

Biotech Daily

Thursday April 4, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: CYNATA UP 8%; ATOMO DOWN 6.45%
- * ACCC OKAYS COCHLEAR OTICON ACQUISITION
- * BLINKLAB UP 32.5% ON \$7m IPO FOR AUTISM TEST
- * CLARITY: NORTHSTAR TO SUPPLY CU-67 SAR-BIS-PSMA
- * NOXOPHARM: \$100k GRANT FOR BRAIN CANCER DRUG
- * IMUGENE WINS CHINA CF33 CANCER VIROTHERAPY PATENT
- * ANTEOTECH REQUESTS 'CAPITAL RAISING' TRADING HALT
- * ISLAND DIRECTOR ALBERT HANSEN INCREASES, DILUTED TO 9.8%
- * ISLAND M-D DR DAVID FOSTER INCREASES, DILUTED TO 5.1%
- * SUJAL SHAH REPLACES OPTHEA DIRECTOR DAN SPIEGELMAN

MARKET REPORT

The Australian stock market was up 0.45 percent on Thursday April 4, 2024, with the ASX200 up 34.8 points to 7,817.3 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 10 were down, 10 traded unchanged and one was untraded.

Cynata was the best, up 1.5 cents or 8.1 percent to 20 cents, with 298,521 shares traded.

Prescient climbed 7.4 percent; Impedimed and Universal Biosensors improved more than five percent; 4D Medical was up four percent; Actinogen and Genetic Signatures were up more than three percent; Curvebeam, Neuren, Nova Eye, Polynovo and Pro Medicus rose two percent or more; Amplia, Avita, Cochlear, Compumedics, Mesoblast, Next Science and Telix were up more than one percent; with SDI up by 0.6 percent.

Atomo led the falls, down 0.2 cents or 6.45 percent to 2.9 cents, with 786,976 shares traded. Micro-X fell four percent; Opthea lost 3.3 percent; Percheron shed 2.5 percent; Clarity, Clinuvel, Nanosonics and Orthocell were down more than one percent; with CSL, Cyclopharm, Resmed and Volpara down by less than one percent.

COCHLEAR, AUSTRALIAN COMPETITION & CONSUMER COMMISSION

The Australian Competition and Consumer Commission (ACCC) says it won't oppose Cochlear's acquisition of Oticon Medical's cochlear implant business.

In 2022, Cochlear said it would acquire Oticon Medical for DKK850 million (\$A188 million), after its parent company, the Copenhagen, Denmark-based Demant AS, said it would exit the hearing implant market (BD: Apr 28, 2022).

At the time, the company said the acquisition would be funded from its existing cash balances and that its completion was conditional on satisfying customary closing conditions and jurisdictional approvals.

Cochlear chief executive officer Dig Howitt said that Oticon Medical was, at that time, lossmaking, but was "expected to add \$75 to \$80 million to annual revenue".

The company said it expected the transaction to be completed by the end of 2022.

Today, in a media release from the ACCC posted to the ASX by Cochlear, the Commission said it had "significant competition concerns in relation to Cochlear's proposed acquisition of Oticon Medical's bone conduction solutions business".

Last year, Cochlear said the UK Competition and Markets Authority had provisionally found that its proposed acquisition of Oticon Medical may lessen competition in the UK because recipients who needed hearing implants could end up "losing out, with less choice, reduced quality, or higher prices" (BD: Apr 21, 2023).

Later, the company said UK authorities found the acquisition raised no competition concerns but had stopped its purchase of Oticon's bone implant business, which was expected to add about \$10 million in annual revenue (BD: Jun 23, 2023).

Today, the ACCC said it had approved the transaction which had "now been changed to remove the bone conduction solutions business".

The Commission said in relation to the revised transaction that Oticon Medical had "small market share and does not provide strong competition in the supply of cochlear implants in Australia, including with respect to research and development".

The ACCC added that it considered it "unlikely that Oticon Medical would have become a stronger competitor in the supply of cochlear implants in the foreseeable future".

The ACCC said that Demant would retain Oticon Medical's bone conduction business, selling only its cochlear implants business.

ACCC commissioner Stephen Ridgway concluded that "Cochlear's proposed acquisition of Oticon's cochlear implants business was unlikely to substantially lessen competition in Australia".

"We were concerned that the original proposed acquisition would lead to higher prices, lower quality or service levels and less innovation in the supply of surgical and nonsurgical bone conduction solutions," Mr Ridgeway said.

The ACCC said it had "liaised closely" with other competition authorities during its review, including the UK Competition and Markets Authority and the European Commission. The media release said that on June 22, 2023, Cochlear publicly announced it would

revise its original proposed acquisition to not include Oticon Medical's bone conduction solutions business.

The Commission said that on October 9, 2023 the European Commission had reviewed Cochlear's acquisition of Oticon Medical's cochlear implants business and approved the revised acquisition.

The ACCC said it had recommended its review to consider the revised transaction on March 15, 2024.

The Commission said the UK Competition and Markets Authority had not yet decided on the proposed revised transaction.

Cochlear was up \$3.66 or 1.1 percent to \$333.59 with 87,400 shares traded.

BLINKLAB

Blinklab says its over-subscribed initial public offer at 20 cents a share has raised \$7 million to list under the code BB1 and develop its autism and neurological disorder test. In January, Blinklab said it hoped to raise up-to \$8 million to develop the diagnostic which reduced autism evaluation to one or two 15-minute smartphone-based neuro-metric tests that could reduce the diagnostic age to as low as 18 months (BD: Jan 21, 2024).

At that time the company said Resapp co-founder Brian Leedman was its chair, with directors Jane Morgan, Dr Richard Hopkins and Dr Anton Uvarov who was a co-inventor with Dr Henk-Jan Boele; and Westar Capital acting as lead manager to the raise. Today, in a presentation, the company said that its test outperformed US Food and Drug Administration-approved peers.

Mr Leedman, said Blinklab was "the next ground-breaking venture in digital healthcare". "Our innovative approach leverages the power of smartphones, [artificial intelligence] and machine learning to deliver autism screening tests specifically designed for children as young as 18 months old," Mr Leedman said.

"This will aid healthcare providers to identify these children at a much younger age than presently available providing a pathway to effective treatment and better outcomes for the child and their families," Mr Leedman said.

"This cutting-edge digital technology is poised to capture the imagination of major industry players, eager to embrace transformative solutions in healthcare," Mr Leedman said. Blinklab opened up 50 percent at 30 cents, fell to 24 cents and closed up 6.5 cents or 32.5 percent at 26.5 cents with 3.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has extended its copper-67 supply deal with Northstar to ensure product supply for its trials of the radioisotope as a therapy for prostate cancer.

In 2021, Clarity said it had a long-term exclusive deal with the Beloit, Wisconsin-based Northstar Medical Radioisotopes to supply the therapeutic radioisotope copper-67 but did not detail the term of value of the agreement (BD: May 25, 2021).

Today, the company said the four-year extension was effective immediately, with supply of copper-67 Sar-Bis-prostate specific membrane antigen (PSMA) expected to begin by January 2025.

Clarity said the product would be used in its phase I/II and phase III trials but did not disclose commercial terms of the deal.

Clarity chair Dr Alan Taylor said "this important step is yet another differentiating factor that helps Clarity clearly stand out from the rest of the radiopharmaceutical market, making it possible to have therapeutic isotope supply and product manufacture at the same site".

"We have seen in the past the logistical challenges associated with the separation of radio-isotope and final drug product manufacturing with lutetium-177-based therapies as it causes delays and inefficiencies, ultimately affecting care for oncology patients waiting for their treatments," Dr Taylor said.

"The shift away from limited nuclear reactor-based supply, where even today there is an important facility down in Europe due to maintenance issues, is vital in order for radiopharmaceuticals to grow sustainably into the large oncology sector," Dr Taylor said. "Copper-67 and targeted copper theranostics can now be manufactured and shipped from a single location, a unique feature of copper-67, due to its ability to be manufactured using electron accelerators," Dr Taylor said.

Clarity fell five cents or 1.8 percent to \$2.69 with 882,267 shares traded.

NOXOPHARM

Noxopharm says it has a \$100,000 grant from the charity Tour de Cure to progress research for its brain cancer drug with the University of South Australia.

Noxopharm said it would match the grant with an additional \$100,000 to fund the research, led by Dr Helen Palethorpe at the Tissue Architecture and Organ Function Laboratory at the University of South Australia's Centre for Cancer Biology.

The company said the Alexandria, Virginia-based Tour de Cure had raised more than \$117 million for funding research and supporting cancer prevention campaigns. Noxopharm said the drug candidate was developed from its Chroma library of 'novel chemical entities' that it had developed and optimized for robust anticancer activity. The company said the "'novel chemical entities' underwent a comprehensive and complex screening process to determine the most favorable and potent drug candidate for glioblastoma".

Noxopharm said the grant would be used to assess the mechanism of action of its drug candidate in laboratory-grown models of glioblastoma and identify biological indicators that could assist in determining the patients who could benefit most from the treatment. The company said the research would give it further insights into its other oncology assets, such as its CRO-67 drug candidate for pancreatic cancer.

Dr Palethorpe said the research involved "using advanced human brain tumors in a dish that I developed in our lab to investigate the mechanisms of action of this compound". "At the same time, we are also identifying new biomarkers that can help in stratifying those patients that could benefit the most with this potential new treatment," Dr Palethorpe said. Noxopharm chief executive officer Dr Gisela Mautner said with the grant the company's "preclinical drug candidate is recognized as having potential that warrants further investigation and development".

Noxopharm was up 0.2 cents or 3.1 percent to 6.7 cents.

IMUGENE

Imugene says the People's Republic of China Patent Office has granted a patent for its oncolytic virotherapy CF33, including Vaxinia, or CF33-Hnis, and Checkvacc. Imugene said the patent, titled 'Chimeric Poxvirus Composition and Uses Thereof', protected the composition and method of use of its intellectual property until 2037. The company said CF33 was a chimeric vaccinia poxvirus and oncolytic viruses were designed to both selectively kill tumor cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

Imugene said the patent granted in China followed earlier patent grants in South Korea and Japan (BD: Jan 16, 2022; Sep 12, 2023).

Imugene managing-director Leslie Chong said the company "receiving these patent grants for the CF33 family of oncolytic viruses is a crucial step forward and with China, Japan and South Korea being the largest healthcare markets in Asia, this is a particularly important patent milestone".

Imugene was unchanged at 10.5 cents with 27.6 million shares traded.

ANTEOTECH

Anteotech has requested a trading halt "pending an announcement by the company concerning a capital raising".

Trading will resume on April 8, 2024, or on an earlier announcement. Anteotech last traded at 3.5 cents.

ISLAND PHARMACEUTICALS

Island director Albert Hansen says he has increased and been diluted in Island from 10,837,367 shares (13.38%) to 11,104,034 shares (9.76%).

The Las Vegas, Nevada-based Mr Hansen said on November 18, 2023 he was issued 100,000 shares in lieu of director fees at no cost, and on March 26, 2024 purchased 166,667 shares in a rights issue for \$10,000, or 6.0 cents a share.

Last month, Island said it had raised \$1.95 million in its two-for-five, non-renounceable rights offer at 6.0 cents a share (BD: Mar 19, 2024).

Island was up 0.1 cents or 1.6 percent to 6.2 cents.

ISLAND PHARMACEUTICALS

Island managing-director Dr David Foster says he has increased and been diluted from 5,211,393 shares (6.44%) to 5,803,284 shares (5.10%).

The Dallas, Texas-based Dr Foster said that on June 21, 2022 and March 26, 2024 he bought 71,303 shares on market for \$11,528, or an average of 16.2 cents a share, and with Terry Foster and Vickey Foster bought 520,588 shares in a rights issue on March 26, 2024 for \$31,235, or 6.0 cents a share (see above).

<u>OPTHEA</u>

Opthea says Sujal Shah will replace non-executive director Daniel Spiegelman, effective from today.

Opthea said Mr Shah was previously Cymabay Therapeutics chief executive officer and chief financial officer before its \$4.3 billion acquisition by Gilead Sciences and a healthcare investment banker for Citigroup and Credit Suisse and was currently Tvardi Therapeutics chair and a Stratus Therapeutics director.

The company said Mr Shah held a Bachelor of Science and Master of Science from Chicago's Northwestern University and a Master of Business Administration from the Pittsburgh, Philadelphia-based Carnegie Mellon University.

Opthea chair Dr Jeremy Levin said the company welcomed Mr Shah to its board of directors as it continues to "rapidly advance the registrational program for sozinibercept in wet [age-related macular degeneration] and prepare for key upcoming clinical, regulatory and commercial milestones".

Last month, the company said it had completed enrolment in its about 990-patient, phase III trial of sozinibercept, formerly OPT302, with aflibercept for wet age-related macular degeneration (BD: Feb 15, 2024).

Today, Dr Levin said "Mr Shah's significant experience driving value for biotechnology companies through successful product and commercial development will be an invaluable resource to the Opthea team as we enter this pivotal growth phase of the company." Dr Levin added that Opthea was "very grateful for Mr Spiegelman's contribution to the company."

Opthea fell 2.5 cents or 3.3 percent to 72.5 cents.