Biotech Daily

Monday August 26, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 88%; PRESCIENT DOWN 11%**

*** MEDICAL DEVELOPMENTS REVENUE UP 2.5% TO $33m; LOSS UP 631% TO $41m**

*** NOVA EYE REVENUE UP 37% TO $23m; LOSS DOWN 42.5% TO $9m**

*** IDT REVENUE UP 93% TO $13.6m; LOSS DOWN 36% TO $5m**

*** CORRECTION: PROTEOMICS**

*** RADIOPHARM PAYS $5.9m FOR 24% OF MD ANDERSON J-V**

*** UNIVERSAL BIOSENSORS ADDS $450k TO INDIA XPRECIA PRIME DEAL**

*** ACTINOGEN: XANAMEM CONTROLS BRAIN CORTISOL; ANTI-DEPRESSANT**

*** PHARMAUST: 'NO FUNCTIONAL DECLINE' IN 5 OF 9 MND PATIENTS**

*** LBT DEVELOPING 55mm APAS MODULE**

*** LUMOS, BURNET DEVELOP P-O-C LIVER ALT TESTS**

*** TRYPTAMINE DOSES PHASE Ib TRP-8803 I-V PSILOCYBIN TRIAL**

*** APG BELOW 5% OF COCHLEAR**

*** FIRSTCAPE TAKES 8.8% OF AROA**

*** REGAL FUNDS TAKES 8% OF RADIOPHARM**

*** LANTHEUS TAKES 7% OF RADIOPHARM**

*** MICHELLE PARKER REPLACES CLARITY DIRECTOR ROB THOMAS**

MARKET REPORT

The Australian stock market was up 0.76 percent on Monday August 26, 2024, with the ASX200 up 60.6 points to 8,084.5 points. Eighteen of the Biotech Daily Top 40 companies were up, 16 fell and six traded unchanged. All three Big Caps fell.

Actinogen was the best, up 2.1 cents or 87.5 percent to 4.5 cents, with 180.2 million shares traded. Syntara was up 9.4 percent; Clarity and Compumedics climbed six percent; or more; Aroa rose 5.5 percent; Micro-X and Starpharma were up more than four percent; Telix was up 3.55 percent; Dimerix, Genetic Signatures, Nova Eye and Percheron rose more than two percent; 4D Medical, Avita, Clinuvel and Proteomics were up one percent or more; with Cyclopharm and Neuren up by less than one percent.

Prescient led the falls for the second trading day in a row, down 0.5 cents or 10.6 percent to 4.2 cents, with 2.75 million shares traded. Alcidion lost 8.2 percent; Curvebeam fell 7.5 percent; Resonance retreated 5.2 percent; Atomo and Polynovo fell more than four percent; Medical Developments and Opthea were down more than three percent; Cynata and Pro Medicus shed more than two percent; Cochlear, Emvision, Immutep, Medadvisor and Resmed were down more than one percent; with CSL, Mesoblast, Nanosonics and SDI down by less than one percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says revenue for the year to June 30, 2024 was up 2.5 percent to $33,149,000, with net loss after tax up 630.8 percent to $40,992,000.
Medical Developments said revenue for its Penthrox inhaled methoxyflurane analgesic for pain management was up 4.15 percent to $21,296,000, with revenue for its respiratory products up 1.1 percent to $11,853,000.
The company said an “options program” for its chief executive officer Brent MacGregor was cancelled, resulting in a $5.1 million expense; it paid $15.8 million for the “impairment of capitalized development costs relating to the US market entry” and $600,000 in costs related to “redundant plant and equipment in the manufacturing operations”; and in the prior corresponding period it received $18,928,000 as contract termination revenue.
Medical Developments said it would purse “positive operating cashflow” in the coming financial year, by improving margins, increasing sales of Penthrox and its respiratory products and reducing expenditure to between $1.5 million and $2.0 million.
The company said diluted loss per share was up 613.2 percent to 47.50 cents, net tangible asset backing per share fell 33.75 percent to 26.5 cents, and it had cash and equivalents of $9,735,000 at June 30, 2024, compared to $24,661,000 at June 30, 2023.
Medical Developments fell 1.5 cents or 3.2 percent to 45 cents.

NOVA EYE MEDICAL

Nova Eye says revenue for the year to June 30, 2024 was up 37.0 percent to $23,325,000, with net loss after tax down 42.5 percent to $8,790,000.
Nova Eye said revenue was from sales of its Itrack Advance glaucoma consumable surgical device, which had improved gross margins and returns on investments, particularly in the US, with sales up 71 percent to $US11.4 million ($A16.8 million).
Nova Eye managing-director Tom Spurling told Biotech Daily the company was “very happy with the glaucoma segment second half [earnings before interest, taxation, depreciation and amortization] loss of … $400,000, an improvement of $3.3 million on the prior corresponding period”.
The company said it expected sales to be “strengthened by proposed changes in US Medicare reimbursement rates for surgeries using the company’s products”, with a proposed 30 percent reimbursement increase effective from January 1, 2025.
Nova Eye said diluted loss per share fell 56.1 percent to 4.31 cents, net tangible asset backing per share was down 2.3 percent to 4.3 cents, and it had cash and equivalents of $6,151,000 at June 30, 2024 compared to $7,419,000 at June 30, 2023.
Nova Eye was up half a cent or 2.2 percent to 23.5 cents with 1.6 million shares traded.

IDT AUSTRALIA

IDT says revenue for the year to June 30, 2024 was up 93.2 percent to $13,588,000, with net loss after tax down 36.3 percent to $5,413,000.
IDT said revenue was from sales of its specialty oral products including medical marijuana and psychedelics, as well as active pharmaceutical ingredients and advanced therapies.
The company said several customers had “progressed their assets during the year, which means return sales and larger quantities”.
IDT said diluted loss per share fell 54.3 percent to 1.6 cents, with net tangible assets per share down 15.9 percent to 6.67 cents, and it had cash and equivalents of $504,000 at June 30, 2024 compared to $4,433,000 at June 30, 2023.
IDT was unchanged at 11.5 cents.

CORRECTION: PROTEOMICS INTERNATIONAL LABORATORIES

Friday's edition incorrectly said Proteomics revenue of $892,143 came from sales of Promarker D, when in fact it was obtained from analytic services and licencing income.
The Friday sub-editor also improperly demoted Proteomics managing-director Dr Richard Lipscombe to chief executive officer and has in turn been demoted to chief bottle washer and general dogsbody/gofer.
We apologize unreservedly for the errors.
Proteomics was up 1.5 cents or 1.7 percent to 88 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has paid MD Anderson Cancer Centre $US4 million ($A5.9 million) to increase to 75 percent ownership of its Radiopharm Ventures joint-venture.
In 2022, Radiopharm said it had a joint-venture with the Houston, Texas-based University of Texas MD Anderson Cancer Centre to develop radio-pharmaceutical products for cancer and hoped to develop least four therapeutic products based on the MD Anderson Centre's intellectual property (BD: Sep 14, 2022).
Today, the company it had "committed an additional $US4.0 million ($A5.9 million) to the joint venture to cover future pre-clinical and clinical expenses".
Radiopharm said it had increased its ownership as the joint venture which continued "to show promising progress in its cancer therapeutic pipeline, including the advancement of its leading B7H3 candidate and other preclinical assets".
The company said the B7H3 monoclonal antibody lead candidate was an immune checkpoint protein with high expression in cancer and was associated with greater tumor size and lymphatic invasion.
Radiopharm said two other pre-clinical assets had shown "early positive results and have progressed towards final candidate selection, with potential applications across multiple solid tumor types".
Radiopharm chief executive officer Riccardo Canevari said the company was "encouraged by the progress to date within Radiopharm Ventures […] the increased ownership by RAD, coupled with the advancements in the associated programs, positions us well to enter a phase I clinical trial with B7H3 next year".
Radiopharm was unchanged at 3.4 cents with 3.7 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has revised a sales contract for its Xprecia Prime blood coagulation tests in India worth more than $550,000.
Last year, Universal Biosensors said the Indian Central Drugs Standard Control Organisation had approved its Xprecia Prime blood coagulation test, with the first order delivered, worth "under $100,000" (BD: Aug 31, 2023).
Today, the company said the deal with its New Delhi-based partner Point of Care Biosystems Inc had been amended to include an additional 600 Xprecia Prime units and 55,000 strips to be delivered by the end of 2024.
Universal Biosensors said it had increased its expected orders from Point of Care Biosystems Inc to 1,275 Xprecia devices and 375,000 strips for the year to June 30, 2025, with the total deal anticipated to be worth more than $1,250,000.
Universal Biosensors was unchanged at 15 cents.

ACTINOGEN MEDICAL

Actinogen says further phase IIa data shows 10mg of Xanamem is “clinically active in controlling brain cortisol and has clinically significant anti-depressant activity”.

In 2022, Actinogen said a six-week, phase II, proof-of-concept study of daily oral 10mg Xanamem cortisol synthesis inhibitor would be compared to placebo and anti-depressant therapy, for effects on depression and cognition (BD: Jun 14, 2022).

Earlier this month, the company said the trial did not meet the primary endpoint of superiority to placebo in a cognitive ‘attention composite’ of three Cogstate tests due to an “unexpectedly large improvement in the placebo group” (BD: Aug 12, 2024).

At the time, Actinogen said Xanamem led to “clinically significant benefits” in the secondary endpoint of changes from baseline on the Montgomery-Asberg Depression Rating Scale (MADRS) compared to placebo after six weeks of treatment ($p = 0.11$) and four weeks post-treatment ($p = 0.02$).

Today, Actinogen said “ongoing analysis” had confirmed MADRS depression score improvement ($p < 0.05$) and positive effects were observed in five of six pre-specified subgroups, indicating broad effect in the population studied.

The company said further analysis of Patient Global Impression of Severity (PGI-S) scores showed “consistent Xanamem benefits that corroborate MADRS observations”.

Actinogen said further analysis of depression “responders”, or patients with MADRS score of less than 10 points, “confirmed maximal Xanamem effect at week-10 with 50 percent higher rate of remission of depression seen”, with Xanamem treated patients at 26 percent compared to placebo at 17 percent.

The company said Xanamem’s benefit on depression for all endpoints was “maximal at week 10, four weeks after finishing the six-week course of treatment, pointing to a durable therapeutic effect resulting from controlling brain cortisol”.

Actinogen managing-director Dr Steven Gourlay said the data was “incredibly good news for Actinogen and for the many patients who may benefit from Xanamem in the future”.

“This trial shows that Xanamem’s mechanism of cortisol control in the brain has major clinical impact,” Dr Gourlay said. “This trial confirms our conclusion that a 10mg daily dose of Xanamem is clinically active in the brain and has the potential to be an effective anti-depressant with a novel mechanism.”

“While the anti-depressant market is competitive, Xanamem’s safety profile stands it apart from the competitors and the durability of benefit seen is intriguing,” Dr Gourlay said.

“Anti-depressant activity would also be a beneficial feature of Xanamem treatment for Alzheimer’s disease, where depressive symptoms often occur,” Dr Gourlay said.

Actinogen was up 2.1 cents or 87.5 percent to 4.5 cents with 180.2 million shares traded.

PHARMAUST

Pharmaust says after four months, five of nine patients in its 12-month extension study of monepantel for motor neuron disease (MND) show “no functional decline”.

Earlier this year, Pharmaust said it had dosed nine patients in its up-to 12-patient, open-label, phase I, 12-month extension study of monepantel for motor neuron disease (MND), or amyotrophic lateral sclerosis (ALS); and later, said it had approval to enrol the final three patients (BD: Feb 14, Apr 10, 2024)

Today, Pharmaust said compared to matched controls from a historical database 10mg/kg monepantel led to “significantly increased survival” ($p = 0.00034$), “significantly reduced risk of death by 80.3 percent” ($p = 0.0059$) and “reduced the rate of ALS functional decline by 43.2 percent” with some patients entering their 23rd month of monepantel treatment.

Pharmaust was up one cent or 5.9 percent to 18 cents with 4.0 million shares traded.

LBT INNOVATIONS

LBT says it is developing a module for its automated plate assessment system (Apas) to read 55mm contact plates for pharmaceutical environmental monitoring.
LBT said environmental monitoring was “a critical control measure used to monitor potential contamination within pharmaceutical manufacturing environments”.
The company said pharmaceutical companies used 90mm culture plates and smaller 55mm contact culture plates for monitoring microbial contamination.
LBT said it would develop an Apas module that could process the smaller 55mm contact culture plates, which it expected to complete by July 2025, with “several customers” having already expressed interest in the technology.
The company said customers would choose to buy one module or multiple modules, meaning the additional contact plate module would “increase the annual reoccurring revenue opportunity for every instrument sold”.
LBT said it had reduced its $1.5 million MTP Connect clinical translation and commercialization medical technology program grant to $1.37 million and redirected the funds “towards the hardware and software development required to support the smaller contact plates”.
In 2022, the Federal Government said it would invest $13.9 million for two MTP Connect programs, including LBT’s plate reader (BD: Oct 21, 2022).
Today, the company said as development progressed, it would receive payments from MTP Connect for the remaining $1.1 million of the $1.37 million under the agreement.
Today, LBT managing-director Brent Barnes said the March 2024 Apas Independence launch had generated seven instrument sales and installed two evaluation instruments.
“We have commenced development of a new Apas analysis module to automate another test performed during routine environmental monitoring,” Mr Barnes said.
LBT fell 0.05 cents or 3.2 percent to 1.5 cents.

LUMOS DIAGNOSTICS HOLDINGS, BURNET INSTITUTE

Lumos says it will manufacture point-of-care blood tests to monitor liver function and study the tests in clinical trials with Melbourne’s Burnet Institute.
Last year, Lumos said it would work on a feasibility study with the Burnet’s Diagnostics Initiative for an undisclosed “range of human health applications” (BD: Jul 27, 2023).
At that time, the company said the agreement would build on preliminary proof-of-concept work by Burnet on a “companion diagnostic biomarker”, with the initial feasibility stage worth up-to $US200,000 ($A296,744) in revenue (BD: Jul 27, 2023).
Today, Lumos said it would produce alanine transaminase (ALT) point-of-care lateral flow tests, customized readers and a mobile ’phone application for a US trial to “collect real-world data … [for] product development efforts, including a home based, self-test format”.
The company said the tests would provide “rapid, near-patient measurement of blood levels of the liver biomarker alanine transaminase”, which when elevated could indicate liver injury, possibly from a drug reaction.
Lumos said the collaboration would begin this month and support the production of the tests “for use by healthcare professionals with high-risk patients undergoing routine liver function monitoring.”
The company said it would provide development, regulatory and manufacturing services to the Burnet Diagnostics Initiative for the next nine to 12 months, for $US700,000 to $US1.0 million, and if successful, it expected to further support the Burnet Diagnostics Initiative “in the next phase of trials and regulatory submissions”.
Lumos was up 0.3 cents or 8.1 percent to four cents with 2.2 million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has dosed all 11 participants in its open-label phase Ib study of its intravenous psilocin-based TRP-8803.

In June, Tryptamine said it had dosed the first of up-to 12 participants in a dose-finding study of its intra-venous hallucinogenic TRP-8803 psilocin (BD: Jul 1, 2024).

Today, the company said the study was designed to "refine and optimize dosing and infusion rates for TRP-8803 in volunteers to achieve precise blood levels of psilocin with an acceptable pharmacokinetic profile to determine TRP-8803's ideal safety profile for therapeutic use in patients".

Tryptamine said TRP-8803 was successfully administered at increasing doses for a period of up-to 150 minutes, with all volunteers safely discharged following treatment and dosing follow-up.

The company said a safety review of its data was underway, with results to be used for patent applications, anticipated "in the near term", and underpinning future trials in indications including binge eating disorder and fibromyalgia syndrome.

Tryptamine chief executive officer Jason Carroll said completing dosing of the study was a "major achievement" and that the results would "continue to build on our thesis that Tryp's innovative and proprietary IV-infusion may overcome the significant problems associated with oral dosing of a psychedelic pharmaceutical compound."

Tryptamine was up 0.1 cents or five percent to 2.1 cents with 4.8 million shares traded.

COCHLEAR

The Amsterdam, Netherlands-based APG Asset Management NV says it has ceased its substantial shareholding in Cochlear.

APG said that between June 28, 2021 and August 22, 2024 it bought and sold shares in more than 900 transactions, with the last sale 637,234 shares for $195,195,034 or $306.32 a share.

Cochlear fell $5.69 or 1.9 percent to $300.80 with 171,525 shares traded.

AROA BIOSURGERY

Firstcape Group Ltd says it has increased its substantial shareholding in Aroa from 24,894,494 shares (7.232%) to 30,421,199 shares (8.820%).

The Wellington, New Zealand-based Firstcape said that with Harbour Asset Management, BNZ Investments and Jarden Wealth, between May 30 and July 3, 2024 it sold 1,509,395 shares for $919,663, or 60.9 cents a share, and on August 22 and 23, 2024 bought 7,036,100 shares for 45.0 cents a share.

Aroa was up 2.5 cents or 5.5 percent to 48 cents.

RADIOPHARM THERANOSTICS

Regal Funds Management Pty Ltd says it has increased its substantial shareholding in Radiopharm from 75,246,901 shares (7.12%) to 160,080,333 shares (8.30%).

The Sydney-based Regal Funds said that between August 2 and 12, 2024 it sold 5,369,673 shares for $179,118, or 3.3 cents a share and on August 16 and 21, 2024 bought 90,203,105 shares for $3,607,312, or about 4.0 cents a share.

Earlier this year, Radiopharm said it had "firm commitments" to raise about $62.5 million at 4.0 cents a share in a placement, taking the total with the Lantheus placement to $70 million (BD: Jun 25, 2024).

RADIOPHARM THERANOSTICS

Lantheus Omega LLC says it has become a substantial shareholder in Radiopharm with 149,625,180 shares, or 7.2 percent of the company.
The Boston-based Lantheus said it bought the shares on August 23, 2024 for 5.0 cents a share through a share subscription agreement.
In June, Radiopharm said it raised $7.5 million at 5.0 cents a share in a placement to Lantheus and $3 million for selling two pre-clinical assets to Lantheus (BD: Jun 20, 2024).

CLARITY PHARMACEUTICALS

Clarity says it has appointed chief clinical officer Michelle Parker as an executive director, with director Rob Thomas resigning, effective from August 24, 2024.
Clarity said it had promoted Dr Othon Gervasio to chief medical officer, Dr Matt Harris to chief scientific officer, with head of clinical development Eva Lengyelova to join the executive team.
The company said Ms Parker was recently promoted to chief clinical officer, had worked in clinical operations for more than six years and had more than 20 years of experience in nuclear medicine, positron emission tomography and pharmaceuticals including as head of clinical research operations at Novartis Australia.
The company said Mr Thomas had retired following the completion of his tenure.
Clarity was up 40 cents or 5.95 percent to $7.12 with 2.15 million shares traded.