Biotech Daily

Wednesday August 29, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: AIRXPANDERS UP 24%; COMPUMEDICS DOWN 6%**

*** ANU CLOT DIAGNOSTIC IDENTIFIES CARDIAC, STROKE RISK**

*** BLUECHIIP WINS 3-YEAR, $16m LABCON SUPPLY DEAL**

*** ANTISENSE DOSES 1st PATIENT IN ATL1102 DUCHENNE PHASE II TRIAL**

*** CHINA OKAYS MESOBLAST, TASLY $55m CARDIAC STEM CELL DEAL**

*** MEDIBIO LOSES M-D, CEO JACK COSENTINO**

*** SIRTEX REVENUE DOWN 7% to $221m, PROFIT DOWN 2% TO $41.5m**

*** ELIXINOL H1 REVENUE UP 111% TO $15m, MAIDEN H1 PROFIT $120k**

*** GENETIC SIGNATURES REVENUE UP 39% TO $3m, LOSS UP 22% TO $3m**

*** PROTEOMICS REVENUE UP 27% TO $1.2m, LOSS UP 57% TO $1.4m**

*** MEDICAL DEVELOPMENTS TO ANSWER FDA PENTHROX QUESTIONS**

*** NEUREN, LANSTEAD PAUSE SETTLEMENTS FOR 120 DAYS**

*** MMJ PHYTOTECH SALE, NAME CHANGE, 1m DIRECTOR OPTIONS AGM**

*** DEUTSCHE BANK BELOW 5% IN AVITA**

*** G MEDICAL PLEADS SCHULTZ TO ASX 49% QUERY**

*** ANATARA: SUE MACLEMAN, JANE RYAN IN; JAY HETZEL, PAUL GRUJIC GO**

MARKET REPORT

The Australian stock market was up 0.75 percent on Wednesday August 29, 2018 with the ASX200 up 47.5 points to 6,352.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and eight were untraded.

Airxpanders was the best for the second day in a row, up 2.1 cents or 23.6 percent to 11 cents with 1.6 million shares traded. Neuren climbed 9.1 percent; Ellex rose 6.35 percent; Oncosil improved five percent; Medical Developments and Reva were up more than four percent; Pro Medicus and Starpharma climbed more than three percent; Impedimed rose two percent; with Cynata, Polynovo, Prescient, Resmed and Volpara up more than one percent.

Compumedics led the falls, down three cents or six percent to 47 cents with 21,732 shares traded. LBT and Osprey fell more than four percent; Factor Therapeutics, Pharmaxis and Telix were down more than three percent; Nanosonics shed 2.7 percent; Dimerix and Orthocell were down one percent or more; with Clinuvel, Cochlear, CSL, Mesoblast and Sirtex down by less than one percent.

AUSTRALIAN NATIONAL UNIVERSITY

The Australian National University says it has developed a bio-optics diagnostic that can reveal blood clots to identify patients at risk of stroke or heart attack.

The University said a team of engineers and biochemists, led by Dr Steve Lee from its Research School of Engineering and Prof Elizabeth Gardiner from the John Curtin School of Medical Research, had developed a device that mimicked a damaged blood vessel and formed blood clots from human samples.

The research, titled 'Quantifying Embolism: Label-Free Volumetric Mapping of Thrombus Structure and Kinesis in a Microfluidic System with Optical Holography' was published in the journal Advanced Biosystems and is available at www.onlinelibrary.wiley.com/doi/abs/10.1002/adbi.201800089.

"We can create and quantify clot formation in [three-dimensional] view from a blood sample without any form of labelling such as fluorescence or radiotracer," Dr Lee said.

"This had been impossible to achieve until now," Dr Lee said.

Prof Gardiner said that doctors treated people at risk of heart attack or stroke with blood-thinning medication, but there was no precise way to know a patient's susceptibility to cardiac arrest or stroke.

ANU post-graduate student Sherry He said the device "creates a digital hologram of a microscopic blood clot at a fraction of a second by measuring the delay time for light to travel through the clot".

"We need to shrink our diagnostic device, which takes up a fair amount of space in a research lab at the moment, to something that can fit into a shoebox so that it can be used in a clinical setting," Ms He said.

Ms He said the device could be fitted onto a regular microscope, but was not yet suitable for bedside use.

BLUECHIIP

Bluechiip says it has a three-year deal worth $US11.6 million ($A15.9 million) to supply its tracking chips, hardware and services to Labcon North America.

Bluechiip said the San Francisco-based laboratory vial manufacturer Labcon was "the world's leading manufacturer of Earth-friendly laboratory consumables".

The company said Labcon had agreed to order $US4.2 million worth of chips, readers, software and engineering services for a two-year period, with $US7.4 million of products and services to be ordered and supplied in the third year and an additional two-year deal to be negotiated as the supply agreement progressed.

Bluechiip said that in 2017 Labcon began production of its Coldpoint Bluechiip-enabled range, which included cryo-vials, boxes, readers and software, and in December said it had a $1 million order for its sample tracking technology from Labcon (BD: Dec 5, 2017).

The company said it had delivered more than 290,000 chips since December 2017.

Bluechiip managing-director Andrew McLellan said the agreement was "an extremely exciting announcement for us because it represents our largest ever order".

"It extends our strong and historic partnership with Labcon North America, which has been a loyal and important customer of ours for several years," Mr McLellan said.

Labcon North America president Jim Happ said that Bluechiip's tracking technology "allowed us to bring differentiated products into the market".

"We are delighted to have gained a first-mover advantage in the cryogenic vial market, where the harsh environment severely compromises existing tracking technologies," Mr Happ said.

Bluechiip climbed 3.4 cents or 77.3 percent to 7.8 cents with 37.3 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has dosed the first of nine patients in its phase II trial of ATL1102 for Duchenne muscular dystrophy at Melbourne's Royal Children's Hospital.

Antisense said that nine non-ambulant boys aged between 10 and 18 years with Duchenne muscular dystrophy would be treated in the six-month dosing trial of ATL1102, with the primary endpoints of the study relating to the safety and tolerability of ATL1102, and that efficacy would be assessed in terms of the trial's effects on markers of inflammation, muscle damage and disease progression.

Antisense chief executive officer Mark Diamond said that patient recruitment and dosing were "a key inflection point in the company's progress".

"The important milestone positions us as a clinical stage company in [Duchenne muscular dystrophy] committed to the pursuit of an effective treatment for a devastating disease that is desperately under-served by existing therapies," Mr Diamond said.

Antisense was unchanged at 2.1 cents.

MESOBLAST

Mesoblast says that China has approved Tasly's $US40 million ($A54.5 million) investment to commercialize cell therapies for cardiovascular diseases in China.

In July, Mesoblast said it would receive $US40 million from the Tianjin-based Tasly Pharmaceutical Group for cardiac indications for its mesenchymal precursor cells, pending government approvals (BD: Jul 18, 2018).

Mesoblast said at that time that Tasly was "one of China's largest pharmaceutical companies" and the deal covered the development, manufacture and commercialization in China of Mesoblast's allogeneic, or off-the-shelf, mesenchymal precursor cell (MPC) product candidates MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction.

Today, the company said that Tasly had People's Republic of China approvals for overseas direct investment for the agreements.

Mesoblast said it would receive $US40 million on closing, comprising a $US20 million upfront technology access fee and $US20 million for Mesoblast shares at $1.86 a share.

The company said that the transaction was subject to filing with the State Administration of Foreign Exchange.

Mesoblast fell half a cent or 0.3 percent to $1.555 with 1.6 million shares traded.

MEDIBIO

Medibio says that managing-director and chief executive officer Jack Cosentino "will cease … effective from August 28, 2018".

Yesterday, Medibio requested a trading halt "pending an announcement … regarding an organizational change of senior management" (BD: Aug 28, 2018).

Today, the company said that Mr Cosentino was appointed managing director and chief executive officer on February 16, 2017, but provided no explanation for his departure.

Medibio said that chief financial officer Brian Mower had been appointed interim chief executive officer effective from August 28, 2018, while it began a search for a new chief executive officer and managing director.

Medibio chairman Chris Indermaur said the company would "remain focused and steadfast on its continued mission in identifying the link between physiological measures and mental health".

Medibio fell seven cents or 34.15 percent to 13.5 cents with 2.6 million shares traded.

SIRTEX MEDICAL

Sirtex says that revenue for the 12 months to June 30, 2018 fell 6.8 percent to $220,737,000 with net profit after tax down 2.15 percent to $41,469,000.
Last year, Sirtex published a loss of $26,257,000, including accountancy measures writing off intangible assets, impairment for the write-off of receivables and restructuring costs, with an actual net profit after tax of $42,382,000 (BD: Aug 23, 2017).
Today, the company said that dose sales of its radioactive SIR-spheres for liver cancer fell 5.7 percent to 11,861 doses, with dose sales down in the Americas by 7.7 percent to 8,127 doses; Europe, the Middle East and Africa sales shed 2.0 percent to 2,623 doses; with Asia Pacific sales up 1.6 percent to 1,111 doses.
The company said there would be no dividend, compared to 30.0 cents a share last year.
Sirtex said net tangible asset backing per share was up 11.0 percent to $2.706, with diluted earnings per share of 73.0 cents and it had $69,896,000 in cash and cash equivalents at June 30, 2018, compared to $50,349,000 the previous financial year.
Sirtex fell 30 cents or 0.9 percent to $31.86 with 794,301 shares traded.

ELIXINOL GLOBAL

Elixinol says that sales revenue for the six months to June 30, 2018 was up 110.8 percent to $14,886,000 with a maiden net profit after tax of $120,000.
Elixinol said that the revenue and profit comparison figures were pro-forma as the group was formed last year and listed on the ASX in January (BD: Jan 21, 2018).
Elixinol chief financial officer Ron Dufficy told Biotech Daily that underlying net profit after tax was $599,000 compared to the previous period's pro forma loss of $329,000.
In a teleconference, Elixinol chief executive officer Paul Benhaim said that the revenue from marijuana/hemp based dietary supplements sales in the US was $12,544,000 with hemp foods and skin-care in Australia comprising $2,342,000.
Mr Benhaim said that the company had submitted applications for the cultivation and manufacture of marijuana products to the Australian Office of Drug Control.
Mr Benhaim said that Elixinol would grow marijuana, produce finished medicinal goods and the company was developing specific formulation for specific indications but said he could not elaborate at this stage of the development.
The company said that diluted earnings per share was 0.12 cents, with net tangible assets per share down 6.7 percent to 18.46 cents at June 30, 2018 and it had $14,171,000 in cash and cash equivalents at June 30, 2018, compared to $18,834,000 at June 30, 2017.
Elixinol was up seven cents or 4.9 percent to $1.50.

GENETIC SIGNATURES

Genetic Signatures says that revenue for the year to June 30, 2018, was up 39.4 percent to $2,840,115, with net loss after tax up 21.8 percent to $3,253,809.
Genetic Signatures said its revenue included the first sale of its analyte specific reagent testing kit in the US, as well as orders for its Easyscreen respiratory and virus detection kits from a US customer based in Kenya.
The company said that said that its net tangible asset per share fell 18.5 percent from 15.81 cents at June 30, 2017 to 12.89 cents at June 30, 2018, with diluted loss per share up 12.6 percent, from 2.78 cents at June 30, 2017 to 3.13 cents at June 30, 2018.
Genetic Signatures said that it had cash and cash equivalents of $8,954,775 at June 30, 2018, compared to $13,192,960 at June 30, 2017.
Genetic Signatures was unchanged at 51.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that revenue for the year to June 30, 2018, was up 27.1 percent to $1,176,457 with net loss after tax up 57.1 percent to $1,440,108.
Proteomics said that revenue came from its analytical services and licensing fees, and that in addition to its revenue it received $844,123 from a Federal Research and Development Tax Incentive, with $130,343 in other income.
The company said that said that its net tangible asset per share was up 166.7 percent from 3.0 cents at June 30, 2017 to 8.0 cents at June 30, 2018, with basic loss per share constant at 2.0 cents.
Proteomics said that it had cash and cash equivalents of 2,316,781 at June 30, 2018, compared to $775,140 at June 30, 2017.
Proteomics was untraded at 25.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the US Food and Drug Administration has requested detailed information for its Penthrox investigative new drug application.
Medical Developments said that in relation to a “clinical hold”, the FDA required it to identify an appropriate patient population for its phase I trial for whom the risk/benefit of the inhaled Penthrox methoxyflurane analgesic would be reasonable.
The company said that the population would be healthy volunteers excluding those who previously developed hepatoxicity following methoxyflurane or halothane, but the FDA said it did not consider this population exclusion to be adequate.
Medical Developments said that it could identify an appropriate patient population and satisfy the FDA’s concern.
The company said that the FDA requested additional information and justification for the rare occurrence of idiosyncratic hepatoxicity and it said would “be able to illustrate satisfactorily to the FDA the rare occurrence of idiosyncratic hepatoxicity and the acceptability of this risk in terms of the overall benefit of Penthrox compared with dangerous opioid alternatives”.
Medical Developments said the FDA asked for clarification about a chloroform impurity in the manufacturing of methoxyflurane, and the company responded that its new manufacturing technology met the standard for chloroform and it could comply with the FDA limits.
The company said it could satisfy the FDA’s questions on the instructions for use.
Medical Developments said that it could supply additional information to the FDA on the variability of concentrations of methoxyflurane from closing the inhaler’s dilutor hole, along with information on exhaled methoxyflurane captured by the inhaler and the performance of an inbuilt valve system.
The company said that it could satisfy FDA questions which did not form part of its clinical hold, including inadvertent methoxyflurane exposure to healthcare workers, labelling amendments, additional analytical tests, impurities criteria and the bio-compatibility of the inhaler.
Medical Developments chief executive officer John Sharman said the company was consulting with its scientific team, US and EU advisors on the development program needed to satisfy the FDA’s requirements.
“We will report back to the market as to the impact on costs and timeframes in due course,” Mr Sharman said.
Medical Developments rose 20 cents or 4.6 percent to $4.51 with 289,719 shares traded.

NEUREN PHARMACEUTICALS

Neuren says Lanstead Capital has agreed to pause the monthly settlements it receives under an $8.5 million “sharing agreement” for 120 days.

Last year, Neuren said the London-based Lanstead had invested $10 million in the company, with $8.5 million from Lanstead to be invested in a “sharing agreement” enabling it to secure potential upside from the expected news flow (BD: June 29, 2017).

The company said the agreement meant the funds would be paid in 18 monthly settlements measured against a benchmark price of the then 8.86 cents a share, and the post 20-to-one consolidation price of $1.772, and if the share price exceeded the benchmark, Neuren would receive more than 100 percent of the settlement on a pro-rata basis, with no upper limit, but if the share price fell below the benchmark, the company would receive less than 100 percent of the settlement on a pro-rata basis.

Neuren said that a share price fall would not result in an increase in the number of shares received by Lanstead or any other benefit accruing to Lanstead.

Today, the company said the settlement due in August 2018 would be received in December 2018, with the final monthly settlement due in February 2019 to be received in June 2019.

Neuren said that given its strong cash positions, the settlements were not required to fund short-term expenditure and it believed the current share price did not represent the underlying value of the company, therefore making it in Neuren’s best interests to defer the remaining settlements.

Neuren climbed 9.5 cents or 9.1 percent to $1.135.

MMJ PHYTOTECH

MMJ says shareholders will vote to divest its Phytotech subsidiary, change its name to MMJ and issues 1,000,000 options to director Douglas Halley.

MMJ said that it proposed to sell Phytotech Therapeutics to its 30.7 percent Canada subsidiary Harvest One Cannabis for $C8 million ($A8.5 million).

The company said that it proposed to change its name to MMJ Group Holdings and change the nature of its activities.

MMJ said that investors would vote to issue 1,000,000 shares to Mr Halley, exercisable at 135 percent of its 5-day volume-weighted average price to the date of issue, expiring three years from issue.

The meeting will be held at the Westin Hotel, 1 Martin Place, Sydney, on September 28, 2018 at 2pm (AEST).

MMJ fell one cent or 4.1 percent to 23.5 cents.

AVITA MEDICAL

Deutsche Bank and related corporate bodies say they have ceased their substantial shareholding in Avita, selling 9,400,672 shares.

On July 27, 2018, Deutsche Bank filed a substantial shareholder notice saying it held 72,856,256 shares, or 5.70 percent of Avita.

Today, Deutsche Bank AG said its Sydney branch bought and sold shares between July 26, 2018 and August 24, 2018, with the single largest purchase of 591,882 shares for $47,350.56, or 8.0 cents a share on July 30 and the single largest sale of 3,192,717 shares for $319,271.7, or 10.0 cents a share on August 24.

Biotech Daily believes Deutsche Bank retains 63,455,584 shares, or 4.7 percent of Avita.

Avita was unchanged at 10 cents with 7.6 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical has 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 the company's share price rose 49.1 percent from a closing price of 27.5 cents on August 21, 2018 to an intra-day high of 41.0 cents on August 28, 2018, but did not note an increase in the trading volume.
G Medical fell 2.5 cents or 6.5 percent to 36 cents.

ANATARA LIFESCIENCES

Anatara says it has appointed Sue MacLeman and Dr Jane Ryan as non-executive chair and non-executive director, respectively, from September 1, 2018.
Anatara said Ms MacLeman would replace Dr Jay Hetzel who had been interim chairman since the retirement of co-founder Dr Mel Bridges earlier this year (BD: May 17, 2018).
The company said that following the decision "to focus on the development of products and technologies in the human health sector … [it had] undertaken an extensive search to identify new directors with the relevant background and experience which has resulted in these appointments".
Anatara said that Ms MacLeman had more than 25 years' experience as a pharmaceutical, biotechnology and medical technology executive with senior roles at Schering-Plough Corporation, now Merck, Amgen, Bristol-Myers Squibb and Mesoblast.
The company said that Ms MacLeman recently retired as the Medical Technologies and Pharmaceuticals Growth Centre, or MTP Connect, chief executive officer and move to non-executive chairman later this year.
Anatara said that previously Ms MacLeman was the chief executive officer of Eqitx, Benitec and Progen, a current director of Oventus and was formerly a director of the Adelaide-based RHS or Reproductive Health Science.
The company said Ms MacLeman had experience in commercialization, strategic planning, capital markets, fund raising, mergers and acquisitions and alliance management.
Anatara said that Dr Ryan has more than 25 years' experience in the pharmaceutical and biotechnology industries, had managed research and development programs and held roles in business development and alliance management.
The company said that previously Dr Ryan had worked for Peptech, later Arana, now Teva Australia, Roche, Cambridge Antibody Technology and Biota and had led fundraising campaigns including the awarding of Biota's $US230 million BARDA contract.
Anatara said that director Paul Grujic would retire on August 31 and Dr Hetzel would retire at the annual general meeting in November 2018, with Iain Ross and acting chief executive officer Dr Tracie Ramsdale continuing as directors.
The company said that a search was underway for a new chief executive officer.
Anatara said it had appointed Sydney's Peloton Capital as a corporate advisor issuing the company 750,000 options exercisable at $1.45 each by December 14, 2020.
Anatara was up three cents or 5.3 percent to 60 cents.