



Biotech Daily

Friday October 14, 2016

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: OSPREY UP 10%; CYCLOPHARM DOWN 4%
- * CSL RAISES \$727m TO BUY \$500m SHARES, WORKING CAPITAL
- * SIENNA EARNS ISO 13485, \$638k R&D TAX INCENTIVE
- * MMJ RAISES \$4m, RELEASES 17.5m ESCROW SHARES
- * FDA WANTS MORE DATA FOR ADALTA AD-114 FIBROSIS ORPHAN STATUS
- * MEDIBIO RECEIVES \$3m FEDERAL R&D TAX INCENTIVE
- * ANATARA RECEIVES \$420k FEDERAL R&D TAX INCENTIVE
- * PARADIGM REQUESTS CAPITAL RAISING TRADING HALT
- * PHARMAUST TREATS 2nd DOG IN PHASE II MONEPANTEL CANCER TRIAL
- * BLACKROCK TAKES 5% OF COCHLEAR, AGAIN
- * JK, HOGAN, BELOW 5% IN ACTINOGEN
- * IBSEN, EZAHC, NARULA INCREASE, DILUTED TO 5.7% OF OPTISCAN
- * MEMPHASYS DIRECTOR ANDREW GOODALL TAKES 39%
- * CYNATA 800k DIRECTORS OPTIONS AGM
- * PROTEOMICS APPOINTS EX-NOVO NORDISK ROGER MOORE DIRECTOR
- * BRAIN FOUNDER DAN SEGAL RETIRES

MARKET REPORT

The Australian stock market slipped 0.03 percent on Friday October 14, 2016 with the ASX200 down 1.5 points to 5,434.0 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and two were untraded. All three Big Caps were up.

Osprey was the best, up 3.5 cents or 9.7 percent 39.5 cents with 311,794 shares traded. Universal Biosensors was up 5.9 percent; Actinogen and Avita rose more than four percent; Admedus, Atcor, Impedimed, Nanosonics and Pharmaxis were up more than one percent; with Clinuvel, Cochlear, CSL and Resmed up by less than one percent. Just outside the BDI-40, LBT climbed a further 14.5 percent to 87 cents, up 357.9 percent since Monday's FDA approval.

Cyclopharm led the falls, down five cents or 4.3 percent to \$1.11, with 48,300 shares traded. Oncosil fell 4.2 percent; Ellex, Living Cell, Orthocell and Polynovo lost more than three percent; Airxpanders, Bionomics and Prana shed more than two percent; Acrux, Compumedics, Factor Therapeutics and Medical Developments fell more than one percent; with Mesoblast, Opthea, Reva, Sirtex and Viralytics down less than one percent.

CSL

CSL says it has raised \$US550 million (\$A726.5 million) in a US placement to buy back \$500 million in shares and for working capital, and has closed a \$350 million debt facility. CSL said the oversubscribed private placement consisted of \$US150 million for 10 years at 2.87 percent, \$US200 million for 12 years at 2.97 percent and \$US200 million for 15-years at 3.12 percent, giving a weighted average interest rate of 3.0 percent.

The company said that it had closed a new \$350 million three-year debt facility with two of its existing banks.

CSL said that the proceeds from the new debt raisings would be used “to fund the group’s capital management plan and for general corporate purposes”.

CSL chief financial officer David Lamont said the placement was “our fifth issue in this market since 2011 and we now have in excess of \$US2.7 billion of US private placement debt outstanding”.

“This market provides CSL with great flexibility in terms of funding currencies and maturities,” Mr Lamont said.

CSL said that the \$500 million share buy-back would begin on October 27, 2016 and close on October 25, 2017 or earlier if the maximum number of shares was bought back prior to that date.

CSL was up 68 cents or 0.65 percent to \$105.65 with 477,267 shares traded.

SIENNA DIAGNOSTICS

Sienna says it has secured ISO13485 certification and received \$637,524 from the Federal Government Research and Development Tax Incentive program.

Sienna said that said that ISO13485 certification related to the documentation of the design process, application and manufacturing and meant that the company’s quality management system complied with the laws and regulations of the medical device industry.

The company said that ISO 13485 was the quality management system standard accepted as the basis for Conformité Européenne (CE) mark for medical devices under European Directives and it was increasingly required, or was beneficial, for supporting regulations around the world.

Sienna chief operating officer Matthew Hoskin said that the certification was “recognized as a harmonized standard by the European Commission”.

“It allows Sienna to register their telomerase detection product as a CE-marked in-vitro diagnostic for human clinical use,” Mr Hoskin said.

“Achieving certification takes a substantial investment in time and resources, but the return is significant because it creates a foundation on which to base [in-vitro diagnostic] product registration in all our target markets around the world,” Mr Hoskin said.

“ISO 13485 certification is an important step ... to launch the first ever in-vitro diagnostic test for telomerase as an adjunct to urine cytology, the most common non-invasive test for bladder cancer,” Mr Hoskin said.

Sienna said the Federal Government Research and Development Tax Incentive related to work done on the telomerase-detection technology, including clinical studies, developing manufacturing processes and conducting verification, validation and stability testing in preparation for product registration.

Sienna chief financial officer Tony Di Pietro said the “receipt of these non-dilutive funds will go towards Sienna’s efforts to register an [in-vitro diagnostic] product, further penetrate the US, and enter the European diagnostic market”.

Sienna is a public unlisted company.

MMJ PHYTOTECH

MMJ says it has raised \$4,000,000 in a placement at 20.5 cents a share and will release 17,510,000 shares from escrow on October 27, 2016.

MMJ said that the placement to institutional and sophisticated investors would provide funds for additional working capital as it completed the spin-out of its cannabis subsidiaries United Greeneries and Satipharm AG to Toronto Stock Exchange Venture Exchange-listed Top Strike Resources.

The company said that with the release of the 17,510,000 escrow shares on October 27, 2016 there would be a total of 166,360,011 shares available for trading with a further 24,833,332 shares held in escrow until January 21, 2017, with a total on issue of 191,193,343 shares.

MMJ was up half a cent or 2.1 percent to 24.5 cents.

ADALTA

Adalta says the US Food and Drug Administration has requested further information for the orphan drug application for AD-114 for idiopathic pulmonary fibrosis.

Adalta said that the FDA requested data from an additional mouse fibrosis model, which was underway, with the company on-track to re-submit its application by the end of 2016.

The company said that allowing for a standard 120-day review and response time, it expected an FDA response by July 2017.

Adalta chief executive officer Samantha Cobb said the company was “focused on delivering on our development milestones and advancing ... AD-114 to the clinic”.

“This new data will add to the existing body of data Adalta already has around AD-114 ... [and] we remain on track to file for an investigational new drug application with the FDA by July 2018,” Ms Cobb said.

Adalta said that AD-114 was developed from its platform that produced human proteins which mimicked the shape of shark antibodies and engineers their key antigen binding and stability features to create unique compounds, known as I-bodies, for therapeutic intervention in disease.

Adalta fell half a cent or 2.3 percent to 21.5 cents.

MEDIBIO

Medibio says it has received \$3,074,224 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Medibio said that the funds related to expenditure for the year to June 30, 2016.

Medibio fell one cent or two percent to 49 cents.

ANATARA LIFESCIENCES

Analytica says it has received \$420,460 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anatara said the cash incentive related to research and development expenditure for the year to June 30, 2015 “and future refunds will increase significantly”.

Anatara executive chairman Dr Mel Bridges said “the R&D tax rebate is an important source of non-dilutive funding for the company and will provide an ongoing source of valuable funds for the company’s R&D initiatives”.

“The refund further strengthens Anatara’s balance sheet,” Dr Bridges said.

Anatara was unchanged at \$1.20.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested a trading halt "to finalize ... a potential capital raise".

Trading will resume on October 18, 2016 or on an earlier announcement.

Paradigm last traded at 51 cents

PHARMAUST

Pharmaust says it has treated the second dog with monepantel for cancer in a phase II study at England's University of Cambridge, Department of Veterinary Sciences.

Last month, Pharmaust said it had treated the first dog for metastatic mammary cancer but has not disclosed how many dogs will be treated in the trial (BD: Sep 19, 2016).

Today, the company said the second dog had metastatic prostatic carcinoma with peritoneal effusion and was being treated with monepantel and the chemotherapy drug mitoxantrone at the Animal Referral Hospital in Homebush, Sydney.

Pharmaust fell 0.1 cents or 1.2 percent to eight cents.

COCHLEAR

Blackrock Investment Management has become a substantial shareholder, yet again, in Cochlear with a holding of 2,876,723 shares or 5.01 percent.

In 2009, Blackrock became a substantial shareholder with 2,993,832 shares (5.3%) falling below five percent in February 2010, returning to a 5.03 percent holding in March 2014, and three days later dropping below five percent (BD: Dec 15, 2009; Mar 7, 10, 2014).

Today, Blackrock said that between June 14 and October 12 it bought shares in about 500 separate trades at prices ranging from \$118.44 to \$143.12 and said it had a 'Global Master Securities Lending Agreement' with Citigroup and HSBC.

Cochlear was up 90 cents or 0.7 percent to \$138.08 with 121,128 shares traded.

ACTINOGEN

The Perth, Western Australia-based JK Nominees says it has reduced below the five percent substantial holding in Actinogen.

In 2015, Kim Hogan for JK Nominees said the company held 34,717,184 shares (5.8%) (BD: Apr 28, 2015).

Today, Mr Hogan said that JK Nominees bought and sold shares between April 30, 2015 and October 13, 2016 with the single largest sale 2,500,000 shares for \$163,500 or 6.5 cents a share on October 2, 2015.

The substantial notice said that on September 1 and 2 JK bought 1,994,301 shares for \$100,123 and sold the same number of shares on September 8, 2016 for \$126,757.

Actinogen was up 0.2 cents or 4.35 percent to 4.8 cents with 1.3 million shares traded.

OPTISCAN

Ibsen Pty Ltd, Ezahc Pty Ltd and Narula Family Settlement No 3 have increased and been diluted in Optiscan from 13,334,167 shares (7.19%) to 17,668,445 shares (5.67%).

The substantial shareholder notice, signed by Canterbury, Victoria-based director Ian Mann, said the entities bought and sold shares between July 13, 2015 and August 19, 2016 with the single largest acquisition 2,360,000 shares for \$59,000 or 2.5 cents a share in the recent rights issue (BD: Sep 8, 2016).

Optiscan was up 0.2 cents or 5.4 percent to 3.9 cents.

MEMPHASYS (FORMERLY NUSEP)

Memphasys director Andrew Goodall says he has increased his shareholding from 217,167,289 shares (38.15%) to 220,167,289 (38.67%).

Mr Goodall said that he held a direct interest in Memphasys, as well as an indirect interest through Ti Rakau Developments and Aemagood Pty Ltd, with Mr Goodall acquiring 3,000,000 shares on market for \$18,000 or 0.6 cents a share.

Memphasys was up 0.1 cents or 16.7 percent to 0.7 cents.

CYNATA THERAPEUTICS

Cynata will vote to issue four directors 800,000 options exercisable within three years at 145 percent of the 5-day volume-weighted average price to the date of grant.

Cynata said that shareholders would vote on the proposal to issue 200,000 options each to chief executive officer Dr Ross Macdonald, Dr John Chiplin, Dr Paul Wooton and Peter Webse.

The company said that shareholders would vote to ratify the previous issue of 750,000 employee options, 600,000 advisor options, refresh the 10 percent placement capacity and re-elect directors Dr Wooton and Mr Webse.

The meeting will be held at Giorgios Restaurant Function Room, 1235 High Street, Armadale, Victoria on November 16, 2016 at 9.30am (AEDT).

Cynata fell one cent or 1.8 percent to 55 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has appointed Roger Moore as a non-executive director.

Proteomics said that Mr Moore had 40 years' experience in the pharmaceutical industry, including about 30 years as Novo Nordisk Japan president, establishing the Japan office in 1977 and working for the company until retiring as chairman in 2007.

The company said that from 2000, Mr Moore was responsible for Novo Nordisk's business in Japan, Australia, New Zealand and the Pacific and was a member of Novo Nordisk A/S senior management board.

Proteomics said that since 2008 Mr Moore had assisted Australian biotechnology companies and Japanese pharmaceutical companies in business development activities. Proteomics was up two cents or 7.7 percent to 28 cents.

BRAIN RESOURCE LIMITED

Brain Resource says that founder and executive director Dan Segal has resigned effective from the company's annual general meeting.

Brain said that Mr Segal was appointed a director in August 2000 and thanked him for his "significant contribution and service".

The company said that Mr Segal would "transition from his current full-time executive position to a part-time consulting role".

Brain was unchanged at 11.5 cents.