Biotech Daily

Thursday February 15, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 14%; PRO MEDICUS DOWN 13%**

*** PRO MEDICUS H1 REVENUE UP 30% TO $74m, PROFIT UP 33% TO $36m**

*** CLARITY: PROSTATE CANCER IMAGING 'SAFE, HIGHLY EFFECTIVE'**

*** BRANDON BIOCATALYST, AND HEALTH $50m FOR DEMENTIA**

*** OPTHEA ENROLS PHASE III OPT-302 (SOZINIBERCEPT) WET AMD TRIAL**

*** IMUGENE DOSES 1st I-V ONCARLYTICS CD19 TUMOR PATIENT**

*** MESOBLAST: REVASCOR WINS FDA ORPHAN DRUG STATUS FOR HLHS**

*** ACTINOGEN AWARDED XANAMEM UK 'INNOVATION PASSPORT'**

*** BIOINTELECT PARTNERS WITH CR2O FOR CRO CONSULTANCY**

*** ALGORAE TERMINATES NZENO PIG CELL AGREEMENT**

*** ANTEOTECH COMPLETES ANTEO X PRODUCTION FACTORY**

*** CRYOSITE EGM 99.99% BACK CAPITAL RETURN**

*** RHINOMED REQUESTS SUSPENSION FOR REMOVAL FROM ASX**

*** AUSCANN WITHDRAWS $1m SHARE PLAN FOR 'COMPLIANCE'**

*** PERENNIAL REDUCES TO 12.5% OF LUMOS**

MARKET REPORT

The Australian stock market was up 0.77 percent on Thursday February 15, 2024, with the ASX200 up 58.0 points to 7,605.7 points. Twenty of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Actinogen was the best for the second day in a row, up 0.6 cents or 13.95 percent to 4.9 cents, with 21.9 million shares traded. Cynata, Dimerix and Mesoblast climbed more than nine percent; Genetic Signatures was up 5.1 percent; Syntara (Pharmaxis) improved 4.35 percent; Amplia was up 3.8 percent; Impedimed, Nanosonics, Polynovo and Prescient rose two percent or more; Clarity, CSL, Orthocell, Paradigm, Percheron (Antisense), Proteomics and SDI were up one percent or more; with Clinuvel, Cochlear, Cyclopharm, Neuren and Resmed up by less than one percent.

Pro Medicus led the falls, following record half-year results, down $14.09 or 13.0 percent to $94.00, with 708,163 shares traded. Immutep lost 5.5 percent; Atomo, Compumedics, Medical Developments and Telix were down more than three percent; Alcidion shed two percent; with Avita and Emvision down by less than one percent.

PRO MEDICUS

Pro Medicus says revenue for the six months to December 31, 2023 was up 30.3 percent to a record $74,110,000 with net profit after tax up 33.3 percent to a record $36,250,000.
Pro Medicus said that revenue came from sales of its Visage 7 imaging platform, picture archiving communications systems and radiology information systems.
The company said that during the six-month period it won four contracts worth a total of $200 million, with contract terms ranging from seven-to-10 years.
Pro Medicus said a fully franked interim dividend of 18.0 cents a share for holders at the record date of March 1 would be paid on March 22, 2024.
Pro Medicus chief executive officer Dr Sam Hupert said the company was “very pleased with the results, which was a record one for the company in terms of revenue and net profit as well as new sales”.
“We benefited from above industry growth in exam volumes across our client base and successfully completed four new implementations all of which will provide a full six months of revenue in the second half,” Dr Hupert said. “On top of this, we had our strongest start to the year in terms of sales, so, we believe our second half will be stronger than our first, forming the base for future growth [in 2024-’25] and beyond.”
The company said it aimed to “further build on its presence in North America, Germany and Australia and is actively pursuing a growing number of opportunities across key markets, academic medical centres, integrated delivery networks and corporate and private imaging centres”.
Pro Medicus said diluted earnings per share rose 33.3 percent to 34.61 cents, with net tangible assets up 58.3 percent to $1.33, and that it had cash of $99,759,000 at December 31, 2023 compared to $65,470,000 at December 31, 2022.
Pro Medicus fell $14.09 or 13.0 percent to $94.00 with 708,163 shares traded.

CLARITY PHARMACEUTICALS

Clarity says its 52-patient, phase I/II trial of copper-64 Sar-Bis-prostate specific membrane antigen (PSMA) shows it is “safe and highly effective in detecting tumors”.
Clarity said that the trial tested the effectiveness of copper-64 Sar-Bis-PSMA at detecting prostate cancer lesions in patients with biochemical recurrence.
The company said the primary efficacy endpoints of the trial were “patient-level correct detection … and region-level positive predictive value” and that 42 patients “were included in the calculation of efficacy endpoints”.
Clarity executive chair Dr Alan Taylor told Biotech Daily that the company’s same-day imaging agent was able to identify 29 of 50 patients, or 58.0 percent, with lesions undetectable by standard-of-care imaging, and with next-day imaging it identified up-to 40 of 50 patients, or 80.0 percent, with high specificity on both days.
The company said the number of lesions identified on next-day imaging “almost doubled compared to same-day imaging” from 80 to 153 lesions.
Clarity said one adverse event was related to the administration of copper-64 Sar-Bis-PSMA, a grade two worsening of type II diabetes which resolved.
The company said clinicians reported that “they would change their treatment plan in approximately 50 percent of patients due to copper-64 Sar-Bis-PSMA scans”.
Clarity said it had begun planning a registrational phase III trial.
Dr Taylor said “the high rate of detection of [prostate cancer] in up-to 80 percent of patients that were negative or equivocal on [standard-of-care] imaging further brings to light the low sensitivity issues of current [standard-of-care] imaging”.
Clarity climbed four cents or 1.5 percent to $2.78 with 1.2 million shares traded.

BRANDON BIOCATALYST, AUSTRALIA'S NATIONAL DIGITAL HEALTH INITIATIVE

Brandon Biocatalyst says with AND Health, it has been awarded $50 million from the Federal Government's Medical Research Future Fund for dementia research.

Brandon Biocatalyst said it and AND Health had joined with Dementia Australia to deliver a Biomedtech Incubator to develop research discoveries and medical innovations with commercial potential to address dementia and cognitive decline.

The company said its program was designed to help participants be "investor-ready", with participating companies receiving access to research, translation and commercialization expertise across early-stage therapeutics, medical devices, diagnostics and digital health.

Brandon Biocatalyst said Dementia Australia would lead "a community advisory board comprising people impacted by dementia to ensure the views of the community, health providers, patients, and carers inform projects and guide the development of new technologies and treatments".

Brandon Biocatalyst chief executive officer Dr Chris Nave said that "nurturing the development of translational and commercialization skills in life sciences drives growth in a sector that employs individuals in high-skilled roles and facilitates the creation of therapies that save lives and enhance well-being locally and globally".

The company said the program was scheduled to open "later in 2024".

OPTHEA

Opthea says it has completed enrolment in its about 990-patient, phase III trial of OPT-302 with aflibercept for wet age-related macular degeneration (AMD).

In 2021, Opthea said it had treated the first of about 1,980 patients in the US and Canada, for its two randomized, double-blinded, controlled trials, evaluating the efficacy and safety of OPT-302, or sozinibercept, in combination with ranibizumab or OPT-302 with aflibercept, compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021)

Today, the company said it expected to complete enrolment of the phase III trial of OPT-302 with ranibizumab by January 2025, with top-line results from both trials expected by "mid 2025".

Opthea said both phase III multi-centre, double-blinded, placebo-controlled trials were designed to "assess the efficacy and safety of intravitreal 2.0 mg sozinibercept in combination with anti [vascular endothelial growth factor]-A treatments".

The company did not disclose the exact number of patients recruited in the study.

Opthea was unchanged at 57 cents.

IMUGENE

Imugene says it has dosed the first of 52 patients in the intravenous monotherapy arm of its phase I trial of its Oncarlytics CD19 oncolytic virotherapy for solid tumors.

Last year, Imugene said it had dosed the first combination patient in its up-to 52 patient, phase I trial with Oncarlytics and blinatumomab (BD: Oct 26, 2023).

At that time, the company said the trial of adult patients with advanced or metastatic solid tumors aimed to evaluate the safety and efficacy of both intra-tumoral injection and intravenous infusion of Oncarlytics alone and in combination with blinatumomab.

Today, the company said the patient was a bile tract cancer patient dosed at the Duarte, California-based City of Hope's Comprehensive Cancer Center, and that it expected to open additional sites for recruitment.

Imugene was unchanged at 11 cents with 17.85 million shares traded.

MESOBLAST

Mesoblast says the US Food and Drug Administration has granted Revascor orphan-drug designation for paediatric hypoplastic left heart syndrome (HLHS).

Last month, Mesoblast said it had FDA rare paediatric disease designation for its mesenchymal precursor cells Revascor, or rexlemestrocel-L, for hypoplastic left heart syndrome in children (BD: Jan 21, 2024).

Today, Mesoblast chief executive said Prof Silviu Itescu said the company was “very pleased to have now been granted both orphan-drug designation and rare pediatric disease designation by [the] FDA for Revascor in the treatment of children with this often-fatal congenital heart condition”.

“The designations were granted on the back of the results from children in a randomized, controlled trial indicating that Revascor may increase the ability to successfully accomplish life-saving surgery,” Prof Itescu said.

The company said its 19-patient trial of a single intra-myocardial administration of Revascor led to “significantly larger increases in left ventricular end-systolic and end-diastolic volumes over 12 months compared with controls as measured by 3-dimensional echocardiography ($p = 0.009$ and $p = 0.020$, respectively)”.

“We plan to meet with [the] FDA to discuss the pathway for approval in this indication,” Prof Itescu said.

Mesoblast was up 2.5 cents or 9.1 percent to 30 cents with 12.8 million shares traded.

ACTINOGEN MEDICAL

Actinogen says the UK Medicines and Healthcare products Regulatory Agency has approved an innovation passport for Xanamem as a treatment of Alzheimer’s disease.

According to the UK Medicines and Healthcare products Regulatory Agency (MHRA) website, an innovation passport “provides applicants with access to a toolkit to support the design, development and approvals process”.

The company said “the next step in the Innovative Licencing and Access Pathway process will be to commence development of the Target Development Profile”.

According to the MHRA website a target development profile toolkit “provides activities to support the design and development of medicines”.

Actinogen managing-director Dr Steven Gourlay said the approval validated the company’s “belief in Xanamem” for the treatment of Alzheimer’s disease.

Actinogen was up 0.6 cents or 13.95 percent to 4.9 cents with 21.9 million shares traded.

BIOINTELECT

Biointelect says it will work with the Utrecht, Netherlands-based CR2O BV and provide “strategic product development consultancy and commercialization capabilities”.

Biointelect said CR2O was a contract research organization for public organizations in the biotechnology and pharmaceutical industries and had managed clinical development programs and trials in Australia, Europe and the US.

Biointelect chief executive officer Leah Goodman said the partnership would “mean strengthened confidence for clients in reaching their goals and an enhanced customer experience with a focus on performance”.

“The alliance with CR2O will generate even greater returns for clients across the full innovation journey via a consolidated service offer with a trusted partner,” Ms Goodman said.

Biointelect is a private company.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has terminated its agreement with NZeno to reduce its monthly expenditures and focus on “new avenues of research enquiry” for its NTcell program.

In 2022, the-then Living Cell said it would pay the Auckland-based NZeno up-to $NZ1.25 million ($A1.17 million) for pig tissue for a third trial of its encapsulated pig brain choroid NTcell for Parkinson’s disease (BD: Jan 24, 2022).

Today, the company said it was investigating the utility of a therapeutic approach that combined deep brain stimulation and its NTcell implanted therapy, and no longer needed a supply of pig tissue.

Algorae said it would enter discussions with NZeno “for the provision of choroid plexus tissue on a good faith basis in the future, considering the status of both businesses at that time”.

Algorae was unchanged at one cent.

ANTEOTECH

Anteotech says it has completed construction of its Anteo X production factory in Brisbane, for a total cost of about $700,000.

Anteotech said the facility, located adjacent to its corporate offices and laboratories would enable the initial production of 20,000 litres of Anteo X, and could potentially be expanded to 80,000 litres a year at a nominal incremental cost.

The company said that Anteo X was a “cross-linker additive that reinforces battery binders in silicon-containing anodes boosting the performance”.

Anteotech has also developed molecular binding agents for use in biotechnology and medical research.

Anteotech chief executive officer David Radford said completing the facility “was a key milestone … [and] a timely investment given the rapid developments within the Lithium-ion battery markets”.

Anteotech was up 0.1 cents or 3.2 percent to 3.2 cents with 3.45 million shares traded.

CRYOSITE

Cryosite says its 99.99% of its extraordinary general meeting approved its resolution to conduct an equal reduction of capital.

Last month, Cryosite said it would conduct a reduction of capital through a capital return to shareholders at 5.0 cents a share, subject to shareholder approval (BD: Jan 21, 2024).

At that time, the company said the return was conditional on the number of issued shares in the company not exceeding 49,000,000, which would mean that it would return up-to $2,450,000.

Cryosite said the capital return had a record date of February 22 and would be paid on February 29, 2024.

Cryosite was untraded at 68 cents.

RHINOMED

The ASX says Rhinomed will be suspended from the close of trading today, at its request under Listing Rule 17.2, to facilitate its removal from the official list.

Earlier this year, Rhinomed said that 98.79 percent of its extraordinary general meeting voted to delist from the ASX (BD: Dec 11, 2023; Jan 21, 2024).

Rhinomed last traded at four cents.

AUSCANN GROUP HOLDINGS

Auscann says it has withdrawn its $1 million share plan due to “potential implications” it may have on re-compliance with Chapters 1 and 2 of the ASX Listing Rules.

Last month, Auscann said it hoped to raise $1 million through a non-underwritten share plan at 1.6 cents a share to fund ongoing operating costs, including costs incurred seeking to re-comply with the ASX’s admission and quotation requirements (BD: Jan 25, 2024).

In 2022, the ASX said the company had been suspended pending a proposed transaction and re-compliance with the chapters 1 and 2 of the Listing Rules, requiring a proposed acquisition to have shareholder approval (BD: Sep 1, 2022).

Today, Auscann said all payments already received under the capital raising would be refunded to shareholders in full without interest within five-to-seven business days.

Auscann was in a suspension and last traded at four cents a share.

LUMOS DIAGNOSTICS

Perennial Value Management says it has reduced its substantial shareholding in Lumos from 65,644,275 shares (13.64%) to 59,963,027 shares (12.46%).

The Sydney-based Perennial said that between January 16 and February 12, 2024 it bought and sold shares, with the single largest sale on February 7 of 1,583,913 shares for $134,969, or 8.5 cents a share.

Lumos fell 0.1 cents or 1.3 percent to 7.8 cents with 5.4 million shares traded.