



Biotech Daily

Thursday February 13, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: AMPLIA UP 21%; IMPEDIMED DOWN 14%**
- * **PRO MEDICUS H1 REVENUE UP 16% TO \$29m, PROFIT UP 33% TO \$12m**
- * **MICRO-X \$780k DRX REVOLUTION NANO ORDERS FOR COVID-19**
- * **MTP CONNECT TRANSLATION FUND CLOSING MARCH 6**
- * **VICTORIA INNOVATION TASKFORCE**
- * **VISIONEERING REVENUE UP 74% TO \$8.5m, LOSS DOWN 25% TO \$19m**
- * **PHARMAXIS H1 REVENUE UP 36% TO \$4m, LOSS DOWN 18% TO \$10m**
- * **COCHLEAR INCREASES NYXOAH INVESTMENT BY \$13m**
- * **STARPHARMA VIVAGEL BV IN UNNAMED ASIAN COUNTRIES**
- * **OVENTUS LAUNCHES 3 MORE US O2VENT 'LAB IN LAB' SITES**
- * **PARADIGM PPS FOR MPS - 9 MONTHS BEHIND SCHEDULE**
- * **MGC REQUESTS CAPITAL RAISING TRADING HALT**
- * **PROF PAUL TIMPSON JOINS AMPLIA SCIENTIFIC ADVISORY BOARD**

MARKET REPORT

The Australian stock market was up 0.21 percent on Thursday February 13, 2020, with the ASX200 up 15.0 points to 7,103.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and one was untraded.

Amplia (formerly Innate) was the best for the second day in a row, up 1.8 cents or 20.7 percent to 10.5 cents with 1.3 million shares traded. Antisense and Imugene climbed more than six percent; Telix was up 5.8 percent; Prescient improved 4.3 percent; Dimerix, LBT, Polynovo and Starpharma were up more than three percent; Ellex rose 2.5 percent; with Clinuvel, CSL and Medical Developments up by less than one percent.

Impedimed led the falls, down 1.7 cents or 14.8 percent to 9.8 cents with 6.5 million shares traded. Osprey lost 10 percent; Alterity and Paradigm fell more than five percent; Pro Medicus and Uscom were down more than three percent; Avita, Cochlear, Cyclopharm and Opthea shed two percent or more; Mesoblast, Next Science and Orthocell were down more than one percent; with Cynata, Genetic Signatures, Nanosonics, Neuren, Resmed and Volpara down by less than one percent.

PRO MEDICUS

Pro Medicus says revenue for the six months to December 31, 2019 was up 15.7 percent to \$29,288,000 with net profit after tax up 32.7 percent to \$12,051,000.

Pro Medicus said underlying profit before tax was up 45.3 percent to \$14,810,000 compared to the previous corresponding period and included the one-off \$3,049,000 capital sale to the German government (BD: Dec 10, 2018).

The company said revenue was from its picture archiving communications systems and Visage 7, its radiology information systems, other hardware and contracts including its five-year \$9 million deal with Ohio State University and five-year \$6 million deal with Palo Alto, California teleradiology business Nines (BD: Nov 4, 2019; Jan 19, 2020).

Pro Medicus said that a fully franked interim dividend of 6.0 cents a share for holders at the record date of March 6 would be paid on March 20, 2020.

The company said diluted earnings per share rose 32.6 percent from 8.70 cents to 11.54 cents for the six months to December 31, 2019 and it had cash and cash equivalents of \$38,844,000 at December 31, 2019 compared to \$24,735,000 at December 31, 2018.

Pro Medicus chief executive officer Dr Sam Hupert said that underlying revenue growth figure was up 39.1 percent and transaction revenue was up 30 percent.

“The added benefit is that this revenue is recurring rather than one-off, so provides us with a good base for growth in the next half and future period,” Dr Hupert said.

“There is no doubt we are experiencing an increased network effect generated by our growing customer base in North America,” Dr Hupert said.

Pro Medicus fell 88 cents or 3.2 percent to \$26.42 with 1.3 million shares traded.

MICRO-X

Micro-X says two unnamed Asian nations have ordered \$780,000 of its Carestream DRX Revolution Nano portable x-ray to manage the coronavirus disease-19 (Covid-19).

Micro-X said that the orders through distributor Carestream Health were in relation to the countries' responses to Covid-19 and required urgent delivery, with production moved to full capacity to fulfill the orders within four weeks.

The company said that early-stage diagnosis of Covid-19 was confirmed by a blood test, but a chest x-ray was used to diagnose the development and progression of severity by detecting fluid in the lungs of patients with severe acute respiratory disease.

Micro-X said the World Health Organisation had defined diagnostic progression from confirmed case to severe illness as a chest x-ray with multi-lobar infiltrates or pulmonary infiltration to more than 50 percent within 24 to 48 hours.

The company said the Carestream DRX Revolution Nano units would be packaged for shipment and air freighted once end-of-line testing was completed and it was working with supply chain partners to maximize its ability to respond to any future requirements to deliver units in a short time frame, but it could not estimate if future orders would be received. Micro-X managing director Peter Rowland told Biotech Daily that the larger Carestream DRX Revolution was on sale in the People's Republic of China but the much smaller Micro-X Nano version did not have China Food and Drug Administration approval. He said that the Nano was approved in more than 40 countries including several in Asia. In a media release Mr Rowland said that “chest x-rays are a key tool in monitoring the progression of the pneumonia-like symptoms of severe coronavirus infection”.

Separately, Micro-X said revenue for the six months to December 31, 2019 fell 12.2 percent to \$840,000 with loss down 33.85 percent to \$4,152,000, but it had \$12,372,000 in cash and equivalents at December 31, 2019 compared to \$4,373,000 the previous year. Micro-X was up 4.5 cents or 29.0 percent to 20 cents with 21.1 million shares traded.

MTP CONNECT

MTP Connect says the Biomedical Translation Bridge program's second round opens on February 17 and closes on March 6, 2020, offer up to \$1 million per project.

A media release from MTP Connect said it had \$22.3 million over three years for the Medical Research Future Fund initiative and would offer funding to support development and commercialization of new biological, pharmaceutical, medical and health technology projects.

MTP Connect said the program would be delivered in partnership with Melbourne and Monash University's Biocurate, the University of Queensland's Uniquest, the Flinders University-led Medical Device Partnering program and the Queensland University of Technology Bridge and Bridgetech programs, who would provide applicants with expert mentoring.

MTP Connect chief executive officer Dr Dan Grant said the organization was looking to support small and medium-sized enterprises and research organizations with "projects that provide innovative solutions in any disease area using any therapeutic modality or medical technology".

"With applications only open for three weeks, from Monday, the Australian research community needs to move quickly to take advantage of the substantial funding on offer," Dr Grant said.

For details on the program and how to apply go to:

<https://www.mtpconnect.org.au/projects/biomedicaltranslationbridgeprogram>.

VICTORIA GOVERNMENT

The Victoria Government says start-ups, universities, businesses and the investment community will combine for a taskforce to support its innovation agenda.

A media release from Victoria's Minister for Jobs, Innovation and Trade Martin Pakula said the taskforce would collaborate with the government on programs to develop local technology talent, to support local entrepreneurs and startups, to scale and advance priority and emerging industry sectors and to promote Victorian innovation.

The Government said the 13-member group included CSL executive Dr Andrea Douglas, Bio-Melbourne Network chair Lusia Guthrie and Grey Innovation founder Jefferson Harcourt.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the year to December 31, 2019 was up 73.7 percent to \$US5,722,000 (\$A8,513,277.43) with net loss after tax down 24.6 percent to \$US12,617,000 (\$A18,771,761.86).

Visioneering said revenue was from sales of its Naturalvue multifocal one-day contact lenses.

The company said net tangible asset backing was down 95.0 percent to 0.2 cents, diluted loss per share was down 50.0 percent to 4.0 US cents and it had cash and cash equivalents of \$US1,919,000 at December 31, 2019 compared to \$US7,275,000 at December 31, 2018.

Visioneering fell half a cent or 11.6 percent to 3.8 cents.

PHARMAXIS

Pharmaxis says that revenue for the six months to December 31, 2019 was up 36.3 percent to \$4,021,000, with net loss after tax down 18.0 percent to \$10,319,000.

Pharmaxis said that Bronchitol sales for cystic fibrosis were up 214.2 percent to \$2.2 million due to the timing of orders from the UK and Italy and a shipment to Russia, while Aridol sales fell \$500,000 to \$1.1 million.

Pharmaxis said that diluted loss per share was constant at 0.03 cents, with net tangible assets per share down 79.6 percent to 1.1 cents and cash and cash equivalents of \$25,864,000 at December 31, 2019, compared to \$42,003,000 at December 31, 2018. Pharmaxis was unchanged at 11 cents.

COCHLEAR

Cochlear says it has increased its investment in Nyxoah SA by EUR8 million (\$A13 million) as part of a Nyxoah EUR25 million private financing round.

In 2018, Cochlear said it had invested EUR13 million (\$20.3 million) in the Mont-Saint-Guibert, Belgium-based Nyxoah for its hypoglossal nerve stimulation for obstructive sleep apnoea (BD: Nov 13, 2018).

Today, the company said its original EUR13 million investment had been revalued to EUR35.5 million at December 31, 2019, for a pre-tax gain of EUR25.5 million (\$A35.8 million) and an after-tax gain of \$25 million for the first half of 2020.

Cochlear fell \$4.66 or 2.0 percent to \$228.21 with 257,576 shares traded.

STARPHARMA HOLDINGS

Starpharma says its distributor Mundipharma has launched Vivagel BV as Betadine BV gel for bacterial vaginosis in an unnamed country in Asia.

Last year, Starpharma said it had regulatory approvals for Vivagel BV in unnamed South East Asian countries (BD: Aug 15, Sep 3, 2019).

Today, the company said Asia was the third region in which it had launched over-the-counter Vivagel BV, with a further roll-out to additional countries, pending approvals.

Asia stretches from Japan to Iran and includes 48 separate countries.

Starpharma was up 3.5 cents or 3.1 percent to \$1.165.

OVENTUS MEDICAL

Oventus says it has launched three additional us laboratory-inside-a-laboratory or 'lab in lab' sites in South Carolina, Illinois and Texas for a total 14 of 36 sites contracted.

Oventus previously said its 'lab in lab' business model used "a scanner to measure the patient's mouth size for a custom-fit for the O2vent" for sleep apnoea (BD: Jun 24, 2019).

In October, the company said it had launched the first five 'lab in lab' sites and a further two sites in November (BD: Oct 11, Nov 18, 2019).

Today, the company said many of the recently launched sites were scheduling patients within 30 days compared to within 60 days for the five sites launched in 2019 and early data indicated that 50 percent of patients moved from initial consultation to treatment over a 90-day period and it had 140 patient consultations to the end of January, unit sales doubled from December to January.

The company said its deal pipeline had increased from \$20 million at December 31, 2019 to currently more than \$33 million.

Oventus was up 6.5 cents or 16.5 percent to 46 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its planned trials of its pentosan polysulfate sodium for muco-poly-saccharidosis type VI (MPS VI) are running nine months behind time.

Last year, Paradigm said it was planning a phase II/III, randomized, double-blind, placebo-controlled, multi-centre trial of injectable pentosane polysulfate sodium for MPS in Australia, the US, the UK and Germany and would submit an investigational new drug application to the US Food and Drug Administration by July 2019 (BD: Feb 14, 2019).

Today, Paradigm said it had identified fine motor tasks and sleep as the major issues faced by people with MPS VI and it would tailor its program to meet unmet needs of patients and provide clinical endpoints for its proposed trial of injectable pentosan polysulfate sodium (PPS) for MPS in conjunction with enzyme replacement therapy.

The company said it would discuss the trial protocols in a joint scientific advice submission to the US Food and Drug Administration and European Medicines Agency, in March 2020. Paradigm said it presented a poster on the research into muco-poly-saccharidosis type VI at the Orlando, Florida World MPS Symposium, February 10 to 13, 2020.

The company said that MPS VI was an orphan designation rare autosomal recessive, inherited lysosomal storage disorder caused by a deficiency of N-acetylgalactosamine 4-sulfatase and led to an accumulation of glycosaminoglycans (GAGs) in the lysosomes and physical manifestations, and patients undergoing enzyme replacement therapy reported ongoing stiffness, pain, inflammation and heart and airway soft tissue manifestations.

Paradigm said it conducted a focus group and interactive forum with nine MPS VI patients between four and 18 years of age and their caregivers to better understand the symptoms, impact on function and activities, and specific needs of patients.

The company said three patients identified mobility and independence as their biggest challenge, with five or more saying it was their biggest or second biggest challenge, that seven patients identified fine motor tasks as their biggest or second biggest challenge and three identified sleep as their biggest or second biggest challenge.

Paradigm chief medical officer Dr Donna Skerrett said that the “patient-centric research ... provides an opportunity to adopt and use these as a reference point for consistent patient engagement and to develop clinically meaningful endpoints”.

Paradigm fell 22 cents or 5.1 percent to \$4.13 with 1.2 million shares traded.

MGC PHARMACEUTICALS

MGC has requested a trading halt “pending the release of an announcement by the company regarding a capital raising”.

Trading will resume on February 17, 2020 or on an earlier announcement.

MGC last traded at 3.1 cents.

AMPLIA THERAPEUTICS

Amplia says it has appointed Prof Paul Timpson to its scientific advisory board.

Amplia said Prof Timpson was the leader of Sydney’s Garvan Institute of Medical Research invasion and metastasis laboratory.

The company said that Prof Timpson would advise on the design of its clinical studies of focal adhesion kinase inhibitors for cancer and fibrosis.

Amplia was up 1.8 cents or 20.7 percent to 10.5 cents with 1.3 million shares traded.

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