



# Biotech Daily

Wednesday July 17, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: USCOM UP 7%; LBT DOWN 8%**
- \* **IMUGENE - PROF YUMAN FONG: 'INDUSTRIAL PROCESS TO INVENT CF33'**
- \* **TELIX PLACEMENT RAISES \$40m; SHARE PLAN FOR \$5m MORE**
- \* **AIRXPANDERS GOES UNDER**
- \* **IMMURON TO RAISE \$1.9m; TRADING HALT**
- \* **SHAREROOT RIGHTS RAISE \$510k, \$445k SHORTFALL**
- \* **FDA APPROVES LIVAC ORGAN RETRACTION SYSTEM**
- \* **US, EUROPEAN PATENTS FOR USCOM 1A, BP+ COMBO**
- \* **PATRYS EUROPEAN PATENT FOR DOEXYMAB 3E10**
- \* **MEMPHASYS PLEADS SCHULTZ TO ASX 21% QUERY**
- \* **CYNATA REQUESTS ASX QUERY TRADING HALT**
- \* **BOD REQUESTS 'MATERIAL STRATEGIC PARTNERSHIP' TRADING HALT**
- \* **ELIXINOL'S NUNYARA WINS MARIJUANA MANUFACTURE LICENCE**
- \* **CORRECTION: NUHEARA, FARJOY**
- \* **PINACLE'S HYPERION BELOW 5% IN COCHLEAR**
- \* **CSL APPOINTS ANJANA NARAIN SEQIRUS HEAD**
- \* **NANOSONICS APPOINTS GEOFF WILSON DIRECTOR**

## MARKET REPORT

The Australian stock market was up 0.49 percent on Wednesday July 17, 2019, with the ASX200 up 32.3 points to 6,673.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and four were untraded.

Uscom was the best, up one cent or 7.4 percent to 14.5 cents, with 3,124 shares traded. Osprey climbed 6.6 percent; Dimerix was up five percent; Impedimed, Patrys and Universal Biosensors improved four percent or more; Polynovo rose 2.85 percent; Amplia (Innate), Avita, Ellex, Genetic Signatures and Volpara were up more than one percent; with CSL, Nanosonics and Pro Medicus up by less than one percent.

LBT led the falls, down one cent or eight percent to 11.5 cents, with 1.3 million shares traded. Neuren lost seven percent; Benitec, Kazia, Optiscan and Prescient fell five percent or more; Immutep, Medical Developments, Opthea and Telix were down more than four percent; Mesoblast, Orthocell, Pharmaxis and Starpharma shed two percent or more; Clinuvel, Paradigm and Resmed were down one percent or more; with Cochlear and Compumedics down by less than one percent.

## IMUGENE

**By ALICE LYNCH**

The City of Hope's chair of surgery Prof Yuman Fong says Imugene's newly-acquired CF33 oncolytic virus (OV) has been invented through "industrial not academic processes".

Imugene chief executive officer Leslie Chong and Prof Fong spoke to Biotech Daily as part of an Australian roadshow for the company's new immunotherapy drug, CF33, acquired from the Duarte, California-based City of Hope, through Imugene chairman Paul Hopper's majority-owned Vaxinia Pty Ltd (BD: Jul 15, 2019).

Prof Fong said immune-oncology therapies harnessed the weapons in the immune system, including antibodies, B-cells, T-cells, natural killer (NK) cells and proteins, to kill cancer.

Prof Fong said that CF33 was the result of a new approach to an old idea: it had been known since the 1970s that viruses could kill cancer and many were tried, but without significant results.

He said that despite advances in development, by the 1990s no virus reached a maximum tolerated dose, indicating they were safe, but few, if any, were effective.

Prof Fong said regulatory concerns over safety meant there were very long timelines for escalating safety trials, leading to a lapse in patent life before a virus could be brought to market.

Prof Fong said that the "industrial" approach to oncolytic virus discovery at the City of Hope began with nine different virus strains put together in cancer cells and allowed to naturally combine.

Prof Fong said the previous "academic" approach was to alter genes in the viruses based on theory and then testing them.

"We said: 'Let's make really good viruses to kill cancer.' Certain viruses enhance the local characteristics of the immune system to help kill cancer, like turning on checkpoints, making them vulnerable to checkpoint inhibitors," Prof Fong said.

He said that CD8 cells were T-cells that "kill bacteria, fungus and cancer and the more you have the better", while T-reg cells "hide things so we don't kill them and we want to reduce them to prevent the body hiding cancer".

Prof Fong said the aim was to turn on the checkpoints, increase CD8 cells and decrease T-reg cells.

"CF33 does all that and kills cancer in petri dishes and mice," Prof Fong said.

Prof Fong said that allowing the nine different virus strains to combine which resulted in 400 new viruses.

He said each virus was individually cloned and tested for their ability to kill the range of 60 human cancers in the National Cancer Institute-60 (NCI-60) cancer cell line panel, used for screening compounds to detect anti-cancer activity.

Prof Fong said that if a researcher found two or three cancers responding to a compound “you’re doing really well”.

But he said that he set targets of finding viruses which killed all or most of the cancers in the NCI-60 panel; then demonstrating they were safe in mice; and selecting those which stimulated the immune system.

“There is a whole bunch of them that we are still working on, but CF33 is really good,” Prof Fong said.

He said that not only did CF33 kill cancer in mice, but it only required 1,000 virus particles to be effective, compared to the tens of millions and hundreds of millions of particles currently being used and developed.

Prof Fong said that the first trial in a “basket” of cancers including lung, triple negative breast, melanoma, gastro-intestinal and bladder cancers was expected to begin by July 2020.

Ms Chong said the phase I CF33 basket of cancers trial was fully funded and the company had funds to take all programs through to the end of 2020.

Ms Chong said the existing HER-Vaxx and B-cell pipeline, including PD1-Vaxx, and B-Vaxx and the HER-2 and PD-1 vaccine combination, was progressing on schedule.

Ms Chong said the 68-patient, open-label, randomized, multi-centre phase II trial was underway to study the highest dose of HER-Vaxx, following positive day-182 results from the 14-patients phase Ib trial (BD: Mar 14, Jun 4, 2019).

Ms Chong said the B-Vaxx phase II trial was underway, supported by the US National Cancer Institute, and results expected by the end of 2019 would support the overall B-Cell program.

Ms Chong said that Imugene’s end-of-year expected cash balance was \$11 million, not including the potential exercise of options to raise up to \$6 million, or an expected \$3.2 million Federal Government Research and Development Tax Incentive.

Ms Chong said that the details of the payments to Vaxinia for the City of Hope intellectual property had been released, but the details of the financial arrangements with the City of Hope itself would be released in a notice of meeting to approve the City of Hope and Vaxinia acquisition, which was expected to be dispatched to shareholders in August 2019.

Imugene was unchanged at 1.6 cents with 6.4 million shares traded.

## TELEX PHARMACEUTICALS

Telex says it a “heavily oversubscribed” placement at \$1.30 a share has raised \$40.0 million and it hopes to raise \$5 million through a share purchase plan.

Telex said the placement and share plan price of \$1.30 was a nine percent discount to the 10-day weighted average price of shares to July 12, 2019.

The company said the share purchase plan for shareholders at the record date of July 16, 2019 would allow purchases of up to \$15,000 in shares per shareholder.

Telex said the capital raised would fund its pipeline including European clinical activity for its TLX591-CDx for prostate imaging, manufacturing and biologics license application for its TLX250-CDx renal cancer imaging, phase III clinical testing of TLX591 for prostate therapy, and the launch of TLX591-CDx, branded as Illumet, in the US.

The company said that Taylor Collison was the lead manager to the placement, with Goetzpartners Securities co-lead manager and Wilsons Corporate Finance co-manager. Telex fell seven cents or 4.2 percent to \$1.60 with 2.6 million shares traded.

## AIRXPANDERS

Airxpanders says it has cut staff, will cease operations, has ceased sales and will not provide customer service or sales support after July 18, 2019.

Airxpanders said it would immediately reduce its workforce from 35 staff to about eight employees, with further reductions planned for the near future.

The company said it expects to file for relief under Chapter 7 of Title 11 of the United States Code, relating to liquidation in bankruptcy, by July 26, 2019.

In 2015, Airxpanders raised \$36.5 million at 50 cents a share to list on the ASX and commercialize its Aerofoam, patient-controlled, post-mastectomy breast tissue expansion system (BD: Jun 10, 2015).

Last year, the company reported revenue for the year to December 31, 2017, up 585.3 percent to \$US3,906,000 (\$A5,009,140), with net loss after tax up 33.0 percent to \$US28,983,000 (BD: Feb 28, 2018).

In April last year, chief executive officer Scott Dodson resigned and was replaced by chief financial officer and chief operating officer Scott Murcay as interim chief executive officer (BD: April 9, 2018).

Two months later, Frank Grillo was appointed chief executive officer on a base salary of \$US450,000 (\$A590,999) a year (BD: Jun 12, 2018).

The company reported receipts for the six months to June 30, 2018 up 649.3 percent to \$US4,241,000 and later raised \$20.3 million at 7.5 cents a share (BD: Aug 1, 27, 2018).

In January, Airxpanders reported customer receipts for the 12 months to December 31, 2018 up 211.3 percent to \$US8,857,000, but a cash burn for the three months to March 31, 2019 of \$US6,860,000 (BD: Jan 30, 2019).

In March, the company requested a trading halt “pending notification to its lender [Oxford Finance LLC] of the anticipated breach of certain financial covenants in its debt agreement” later requesting a suspension to “finalize its review of financial and strategic alternatives” (BD: Mar 29, Jun 26, 2019).

In May, Airxpanders cut its workforce by 45 percent and expenditure by 33 percent and hired the New York-based Cowan Inc for financial advice (BD: May 2, 9, 30, 2019).

In June, the company paid Oxford \$US500,000 (\$A727,000) (BD: Jun 19, 2019).

Last week, Airxpanders said that due to lymphoma fears, the Australian Therapeutic Goods Administration has proposed the potential suspension of its Aeroform breast tissue expander (BD: Jul 10, 2019).

Airxpanders last traded at 3.5 cents.

## IMMURON

Immuron says it expects to raise \$US1,356,520 (\$A1,936,785) through the issue of 339,130 American depositary shares (ADSs) at \$US4.00 (\$A5.71) each.

Immuron said that each ADS was equivalent to 40 Australian shares, implying the capital raise was equivalent to 14.3 cents a share.

The company said it would grant underwriters a 45-day option to purchase up to 50,869 ADSs for any overallocments in the offering.

Immuron said the funds would be used for clinical development expenses for its clinical candidates and for working capital.

The company said Fordham Financial Management division ThinkEquity represented the underwriters for the offering.

Immuron requested a trading halt in relation to the capital raising.

Trading will resume on July 19, 2019 or on an earlier announcement.

Immuron last traded at 14.5 cents.

## SHAREROOT

Shareroot says it has raised \$509,612 of the hoped for \$954,342 in its rights issue at 0.1 cents a share and hopes to raise a further \$444,731 from shortfall shares.

Shareroot said it would have three months from the closing date to allot the shortfall.

The company said the funds would be used to scale existing digital client services capabilities, to complete and launch new products, for marketing, to develop Mediaconsent Clinical, to re-name the company and for working capital.

Shareroot was unchanged at 0.2 cents with 17.5 million shares traded.

## LIVAC PTY LTD

Melbourne's Livac says the US Food and Drug Administration has approved its organ retractor system for laparoscopic procedures, or keyhole surgery, in the US.

Livac said its Livac Retractor System was invented by surgeon Dr Phillip Gan and used "a soft and flexible silicon ring" and suction to retract the liver or spleen and provide a clear visual field for surgeons.

"The Livac Retractor reduces the number or size of incisions in a wide range of operations, is gentle in its mechanism of action, and to date has never had a reported device related adverse event." Dr Gan said.

"We conducted a retrospective clinical study over three years and found that those patients who had their gallbladders removed through three incisions instead of four had less narcotic analgesia ... and a shorter length of stay, including many who were happy to go home the same day," Dr Gan said.

"The Livac Retractor had been used in virtually all the three-incision technique patients ... [and] these patients had less scarring and great satisfaction," Dr Gan said.

Livac said the system had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval and was currently used in hospitals in Australia, Asia and Europe and had been trialled in a robotic surgical procedure.

Livac chief executive officer Dr Anabela Correia said the FDA Establishment Registration would "enable Livac to continue to make in-roads to support clinical use, sales and distribution of Livac in the US market".

"Discussions are already underway with selected US surgeons and hospital groups interested in clinical evaluation of our innovative product," Dr Correia said.

Livac is a private company, with Dr Paul MacLeman as its chairman.

## USCOM

Uscom says it has been allowed US and European patents for the combination of its Uscom 1A blood flow and Uscom BP+ blood pressure monitors.

Uscom said the patents, titled 'Combined blood flow and pressure monitoring system and method' would protect its intellectual property until July 2035.

The company said that the method combined the two outputs and generated "novel signals and measures of flow and pressure within the heart and vessels".

Uscom said the signals varied during normal function, and with disease and therapy, and could be applied widely and provided "non-invasive measures of the function of the heart and vessels only previously available using invasive catheters and transducers".

Uscom was up one cent or 7.4 percent to 14.5 cents.

## PATRYS

Patrys says it has a European patent for the humanized form of its DNA damage repair antibody Doexymab 3E10 technology, PAT-DX1 for multiple cancers.

Patrys said the patent, titled 'Cell-penetrating anti-DNA antibodies and uses thereof to inhibit DNA repair' would provide coverage until 2032.

In 2017 and 2018, the company said it had US, Japanese and Chinese patents for its Doexymab 3E10 technology (BD: Jul 12, 2017, Jul 3, 2018).

Patrys was up 0.1 cents or 4.35 percent to 2.4 cents with 3.1 million shares traded.

## MEMPHASYS

Memphasys 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 intraday price rose 1.1 cents or 20.75 percent from 5.3 cents to 6.4 cents, today, and noted a "significant increase" in the volume of securities traded.

Memphasys closed up 1.1 cents or 22 percent to 6.1 cents with 9.4 million shares traded.

## CYNATA THERAPEUTICS

Cynata has requested a trading halt "pending an announcement by the company in response to an ASX price query".

Trading will resume on July 19, 2019 or on an earlier announcement.

Cynata last traded at \$1.60.

## BOD AUSTRALIA

Bod Australia has requested a trading halt "pending an announcement in relation to a potential material strategic partnership".

Trading will resume on July 19, 2019 or on an earlier announcement.

Bod last traded at 36.5 cents.

## ELIXINOL GLOBAL

Elixinol says the Australian Office of Drug Control has granted wholly-owned subsidiary Nunyara Pharma a medicinal cannabis manufacturing licence.

Elixinol said Nunyara would be able to manufacture extracts, tinctures and resin.

Elixinol fell five cents or 1.25 percent to \$3.95 with 499,514 shares traded.

## [NUHEARA](#)

Last night's edition reported that the Sydney-based Farjoy had increased and been diluted in Nuheara from 70,407,585 shares (7.90%) to 108,740,919 shares (10.24%).

In fact, Farjoy and its managing-director and Nuheara director Tim Robertson had simply increased their holding.

The mistake was made by the former Tuesday sub-editor.

Biotech Daily apologizes unreservedly to Mr Robertson, Farjoy and Nuheara.

Nuheara fell 0.1 cents or 1.9 percent to 5.1 cents with 3.2 million shares traded.

## [COCHLEAR](#)

Hyperion Asset Management says it has ceased its substantial shareholding in Cochlear.

The Brisbane-based Hyperion said that it bought and sold shares between March 1 and July 11, 2019, with the single largest sale 52,375 shares for \$11,446,783 or \$218.55 a share.

Cochlear fell \$1.40 cents or 0.6 percent to \$219.88 with 128,720 shares traded.

## [CSL](#)

CSL says it has appointed Anjana Narain to replace Gordon Naylor as executive vice president and general manager of its Seqirus influenza vaccine business.

CSL said Ms Narain had more than 27 years' experience at Bayer, Glaxosmithkline and Merck Inc in North America, Europe and Asia.

The company said Ms Narain held a Bachelor of Arts from the Meerut, India-based RG College, a Masters of Business Administration from the West Haven, Connecticut-based University of New Haven and was a graduate from Harvard Business School's General Management Program.

CSL was up \$1.49 or 0.7 percent to \$224.08 with 492,442 shares traded.

## [NANOSONICS](#)

Nanosonics says it has appointed Geoff Wilson as non-executive director, replacing Richard England, effective from July 17, 2019.

Nanosonics said Mr Wilson had more than 37 years' experience, including roles as the chief executive officer of KPMG in Australia and the chief operating officer of KPMG in the Asia Pacific.

The company said Mr Wilson was currently a non-executive director at Toll Holdings, HSBC Bank Australia, Future Generation Global Investment Co and Ipscape.

Nanosonics said Mr Wilson held a Bachelor of Commerce from the University of New South Wales.

Nanosonics was up three cents or 0.6 percent to \$5.10 with one million shares traded.