Biotech Daily

Thursday July 18, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: IMPEDIMED UP 19%; PARADIGM DOWN 5%**

*** SIENNA: BUILDING AN IN-VITRO DIAGNOSTIC PORTFOLIO**

*** TELIX RECEIVES $9.3m R&D TAX INCENTIVE**

*** FEDERAL $21m FOR 13 DEMENTIA PROJECTS**

*** SUDA APPEALS TGA EASTER ARTIMIST REGULATORY REFUSAL**

*** IMAGION UP 155% ON MAGSENSE FDA BREAKTHROUGH DESIGNATION**

*** NEUROTECH PLEADS SCHULTZ TO ASX 32% QUERY**

*** VISIONEERING H1 RECEIPTS UP 103% TO $3.5m, TWO QUARTERS CASH**

*** ANTEO UNMARKETABLE PARCEL FACILITY**

*** SHAREROOT REQUESTS SHORTFALL PLACEMENT TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.36 percent on Thursday July 18, 2019, with the ASX200 down 24.2 points to 6,649.1 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and three were untraded. All three Big Caps were up.

Impedimed was the best, up 2.5 cents or 19.2 percent to 15.5 cents, with 3.3 million shares traded.

Amplia (Innate) climbed 12.9 percent; Imugene was up 6.25 percent; Prescient was up 5.3 percent; Compumedics, Dimerix, LBT, Opthea and Pharmaxis improved more than four percent; Ellex, Neuren, Pro Medicus and Proteomics were up more than three percent; Clinuvel, Genetic Signatures and Polynovo rose more than two percent; Kazia, Orthocell, Resmed and Telix were up more than one percent; with Cochlear, CSL, Cyclopharm and Nanosonics up by less than one percent.

Paradigm led the falls, down 8.5 cents or five percent to $1.61, with 524,300 shares traded.

Resonance fell four percent; Oncosil lost 3.6 percent; Avita, Immutep, Osprey and Volpara shed more than two percent; Starpharma was down 1.5 percent; with Medical Developments and Mesoblast down by less than one percent.

SIENNA CANCER DIAGNOSTICS

Sienna chief executive officer Matthew Hoskin says the company is building a portfolio of in-vitro cancer diagnostic products to support researchers and laboratories.

Mr Hoskin told Biotech Daily that with the original human telomerase reverse transcriptase (hTERT) adjunct test for bladder cancer and the acquisition of Sevident for its biomarker capture technology, renamed Sien-net, the company was on the way to developing a pipeline of cancer diagnostics.

In April, Sienna said it would buy the San Francisco-based Sevident for up to $US2.8 million ($A3.95 million) in cash and scrip for its biomarker capture technology, with Sevident chief scientist and technology inventor Dr Emily Stein leading development and commercialization of the technology and Sevident chief executive officer, former Benitec chief executive officer, Dr Peter French, joining as an advisor (BD: Apr 2, 2019).

Today, Mr Hoskin told Biotech Daily that the Sien-net molecular “net” was a matrix designed to attract and capture analyte targets that were biomarkers of disease.

“It builds a scaffold around a magnetic nano-bead and will attract and bind the target,” Mr Hoskin said.

“It has porosity, so it has gaps and spaces, so the smaller targets can enter but it excludes larger cells and molecules,” he said.

Mr Hoskin said the size of the gaps could be designed like a fishing net to capture the desired target.

Mr Hoskin said that Sien-net was a sample preparation technology to ensure that the appropriate anolytes were used as biomarkers for diagnostics.

He said samples for diagnostics needed to be prepared to retain “certain antibodies, proteins and lipids” while excluding other matter.

“We can out-licence or sell the Sien-net system to other companies and researchers, or we can use it in-house to develop our own diagnostics,” Mr Hoskin said.

“They all need solid sample preparation to design effective tests,” Mr Hoskin said.

Mr Hoskin said that the hTERT adjunct test for bladder cancer was not intended to replace existing diagnostics, but to support their results.

He said that existing diagnostics could miss potential bladder cancers, but the Sienna test could pick-up abnormalities before they became cancers.

Mr Hoskin said the company was working to encourage existing bladder cancer diagnostic companies to adopt its test to provide more definitive diagnoses.

He said the company had the hTERT test, was developing the Sien-net and expected to develop additional tests using the Sien-net technology.

“We want to have a portfolio of [in-vitro diagnostic] products coming through to create an ever-growing revenue opportunity for the company,” Mr Hoskin said.

Sienna said the technology would be used to develop exosome-based cancer tests.

Sienna was up 0.1 cents or 1.7 percent to six cents.

TELIX PHARMACEUTICALS

Telix says it has received $9.3 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Telix said the rebate related to domestic and international research and development expenditure for the year to December 31, 2018.

Telix chairman Kevin McCann said the Federal R&D tax credit scheme “continues to be vitally important in enabling Telix to pursue its multiple clinical development programs and research partnerships in Australia and abroad”.

Telix was up three cents or 1.9 percent to $1.63 with 694,629 shares traded.

FEDERAL GOVERNMENT

The Federal Government says that it will provide $21 million for 13 dementia research projects.

A media release from Federal Health Minister Greg Hunt said there was a need for investment in research to develop dementia treatments and improve care.

The Government said it was predicted that without a medical breakthrough, more than 1.1 million Australians would be living with dementia by 2056.

The media release said the University of Queensland's Prof Annette Dobson would receive $2,154,096 for 'Improving Australia's dementia statistics'.

The Government said Monash University's Dr Johnson George would receive $1,999,500 for 'Holistic approach in primary care for preventing memory impairment and dementia (Happi Mind)'.

The media release said the Garvan Institute of Medical Research's Prof Katherine Samaras would receive $1,998,025 for 'Preventing cognitive decline with metformin: a randomized controlled trial'.

The Government said the University of New South Wales' Prof Kaarin Anstey would receive $1,995,481 for 'Translating the evidence on dementia risk reduction to generate assessments, advice and training for health professionals, policy makers, patients and public'.

The media release said Swinburne University of Technology's Prof Andrew Pipingas would receive $1,772,616 for 'Mediterranean diet and exercise to reduce cognitive decline and dementia risks in independently living older Australians: the Medwalk randomised controlled trial'.

The Federal Government said the University of Melbourne's Prof Lisbeth Evered would receive $1,615,119 for 'The Protect trial: perioperative enhancement of cognitive trajectory'.

The media release said the University of Melbourne's Prof Amy Brodtmann would receive $1,613,508 for 'Cardiovascular exercise to prevent cognitive decline in high risk patient populations: a post-ischaemic stroke exercise intervention study'.

The Government said the University of Melbourne's Dr Yen Ying Lim would receive $1,568,807 for 'Better brains: person-centred, multi-domain, primary prevention strategies to delay memory decline'.

The media release said James Cook University's Prof Edward Strivens would receive $1,515,145 for 'Reducing dementia risk in Aboriginal and Torres Strait Islander Communities'.

The Federal Government said the University of Queensland's Dr Paul Gardiner would receive $1,480,827 for 'Taking a whole-of-day approach to optimising activity to prevent dementia in people with type 2 diabetes'.

The Government said the University of Sydney's Prof Sharon Naismith would receive $1,468,685 for 'Reducing sleep apnoea for the prevention of dementia (Reshaped): a multi-site feasibility randomised controlled trial'.

The media release said the University of South Australia's Dr Ashleigh Smith would receive $1,234,805 for 'Living your best day – optimising activity and diet compositions for dementia prevention'.

The Government said Monash University's Prof Velandai Srikanth would receive $617,336 for 'Leveraging electronic medical records and routine administrative data towards a population approach for monitoring dementia frequency, risk factors and management'.

SUDA PHARMACEUTICALS

Suda says it is preparing an appeal against a regulatory knockback from the Australian Therapeutic Goods Administration for its Artimist oral spray for malaria.
On Easter Thursday, April 18, Suda requested a trading halt “pending an announcement … [on] the submission to the [Australian] Therapeutic Goods Administration of its anti-malarial product Artimist” (BD: Apr 18, 2019).
Just before the Australian Stock Exchange closed for the four-day Easter public holiday, at 3.43pm on that day, Suda published an ‘Artimist regulatory update’ to the ASX.
The notice said the TGA had issued “a preliminary notice of denial for marketing approval of its Artimist oral spray” for paediatric malaria.
Biotech Daily apologizes for missing that announcement, which was routinely removed from trading screens before the open on Tuesday April 23, 2019.
The company said a May 14, 2019 TGA delegate’s letter did not differ materially from the preliminary TGA marketing denial, but did not publish the delegates letter.
Today, Suda said it had “strong grounds for an appeal under Section 60 of the Therapeutic Goods Act 1989 and is currently preparing its submission”.
The company said the appeal needed to be filed by August 14, 2019 and the [Health] Minister would have 60 days to reply, and if not satisfied with the appeal outcome it would consider an application to the Administrative Appeals Tribunal or the Federal Court.
Suda fell 0.05 cents or 14.3 percent to 0.3 cents.

IMAGION BIOSYSTEMS

Imagion says the US Food and Drug Administration has granted ‘breakthrough device designation’ for its Magsense HER2 breast cancer staging test.
Imagion said devices that provided a more effective treatment of a human disease or condition and either represent a breakthrough technology, address an application for which there are no alternatives, offer advantages over alternatives or are in the best interests of the patients, qualify for breakthrough device designation.
The company said the designation was designed “to expedite and improve communications between a device manufacturer and the agency during device development and throughout the review process and provides priority review”.
The company said it was in discussions with the FDA on clinical study sites for a first-in-human study of the Magsense HER2 breast cancer test to eliminate unnecessary surgeries and concomitant morbidity from current biopsy procedures.
Imagion executive chairman Bob Proulx said, “the FDA’s designation of our Magsense technology and HER2 test as a breakthrough device is a significant step in our clinical development program”.
“Qualifying as a breakthrough device will allow us to expedite our dialog with the Agency and validates that our Magsense technology is not just another medical device but … could improve the standard of care for staging HER2 breast cancer,” Mr Proulx said.
Imagion was up 3.1 cents or 155 percent to 5.1 cents with 190.7 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech 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 0.7 cents or 31.8 percent from 2.2 cents on July 17 to 2.9 cents, today, and noted a “significant increase” in the volume traded.
Neurotech was up 0.6 cents or 27.3 percent to 2.8 cents with 35.4 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says receipts from customers for its multifocal contact lenses was up 102.9 percent to $US2,457,000 ($A3,495,893) for the six months to June 30, 2019.
In its Appendix 4C, Visioneering said customer receipts for the three months to June 30, 2019 of $US1,305,000 and cash after capital raisings of $US7.8 million.
Earlier this month, Visioneering said it raised $A5.8 million in a nine-for-19 rights issue at 4.5 cents a share, $A1 million in a placement and $A4.3 million in a convertible note with Tiga and Thorney (BD: Jun 6, Jul 1, 2019).
Today, Visioneering said it expected to spend $US4,532,000 in the three months to September 30 and forecast net revenue of between $US6.5 million and $US7.5 million by December 31, 2019.
Visioneering was up 0.1 cents or 1.5 percent to 6.6 cents.

ANTEO DIAGNOSTICS

Anteo says it has established a share sale facility for holders of unmarketable parcels of its shares, worth less than $500.
Anteo said that based on a 10-day closing price to the record date of July 15, 2019 of 1.4 cents a share, an unmarketable parcel was any holding of 35,714 shares or fewer.
The company said there were 2,480 holders of unmarketable parcels, with a total of 18,428,990 shares.
Anteo said the facility would allow holders of unmarketable parcels to sell their shares without brokerage or handling costs.
The company said the opening date would be July 19 and the closing date would be August 30, 2019.
Anteo fell 0.1 cents or 6.7 percent to 1.4 cents with 2.1 million shares traded.

SHAREROOT

Shareroot has requested a trading halt “pending the release of an ASX announcement regarding a placement which includes the shortfall shares”.
Yesterday, Shareroot said it raised $509,612 of the hoped for $954,342 and hoped to raise the remaining $444,731 from shortfall shares (BD: Jul 17, 2019).
Trading will resume on July 22, 2019 or on an earlier announcement.
Shareroot last traded at 0.2 cents.