

Biotech Daily

Monday August 14, 2023

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: MEDICAL DEVELOPMENTS, PATRYS UP 6%; - VOLPARA DOWN 7%

* MEMPHASYS: VITROLIFE 1st JAPAN 150 UNIT FELIX IVF ORDER

* RESPIRI ACQUIRES ACCESS, EXPECTS 'BREAKEVEN' IN 2024

- * STARPHARMA: MUNDIPHARMA PAYS \$6.5m, RETURNS VIVAGEL BV
- * ANTERIS 2nd VALVE-IN-VALVE DURAVR THV PROCEDURE
- * IMUGENE DOSES VAXINIA-ALONE INTRA-TUMORAL COHORT 3
- * ANATARA RECEIVES \$923k FEDERAL R&D TAX INCENTIVE
- * HSBC TAKES 11.7% OF PHARMAXIS

MARKET REPORT

The Australian stock market fell 0.86 percent on Monday August 14, 2023, with the ASX200 down 63.1 points to 7,277.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and two were untraded.

Patrys and Medical Developments were the best, up 5.56 percent and 5.53 percent, respectively, to 0.95 cents and \$1.05, respectively, with 2.6 million and 108,638 shares traded, respectively.

Micro-X climbed five percent; Mesoblast improved 4.2 percent; Cynata, Imugene and Kazia were up more than three percent; 4D Medical, Dimerix, Impedimed and Opthea rose more than two percent; Neuren and Resmed were up more than one percent; with Genetic Signatures, Next Science and Pro Medicus up by less than one percent.

Volpara led the falls, down 5.5 cents or 6.75 percent to 76 cents, with 191,699 shares traded. Alcidion and Orthocell fell more than four percent; Actinogen, SDI and Universal Biosensors were down three percent or more; Clinuvel and Proteomics shed two percent or more; Antisense, Avita, CSL, Cyclopharm, Immutep and Nanosonics were down more than one percent; with Cochlear, Emvision, Paradigm, Polynovo and Telix down by less than one percent.

MEMPHASYS

Memphasys says it has received its first order of 150 Felix sperm separation systems for in-vitro fertilization from distribution partner Vitrolife Japan KK.

Last week, Memphasys said it had appointed the Göteborg, Sweden-based Vitrolife Group AB subsidiary Vitrolife Japan KK to distribute its Felix sperm separation system for in-vitro fertilization in Japan (BD: Aug 7, 2023).

Today, the company said the initial order of 150 cartridges would be directed to five key opinion leader client clinics in Japan "as the front end of a product marketing campaign" with Vitrolife to provide Felix system training to the clinics and supply ongoing services. Memphasys said the Felix system was an automated device comprising a console with single-use cartridges for sperm preparation in human in-vitro fertilization procedures. The company said that the Felix device "gently separates sperm from a semen sample in six minutes, using electrophoresis and size exclusion membranes without causing damage to sperm DNA".

Memphasys said the device was its first commercial product, and that it did not require regulatory clearance to sell it in Japan as it was an early access market.

The company said it was unable to provide Felix for use under the national insurance system, but could sell to clinics offering private services which were the initial targets. Memphasys said it had sold two systems to a Japanese clinic prior to its agreement with Vitrolife and had a working relationship with another clinic which had been undertaking invitro and in-vivo testing of the Felix system.

The company said Vitrolife would use the data from these early clinics as points of reference for other clinics to build endorsement for Felix throughout Japan. Memphasys said it was "expediting plans to explore the best avenue for participating clinics to obtain full insurance reimbursement for using Felix in their lin-vitre fortilization.

clinics to obtain full insurance reimbursement for using Felix in their [in-vitro fertilization] procedures".

Memphasys was up 0.3 cents or 21.4 percent to 1.7 cents.

<u>RESPIRI</u>

Respiri says it has completed the acquisition of Access Managed Services LLC for about \$4.5 million, with the first payment of US\$1.25 million completed.

In May, Respiri said it would raise \$4.5 million in convertible notes to buy distributor Access Managed Services LLC and raise a further \$2 million in a share plan at 3.4 cents a share (BD: May 24, 2023).

Last year, the company said it had a five-year, distribution and marketing agreement with the Coral Springs, Florida-based Access Managed Services which was a remote patient monitoring and chronic care management services provider (BD: Feb 7, 2022).

Today, Respiri said the Access acquisition followed the share plan placement with the funds used for the first payment and for working capital "ensuring a number of significant private payer business development opportunities pursued by Access continue to progress" and that operational plans to accelerate patient use with existing clients remained on track (BD: Aug 8, 11, 2023).

The company said the acquisition increased its remote patient monitoring per patient monthly recurring revenues from \$US10 to \$US20 to \$US70 to \$US100 per user. Respiri said it total addressable US market increased from 50 million to respiratory patients to about 150 million respiratory, cardiovascular, diabetes and obesity patients, increasing "customer synergies and … customer revenue opportunities".

The company said that it forecast achieving "breakeven" in 2024.

Respiri was up 0.1 cents or 2.9 percent to 3.5 cents.

STARPHARMA

Starpharma says Mundipharma will pay it \$6.54 million in cash after terminating its Vivagel bacterial vaginosis (BV) licence and supply agreement.

In 2018, Starpharma said it had extended its licence with the Singapore-based Mundipharma to market Vivagel BV to European countries and Latin America, in addition to the previously announced up-to \$12.2 million 15-year licence China, Japan, Korea, the Middle East and Africa (BD: May 3, Jun 27, 2018).

In June, the company said that Inova Pharmaceuticals, which was majority owned by TPG Inc, had acquired Mundipharma's consumer health product portfolio including its Vivagel BV for bacterial vaginosis (BD: Jun 27, 2023).

Today, the company said its decision to terminate the agreement followed the recently announced sale of Mundipharma's consumer health product portfolio to Inova Pharmaceuticals.

Starpharma chief executive officer Dr Jackie Fairley said the cash payment was in addition to the \$US3.1 million (\$A4.8 million) in milestone payments already received from Mundipharma for the product.

"Starpharma is pleased to monetize the Vivagel BV licence following negotiations with Mundipharma over recent months," Dr Fairley said.

"This commercial development represents a positive step towards expanding Vivagel BV sales, with Starpharma now free to engage with healthcare companies that have strong consumer franchise and have already expressed interest in Vivagel," Dr Fairley said. Starpharma was unchanged at 15 cents with 5.5 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says its Duravr transcatheter heart valve (THV) has been used in a second valvein-valve procedure as part of Health Canada's special access program.

Last month, Anteris said the bio-mimetic, balloon-expandable Duravr THV device had been used for the first time in a valve-in-valve procedure at the Institut de Cardiologie de Montreal, in Canada (BD: Jul 31, 2023).

Today, the company said that a valve-in-valve procedure was required for patients whose current prosthetic aortic valve was failing due to calcification or structural deterioration, and a new heart valve must be implanted inside the failing valve.

Anteris said these patients were "at high risk for another surgery and required a minimally invasive treatment option".

The company said that currently available commercial products could leave patients with a high risk of remaining in a diseased state post-procedure, with unsatisfactory high gradients and the special access program allowed "life-saving technology not currently available for commercial use ... [to] be provided when no other commercially available alternatives are suitable".

Anteris said the second successful procedure was performed on a 79-year-old female. The company said the patient was safely discharged less than a day after the procedure with "phenomenal" intraoperative results including near-normal physiology and a mean pressure gradient of 7mmHg.

Anteris technologies chief medical officer Dr Chris Meduri said Duravr had been designed to achieve near normal blood flow and the company was progressing clinical evidence. "We believe that the unique design of this valve is behind the exceptional best-in-class results and will be the ideal choice for patients with both native sever aortic stenosis, and those needing a valve-in-valve procedure," Dr Meduri said.

Anteris was up 15 cents or 0.7 percent to \$20.90.

IMUGENE

Imugene says it has completed the third intra-tumoral mono-therapy cohort in its phase I trial of Vaxinia for metastatic advanced solid tumors, with a fourth cohort to follow. In April, Imugene said it had dosed the first patients in the third cohort of the intra-tumoral arm of its phase I monotherapy dose escalation study of CF33-hNIS, or Vaxinia, in combination with pembrolizumab (BD: Mar 3, 2023).

Today, the company said it would begin recruitment for cohort four of the intra-tumoral arm, with Vaxinia to be administered to three-to-six patients.

Imugene said the trial commenced in May 2022, and was anticipated to run for about 24 months while being funded by existing budgets and resources (BD: May 18, 2022).

Imugene managing director Leslie Chong said the company continued to advance its monotherapy dose along with the combination study of Vaxinia and pembrolizumab, or Keytruda.

"We remain incredibly eager to bring the results of this trial to our shareholders, patients and the wider public," Ms Chong said.

Imugene was up 0.3 cents or 3.4 percent to 9.2 cents with 42.5 million shares traded.

ANATARA LIFE SCIENCES

Anatara says it has received \$923,236 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

Anatara said the incentive related to expenditure on its stage one trial of gastrointestinal reprogramming (Garp) for irritable bowel syndrome for the year to June 30, 2023. The company said interim safety and efficacy data from the study was expected to be available by October 2023.

Anatara said it was an "imminent and possible highly valuable inflection point for the company ... [and it was] confident that positive results will be of significant commercial interest to potential partners".

Anatara was up 0.1 cents or 3.2 percent to 3.2 cents.

PHARMAXIS

HSBC Holdings and its controlled entities says they have increased their substantial holding in Pharmaxis from 76,910,841 shares (10.68%) to 84,453,719 shares (11.72%). The London-based HSBC said that between July 3 and August 9, 2023 it bought shares in 26 transactions at five and six cents a share, with the single largest purchase of 922,497 shares on July 27, 2023.

Pharmaxis was unchanged at five cents.