent; Anteo, Medical Developments, Osprey, Starpharma, Universal Biosensors and Viralytics shed two percent or more; Acrux, Airxpanders, Impedimed and Pharmaxis were down more than one percent; with Nanosonics down 0.4 percent.

SIRTEX MEDICAL

Sirtex says that revenue for the six months to December 31, 2015 was up 0.2 percent to $112,596,000, with net profit after tax down 25.6 percent to $20,400,000.

Sirtex interim chief executive officer Nigel Lange said the “three pillars, 2020” policy promoted by former chief executive officer Gilman Wong had been “abandoned” and “non-core” research and development programs would be wound down (BD: Aug 3, 2012).

Mr Lange said the company had not “seen the return we’re looking for” from the research and development programs announced in November (BD: Nov 28, 2016).

Mr Lange told a teleconference that the carbon-cage nanoparticles, polymer-coated nanoparticles and radioprotector programs would cease, pending contractual obligations, and divested if possible, while the histone inhibition program STC314 phase I trial would proceed with commercial options to be evaluated pending results.

Mr Lange said that research and development would be focused on SIR-Spheres product enhancements and user interface enhancements and the company had an expansion strategy to new markets and for new indications including kidney, lung and other cancers.

Mr Lange announced a $30 million, 2,000,000 share buy-back.

Any reference to Mr Wong was absent from the teleconference (BD: Jan 22, 2017).

Mr Wong stepped aside as chief executive officer last year while the company investigated his sale of shares six weeks before a profit warning (BD: Dec 15, 2016).

Mr Wong said that on October 27 he sold 74,968 shares of his 274,968 shares, returning about $2.1 million, to cover tax on recently vested performance rights” (BD: Nov 7, 2016).

Six weeks later, Sirtex downgraded its SIR-Spheres growth estimates leading to a significant fall in the share price (BD: Dec 9, 2016).

Today, Sirtex chief financial officer Darren Smith told the teleconference that dose orders were reviewed on a daily basis.

Sirtex said dose sales were up 5.6 percent to 6,047 units for the six months, implying an average cost of $18,620 per dose compared to $19,657 per dose in the previous year.

Sirtex said in the six months to December 31, 2016, dose sales in the Americas rose 5.5 percent to 4,248 doses, returning revenue up 0.7 percent to $90.1 million; Asia Pacific sales were up 10.2 percent to 530 doses, taking revenue up 8.6 percent to $4.4 million; with Europe, Middle East and Africa sales up 4.1 percent to 1,269 doses, but revenue was down 4.3 percent to $18.2 million.

Sirtex Europe, Middle East and Africa chief executive officer Tony Dixon said that sales were flat in Germany but had increased in countries that provided lower returns through third party distributors, in particular in the Middle East and North Africa.

In a media release, Sirtex said that the decrease in profit “was mainly due to a negative currency impact [with a stronger Australian dollar], and to higher manufacturing costs”.

Sirtex said that research and development expenditure increased 5.7 percent to $4,982,000 or 4.4 percent of total revenue compared to 4.2 percent of revenue in the previous corresponding period, with marketing expenses up 7.2 percent to $42,422,000 and administration expenses up 14.4 percent to $10,897,000.

The company said that diluted earnings per share fell 19.7 percent to 35.8 cents, with cash and cash equivalents of $30,954,000 at December 31, 2016, compared to $21,738,000 at December 31, 2015.

Sirtex said that net tangible asset per share increased 18.8 percent from $1.48.8 at December 31, 2015 to $1.768 at December 31, 2016.

Sirtex said that there would be no interim dividend but a partly-franked final dividend of 30.0 cents per share was paid on October 19, 2016 for the financial year to June 30, 2016, compared to the previous year’s fully franked 20.0 cents per share dividend.

Sirtex was up 36 cents or 2.3 percent to $15.75 with 791,320 shares traded.

FEDERAL GOVERNMENT

The Minister for Health Greg Hunt says the Federal Government will facilitate faster access by doctors to medicinal cannabis for patients with the necessary approvals.
A media release from Mr Hunt said the Government would “authorize controlled importation by approved providers from approved international sources for interim supply in Australia, until domestic production meets local needs”.
On ABC Radio National this morning, Mr Hunt said that the Victoria Government expected to have supplies of medical marijuana by the middle of this year and an amnesty for people wanting to buy medical marijuana from local, currently illegal, providers was a matter for state governments, not the Federal Government.
Mr Hunt’s media release said that, at present, doctors approved to supply medicinal cannabis products must import the product as local production is only starting to be developed following the passage of legislation to allow domestic production last year.
“We have listened to the concerns of patients and their families that are having difficulty accessing the product on prescription whilst domestic production becomes available,” Mr Hunt said. “The Office of Drug Control, within the Department of Health, will implement this policy, effective immediately.”
The media release said importers would be able to source medicinal cannabis from a reputable supplier overseas and store it in a safe, secure warehouse.
Mr Hunt’s media release said that patients prescribed medicinal cannabis would be able to source the medication from a company in Australia, rather than on a case-by-case basis from overseas which involved import delays.
The media release said that the Department of Health had advised companies interested in supplying the Australian market to advise them of the interim arrangement.
Mr Hunt said that it was expected that within eight weeks Australia would have a store of imported medicinal cannabis products.
More information is at the Office of Drug Control website: https://www.odc.gov.au/.

MEDLAB CLINICAL

Medlab said it welcomed the Federal Government announcement, had obtained clearances from Australian health departments and was awaiting a final shipment clearance from Canadian health authorities to import cannabis material from Canada.
The company said that the cannabis was a combination of the two most active cannabis ingredients, which it had formulated and was being supplied by Canadian licenced producer of medical marijuana, Aphria Inc.
Medlab said it had arranged delivery of the cannabis to a contractor in Melbourne, licenced for controlled substance manufacture and the material would be incorporated with its Nanocelle small-particle medicine delivery system to be readied for a trial for cancer pain, pending approvals. (BD: Nov 7, 2016).
Medlab was up three cents or 4.1 percent to 76 cents.

CRESO PHARMA, AUSCANN, MGC PHARMACEUTICALS

In a joint media release, Auscann managing-director Elaine Darby, Creso Pharma chief executive officer Miri Halperin Wernli, and MGC Pharmaceuticals managing director Nativ Segev also welcomed the announcement.
Auscann was up 6.5 cents or 31.7 percent to 27 cents with 9.6 million shares traded.
Creso was up two cents or 8.2 percent to 26.5 cents with 1.4 million shares traded.
MGC was up half a cent or 12.8 percent to 4.4 cents with 31.6 million shares traded.

CYCLOPHARM

Cyclopharm says that revenue for the 12 months to December 31, 2016 was up 14.3 percent to $14,385,507 with net profit after tax down 81.4 percent to $891,368.
Last year, Cyclopharm reported revenue for the 12 months to December 31, 2015 of $14,733,418 which included an insurance settlement of $2,104,689 for water damage at Macquarie University Hospital which damaged its cyclotron (BD: Jan 25, 2016).
Cyclopharm said that sales revenue was driven by sales of its Technegas patient administration sets and Technegasplus generators.
Cyclopharm managing-director James McBrayer told Biotech Daily that the company was investing in US regulatory approval which was expected to significantly expand sales and profitability and the sale to China of 50 generators and 250 boxes of patient administration sets meant that the distributor might not re-order for up to 18 months.
The company said it would pay an unfranked final dividend of 0.5 cents on April 10, for investors at the record date of April 3, 2017, having paid an interim partly-franked dividend of 0.5 cents.
Cyclopharm said that diluted earnings per share fell 83.4 percent to 1.39 cents with net tangible assets per share down 10 percent from 20 cents to 18 cents.
Cyclopharm said it had $4,590,760 in cash and equivalents at December 31, 2016 compared to $6,444,995 for the previous corresponding period.
Cyclopharm fell six cents or 6.6 percent to 85 cents.

CRYOSITE

Cryosite says revenue for the six months to December 31, 2016, was up 4.5 percent to $5,183,000 with net profit after tax up 22.8 percent to $253,000.
Cryosite said that it provided cord blood storage, bio-repository management and distribution of biological materials and pharmaceutical products used in clinical trials.
The company said it would pay an interim unfranked dividend of 0.5 cents a share with a record date of March 15 to be paid on March 31, 2017.
Cryosite said that net tangible assets per share fell 7.6 percent to 6.1 cents with diluted earnings per share up 22.7 percent to 0.54 cents at December 31, 2016 compared to 0.44 cents for the previous corresponding period, with $4,073,192 in cash and cash equivalents at December 31, 2016 was compared to $4,106,959 at December 31, 2015.
Cryosite was up half a cent or 2.6 percent to 19.5 cents.

REGENEUS

Regeneus says that revenue for the six months to December 31, 2016, was up 829.5 percent to $8,189,000, turning the previous loss to a $3,757,000 net profit after tax.
In January, Regeneus said it received $US5.5 million ($A7.3 million) from the Tokyo, Japan-based AGC Asahi Glass as an upfront payment for the rights to manufacture Progenza and expected to receive a further $US11 million in development and approval milestone payments and would be entitled to a share of upfront licence fees, milestone payments and royalties from sub-licencing the development and commercialisation of Progenza for osteoarthritis and other indications in Japan (BD: Jan 22, 23, 2017).
Regeneus said diluted earnings per share for the six months to December 31, 2016 was 1.7 cents compared to a diluted loss per share of 1.5 cents for the six months to December 31, 2015, with net tangible assets per share up 64.0 percent to 4.1 cents, with cash and cash equivalents of $395,558 at December 31, 2016.
Regeneus fell half a cent or 3.3 percent to 14.5 cents.

ORTHOCELL

Orthocell says the first two patients in its 20-patient trial of Celgro to augment nerve damage repair have shown Celgro to be safe and tolerable.

Orthocell said the first two patients in the trial at the Perth, Western Australia-based St John of God Hospital previously had traumatic peripheral nerve injury resulting in the inability to bend their elbow and impacting daily living activities (BD: Oct 18, 2016).

The company said that an interim review at 20 days post-operation for the two patients showed that the Celgro collagen-based device was safe and well-tolerated with no inflammatory reactions or complications.

Orthocell managing-director Paul Anderson said the initial assessment was "very positive and represents an important step forward in the development of Celgro in the very important area of human nerve regeneration".

"Celgro allows for suture-less reconnection of the damaged nerve while guiding nerve regeneration and accelerating the healing process," Mr Anderson said.

The company said that peripheral nerve injury was commonly caused by trauma, with more than 20 million people in the US affected each year, costing about $US150 billion.

Orthocell said that Celgro was a biological medical device used in a variety of orthopaedic and general reconstructive surgical applications.

The company said it expected Conformité Européenne (CE) mark by April 2017 and had filed a US Food and Drug Administration 510(k) application for approval.

Orthocell was unchanged at 45 cents.

MEDICAL AUSTRALIA

Medical Australia says the Australian Breastfeeding Association will endorse the Ardo range of breast pumps that it distributes exclusively in Australia and New Zealand.

Last year, Medical Australia said it signed an agreement to distribute the Switzerland-based Ardo Medical AG's breast pumps, initially for three years (BD: May 17, 2016).

Today, Medical Australia said it had a three-year bonding corporate partnership and product endorsement agreement with the Australian Breastfeeding Association in which all Association community groups in Australia would buy the Ardo Carum and Calypso breast pumps, to distributed through the company's Clements division.

The company said that the hospital grade Ardo Carum and the battery-powered Calypso portable pump were World Health Organisation code compliant and would be the only breast pumps endorsed by the Association.

Medical Australia said that the Australian Breastfeeding Association would actively promote the products through its communication network.

The company said that the Association established an expert working group to develop and implement a rigorous evaluation process and survey, with the pumps tested using standardized criteria by mothers with babies of various ages and reasons for requiring the need to express breast milk.

Medical Australia said that the Australian Breastfeeding Association was a voluntary organisation founded by six mothers in 1964 and had become one of the country's largest women's not-for-profit organisations and Australia's leading authority on breastfeeding, with 735 trained breastfeeding counsellors, 39 community educators and 366 trainees.

Medical Australia chief executive officer Darryl Ellis said the agreement was "both an honour and a great achievement".

"It is also a ringing endorsement for the Ardo range and one we have worked hard to achieve," Mr Ellis said.

Medical Australia was untraded at five cents.

ANALYTICA

Analytica says the Japan Patent Office has granted a patent protecting its intra-vaginal Pericoach pelvic floor force sensing technology

Analytica chief executive officer Geoff Daly told Biotech Daily that the patent, entitled 'An intra vaginal device to aid in training and determining muscle strength', would provide intellectual property protection until January 2032.

The company said that patents on the Pericoach force sensors had been issued in China and Japan, with patents pending in US, India, Brazil, Australia and Europe.

Analytica said that Japan had "enormous market potential for a global licencee with an estimated 15.8 million women aged 15 to 85 years with urinary incontinence.

"We have other Pericoach patents pending for inventions developed since this first one, which will extend a licencee's freedom to operate even further," Mr Daly said.

Analytica was up 0.1 cents or 14.3 percent to 0.8 cents with 2.6 million shares traded.

AIRXPANDERS

Airxpanders says the London-based Prolog Capital holds the equivalent to 20,334,507 Chess depository instruments (CDIs) and has been diluted to 7.70 percent.

Airxpanders fell one cent or 1.15 percent to 86 cents.

COMPUMEDICS

Compumedics says it has appointed Rob Ferguson as US general manager and interim national sales manager.

Compumedics said that Mr Ferguson would be responsible for the delivery of the revenue and profit goals for the US business.

The company said that Mr Ferguson had more than 17 years of experience in sales and marketing of healthcare medical devices, including sleep diagnostics, neurological and vascular software and hardware applications and associated services.

Compumedics fell five cents or 6.85 percent to 68 cents.