Biotech Daily

Monday October 21, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 11.5%; PARADIGM DOWN 15%**

*** IDT UNAUDITED Q1 REVENUE UP 70% TO $5.2m**

*** CHIMERIC 'COMMITMENTS' FOR $5m PLACEMENT**

*** RADIOPHARM, BAMF HEALTH PARTNER FOR PHASE IIb RAD101 TRIAL**

*** ONCOSIL UK DEVICE RENEWAL CERTIFICATION**

*** ANU: NLRC4 PROTEIN HELPS FIX CANCER-CAUSING DNA**

*** MONASH DISCOVERY 'MAY HELP FIGHT ANTIBIOTIC-RESISTANT BUGS'**

*** PYC VP-001 WINS FDA ORPHAN DRUG STATUS FOR RP11; TRADING HALT**

*** PARADIGM PREPARES FDA PHASE III PPS KNEE PAIN PROTOCOL**

*** COGSTATE UP-TO 10% SHARE BUY-BACK**

*** GENETIC SIGNATURES 500k BOARD OPTIONS, 56% DIRECTOR FEE HIKE AGM**

*** 4D MEDICAL 1m BOARD OPTIONS, 198k STOCK UNITS AGM**

*** ARCHER 11m BOARD OPTIONS AGM**

*** HERAMED REQUESTS 'CAPITAL RAISE' TRADING HALT**

*** GENETIC TECHNOLOGIES TAKES 'FUND RAISING' HALT TO SUSPENSION**

*** PARADIGM EXECUTIVE DIRECTOR DR DONNA SKERRETT TO CMO**

MARKET REPORT

The Australian stock market was up 0.74 percent on Monday October 21, 2024, with the ASX200 up 61.2 points to 8,344.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 19 were down, five traded unchanged and one was untraded. All three Big Caps rose.

Universal Biosensors was the best, up 1.5 cents or 11.5 percent to 14.5 cents, with 221,576 shares traded. Atomo climbed 4.8 percent; Avita and Syntara were up more than three percent; Cochlear, Orthocell, Polynovo and Prescient rose more than two percent; Cyclopharm, Dimerix, Opthea, Pro Medicus, Resmed and SDI were up more than one percent; with CSL, Genetic Signatures, Mesoblast and Nanosonics up by less than one percent.

Paradigm led the falls (see below), down four cents or 15.1 percent to 22.5 cents, with 3.2 million shares traded. Amplia lost 6.45 percent; Compumedics, Cynata and Impedimed fell more than four percent; 4D Medical, Actinogen, Clarity, Curvebeam and Percheron were down more than three percent; Medadvisor, Nova and Telix shed more than two percent; Aroa, Emvision, Medical Developments, Neuren and Proteomics were down more than one percent; with Alcidion down by 0.9 percent.

IDT AUSTRALIA

IDT says unaudited revenue for the three months to September 30, 2024 was up 70 percent to $5.2 million, the highest since starting its “strategic transformation program”.
IDT said that sales of its specialty orals business including medical marijuana products were up 2.3 percent on the previous corresponding period to $1.5 million, with revenue from its active pharmaceutical ingredient manufacturing business down 36.1 percent to $761,000 “due to the timing and cycling of orders”.
The company said $1.4 million of revenue was from its advanced therapies business including Sanofi Australia contracts and sales of its antibody drug conjugates and messenger RNA technologies.
IDT said it secured $6.8 million worth of customer contracts in the three months to September 30, 2024 “all from returning customers”.
The company said it submitted 37 customer proposals valued at $24.7 million, with about 60 percent to existing customers, supporting expectations of full-year results to June 30, 2025 “comfortably surpassing the prior year”.
In August, IDT reported revenue for the year to June 30, 2024 up 93.2 percent to $13,588,000 with net loss after tax down 36.3 percent to $5,413,000.
IDT chief executive officer Paul McDonald said that the three-month “performance puts us on track to exceed our 2023-’24 total revenue of $14.1 million”.
“Notably, we are also seeing a substantial amount of work coming from returning customers,” Mr McDonald.
“This trend speaks to the quality of our work, the establishment of more predictable revenue streams for the business and our unique capabilities that supports IDT’s market leadership position,” Mr McDonald said.
IDT was down half a cent or 3.85 percent to 12.5 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has “commitments” to raise $5 million at 0.8 cents a share in a two-tranche placement, with one attaching option for every share purchased.
Chimeric said the issue price was a 45.6 percent discount to the 15-day volume-weighted average price to September 30, 2024, or a 42.9 percent discount to the last closing price of 1.4 cents.
The company said the options were exercisable at 0.8 cents each within 12 months.
Chimeric said 69,990,000 shares would be issued in a first tranche under its placement capacity and the remaining 555,000,0000 shares and the options were subject to shareholder approval.
The company said the funds would be used “primarily to support the clinical trial pipeline and therapy portfolio”, including its CHM CDH17 chimeric antigen receptor T-cells and natural killer cell drug candidates, as well as general working capital and costs of the capital raising.
Chimeric said executive chair Paul Hopper had subscribed for 125 million shares, or $1 million of the $5 million placement, subject to shareholder approval.
The company said PAC Partners and Taylor Collison were joint lead managers to the placement.
Chimeric said that PAC Partners and Taylor Collison and would receive 55,000,000 unlisted options, exercisable at 1.6 cents each within three years, subject to shareholder approval.
Chimeric was in a suspension and last traded at 1.4 cents.

RADIOPHARM THERANOSTICS

Radiopharm says the Grand Rapids, Michigan-based BAMF Health will produce doses of RAD101 and run the first site for its phase IIb imaging study in brain metastasis.
Earlier this year, Radiopharm said it had investigational new drug approval from the US Food and Drug Administration for a phase IIb/III trial of fluorine-18 (18F)-pivalate, or RAD101, for imaging brain metastasis (BD: May 29, 2023, Jul 23, 2024).
Today, the company said BAMF (Bold Advanced Medical Future) Health would dose patients with RAD101 to detect and characterize brain metastasis.
Radiopharm said RAD101 was an imaging small molecule that targeted fatty acid synthase, a multi-enzyme protein which was over-expressed in many solid tumors including brain metastasis.
The company said its US, multi-centre, open-label, single-dose trial would study the imaging performance of RAD101 in patients with suspected recurrent brain metastases from solid tumors of different origins and was expected to enrol the first patient this year.
Radiopharm managing-director Riccardo Canevari said that the “disruption of [fatty acid synthase] activity allows for the accurate detection of cancer cells, representing a strongly viable target for the imaging of brain metastases”.
Radiopharm was up 0.2 cents or 7.1 percent to 3.0 cents with 13.7 million shares traded.

ONCOSIL MEDICAL

Oncosil says the British Standards Institution has granted its pancreatic cancer device UK conformity assessed (UKCA) renewal certification, with no post-market restrictions.
Oncosil said the certification allowed it to operate more efficiently in the UK, simplifying regulatory requirements, which would in turn reduce costs and accelerate sales.
The company said the certification showed “the solid clinical evidence supporting the safety of the … device and enables continued access to the UK market without additional compliance burdens”.
Oncosil said it expected to receive medical device regulation approval from the British Standards Institution in the “near future”, which would expand patient access to the device and “further strengthen its market position across Europe”.
Oncosil managing-director Nigel Lange said the renewal certificates without any post-market restrictions were “a major accomplishment”. “This achievement not only reinforces the trust in the safety of our device but also simplifies our operations in the UK.”
Oncosil fell 0.05 cents or four percent to 1.2 cents with 8.5 million shares traded.

AUSTRALIAN NATIONAL UNIVERSITY

The Australian National University says the immune protein NLRC4 “finds cancer-causing damaged DNA and puts up scaffoldings to repair damaged DNA”.
The ANU said that NLRC4 built scaffolds around cancer-causing damaged DNA to “stop less healthy cells from growing and dividing during the repair process”, and that stopping the division of damaged DNA was “important as it helps prevent healthy cells from turning into cancer cells or cells that are becoming cancerous from turning into a tumor”.
The ANU said that people with bowel cancer carried less NLRC4 in their body, making NLRC4 “a promising biomarker, meaning it helps predict who will fare better or worse after being diagnosed with bowel cancer”.
The research article, titled ‘Inflammasome protein scaffolds the DNA damage complex during tumor development’ was published in Nature Immunology, with an abstract available at: https://www.nature.com/articles/s41590-024-01988-6.

MONASH UNIVERSITY

Monash University says it has discovered how a hospital bacteria uses "'nano-weapons to enable their spread" which may help fight antibiotic-resistant superbugs.
Monash University said its researchers studied how the common hospital bacterium Acinetobacter baumannii, or A baumannii, used a 'nano-weapon' called type VI secretion system to inject toxins into nearby bacteria, which killed them and allowed it to spread.
The University said A baumannii was particularly dangerous as it was "often resistant to common antibiotics, making infections hard to treat".
The University said the World Health Organization had listed A baumannii as "a top-priority critical bacterium, where new treatments are urgently needed".
Monash University said the study was conducted at its Biomedicine Discovery Institute (BDI), and that BDI Boyce laboratory lead and senior study author Prof John Boyce said the research was "a significant step in the fight against antibiotic-resistant superbugs".
The research article, titled 'Structure of a Rhs effector clade domain provides mechanistic insights into type VI secretion system toxin delivery' was published in Nature Communications, with the full article available at: https://bit.ly/4eQQMAv.
Study co-author Dr Marina Harper said that "in many environments, A baumannii must engage in bacterial 'warfare' to survive in the presence of other species."
"To outcompete surrounding bacteria, A baumannii uses a nano-weapon called the type VI secretion system," Dr Harper said.
"This is a tiny needle-like machine that injects toxins directly into nearby bacteria, killing them so that A baumannii can dominate," Dr Harper said.
Co-author Dr Brooke Hayes said researchers "learned how this toxin, called Tse15, is attached to the needle and then delivered into other bacteria to kill them".
"We showed that the toxin is stored in a protective cage-like structure inside A baumannii, preventing it from harming the bacterium itself," Dr Hayes said.
"When ready to attack other bacteria, the toxin must be released from the cage," Dr Hayes said.
"This happens through a series of interactions between the toxin, the exterior of the cage, and the T6SS needle," Dr Hayes said.
"Once the needle injects the toxin into a competitor, the toxin activates and kills the other bacterium, allowing A baumannii to take over that surface," Dr Hayes said.
Monash's Prof McGowan said understanding how such toxins were delivered "may allow us to engineer new protein toxins for delivery into bacteria".
"By learning how this system works, we can explore new ways to fight against antibiotic resistant bacteria like A baumannii," Prof McGowan said.

PYC THERAPEUTICS

PYC says it has US Food and Drug Administration orphan drug designation for VP-001 for retinitis pigmentosa type-11 (RP11) and has requested a trading halt.
PYC said designation benefits included tax credits, exemptions from some regulatory fees and the potential for seven years of market exclusivity post approval.
The company said VP-001 was "the first drug candidate for patients" with RP11, a childhood blinding eye disease, to have progressed into human trials.
Separately, PYC said it had requested a trading halt "pending an announcement to the market in relation to the ongoing retinitis pigmentosa type 11 clinical trials".
Trading will resume on October 23, 2024, or on an earlier announcement.
PYC last traded at 20 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it will submit the final protocol for its 'PARA_OA_012' phase III trial of PPS for knee osteoarthritis to the US Food and Drug Administration by next month.

In 2018, Paradigm said its 112-patient, phase IIb trial showed pentosan polysulfate sodium (PPS), or Zilosul, significantly reduced knee osteoarthritis pain compared to placebo (p = 0.031) (BD: Dec 18, 2018).

In 2020, the company said it met the FDA to discuss a phase III trial of PPS for osteoarthritis and the FDA required two large phase III trials (BD: Feb 21, Apr 6, 2020).

In 2021, the company said it had filed an investigational new drug submission to the FDA for a randomized, phase III trial of PPS for knee osteoarthritis, and later said it had FDA approval for a 930-patient, phase III trial of PPS for knee osteoarthritis pain, called 'PARA_OA_002', after it responded to six FDA questions in relation to "non-clinical studies" (BD: Mar 26, Apr 26, May 25, Jun 30, Aug 3, Sep 27, Nov 3, 2021).

In 2022, the company said it had dosed the first two patients in the randomized, double-blind, placebo-controlled phase III trial at one of eight trial sites open in Australia, with first US patient dosing expected by April 2022 (BD: Jan 16, 2022).

Later, Paradigm said it had FDA fast track designation for its phase III program of pentosan polysulfate sodium for treatment of osteoarthritis, and that the designation would expedite development and new drug application review and allow it to submit portions of an applications for rolling review (BD: Apr 12, 2022).

Last year, Paradigm said it had European approval for its 'PARA_0A_002', 470-patient, phase III trial and later said it had recruited all 468 patients in stage 1 of its phase III trial comparing injectable pentosan polysulfate sodium to placebo for knee arthritis joint pain at 120 clinical trial sites in seven countries, including Australia, the US, Canada, Belgium, Poland and the Czech Republic (BD: Mar 14, Jul 4, 2023).

At that time, the company said its FDA new drug application remained on track and a data monitoring committee recommended the trial proceed to a pivotal phase III without modification.

Earlier this year, the company said it had responded to its FDA type D meeting to progress its phase III trial of PPS for osteoarthritis, and that its response included data from five non-clinical studies, its phase II trial, and the available data from the 600 patients dosed in stage one of the phase III trial (BD: Apr 19, 2024).

Last month, Paradigm said the FDA had provided a "clear pathway" for the trial, including guidance for its 2.0mg/kg PPS twice-weekly dosing and amendments to the monitoring and mitigation plan and statistical guidance (BD: Sep 18, 2024).

At that time, the company said it intended to implement these changes and submit the updated protocol under the current investigational new drug application.

Today, Paradigm said the submission would "incorporate amendments that were suggested and agreed upon during a comprehensive review process with the FDA".

The company said it was "optimistic" about completing the 30-day review period once the protocol was submitted before it could begin pre-screening and enrolment at sites in the US and Australia.

Paradigm said the modifications were expected to streamline the trial process, potentially reduce overall costs and it expected the adjustments to "positively impact the phase III trial budget".

The company said it was "confident that the final protocol aligns with the FDA's expectations".

Paradigm said it had shortlisted four contract research organizations to conduct its trial and expected to enrol the first patient by April 2025.

Paradigm fell four cents or 15.1 percent to 22.5 cents with 3.2 million shares traded.

COGSTATE

Cogstate says it has the potential for an on-market buy-back of up-to 10 percent of the shares on issue over the next 12 months, effective from November 11, 2024.
Cogstate said that between February 2023 and June 2024 it conducted a share buy-back and acquired “just over 4.39 million shares at an average price of $1.46”.
The company said the buy-back would be managed by Taylor Collison and “not subject to the same trading volume restrictions … imposed on the previous buyback”.
Cogstate said “the share buy-back program and the removal of volume restrictions reflects the board’s belief in the business’ strong capital position and supports our ambition to improve returns for our shareholders”.
The company said the maximum buy-back would be 17,264,489 shares.
Cogstate was up one cent or 1.1 percent to 92 cents.

GENETIC SIGNATURES

Genetic Signatures says its annual general meeting will vote to issue 500,000 options to director Neil Gunn and increase the total director fee pool by 55.55 percent to $700,000.
Genetic Signatures said shareholders would vote to issue non-executive director Neil Gunn 500,000 options, exercisable at 69 cents each, or the 30-day volume weighted average price to April 30, 2024, within 15 years of their vesting date.
The company said investors would vote to increase the non-executive director fee pool from $450,000 to $700,000 “to attract and retain suitably qualified non-executive directors to facilitate the ongoing program of board succession”.
Genetic Signatures said that shareholders would vote to issue US executive director Michael Aicher 66,666 shares valued at 75 cents each, as well as elect Mr Aicher, Anne Lockwood and Dr Jenny Harry as directors, adopt the remuneration report, ratify the issue of placement shares and options and approve its rights plan.
The meeting will be held at Allens, Deutsche Bank Place, Level 28, 126 Phillip Street, Sydney on November 20, 2024 at 9am (AEDT).
Genetic Signatures was up half a cent or 0.8 percent to 66 cents.

4D MEDICAL

4D Medical says its annual general meeting will vote to issue 1,092,539 options and 197,934 restricted stock units to its managing-director, chair and directors.
4D Medical said investors would vote to issue 775,339 long-term incentive performance options to managing-director Prof Andreas Fouras, exercisable at 75.34 cents each, or a 25 percent premium to the 30-day volume weighted average price, by June 30, 2028.
The company said the meeting would vote to issue chair Lilian Bianchi 91,257 options and directors John Livingston and Julian Sutton 60,147 options, each, with zero exercise price and expiring on June 30, 2029, as well as directors Dr Robert Figlin and Dr Geraldine McGinty 60,147 restricted stock units, each.
4D Medical said shareholders would vote to issue Ms Bianchi 105,649 options in lieu of 50 percent, or $49,327, of her base salary, expiring June 30, 2029 and 77,6409 restricted stock units in lieu of 50 percent, or $36,250, of Dr McGinty’s yearly fees.
The company said investors would vote on the remuneration report, re-elect directors Dr Figlin, approve its 10 percent placement facility and ratify the prior issue shares.
The meeting will be held at 700 Swanston Street, Carlton on November 20, 2024 at 10am (AEDT).
4D Medical fell two cents or 3.7 percent to 52 cents.

ARCHER MATERIALS

Archer says its annual general meeting will vote to issue 11 million options to executive chair Gregory English and directors Bernadette Harkin and Kenneth Williams.
Archer said shareholders would vote to issue Mr English 5,000,000 incentive options as well as 3,000,000 incentive options, each, to Ms Harkin and Mr Williams, exercisable at $1.79 each by May 31, 2025.
The company said the incentive options were in addition to Mr English's $495,664 fixed remuneration with superannuation and a 15 percent bonus for the year to June 30, 2025, as well as Ms Harkin's and Mr Williams' $78,050 annual salaries.
Archer said the meeting would vote to adopt its remuneration report, re-elect Mr Willians as a director and approve its 10 percent additional placement capacity.
The meeting will be held at Stone & Chalk Sydney Scaleup Hub, Level 2, 477 Pitt Street, Sydney on November 20, 2024 at 10.30am (AEDT).
Archer was unchanged at 25 cents.

HERAMED

Heramed has requested a trading halt pending an announcement "regarding a proposed capital raise'.
Trading will resume on October 23, 2024, or on an earlier announcement.
Heramed last traded at 2.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies has requested a suspension following Thursday's trading halt for its "operational review and progress on its fund raising" (BD: Jul 26, Oct 17, 2024).
Genetic Technologies said the suspension would allow it to "execute final agreements to secure funding to finalize its entitlement offer and secure a strategic distribution partnership, investment and minimum orders".
The company said it expected trading to resume on October 24, 2024, or on an earlier announcement.
Genetic Technologies last traded at 3.9 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says Dr Donna Skerrett will step down as executive director at its annual general meeting to "focus exclusively on her responsibilities as chief medical officer".
Paradigm said Dr Skerrett's "deep expertise and commitment to advancing the trial remain a crucial asset as Paradigm moves toward this key milestone".