Biotech Daily

Thursday August 25, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 5%, ANTEO DOWN 6%**

*** MESOBLAST REVENUE UP 115% TO $56m, LOSS DOWN 96% TO $5m**

*** CLINUVEL REVENUE UP 97% to $6m, LOSS DOWN 70% TO $3m**

*** ACRUX REVENUE UP, PROFIT UP, PATENT FIGHT STOPS DIVIDEND**

*** PROBIOTEC REVENUE DOWN 0.3% TO $66m, LOSS TO $4m PROFIT**

*** NEUREN TO EXPAND RETT TRIAL, LANG WALKER FUNDING EGM**

*** ADALTA RECEIVES $738k FEDERAL R&D TAX REFUND**

*** ADMEDUS NOVEMBER LAUNCH OF VASCUCEL FOR VESSEL REPAIR**

*** EURO PATENT FOR PRIMA'S IMP731**

*** US PATENT FOR MACH7 MOBILE MEDICAL IMAGE CAPTURE**

*** TONY GRIST, DENLIN, OAKTONE BELOW 5% IN ACTINOGEN**

*** ADAM BLUMENTHAL, ANGLO MENDA TAKE 8% OF NOXOPHARM**

*** IQ GROUP APPOINTS JIMENA HURTADO RESEARCH, LEI XU ASIA PACIFIC**

MARKET REPORT

The Australian stock market fell 0.36 percent on Thursday August 25, 2016 with the ASX200 down 19.8 points to 5,541.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 13 were unchanged and one was untraded.

Pharmaxis was the best, up 1.5 cents or 5.1 percent to 31 cents with 103,798 shares traded. Benitec and Nanosonics climbed four percent or more; Cellmid and Uscom were up more than three percent; Clinuvel, Compumedics and Starpharma rose more than two percent; Polynovo and Resmed were up more than one percent; with Cochlear, Medical Developments and Pro Medicus up by less than one percent.

Anteo led the falls, down 0.4 cents or 6.1 percent to 6.2 cents with two million shares traded. Factor Therapeutics lost 5.7 percent; Acrux, Biotron, IDT, Osprey, Prana and Sirtex fell more than four percent; Bionomics and Living Cell were down more than three percent; Mesoblast shed 2.1 percent; Actinogen, Avita, CSL and Psivida were down one percent or more; with Viralytics down 0.3 percent.

MESOBLAST

Mesoblast says that revenue for the 12 months to June 30, 2016 was up 115.3 percent to $US42,548,000 ($A55,834,260), with net loss after tax down 95.7 percent to $US4,127,000 ($A5,414,980).

Mesoblast chief financial officer Paul Hodgkinson told Biotech Daily that $US22.5 million of the revenue was an accounting procedure of non-cash recognition of Teva's return of the cardiac program and the original $US130 million payment was amortised over a longer period, with the termination meaning that the accounting consideration was completed in this year's statement (BD: Dec 8, 2010; Jun 14, 2016).

Mr Hodgkinson said that the company had received $US3.5 million in milestone payments for its Temcell product for graft versus host disease in Japan.

Mr Hodgkinson told an investor teleconference that the "tier 2 programs" had been narrowed and deprioritized and the company expected it would require $US13 million for the phase III congestive heart failure trial to reach its interim analysis by April 2017.

Mesoblast executive officer Prof Silviu Itescu told the teleconference that Teva's return of the cardiac program gave his company control, allowing it to "refine the clinical pathway to global commercialization".

Prof Itescu said that the cumulative data from all trials showed an "excellent safety profile and efficacy signals" and the company understood the multiple mechanism of action of its stem cell therapies across multiple disease states including its "tier 1" programs of congestive heart failure, rheumatoid arthritis, diabetic nephropathy, chronic lower back pain and graft versus host disease.

Prof Itescu said the company had brought forward the interim analysis of its phase III congestive heart failure trial to the first three months of 2017.

Prof Itescu said that more than 240 of the planned 600 patients had been recruited for the trial and the analysis would "provide evidence-based support for strategic and scientific decisions regarding the phase III program.

He said the previously published results from the 48-patient phase II rheumatoid arthritis trial were compelling and the company was planning a phase III trial with a short duration to the primary endpoint of 12 to 24 weeks.

Prof Itescu said that the 360-patient, phase II trial for chronic lower back pain was "recruiting well" with an interim analysis planned by April 2017.

Mesoblast said that research and development expenditure fell 20.2 percent to $US50,013,000, with manufacturing costs increasing 25.1 percent to $US29,763,000.

The company said it had cash and cash equivalents of $US80,937,000 at June 30, 2016 compared to $US110,701,000 at June 30, 2015.

Mesoblast said that net tangible assets backing per security was constant at 17.51 US cents, with diluted loss per share down 96.2 percent to 1.14 US cents

Mesoblast fell three cents or 2.1 percent to $1.375.

CLINUVEL

Clinuvel says revenue for the year to June 30, 2016, was up 96.9 percent to $6,419,707 with net loss after tax down 69.7 percent to $3,153,718.

Clinuvel said that revenue from Scenesse for erythropoietic protoporphyria sales in Italy and Switzerland under special access schemes increased 24.1 percent to $3,614,000.

The company said diluted loss per share fell 70.8 percent to 7.0 cents at June 30, 2016, tangible assets per share increased 52.0 percent to 38 cents, with $13,844,703 in cash and cash equivalents at June 30, 2016, compared to $10,572,295 at June 30, 2015.

Clinuvel climbed 11 cents or 2.2 percent to $5.15.

ACRUX

Acrux says its Axiron appeal will take about 12 months, but is rolling out sales of its estradiol product and developing four other generic products.

In an investor teleconference, originally intended to discuss financial results, Acrux chief executive officer Michael Kotsanis said that both the company and US partner Eli Lilly & Co stood by the validity of the Axiron patents and would defend them in court.

Mr Kotsanis said the appeal would be held in the Federal Court in Washington DC which was "very experienced" in patent law.

Mr Kotsanis said that should the appeal be successful, Acrux and Lilly would seek to recover losses from any generic version of Axiron sold in the US.

"It's been a very bad week for the company and its share price," Mr Kotsanis said.

"The impact on our share price has been dramatic," Mr Kotsanis said. "Axiron is our major source of revenue."

"We believe we have good grounds for an appeal," Mr Kotsanis said.

He said that despite increased revenue and profit for the year to June 30, 2016, the company would not pay a dividend this year, following the patent challenge.

Acrux said that revenue for the year to June 30, 2016 was up 12.6 percent to $28,557,000 with net profit after tax up 16.6 percent to $12,981,000.

Acrux chief financial officer Sharon Papworth said that of the $28,009,000 in sales revenue, $25.3 million was Axiron royalties, $2.5 million came from milestone payments from Gedeon Richter Plc for the Lenzetto estradiol product for menopause, and the company had earned about $200,000 so far from the European roll-out of Lenzetto, known as Evamist in the US.

Ms Papworth said the company had $29,360,000 in cash and cash equivalents at June 30, 2016, compared to $23,068,000 at June 30, 2015, with research and development spending for the year was up $1.7 million or 44.7 percent to $5.5 million.

Mr Kotsanis said that the Lenzetto roll-out in Europe had just begun and he expected increasing royalty revenue from the product, as well as from the sales of Axiron outside the US which was protected by non-US patents.

Mr Kotsanis said the company had been diversifying before the Axiron patent news and was focused on its lead program for onychomycosis or nail fungal infection, along with three other generic projects known as ACR-68, ACR-71 and ACR-72, which could not be described as they were generic and patent-free.

He said the programs were transdermal and/or topical and were going through a range of testing and development and the company was in discussions with manufacturers and the US Food and Drug Administration on all programs.

The company said that net tangible asset backing per share was up 25 percent to 15 cents and diluted earnings per share was up 16.4 percent to 7.8 cents.

Acrux fell two cents or 4.55 percent to 42 cents with 2.9 million shares traded.

PROBIOTEC

Probiotec says that sales revenue for the year to June 30, 2016 was down 0.3 percent to $65,930,000 with last year's loss turning to a net profit after tax of $4,014,000.

Probiotec said it would pay a fully-franked 1.5 cents a share dividend for shareholders at the record date of September 5, 2016.

The company said that net tangible asset per share was up 20.4 percent to 49.8 cents and diluted earnings per share was 7.6 cents and it had cash and cash equivalents of $505,622 at June 30, 2016 compared to $120,296 at June 30, 2015.

Probiotec was up 1.5 cents or 2.8 percent to 55.5 cents.

NEUREN PHARMACEUTICALS

Neuren says it will exceed its 64-patient target in its phase II trial of trofinetide for Rett syndrome in girls aged five to 15 years.

Neuren said the randomized, double-blind, placebo-controlled trial was in progress at 12 US sites, with 49 subjects patients randomized, five in screening and 18 more scheduled to enter screening before the end of September, with more patients available.

The company said that to provide “funding flexibility” it would seek shareholder approval to allow major shareholder Lang Walker to increase his holding beyond the current 19 percent.

Neuren said that the trial duration from screening to follow-up was 11 weeks, which meant it could be expanded, while delivering top-line results by April 2017.

Neuren said that the initial 64 subjects were being randomized into four dose groups of trofinetide 50mg/kg, trofinetide 100mg/kg, trofinetide 200mg/kg and placebo.

Neuren executive chairman Dr Richard Treagus told Biotech Daily that the treatment period was twice daily over six weeks, with a follow-up of two weeks.

Dr Treagus said that it was important to note that no safety or tolerability issues had emerged and that three-quarters of the 49 randomized patients – about 36 patients- had received doses of trofinetide, ranging across the three dose strengths.

Dr Treagus said that all patients needed to be treated by December 2016 in order to have results by April 2017 and, depending on availability, the trial could have as many as 80 or 90 patients.

Dr Treagus said that once the first 64 patients had been randomized to the four groups, subsequent patients would be randomized on a one-to-one basis to receive either the highest dose of trofinetide 200mg/kg twice daily for six weeks or placebo.

Neuren said that increasing the sample size would increase the statistical power of the comparison between the highest dose and placebo groups.

The company said that to fund the expansion of the Rett trial, it would defer further investment in certain other trofinetide development activities, including chronic toxicity studies and manufacturing, until the results of the paediatric trial were available, delaying a phase III Rett trial from late 2017 to 2018.

“The Rett syndrome community’s support for our paediatric clinical trial is evidenced by the strong enrolment rate and excellent study compliance,” Dr Treagus said.

“We believe the opportunity to enrol additional girls into the trial while still delivering top-line results [by April] 2017 is in the best interests of all Neuren's stakeholders,” Dr Treagus said.

Neuren said it had completed an evaluation of strategic options, including partnering, assisted by US investment bank Leerink Partners and a number of international pharmaceutical companies expressed interest in [the] Rett syndrome and Fragile X syndrome programs with trial results “an important and valuable component of the trofinetide development package”.

Neuren was unchanged at 4.9 cents.

ADALTA

Adalta says it has received $738,045 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Adalta said the rebate related to research and development expenditure on AD-114 for fibrosis for the year to June 30, 2016.

Adalta fell two cents or 7.7 percent to 24 cents.

ADMEDUS

Admedus says it expects to launch its Adapt process Vascucel for vascular repair in November 2016.
Admedus executive chairman Wayne Paterson said the company was “very excited to be able to add products to the portfolio which provide much needed alternatives to surgeons and patients in the vascular repair space”.
The company said that its Malaga factor in Perth, Western Australia would be able to supply Vascucel alongside its output of Cardiocel by November 1, 2016.
Admedus said that Vascucel was developed for use in the repair of vascular surgical procedures such as carotid endarterectomy, to reduce the risk of stroke by correcting narrowing in the carotid arteries, as well as coronary revascularisation, vascular aneurism repairs and other vascular repairs.
The company said the addressable market was more than US500 million a year, with more than 170,000 carotid endarterectomy procedures performed each year in the US.
Admedus said that Vascucel would have the characteristics and patient benefits of the Adapt-treated Cardiocel, including the lack of calcification and remodelling properties.
Admedus was unchanged at 33.5 cents.

PRIMA BIOMED

Prima says the European Patent Office has granted a patent relating to its IMP731 antibody, originally developed by Immutep SAS.
Prima said the patent, entitled ‘Cytotoxic anti-LAG-3 monoclonal antibody and its use in the treatment or prevention of organ transplant rejection and autoimmune disease’ provided protection for specific sequences of anti-LAG-3 antibodies and their use in depleting LAG-3 and T-cells by complement dependent cytotoxicity and antibody-dependent cell cytotoxicity.
The company said that the rights for the development of the IMP731 antibody were granted to Glaxosmithkline in December 2010, which had begun first-in-human clinical trials of the proprietary antibody (GSK2831781) derived from IMP731.
Prima was unchanged at 3.8 cents with 1.8 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has been awarded a second US patent entitled ‘Handheld Medical Imaging Mobile Modality’ for medical image capture with a mobile device.
Mach7 said the patent covered a method of acquiring medical imaging data via a mobile device and covered user authentication, image and video capture, association to a patient record and secure wireless communication of image/video and metadata to a server.
The company said the method included a program for requesting, providing and transmitting medical image data from any mobile device.
Mach7 said that the patented technology was commercially available in its Imodality mobile image capture mobile telephone application, which used its enterprise imaging platform by securely providing front-line clinicians and care providers with a superior mobile telephone product to capture and integrate photos, videos, sound files and notes and directly connect that data to the patient’s electronic medical record.
Mach7 said that Imodality was accelerating mobile healthcare, enabling point of care delivery and optimizing workflows for image producing specialties beyond radiology and cardiology.
Mach7 fell 0.1 cents or 2.4 percent to four cents.

ACTINOGEN

The Perth, Western Australia-based Denlin and Oaktone Nominees say they have reduced their holdings in Actinogen below the five percent substantial level.
Last year the group said it held 34,717,184 shares or 5.8 percent, when Actinogen raised $10.0 million at 9.5 cents a share (BD: Apr 24, 29, 2015).
Today, Denlin director Tony Grist said that between October 23, 2015 and March 17, 2016, the group had sold 3,798,071 shares for $260,821 or an average price of 6.9 cents a share.
Mr Grist told Biotech Daily that the group held 30,000,000 shares or 4.9 percent.
Actinogen fell 0.1 cents or 1.75 percent to 5.6 cents.

NOXOPHARM

The Sydney-based Anglo Menda Pty Ltd says it has increased its substantial holding in Noxopharm from 5,089,286 shares (6.77%) to 5,804,286 shares (7.72%).
The substantial shareholder notice, signed by director Adam Blumenthal said that the shares were held by Anglo Menda as trustee for the Anglo Australasia Trust.
The notice said that 715,000 shares were acquired for $137,455 or 19.2 cents a share.
Noxopharm was up 2.5 cents or 13.2 percent to 21.5 cents with 4.3 million shares traded.

IQ GROUP

The IQ Group says it has appointed Jimena Hurtado as general manager of its clinical research business and Lei Xu as Asia Pacific business unit director.
IQ said that Ms Hurtado had more than 17 years' experience in pharmaceutical development, sales and human resource management.
The company said that Ms Xu joined to company in 2014 and as head of Asia Pacific investor relations.
IQ Group is the over-arching company with subsidiary companies including IQX and the ASX-listed IQ3 and is a private company.