



Biotech Daily

Thursday February 22, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX EVEN, BIOTECH UP: ORTHOCELL UP 13%; CLINUVEL DOWN 12%**
- * **CLINUVEL H1 REVENUE UP 10% TO \$32m; PROFIT DOWN 4% TO \$11m**
- * **COGSTATE H1 REVENUE UP 3.2% TO \$31m; PROFIT \$3m**
- * **GENETIC SIGS H1 REVENUE DOWN 65% TO \$3.6m; LOSS UP TO \$10.5m**
- * **LBT DELIVERS 1st APAS PHARMA QC TO THERMO FISHER**
- * **ORTHOCELL RAISES \$3.5m**
- * **ALTERITY REQUESTS 'CAPITAL RAISE' TRADING HALT**
- * **ISLAND REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **HERAMED REQUESTS 'MATERIAL CONTRACT' TRADING HALT**
- * **INOVIQ BREAST CANCER TEST '80% ACCURACY, 93% SPECIFICITY'**
- * **TRIVARX PLEADS 'SCHULTZ, STOCKHEAD' TO ASX 64% QUERY**
- * **PHARMAUST APPOINTS SCIENTIFIC ADVISORY BOARD**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Thursday February 22, 2024, with the ASX200 up 2.8 points to 7,611.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and one was untraded.

Orthocell was the best, up five cents or 13.2 percent to 43 cents, with 536,278 shares traded. Cynata climbed 8.8 percent; Curvebeam rose 7.1 percent; Opthea and Prescient were up more than six percent; Paradigm improved 5.8 percent; Alcidion was up 4.1 percent; Nanosonics climbed 3.3 percent; Impedimed and Nova Eye rose more than two percent; Atomo, Avita, Next Science, Pro Medicus, Proteomics, Resonance and SDI were up more than one percent; with CSL, Neuren and Resmed up by less than one percent.

Clinuvel led the falls, down \$1.97 or 12.1 percent to \$14.32, with 472,622 shares traded. Actinogen lost five percent; Medical Developments fell four percent; Starpharma was down 3.45 percent; Amplia and Cyclopharm shed more than two percent; Immutep and Percheron (Antisense) were down more than one percent; with Clarity, Cochlear and Telix down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the six months to December 31, 2023 was up 9.9 percent to \$32,256,885, with net profit after tax down 4.0 percent to \$10,936,043.

Clinuvel said revenue came primarily from sales and reimbursements of its Scenesse, or 16mg afamelanotide, for erythropoietic protoporphyria, which increased 10 percent, as well as sales of its photo-cosmetic products.

The company said profit fell due to a 28 percent increase in total expenses compared to the previous corresponding period.

Clinuvel said that major expenditure included a 32 percent rise in staff costs following a 10 percent staff increase and a 47 percent increase in share-based payments.

The company said that diluted earnings per share fell 3.6 percent to 21.2 cents, with net tangible asset backing per share up 27.3 percent to \$3.54.

Clinuvel said it had cash and cash equivalents at December 31, 2023 of \$38,817,216 compared to \$140,703,376 at December 31, 2022.

Clinuvel fell \$1.97 or 12.1 percent to \$14.32 with 472,622 shares traded.

COGSTATE

Cogstate says revenue for the six months to December 31, 2023 was up 3.2 percent to \$US20,168,909 (\$A30,823,000) with profit up 33-fold to \$US2,005,717(\$A3,065,000).

Cogstate said revenue was up due to the implementation of management, training and monitoring sales to complement its computerized cognitive tests for clinical trials and the healthcare market.

The company said net profit after tax increased due to a reduction in employee benefits expenses, marketing costs, travel expenses, general administration and favorable foreign currency exchange rates.

Cogstate said diluted earnings per share rose 38-fold from 0.03 US cents in the previous corresponding period to 1.15 US cents, with net tangible asset backing per share up 30.6 percent to 14.1 US cents.

The company said it had cash and equivalents of \$US25,285,744 at December 31, 2023 compared to \$ US28,929,880 at December 31, 2022.

Cogstate fell eight cents or 6.35 percent to \$1.18.

GENETIC SIGNATURES

Genetic Signatures says revenue for the six months to December 31, 2023 was down 65.4 percent to \$3,604,000, with net loss after tax up 61.6 percent to \$10,469,000.

Genetic Signatures said the reduced revenue "reflected the anticipated decline in molecular testing for Covid-19 in combination with an unanticipated reduction in respiratory revenue" with 86 percent of sales coming from non-Covid-19 tests.

The company said its increased loss was due to a decrease in its gross margin on sales during the period, from 64 percent in the prior corresponding period to 42 percent in the six months to December 31, 2023.

Genetic Signatures said diluted loss per share rose 61.3 percent to 7.29 cents and that net tangible assets per security fell 32.1 percent to 20.9 cents.

The company said it had cash and cash equivalents of \$18,124,000 at December 31, 2023, compared to \$26,849,000 at December 31, 2022.

Genetic Signatures was unchanged at 50.5 cents.

LBT INNOVATIONS

LBT says it has delivered the first of its Apas Pharma QC instruments to one of the Waltham, Massachusetts-based Thermo Fisher Scientific facilities.

LBT said its automated plate assessment system (Apas) uses “artificial intelligence and machine learning to automate the imaging, analysis and interpretation of microbiology culture plates”.

In 2022, the company said it was developing an automated plate assessment system (Apas) for pharmaceutical companies, Apas Pharma, for microbial quality control, along with other products (BD: Aug 10, 2022).

Today, LBT said the sale reflected “the positive market interest” from customers following initial market development activities in 2023, the sale was completed about six months ahead of previous expectations and it had established a pipeline of potential early adopters who showed an interest in the technology.

The company said its Apas Pharma QC environmental monitoring application was being installed at the undisclosed facility and would be used to support Thermo Fisher’s culture plate media for use in pharmaceutical microbial quality control applications.

LBT managing-director Brent Barnes said the sale was “an important milestone ... being the first deployment of Apas Pharma QC outside of our partnership with Astrazeneca”.

Last year, the company said an Astrazeneca study had shown its Apas Pharma QC had 100 percent sensitivity for detecting microbes from 1,515 plates (BD: Aug 10, 2023).

Today, Mr Barnes said “the evaluation performed by Thermo Fisher will provide meaningful performance data supporting ‘real-world’ use of our technology”.

“This will provide a further third-party validation of Apas Pharma QC and further enhance our commercial activation of the product,” Mr Barnes said.

LBT was up 0.3 cents or 23.1 percent to 1.6 cents with 6.4 million shares traded.

ORTHOCELL

Orthocell says it has raised \$3.5 million in a placement at 37.0 cents a share, including investments from Merchant Biotech Fund.

Biotech Daily calculates the 37 cents a share price is a 2.6 percent discount to the company’s last closing price of 38 cents.

The company said the funds would be used for commercialization of its Striate+ bone repair and Remplir nerve repair, and that it had existing cash of \$19.6 million and a pending Federal Research and Development Tax Incentive of about \$3.0 million.

Orthocell was up five cents or 13.2 percent to 43 cents.

ALTERITY THERAPEUTICS

Alterity has requested a trading halt “pending an announcement in relation to a capital raise”.

Trading will resume on February 26, 2024, or on an earlier announcement.

Alterity last traded at half a cent.

ISLAND PHARMACEUTICALS

Island has requested a trading halt “to finalize arrangements in relation to a proposed capital raising”.

Trading will resume on February 26, 2024, or on an earlier announcement.

Island last traded at 8.3 cents.

HERAMED

Heramed has requested a trading halt “pending an announcement to the market regarding a material new contract”.

Trading will resume on February 26, 2024, or on an earlier announcement.

Heramed last traded at 1.9 cents.

INOVIQ

Inoviq says further results from its 483-sample study shows its Sub-B2M-CA15.3 test detects more than “80 percent of breast cancers ... with 93 percent specificity”.

Last year, Inoviq said its independent, case-control clinical validation study of Sub-B2M-CA15.3 blood test for breast cancer showed an accuracy of 87 percent, a sensitivity of 81 percent and specificity of 93 percent (BD: Feb 8, Jun 27, 2023).

Today, the company said the University of Queensland had provided 277 serum samples, and that the cancer subtype leg of the study used 159 pre-treatment serum samples from women diagnosed with breast cancer.

Inoviq said analysis of these samples showed that the test detected breast cancer across all key subtypes, including hormone receptor+, human epidermal growth factor receptor 2 and triple negative breast cancer.

The company said the test had outperformed the US Food and Drug Administration approved Roche Elecsys test by correctly identifying 19 percent more histologically-confirmed breast cancers.

Inoviq said the monitoring leg of the study assessed CA15-3 concentrations in serum obtained from 12 women before treatment, then at up-to five subsequent time points post-treatment and “established equivalence between [its] test and the comparator test for monitoring breast cancer”.

The company said it intended to use the results to attract potential partners and opinion leaders to secure a partner in the US to “speed the commercialization of the test and revenue generation”.

Inoviq said it was in discussions with its contract research organization about a larger study and would sponsor a “larger in-clinic trial to gain further data to substantiate the performance of its test for monitoring breast cancer treatment responses and to facilitate clinical adoption”.

Inoviq was up 16 cents or 24.2 percent to 82 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx has told the ASX it is unaware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price rose 63.6 percent from 2.2 cents at yesterday’s close to 3.6 cents today, noting the “significant increase” in the number of shares traded.

Trivarx said an article was published in Stockhead titled ‘Diagnosing mental disorder through sleep: How Trivarx could capture this huge research market’ but that it believed there was “nothing in the article which warrants an announcement to the ASX and has not previously been announced”.

Trivarx closed up 0.9 cents or 40.9 percent to 3.1 cents with 5.2 million shares traded.

PHARMAUST

Pharmaust says it has appointed a scientific advisory board to provide guidance on the development of its monepantel for motor neuron disease and amyotrophic lateral sclerosis.

Pharmaust said the board included the Netherlands-based University Medical Center Utrecht's Prof Leonard van den Berg, Harvard Medical School's Dr Sabrina Paganoni, the Austin, Texas-based Berry Consultant's Dr Melanie Quintana and Dr Christian Freitag. The company said the board would provide advice to explore other neurodegenerative diseases, as well as supporting the planning stages for its phase II/III clinical study of monepantel in motor neuron disease and amyotrophic lateral sclerosis, which was expected to begin this year.

Pharmaust was up six cents or 25 percent to 30 cents with 4.3 million shares traded.