Biotech Daily

Monday August 22, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: IDT UP 7%, ADMEDUS DOWN 8%**

*** PRO MEDICUS: 'THE ROLL-OUT HAS JUST BEGUN'**

*** ADALTA OPENS UP 24% FOR AD-114 FOR FIBROTIC DISEASES**

*** OPTISCAN 'CARL ZEISS ENDORSES TWO MICROSCOPE PROTOTYPES'**

*** POLYNOVO REVENUE UP 2366% TO $3.5m, LOSS UP 130% TO $3m**

*** THAILAND APPROVES IMUGENE HER-VAXX GASTRIC CANCER TRIAL**

*** NOXOPHARM TO TRIAL NOX66 FOR CANCER RADIO-RESISTANCE**

*** APHRIA TO SUPPLY CANNABIS FOR MEDLAB CANCER PAIN TRIAL**

*** TBG (PROGEN) SELLS PG500 TO ZUCERO FOR $6m**

*** BIOTRON FINDS ADDITIONAL ANTI-ZIKA COMPOUNDS**

*** CHAIR PROF ROBERT PHILLIPS INCREASES, DILUTED TO 17% OF USCOM**

*** BERGEN TAKES 7.3% OF ANTEO**

*** RACE APPOINTS GORDON BECK V-P EUROPE NAMED PATIENT SALES**

*** NUHEARA APPOINTS JEAN-MARIE RUDD CFO**

MARKET REPORT

The Australian stock market fell 0.21 percent on Monday August 22, 2016 with the ASX200 down 11.6 points to 5,515.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 were unchanged and one was untraded.

IDT was the best, up 1.5 cents or 6.8 percent to 23.5 cents with 158,588 shares traded. Anteo and Biotron climbed more than six percent; Genetic Technologies was up 5.9 percent; Compumedics and Pro Medicus improved more than four percent; Acrux, Atcor and Oncosil were up more than three percent; Ellex and Nanosonics rose more than two percent; Osprey was up 1.6 percent; with Clinuvel, Cochlear, Medical Developments, Reva and Resmed up by less than one percent.

Admedus led the falls, down three cents or 8.1 percent to 34 cents with 2.1 million shares traded. Benitec lost 7.1 percent; Neuren fell four percent; Pharmaxis and Universal Biosensors were down more than three percent; Prima and Viralytics were down more than two percent; Actinogen, Airxpanders, Bionomics, Impedimed and Uscom shed more than one percent; with CSL, Mesoblast and Sirtex down by less than one percent.

PRO MEDICUS

Pro Medicus says it has only just begun the roll-out of its imaging technology despite having secured five major contracts worth $60 million in the past 12 months.

At a packed investor briefing at investment bank Moelis & Co in Melbourne, Pro Medicus co-founder chief executive officer Dr Sam Hupert and chief financial officer Clayton Hatch said the company had future contracted minimum revenue of more than $100 million over the coming five years.

Last week, Pro Medicus reported revenue for the 12 months to June 30, 2016 up 56.9 percent to $27,577,000 with net profit after tax up 97.9 percent to $6,368,000, compared to the previous year's result itself up 21.7 percent to $17,577,000 with net profit after tax up 113.2 percent to $3,217,000 (BD: Aug 21, 2015; Aug 19, 2016).

Today, Mr Hatch said that research and development spending was "around $5.5 million" a figure he expected the company to maintain in the year ahead.

Dr Hupert said that the Pro Medicus imaging system allowed multiple users to see images created on any platform much faster and at better quality to competitors.

Dr Hupert said that winning the Mayo Clinic and Mercy Hospital contracts were important validations for the relatively small Melbourne-based company with research and development conducted in Melbourne and Berlin and all of the radiology standards at the Mayo Clinic were operating on the Pro Medicus software.

Dr Hupert said that in tendering for contracts Pro Medicus had won all but one, and described the technology as not just superior but "generally … always the most expensive".

In answer to a question, Dr Hupert said that the Pro Medicus systems were worth the higher initial costs as the quality of visualization would lead to better health outcomes and longer term lower hospital costs.

He cited the one contract he didn't win and said that establishment was yet to implement the competitor's product and he had heard that some staff were unhappy that the purchasing department had over-ruled the radiology department.

"We can provide gigabytes in seconds rather than minutes and have everything on one desktop," Dr Hupert said.

Dr Hupert said the model of asking the enterprise how many images they handled a year and then supplying a guaranteed minimum price for a range of 70 to 90 percent was an incentive to use the system rather than install and ignore it, while being paid per use.

He said that the installation could be done in as little as two to three weeks, but major public teaching hospitals and other large institutions could take one to two years to install the software across all workstations and train staff in its use.

Dr Hupert said that Pro Medicus provided training on a consultation basis charging about $2,000 per head per day.

"It's highly scalable, there's no capital expenditure and it's a software-only model," Dr Hupert said.

Dr Hupert said Pro Medicus had increasing sales across the US, at a range of institutions, but so far had not been able to make in-roads into the more bureaucratically difficult European market, although it had one major contract with an unnamed German hospital.

Dr Hupert said that the company had "about five percent penetration" of the US market and that tens of thousands of radiology industry personnel would be at the November Radiological Society of North America meeting in Chicago, which was where companies made the most significant contacts with industry users.

Asked about much larger global competitors, Dr Hupert said: "Will they catch-up with us? Maybe. But we're not standing still."

Pro Medicus climbed 25 cents or 4.2 percent to $6.15 with 180,531 shares traded.

ADALTA

Adalta opened on the ASX under the code 1AD, at 30.5 cents 22.0 percent above its over-subscribed $10 million initial public offer at 25 cents a share.
Adalta said the offer had support from several institutional investors and from existing shareholder Yuuwa Capital.
The company said the funds would be used to expedite the first phase of a clinical study aimed at validating its lead candidate drug AD-114 which showed promise in treating fibrosis, notably idiopathic pulmonary fibrosis and other fibrotic diseases, for which current therapies had limited efficacy and with a high-unmet medical need (BD: Jul 7, 2016).
Adalta chief executive officer Samantha Cobb said the company was focussed on taking AD-114 into phase I human trials for the lung disease idiopathic pulmonary fibrosis and the strategy was “to licence this drug candidate on completion of the planned phase I clinical studies”.
The company said that Patersons Securities was the lead manager to the offer.
Adalta climbed as much as six cents or 24 percent to 31 cents before closing up three cents or 12.0 percent at 28 cents with 312,489 shares traded.

OPTISCAN

Optiscan says that Carl Zeiss Meditec has endorsed two of its split-system confocal microscope prototypes.
Optiscan said that the Jena, Germany-based Carl Zeiss company was “the pre-eminent market force in the microsurgical visualization market and their engagement with Optiscan is therefore a key endorsement of Optiscan’s technology”.
The company said that Zeiss believed its confocal neuro-endomicroscopy (CNEM) was “a significant development enabling new applications in neurosurgery and related disciplines” that would become important operating theatre diagnostic visualization tools.
Optiscan said that funds raised in its rights issue would be used to make requested minor modifications to the prototypes for completion and launch.
The company said it expected to meet with Zeiss executives “in the near future”.
Optiscan climbed 0.7 cents or 35 percent to 2.7 cents with 1.6 million shares traded.

POLYNOVO

Polynovo said that revenue for the year to June 30, 2016 was up 2366 percent to $3,470,570 of which $3,274,927 was from its US BARDA burns trial.
Last year, the US Biomedical Advanced Research and Development Authority (BARDA) awarded Polynovo a contract worth up to $US26.2 million ($A37.7 million) for trials of its biodegradable temporising matrix for burns, with $US8.2 million ($A11.8 million), on a reimbursement for activity basis, for a 10-patient trial (BD: Sep 29, 2015).
Today, the company said that it had received $1.5 million in the previous financial year for the sale of the Metabolic business, including the controversial compound AOD9604.
Polynovo said that the loss after tax was up 130.0 percent to $3,252,000.
The company said that its net tangible asset backing per share was up 84.4 percent to 2.25 cents at June 30, 2016, with diluted loss per share up 87.9 percent to 16.8 cents.
Polynovo said that it had cash and cash equivalents of $10,796,691 at June 30, 2016.
Polynovo was unchanged at 27 cents.

IMUGENE

Imugene says that Chiang Mai University of Thailand has approved site activation for its phase Ib/II study of HER-Vaxx immuno-oncology therapy in gastric cancer.

Imugene said that it had previously had approvals from the Taipei Veterans General Hospital in Taiwan and the University of Hong Kong (BD: Jul 11, Aug 11, 2016).

Imugene chief operating officer Leslie Chong said the Chiang Mai University of Thailand approval was “spectacular”.

“With this committee’s approval, we can now commence the necessary steps towards activating this site for the start of patient enrolment for the re-entry of HER-Vaxx in our phase Ib/II study in HER2 positive gastric cancer,” Ms Chong said.

The company said the study would be conducted in two parts with the phase Ib trial treating up to 18 patients with HER-Vaxx with chemotherapy at three dose levels, to provide safety data, immunogenicity data, evaluate the booster schedule and determine the optimal phase II dose.

Imugene said that the open-label phase II study would recruit about 68 patients randomized into either HER-Vaxx plus standard-of-care or standard-of-care alone.

Imugene fell 0.1 cents or 12.5 percent to 0.7 cents with 2.3 million shares traded.

NOXOPHARM

Noxopharm says it will testing the ability of its NOX66 to promote the anti-cancer effects of radiotherapy.

Noxopharm said that the program would run in parallel with it phase Ia/Ib/IIa Europe study tested NOX66 in combination with chemotherapy.

The company said that NOX66 would be used in combination with radiotherapy in specific cancer types including metastatic prostate cancer, particularly where multiple tumors were present and irradiation of all tumors was impractical and where the dosage of radiotherapy is palliative because of the advanced nature of the disease.

Noxopharm said that radiotherapy had “the same challenge as chemotherapy – cancer cells learn how to survive the therapy”.

“Many of the mechanisms that lead to chemotherapy drug-resistance are the same that lead the cell to resist radiotherapy,” Noxopharm said.

The company said that the ability of the active ingredient of NOX66, idronoxil, to cancel cancer drug resistance mechanisms was believed to have the potential to provide the same benefit for radiotherapy.

Noxopharm chief executive officer Dr Graham Kelly said the company had “good reason to believe that idronoxil possesses a potent ability to overturn radio-resistance mechanisms”.

“One of the major benefits that we see for this effect is the ability to turn dosages of radiotherapy only intended to provide a temporary anti-cancer effect, into a far more meaningful anti-cancer effect,” Dr Kelly said. “The main benefits that we see in expanding our clinical program in this way are the dual effects of de-risking the company’s commercial position while … broadening the commercial potential of NOX66.”

“Having the same drug able to provide a potent benefit for the two main frontline anti-cancer therapies opens up an extraordinary and unique market opportunity,” Dr Kelly said.

Noxopharm said the program was based around pilot clinical studies involving relatively small numbers of patients with specific cancer types and was within the company’s budgeted expenditure for the next 18 months.

Noxopharm fell half a cent or three percent to 16 cents.

MEDLAB CLINICAL

Medlab says it has “a significant cannabis supply agreement” with Canadian licenced producer of medical marijuana, the Leamington, Ontario-based Aphria Inc.
Medlab said the two companies had collaborated on cannabis plant species, yields and a novel extraction process, allowing Aphria to produce large-scale supply.
The company said that Aphria would grow and prepare the high yield cannabis for Medlab in Canada and Medlab would complete the manufacturing at a licenced schedule 8 Australian Therapeutic Goods Administration approved facility, expected to be in Australia.
Medlab said the facility would combine the cannabis product with its Nanocelle delivery system, which enabled sub-micron-sized particles to be taken by mouth spray, allowing a swifter and more direct absorption of medicine into the bloodstream.
The company said that its oncology pain trial would combine whole plant extract of both cannabidiol and tetrahydrocannabinol in a one-to-one ratio with Nanocelle, “making it the first trial of its kind, globally”.
Medlab said it had “exclusivity over the cannabis product it has developed with Aphria and the agreement also marks the beginning of Aphria’s entry into export markets and pharmaceutical development with the use of its product in human trials”.
Medlab was up half a cent or 1.45 percent to 35 cents.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG says it has completed its strategic review by selling its PG500 assets to Zucero Therapeutics Pty Ltd for a total deferred consideration of $6,000,000.
TBG said that the sale was the final step in the strategic review and company restructure which commenced in May 2015 and it was “now able to solely focus on growing its molecular diagnostics business”.
The company said that Zucero was established for the sale and staff, including TBG drug development director Dr Keith Dredge, would to be involved in the PG500 business.
TBG said that the consideration was payable in three years and it would be able to convert the deferred consideration into equity so that TBG would hold 20 percent of Zucero, giving it “the opportunity to share in any upside that may eventuate from Zucero’s activities with the PG500 assets”.
The company said it had security interest agreements and a guarantee and the right to appoint a Zucero director.
TBG was unchanged at 21 cents.

BIOTRON

Biotron says that additional compounds in its proprietary compound library have shown activity against Zika virus.
Biotron previously said that screening its library of small molecule compounds against Zika virus identified two compounds with anti-Zika activity (BD: Feb 16, May 23, 2016).
Today, the company said it had identified additional compounds able to inhibit Zika virus activity, several of which had greater potency than the first two compounds.
Biotron said it had an agreement to use the non-clinical and pre-clinical services program of the US National Institute of Allergy and Infectious Diseases.
The company said that the NIAID had identified Zika as a priority area for research funding, including creating treatments and broad-spectrum antiviral drugs that would be effective against the virus and similar diseases such as Dengue”.
Biotron was up 0.4 cents or 6.15 percent to 6.9 cents with 1.5 million shares traded.

USCOM

Uscom executive chairman Prof Robert Phillips has increased his holding in the company from 17,080,066 shares to 18,080,066 shares but has been diluted to 16.59 percent.
In his substantial shareholder notice Prof Phillips said that through Australian Cardiac Sonography Pty Ltd Phillips Superannuation account he acquired 1,000,000 employee share plan shares for $59,000 or 5.9 cents a share in two tranches on September 30, 2015 and August 18, 2016.
In June, Uscom raised $2,214,425 in a private placement at 20 cents a share.
Uscom fell half a cent or 1.5 percent to 32 cents.

ANTEO

Bergen Global Opportunity Fund, Bergen Asset Management and Eugene Tablis have become substantial shareholders in Anteo with 82,886,736 shares (7.31%).
The New York-based Bergen said that the acquisition was from the conversion of $2,280,000 of convertible securities to 82,886,736 shares or 2.75 cents per share.
Anteo was up 0.4 cents or 6.45 percent to 6.6 cents with 2.9 million shares traded.

RACE ONCOLOGY

Race says it has appointed Gordon Beck, as vice-president of European Operations responsible for implementing a named patient sales and marketing program.
Race said Mr Beck had been an executive at Roche and Bristol-Myers Squibb for 13 years and had consulted in strategic planning, medical communications and business development with Amgen, Genentech, Novartis, Seattle Genetics, Gilead and Takeda.
The company said that Mr Beck would be issued $50,000 in shares for achieving the first sales order for bisantrene in the first named patient program country by September 30, 2017, with the number of shares to be based on the 30-day volume-weighted average price prior to the that first milestone.
Race said that a second tranche of $50,000 in shares would be issued for the first sales order in a second named patient program country by December 31, 2017.
The company said that under the terms of the consultancy agreement with Dr Dan Levy it would grant Dr Levy's company, DEL Biopharma 200,000 options in mid to late October 2016, with the options vesting on August 1, 2017, based on performance milestones related to the manufacturing program for bisantrene.
Race fell half a cent or 2.4 percent to 20.5 cents.

NUHEARA

Nuheara says it has appointed Jean-Marie Rudd as its chief financial officer.
Nuheara said that Ms Rudd had more than 20 years' experience in the corporate sector and professional services, including almost 10 years as chief financial officer and company secretary in ASX listed companies and held leadership roles at ILH Group, Thinksmart, the Heytesbury Group and law firm Minter Ellison.
The company said that Ms Rudd was a graduate of Curtin University, Perth, Western Australia.
Nuheara was up 0.1 cents or 1.9 percent to 5.3 cents.