Biotech Daily

Wednesday February 20, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AIRXPANDERS UP 12%; PROTEOMICS DOWN 3%**

*** MEDICAL DEVELOPMENTS H1 REVENUE UP 22% TO $9.5m, PROFIT $132k**

*** IDT H1 REVENUE UP 31% TO $6.5m, LOSS DOWN 22% TO $2.4m**

*** NUHEARA H1 REVENUE DOWN 28% TO $1.4m, LOSS DOWN 6% TO $4m**

*** REVA TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

*** VISIONEERING LAUNCHES NATURALVUE CONTACTS IN UK**

*** RHYTHM COLOSTAT COLORECTAL CANCER BLOOD TEST TRIAL**

*** IMAGION BREAST CANCER NANOPARTICLE TOXICOLOGY TRIAL**

*** ADMEDUS TO ASX: 'SELL INFUSION BUSINESS OR RAISE CAPITAL'**

*** PHARMAUST BEGINS PHASE I MONEPANTEL DOG CANCER TRIAL**

*** JOHN DARLING REPLACES INVICTUS CO SEC MOURICE GARBUTT**

MARKET REPORT

The Australian stock market fell 0.17 percent on Wednesday February 20, 2019, with the ASX200 down 10.4 points to 6,096.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, nine fell, 14 traded unchanged and two were untraded.

Airxpanders was the best, up 0.4 cents or 12.1 percent to 3.7 cents, with 4.8 million shares traded.

Avita climbed 7.1 percent; Orthocell and Osprey improved four percent or more; Oncosil and Telix were up more than three percent; Dimerix and Medical Developments rose more than two percent; Actinogen, Compumedics, Genetic Signatures and Kazia were more than one percent; with CSL, Mesoblast, Paradigm and Polynovo up less than one percent.

Proteomics led the falls for the second day in a row, down one cent or 2.9 percent to 33 cents, with 169,979 shares traded.

Cochlear, Neuren and Prana shed more than two percent; Nanosonics, Optiscan, Resmed and Volpara were down more than one percent; with Clinuvel, Cynata and Opthea down by less than one percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says revenue for the six months to December 31, 2018 was up 22.0 percent to $9,520,000 with net profit after tax up 3.9 percent to $132,000.

Medical Developments said revenue came from sales of its Penthrox inhaled methoxyflurane analgesic for acute pain and its respiratory medical devices.

The company said that a fully-franked interim dividend of two cents a share for shareholders on the record date of March 8 would be paid on April 17, 2019.

Medical Developments said diluted loss per share was constant at 0.21 cents for the six months to December 31, 2018, with net tangible assets up 32.0 percent to 13.46 cents and cash and cash equivalents of $32,273,000 at December 31, 2018, compared to $913,000 at December 31, 2017.

Medical Developments was up 11 cents or 2.9 percent to $3.96.

IDT AUSTRALIA

IDT says revenue for the six months to December 31, 2018 was up 30.5 percent to $6,510,000 with net loss after tax down 21.8 percent to $2,392,000.

In 2017, IDT said it had a net profit after tax of $11,729,000, which included the sale of its CMax clinical trials unit at the Royal Adelaide Hospital (BD: Feb 21, 2017).

Last year, IDT said its loss was $17.20 million, which included an impairment of $14.14 million, implying a net loss for continuing activities of $3.06 million.

The company said revenue was from “the manufacture and supply of products and provision of research and development and other technical services”.

IDT said that diluted loss per share fell 85.5 percent from 6.9 cents in the previous year to 1.0 cent in the six months to December 31, 2018, with net tangible assets per security up 10.5 percent to 11.6 cents and cash and cash equivalents of $9,056,000 at December 31, 2018, compared to $8,822,000 at December 31, 2017.

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

NUHEARA

Nuheara says revenue for the six months to December 31, 2018 was down 27.6 percent to $1,419,232 with net loss after tax down 6.0 percent to $4,011,140.

Nuheara said revenue was from sales of its hearing and sound filtering earplugs, down due to “costs associated with the repurposing of the production line and test equipment from Iqbuds to Iqbuds Boost and negative foreign exchange impacting the cost of sales”.

The company said revenue was also impacted by the 86 percent retail shift of average selling price from $181 to $337.

The company said diluted loss per share fell 14.6 percent from 0.48 cents in the previous year to 0.41 cents in the six months to December 31, 2018, with net tangible assets constant still at 1.0 cent and cash and cash equivalents of $8,080,492 at December 31, 2018, compared to $8,345,698 at December 31, 2017.

Nuheara fell 0.2 cents or 2.5 percent to 7.7 cents with 6.1 million shares traded.

REVA MEDICAL

Reva has requested a voluntary suspension to follow the trading halt requested last week pending an announcement of “an accurate update on its capital raising efforts” (BD: Feb 18, 2019).

Reva last traded at 17 cents.

VISIONEERING TECHNOLOGIES

Visioneering says it has launched its Naturalvue multifocal contact lenses in the UK.
Visioneering said the one-day contact lenses were indicated for paediatric myopia progression, or progressive near-sightedness in children, as well as presbyopia, or the loss of ability to see close objects in adults over 40 years.
Visioneering chief executive officer Stephen Snowdy said that following launches in Australia, New Zealand and [the] Nordic markets in late 2018, "we are pleased to make this revolutionary product available to patients and practitioners in the United Kingdom" and the company was to launch in Canada and some Asian markets in 2019.
Visioneering was up one cent or 9.5 percent to 11.5 cents.

RHYTHM BIOSCIENCES

Rhythm says it expects to begin a 1,000-patient prospective clinical trial of its Colostat blood test for the early detection of colorectal cancer "in the coming months".
Rhythm said the study would be a prospective, cross-sectional, multi-centre study with the primary endpoint of evaluating the diagnostic performance of the Colostat in-vitro diagnostic relative to colonoscopy.
The company said the secondary endpoints included assessing the ability of Colostat to detect advanced adenomas and a comparison of the performance of Colostat with the currently used faecal immune test, both relative to colonoscopy.
Rhythm said that Adelaide's Lyell McEwin Hospital would be the first study site with Prof Rajvinder Singh the Hospital's principal investigator.
The company said it had appointed Melbourne's Plunkett Consulting Group to manage trial operations, including recruitment, monitoring and data collection, with Sonic Healthcare subsidiary Sonic Clinical Trials to facilitate sample collection, processing, analytical testing, recording of results, transport and storage across the trial sites.
Rhythm said that Prof Singh was recognized for his work in endoscopic imaging techniques and endoscopic treatment of pre-malignant and malignant lesions in the gastrointestinal tract.
"There is a real need for inexpensive, minimally invasive screening tests," Prof Singh said.
Rhythm said that the results were expected by the end of 2019 and with the technical performance and validation documentation to form components for Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration registration and ultimately the approval to market Colostat in 2020.
Rhythm was unchanged at 15 cents.

IMAGION BIOSYSTEMS

Imagion says it will begin its first human trial of the nanoparticle formulation to be used with its Magsense diagnostic for breast cancer.
Imagion said it had engaged an unnamed contract research organization for the clinical toxicology safety trial for the iron oxide nanoparticles to be used in the detection of human epidermal growth factor receptor 2 (HER2) metastatic breast cancer.
The company said the study would be completed in early May 2019 and the safety profile of its nanoparticle formulation would allow it to begin first-in-human studies.
Imagion executive chairman Bob Proulx said the study was "a significant milestone in the development of our Magsense diagnostic imaging technology … [and] a big de-risking step".
Imagion fell 0.4 cents or 13.8 percent to 2.5 cents.

ADMEDUS

Admedus has told the ASX it would divest its infusion business, “or if that does not eventuate [have] a further capital raising to have funds for more than two quarters.

In January, Admedus said it expected a net operating cash burn for the three months to March 31, 2019 of $15,494,000 with cash at the end of the quarter of $12,036,000 and in the three months to December 31, 2018, the company earned $6,439,000 in customer receipts, and spent $5,844,000 (BD: Jan 21, 2019).

In December, the company said that it had raised $18,964,198 of a hoped-for $20 million with applications for $5,374,530 shares at eight cents a share and underwriters taking $13,589,668 of the shortfall shares (BD: Dec 14, 2018).

In its Appendix 4C December 2018 quarterly report, Admedus said its infusion supply division was up 17 percent to $3.5 million for the three months to December 31, 2018.

Today, the company said that the ASX asked: “Does [Admedus] expect that it will continue to have negative operating cash flows for the time being and, if not, why not?”

Admedus said that in its November 28, 2018 rights issue prospectus “the company’s capital requirements will be partly determined by a divestiture of the infusion business, or if that does not eventuate, a further capital raising”.

The company said it was “in negotiations with an external party to divest the non-core infusion business [and] while negotiations between the parties have advanced, no binding offer has been received, and negotiations are incomplete”.

Admedus said that if it could not sell the infusion business in the short term, it was “confident that it can complete another capital transaction”.

The company said that as a result of the 2018 capital raisings it had two substantial shareholders that it would intend to engage with for any planned capital transaction.

Admedus said it was considering options with respect to its transcatheter aortic valve replacement (TAVR) project “including the potential for a strategic partnership with a medical device company and has commenced early stage discussions with potential partners in relation to this”.

Admedus fell 0.1 cents or 2.7 percent to 3.6 cents.

PHARMAUST

Pharmaust says it has begun a phase I trial of monepantel for dog cancer to validate food-related tablet performance and establish drug dose, safety and tolerability.

Pharmaust said the first component of the trial in an undisclosed number of Beagles would “validate the performance of the scaled tablet in different dietary conditions that dogs may encounter at home with their owners” and the second component would determine dose, frequency and safety of monepantel.

The company said it expected the first data set on tablet performance in March 2019.

Pharmaust chief scientific officer Dr Richard Mollard said the study would “determine the dose and frequency of administration required for the predicted anti-cancer activity” which were required for the longer-term dosing and evaluation in phase II studies.

Earlier this month Pharmaust said the phase I had four stages: validating the optimal dietary conditions for monepantel administration, for example whether to take on a full or empty stomach; confirming the safety of monepantel at single dose in a dose escalation study; determining the frequency of dosing required to achieve blood levels predicted to be compatible with anti-cancer activity; and based on those results establish a 28-day repeat-dose drug level study to determine optimal tablet administration frequency for phase II anti-cancer studies.

Pharmaust fell 0.2 cents or 5.4 percent to 3.5 cents with one million shares traded.

INVICTUS BIOPHARMA

Invictus says it has appointed John Darling as company secretary, replacing Mourice Garbutt who resigned on February 1, 2019.

Invictus said that Mr Darling was a lawyer and corporate advisor and who had held non-executive and executive directorships with public and private companies.

The company said that Mr Darling was chairman of the Darling Group which had interests in health businesses as well as securities, investment advisory and funds management.

Invictus is a public unlisted company.