



Biotech Daily

Wednesday February 21, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: FACTOR UP 8%; OSPREY DOWN 8%**
- * **QUEENSLAND UNI, ZEALAND WORK ON VENOM FOR GI DISEASE**
- * **SIRTEX H1 REVENUE DOWN 3% TO \$109m, PROFIT UP 22% TO \$25m**
- * **COGSTATE H1 REVENUE DOWN 8% TO \$17m, PROFIT TO \$1.6m LOSS**
- * **NUHEARA 'MAIDEN' H1 REVENUE UP 90% TO \$2m, LOSS UP 151% TO \$4m**
- * **SOMNOMED RAISES \$5.9m, \$4.5m TO GO**
- * **DIMERIX RAISES \$4.5m, TOTAL \$7.6m**
- * **ACRUX QUIETLY DROPS LEAD PROGRAM ACR-065 FOR ONYCHOMYCOSIS**
- * **SECOND US PATENT FOR RACE BISANTRENE**
- * **ESENSE BOARD SPILL AGM, EGM TO BE HELD IN ISRAEL**
- * **CLARITY APPOINTS PROF ANDREAS KJAER ADVISOR**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Wednesday February 21, 2018 with the ASX200 up 2.8 points to 5,943.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and four were untraded. All three Big Caps were up.

Factor Therapeutics was the best, up 0.3 cents or 8.3 percent to 3.9 cents with 328,630 shares traded. Impedimed and Oncosil climbed four percent or more; Mesoblast was up 3.7 percent; Benitec rose 2.3 percent; Clinuvel, Cochlear, Compumedics and Resmed were up more than one percent; with CSL, Medical Developments, Nanosonics, Neuren and Opthea up by less than one percent.

Osprey led the falls, down 2.5 cents or 7.7 percent to 30 cents with 93,295 shares traded. Pro Medicus lost 5.8 percent; Immutep (Prima) fell 4.35 percent; Dimerix, Prana and Telix were down more than three percent; Actinogen, Cyclopharm, ITL and Volpara shed more than two percent; Admedus, Optiscan, Orthocell, Pharmaxis, Starpharma and Uscom were down more than one percent; with Sirtex and Viralytics down less than one percent.

UNIVERSITY OF QUEENSLAND, UNIQUEST

The University of Queensland says it will collaborate with the Denmark's Zealand Pharma AS to develop venom peptides for gastrointestinal diseases.

The University of Queensland's research commercialization company Uniquet said the collaboration would combine the University's "expertise in identifying therapeutically-relevant bioactive peptides from venoms with the peptide drug discovery and development expertise of Zealand Pharma".

Uniquet intellectual property executive director Dr Mark Ashton told Biotech Daily that the collaboration "aims to develop drug candidates for gastrointestinal diseases which includes diseases of the digestive system such as ulcerative colitis, Crohn's disease and irritable bowel syndrome".

University of Queensland vice-chancellor Prof Peter Høj said that Zealand would use the peptide technology and expertise of the University's Institute for Molecular Bioscience as well as expertise from Flinders University in South Australia.

Prof Høj said that the Institute was "world-renowned in peptide drug discovery, possessing one of the largest collections of animal venoms and extensive experience in identifying novel bioactive peptides from venoms".

"Zealand Pharma has a strong track record and world-leading capabilities in the discovery and development of peptides for therapeutic use in gastrointestinal and metabolic diseases," Prof Høj said.

The University said that Zealand and the researchers would characterize venom-derived peptides that acted against undisclosed targets to identify novel drug candidates for development by Zealand.

SIRTEX MEDICAL

Sirtex says that revenue for the six months to December 31, 2017 fell 3.0 percent to \$109,396,000, with net profit after tax up 22.3 percent to \$24,957,000.

Sirtex said SIR-sphere dose sales fell 0.4 percent to 6,023 units for the six months, implying an average cost of \$18,163 per dose compared to \$18,620 per dose in the previous year.

The company said that in the six months to December 31, 2017, revenue from the Americas fell 4.4 percent to \$86,169; Asia Pacific sales climbed 4.75 percent to \$4,649,000; with Europe, Middle East and Africa revenue up 1.8 percent to \$18,578,000. Sirtex said that the lower sales revenue growth compared to dose sales was "a result of changes in geographic revenue mix with stronger growth in the [Asia Pacific] region, and of negative foreign currency fluctuations, as the Australian dollar appreciated against the US dollar".

The company said research and development expenditure fell 62.6 percent to \$1,863,000 or 1.7 percent of total revenue compared to 4.4 percent of revenue in the previous corresponding period, following the axing of "non-core" programs (BD: Feb 22, 2017).

Sirtex said that diluted earnings per share was up 16.5 percent to 41.7 cents, with cash and cash equivalents of \$42,808,000 at December 31, 2017 compared to \$30,954,000 at December 31, 2016.

The company said that net tangible asset per share increased 14.2 percent from \$1.768 at December 31, 2016 to \$2.019 at December 31, 2017.

Sirtex said that there would be no interim dividend but an unfranked final dividend of 30.0 cents per share was paid on October 18, 2017 for the financial year to June 30, 2017, compared to the previous year's partly-franked 30.0 cents per share dividend.

Sirtex fell six cents or 0.2 percent to \$27.68 with 251,812 shares traded.

COGSTATE

Cogstate says revenue for the six months to December 31, 2016, fell 4.5 percent to \$US13,400,820 (\$A17,070,093), with net loss after tax \$US1,289,999 (\$A1,643,166) compared to last year's profit of \$966,417.

Last August, Cogstate said that it moved to reporting in US dollars "given that around 98 percent of Cogstate's revenue and more than 70 percent of its costs are denominated in US dollars, [so] this change will provide shareholders with a more accurate reflection of the company's underlying performance".

But translating Cogstate's data from US to Australian dollars shows that revenue for the six months to December 31, 2016 fell 8.1 percent to \$US13,400,820 (\$A17,070,093) compared to the revenue for the six months to December 31, 2016 of \$18,570,060.

Cogstate said that revenue from cognitive testing services to clinical trials for the six months to December 31, 2017 fell by about \$US1.1 million.

The company said that net tangible assets per share was steady at 7.0 US cents (8.9 cents) but last year said that net tangible assets per share was 11.0 cents, with diluted loss per share of 1.1 US cents (1.4 cents) compared to last year's diluted earnings per share of 0.8 cents and the company had cash and cash equivalents of \$US4,239,833 (\$A5,399,879) compared to \$11,212,088 at December 31, 2016.

Cogstate fell 3.5 cent or 3.7 percent to 90 cents.

NUHEARA

Nuheara says that revenue for the six months to December 31, 2017 climbed 89.7 percent to \$1,959,994 with net loss after tax up 150.6 percent to \$4,269,117.

Nuheara chief executive officer Justin Miller told Biotech Daily that the company had "crowd-funded" \$1,033,000 in sales of its Iqbud sound filtering and hearing ear buds in the six months to December 31, 2016, "but the company was advised that accounting standards meant that it was considered as a deposit rather than income until the Iqbuds were shipped to customers".

The company said that diluted loss per share was up 84.6 percent to 0.48 cents, net tangible asset backing per share was steady at 0.01 cents and it held cash and cash equivalents of \$5,635,553 at December 31, 2017 compared to \$4,217,847 at December 31, 2016.

Nuheara fell 0.3 cents or 4.8 percent to six cents with 5.8 million shares traded.

SOMNOMED

Somnomed says its institutional entitlement offer has raised \$5.9 million at \$3.00 a share with a retail offer to raise a further \$4.5 million.

Somnomed said that the institutional offer had "strong support from existing shareholders" and the shortfall would be taken up by TDM Asset Management Pty Ltd and other existing shareholders.

The company said that retail shareholders could subscribe for one new share for every 17 existing shares held on February 21, 2018, with the offer opening on February 26, 2018 and close on March 15, 2018.

Somnomed said that TDM and other existing shareholders had committed to subscribe for any shortfall under the retail offer.

Somnomed fell three cents or 1.0 percent to \$3.00.

DIMERIX

Dimerix says it has raised \$4.5 million in a “significantly oversubscribed placement” at 12 cents a share, taking the total raised to \$7,556,116.

In January, Dimerix raised \$3,056,116 in an entitlement offer (BD: Jan 24, 2018).

The company said the placement was to wholesale and institutional clients of Westar Capital and Baker Young Stockbrokers who were joint lead managers to the issue.

Dimerix chief executive officer Kathy Harrison said that Dimerix was “fully funded” to take DMX-200 into a phase II trial by April for the treatment of the kidney disease focal segmental glomerulosclerosis.

Ms Harrison said that the company had funds to “complete the steps required to develop commercial scale batches of DMX-200 and complete the remaining non-clinical studies to take DMX-200 to phase III-ready for [focal segmental glomerulosclerosis]”.

“We are now in a strong position to continue our partnering discussions and exploit the full commercial potential for DMX-200 in diabetic nephropathy and other pipeline opportunities,” Ms Harrison said.

Dimerix fell half a cent or 3.7 percent to 13 cents.

ACRUX

In a teleconference on its half-year results, Acrux chief executive officer Michael Kotsanis said the company dropped its lead ACR-065 for onychomycosis program last year.

Mr Kotsanis said that the announcement that ACR-065 for onychomycosis was on a slide in the annual general meeting presentation on October 26, 2017.

Slide seven of 25 said that a US Food and Drug Administration pre-investigational new drug application meeting was “supportive of Acrux proposed clinical program” and an ethics application had been submitted for a phase I program in Australia.

The slide said that the “project will now be suspended to preserve and focus cash on nearer term opportunities in topical generic pipeline”.

In 2016, Acrux said that it had filed a provisional patent application covering ACR-065 for fungal infection of the nail bed in toes and fingers, or onychomycosis and expected to begin clinical trials by the end of 2017 (BD: Nov 2, 2016).

The following day, the company filed a US patent review petition challenging an existing patent covering an anti-fungal treatment for onychomycosis (BD: Nov 3, 2016).

Today, Mr Kotsanis said that the program was shelved because it was considered too expensive and would take several years to complete.

Mr Kotsanis said the company had a pipeline of seven generic products in active development with plans to expand to 12 products by July 2018 and 19 products by July 2019.

The 2017 annual general meeting voted a remuneration report first strike with 55.1 percent against the report and 44.9 percent in favor, and in a separate vote 40.2 percent opposed the issue of 4,000,000 performance rights to Mr Kotsanis worth \$660,000 at that time (BD: Oct 26, 2017).

The Acrux annual report said that Mr Kotsanis received a base salary of \$399,713 for the year to June 30, 2017 and a total remuneration, including a bonus, post-employment superannuation and equity options of \$701,846.

Acrux was unchanged at 16 cents.

RACE ONCOLOGY

Race says a second US patent has been allowed covering for Bisantrone for leukaemias, as well as breast cancer, lymphoma and other cancers.

Race said the patent, entitled 'Compositions to Improve the Therapeutic Benefit of Bisantrone and Analogs and Derivatives Thereof' provided protection until 2034.

The company said that it was the second of two Bisantrone patents filed in the US, Europe and five other key countries (BD: Jan 29, 2018).

Race chief executive officer Peter Molloy said the company had been "developing second-generation Bisantrone formulations with potentially improved characteristics over the current Bisantrone product ... [and the] patent provides commercial protection for these potential new products".

Race was untraded at 43 cents.

ESENSE-LAB

Esense says that an extraordinary general meeting to spill the board and an annual general meeting to pre-empt any spill will be held in Israel.

Last week, Esense said that directors Dr Brendan de Kauwe and Quentin Megson had begun proceedings against the company and the remaining directors, seeking cancellation of the resolution replacing Dr de Kauwe as chairman, cancellation of the annual general meeting scheduled for March 29 and an order relating to the previously scheduled annual general meeting (BD: Feb 13, 2018).

Esense said the Court rejected all motions brought by Dr de Kauwe and Mr Megson, found the board acted properly in passing the February 8 resolutions and ruled the meetings were to be held on March 29, 2018 with any date changes requiring approval. The company said the board resolved at its February 8 meeting to appoint Ilan Saad as chairman replacing Dr de Kauwe, cancel the annual general meeting scheduled for February 15, and convene the meeting with the extraordinary general meeting requisitioned for March 29, 2018 (BD: Feb 9, 2018).

Last week, Esense said that Benjamin Karasik has been appointed as a director and Dr de Kauwe continued as a director (BD: Feb 9, 2018).

In January, Esense said it had a request under Israeli Companies Law from shareholders Romfal Sifat, Buzz Capital and Attollo Investments for a meeting to remove directors Haim Cohen, Eran Gilboa and Ilan Saad; and appoint as directors current chairman Dr de Kauwe, if he was not re-elected at the annual general meeting, as well as MMJ Phytotech chief executive officer Andreas Gedeon and Faldi Ismail (BD: Jan 29, 2018).

Today, Esense said the extraordinary general meeting would follow the annual general meeting on March 29, 2018.

The company said the annual general meeting would vote to re-elect directors Mr Cohen, Mr Gilboa, Mr Saad and Mr Karasik, but did not seek the re-election of Dr de Kauwe.

Esense said the annual general meeting would vote on compensation for officers and directors, increase the number of securities by 10 percent for the coming 12 months, re-appoint BDO Ziv Haft as its accounting firm and ratify previous share and option issues, including 5,000,000 options to Otsana Capital, of which Dr de Kauwe was a director.

The company said the subsequent extraordinary general meeting would vote on the removal as directors of Mr Cohen, Mr Gilboa and Mr Saad, and re-elect Dr de Kauwe and elect as directors Mr Gedeon and Otsana Capital managing-director Faldi Ismail.

The meetings will be held at 3 Pinchas Sapir Street, Ness Ziona, Israel on March 29, 2018 at 3pm (AWST).

Esense fell half a cent or 2.8 percent to 17.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Prof Andreas Kjaer to its scientific advisory board.

Clarity said that Prof Kjaer was the Copenhagen, Denmark's Rigshospitalet (national hospital) chief physician and head of research in the clinical physiology, nuclear medicine and positron emission tomography department and a professor at the University of Copenhagen.

The company said that Prof Kjaer was "one of the world leaders" in the molecular imaging with positron emission tomography and magnetic resonance imaging targeted radionuclide therapies and had developed several new tracers in first-in-human clinical use.

Clarity said that Prof Kjaer was the former president of the Scandinavian Society of Clinical Physiology and Nuclear Medicine and was currently a member of the European Association of Nuclear Medicine oncology committee.

Clarity is a public unlisted company.