Biotech Daily

Tuesday July 15, 2014

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: IDT UP 14%, ANALYTICA DOWN 8%**

*** CELLMID HAILS US FGF5 HAIR GROWTH STUDY**

*** FDA APPROVAL FOR DORSAVI'S VIMOVE SPINAL DIAGNOSTIC**

*** OPTISCAN RAISES $634k, ZEISS $260k NEUROSURGERY MILESTONE**

*** ETHICS APPROVAL FOR ONCOSIL PANCREATIC CANCER TRIAL**

*** CALZADA EXECUTIVE SEARCH, LAURENT FOSSAERT TO GO**

*** BLUECHIIP TRACKING INSTALLED AT SHANGHAI OUTDO**

*** RHINOMED PLEADS SCHULTZ, PUBLICATION TO ASX 87% QUERY**

*** HUNTER HALL TAKES MORE PROFIT, REDUCES TO 14% OF SIRTEX**

*** SUDA, BERGEN END DRAW-DOWN EQUITY FACILITY**

MARKET REPORT

The Australian stock market was flat on Tuesday July 15, 2014 with the S&P ASX 200 down 0.1 points to 5,511.3 points.

Nine of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and five were untraded.

IDT was the best, up three cents or 13.6 percent to 25 cents with 15,297 shares traded.

Living Cell and Neuren climbed more than four percent; Cellmid was up 3.7 percent; Anteo, Circadian, Oncosil and Psivida rose more than two percent; with CSL and Sirtex up by less than one percent.

Analytica led the falls, down 0.3 cents or 8.3 percent to 3.3 cents with 1.4 million shares traded.

Benitec lost 7.9 percent; GI Dynamics and Pharmaxis fell five percent or more; both Avita and Biotron fell 4.8 percent; Acrux, Patrys and Prana were down more than three percent; Atcor, Optiscan and Universal Biosensors shed more than two percent; Bionomics, Mesoblast and Viralytics were down more than one percent; with Cochlear and Starpharma down by less than one percent.

CELLMID

Cellmid says that, for the first time, a peer-reviewed scientific paper has linked directly FGF5 as a regulator of human hair and eyelash growth.

Cellmid said that the article, entitled 'FGF5 is a crucial regulator of hair length in humans' was published by the Proceedings of the National Academy of Sciences and an abstract was available at: http://www.pnas.org/content/early/2014/07/02/1402862111.abstract.

The company said that its hair growth products contained FGF5-inhibiting botanical extracts and the study's findings confirmed that blocking FGF5 was an attractive therapeutic approach to increase hair growth.

Cellmid said that the hair growth products containing FGF5-inhibiting botanical extracts were developed using mechanism of action evidence obtained from other mammals.

The company said that while clinical trials confirmed the products reduced hair loss and increases hair growth in humans, this was the first time an independent study provided direct mechanism of action between excessive hair growth and defective FGF5 genes in humans.

Cellmid said that the study was conducted by New York's Columbia University Medical Centre with scientists from the departments of dermatology, biochemistry, genetics and epidemiology.

The company said that the study's aim study was to determine the cause of trichomegaly, or extreme eyelash growth, presenting in two families.

Cellmid said that inherited trichomegaly was extremely rare, with only two cases reported in the literature prior to this study.

The company said that people with trichomegaly were otherwise healthy apart from extremely long eyelashes.

Cellmid said that eyelashes were a modified form of hair with the same growth cycle as scalp and other terminal hair follicles and were susceptible to the same molecular signals that affect head hair.

The company said that the study authors sequenced the DNA from every gene in five trichomegaly-affected subjects and from nearly 43,000 variants identified across the full genome of about 20,000 genes analyzed and found that only mutations arising in a single gene, FGF5, caused trichomegaly.

Cellmid said that genetic studies in animals with abnormally long coats had identified deletion of, or mutation to, fgf5 as the culprit, or the 'angora mutation', but this study was the first to prove that FGF5 was critical to limiting human hair growth.

Cellmid head of product development Darren Jones said the study "comprehensively demonstrates the critical role FGF5 plays in human hair loss ... [and] validates the approach of our scientists in seeking to block FGF5 to restore hair growth".

"It also re-affirms FGF5 inhibition to be a safe and specific mechanism by which to promote hair growth," Mr Jones said.

Cellmid chief executive officer Maria Halasz said that the developers of her company's product at Japan's Advangen Inc "were far ahead of the curve in targeting FGF5".

"From the first scientific reports of FGF5's significance in animals, the team recognized the potential to safely and effectively treat hair loss and restore hair growth by blocking FGF5," Ms Halasz said.

Cellmid said that through its wholly owned subsidiary Advangen International it was the leader in developing clinically validated products for boosting healthy hair growth through FGF5 inhibition.

Cellmid said that the market leader in drug treatments for eyelash growth, Allergan's Latisse, sold more than $150 million a year in the US alone.

Cellmid was up 0.1 cents or 3.7 percent to 2.8 cents with 2.3 million shares traded.

DORSAVI

Dorsavi says it has US Food and Drug Administration 510k pre-market approval for its wearable Vimove diagnostic for reporting lower back movement and muscle activity.
Dorsavi chief executive officer Dr Andrew Ronchi said the approval “opens up substantial opportunities for us in the United States”.
“Dorsavi has successfully implemented a stepped approach in the US, one of the biggest market opportunities for the company with approximately 280,000 physical therapists and 660,000 physicians,” Dr Ronchi said.
The company said that Vimove’s wearable sensors were placed on the body to measure movement and muscle activity and patients could be assessed through a series of movements or exercises performed in the clinic, at home or at work.
Dorsavi US president John Kowalczyk said that hHealthcare reform in the US was mandating quantitatively generated data and Vimove gave healthcare providers the ability to assess movement of the lower back and would aid the development of treatment plans.
Dorsavi was unchanged at 44.5 cents.

OPTISCAN

Optiscan says it has a five-month $500,000 convertible debt facility with Melbourne advisors, Platinum Road, convertible at five cents a share.
Optiscan said the note was secured against its expected payment under the Federal Government’ Research and Development Tax Incentive scheme.
The company said that with Melbourne’s Menzies Securities it had raised about $134,000 in “a small specific purpose placement” at 2.54 cents a share to buy-out the convertible note outstanding with the New York-based Magna Group.
Optiscan said that it expected to complete the final stage of pre-regulatory product development for its neurosurgery visualization technology in August, with the final clinical trial work also expected to begin in August.
The company said that it would receive a milestone payment of $260,000 from Germany’s Carl Zeiss Group although there was “still much to be done” for the US Food and Drug Administration and European regulatory submissions (BD: Sep 24, 2012).
Today, the company said that in addition to the application of the second generation technology within neurosurgery, significant near term applications existed within the research and gastrointestinal markets.
Optiscan said it was working on the final stages of development of the FIVE-2 research system with its partner, MR Solutions, with a launch of the product expected later this year (BD: Feb 18, 2014).
The company said that the application of its endomicroscopy for Barrett’s oesophagus “boasts countless successful clinical trials, level 1 clinical evidence and [current procedural terminology] codes, which allow reimbursement in the US”.
Optiscan said that development of the new platform to a pre-product prototype stage would require further capital in the near term to optimize the development of the flexible endomicroscopy systems to make them standalone and compatible with gastro-intestinal endoscopes across all manufacturers.
The company said compatibility would eliminate the need to integrate the device into endoscope manufacturers’ products.
Optiscan said that the second generation flexible endomicroscopy systems would have greatly enhanced imaging, with smaller probes and more flexible high resolution imaging.
The company said that there was no competing product with that capability.
Optiscan fell 0.1 cents or 2.8 percent to 3.5 cents.

ONCOSIL MEDICAL

Oncosil says it has been granted ethics approval for the Australian hospital sites its pivotal 150-patient clinical trial for pancreatic cancer (BD: Mar 17, 2014).

Oncosil chief executive officer Dr Neil Frazer told Biotech Daily he hoped to treat the first patient before the end of 2014.

Oncosil said that it would finalize arrangements for the first group of hospitals to begin recruiting patients and was making preparations for an investigational device exemption submission to the US Food and Drug Administration.

Oncosil said that its technology, also called Oncosil, was an implantable device that emitted radiation directly into a pancreatic tumor and the surrounding pain conducting nerves and delivered radiation therapy locally for up to three months.

The company said that the device was inserted directly into the centre of the tumor in a 15 to 30 minute procedure.

Oncosil said that the targeted radiation therapy was classified by regulators as a class III medical device, not a drug so instead of phase I, phase II and phase III studies the device would had pilot and pivotal or registration studies.

Dr Frazer said that ethics approval for the Australian arm of the trial was “another step in the product’s development pathway and ...over the coming months we look forward to bringing the first group of trial hospitals on-line and commencing the patient recruitment process”.

Oncosil was up 0.2 cents or 2.1 percent to 9.9 cents with 3.2 million shares traded.

CALZADA

Calzada says it will “expand the organizational structure by making several new appointments” with Polynovo chief executive officer Laurent Fossaert departing.

Calzada has had two main arms, Polynovo developing its bioresorbable Novosorb material for wound scaffolds and other applications, as well as its wholly owned subsidiary Metabolic with the AOD9604 molecule, which failed to meet its anti-obesity endpoints and has been at the centre of the Australian drugs in sports inquiries including the Essendon Football Club (BD: Feb 21, 2007; Jan 28, Jun 5, 2014).

Today, Calzada said that it recognized “the immediate requirement to appoint a managing director who will be responsible for the corporate and Polynovo business”.

The company said the person to be appointed would have “broad experience commercializing medical devices or pharmaceuticals and will have experience in the relevant areas of his or her direct reports”.

Calzada said it also wanted to expand its commercial, clinical, regulatory, quality and manufacturing expertise and would be briefing recruitment agents to identify and appoint experienced and proven talent in these areas.

The company said that while it searched for permanent appointments David McQuillan and Philip Powell would assume the roles of joint acting managing directors.

Calzada said that Mr McQuillan had been a director of Calzada since August 6, 2012 and had more than 25 years technical, scientific and regulatory medical device experience.

The company said that Mr Powell had experience in investment banking and regulatory requirements and held a Bachelor of Commerce from the University of Melbourne.

Calzada fell half a cent or 4.55 percent to 10.5 cents with 1.05 million shares traded.

BLUECHIIP

Bluechiip says its tracking system has been installed at the Shanghai Outdo Biotech Co a bio-bank owned by the People's Republic of China.

Bluechiip said that Shanghai Outdo was "a best practice organization in industry standardization, academic communication, education, training and information exchange between countries, scientific services and others [and was] ... the largest tissue bank in China with more than 200,000 samples".

The company said that Shanghai Outdo provided training to nearly 100 hospitals in 20 provinces and 50 cities throughout China.

Bluechiip chief executive officer Dr Jason Chaffey said that the adoption of the Bluechiip system by Shanghai Outdo was "an important showcase of our technology in a leading bio-bank at the cutting edge of best practice and further validation of the unique properties provided by our identification and tracking technologies".

Dr Chaffey told Biotech Daily that the value of the contract was commercial in confidence.

Bluechiip was up half a cent or 14.3 percent to four cents.

RHINOMED

Rhinomed has again told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said in a letter to Rhinomed dated July 10, 2014 that the company's share price climbed from 2.3 cents on June 30 to 4.3 cents on July 4, 2014, an 86.96 percent increase.

Earlier this month the ASX said the company's share price climbed from 2.3 cents on June 30 to 3.5 cents, on July 4, 2014, a 52.2 percent increase and noted an increase in trading volumes (BD: Jul 4, 2014).

Rhinomed said at that time that it had made seven announcements to the ASX and had been the subject of five media and investor reports between April 11 and July 3, 2014 and concluded that the company had been oversold and was being re-rated by market analysts.

Today, the ASX defined the meaning of "aware" in Chapter 19 of the Listing Rules and asked Rhinomed when it became aware of the information in its July 9, 2014 announcement relating to the Fitness First collaboration.

Rhinomed said that it made announcements in April and May 2014 that it would expand to gymnasiums and health clubs and completed the agreement on June 6, 2014, with the campaign beginning on July 14, 2014.

The company said that it concluded the announcement "would not have a material effect on the price or value of its securities".

Rhinomed climbed 0.4 cents or 9.5 percent to 4.6 cents with six million shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex, from 8,758,488 shares (15.61%) to 8,036,651 shares (14.23%).

Hunter Hall bought and sold shares between June 2 and July 10, 2014 with the single largest sale and most recent the sale of 282,393 shares for $5,267,547 or $18.65 a share.

Hunter Hall has been reducing its holding in Sirtex since May 2013 (BD: May 29, 2013).

Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at $2.35 a share (BD: Mar 5, 2009).

Sirtex was up one cent or 0.05 percent to $18.51 with 288,975 shares traded.

SUDA

Suda says it has ended its 2012 draw-down equity facility with New York's Bergen Global Opportunity Fund.

Suda said the 24-month agreement was postponed following the company's $5.6 million capital raising in November 2013.

The company said that it had a strong financial position and the agreement had been terminated, by mutual consent of both parties.

Suda said that Bergen would advance a final tranche of $100,000 as a prepayment for the purchase of shares.

Suda chief executive officer Stephen Carter said the company had "a strong relationship with Bergen who has played a key and positive role in financing the business during the previous calendar year".

"The funding offered us the flexibility to raise capital in a highly efficient and cost effective manner, thus maximizing value for our shareholders," Mr Carter said.

Bergen Asset Management managing director Eugene Tablis said that the funding had been "beneficial for both parties and continued our string of successful biotech investments in Australia".

Suda fell 0.2 cents or 3.8 percent to 5.1 cents with 1.2 million shares traded.