Biotech Daily

Friday January 31, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MEDICAL DEVEL UP 51%; NOVA EYE DOWN 14%**

*** RESMED H1 REVENUE UP 11% TO $4b, PROFIT UP 32% TO $1.1b**

*** DR BOREHAM'S CRUCIBLE: MESOBLAST**

*** MEDICAL DEVELOPMENTS H1 RECEIPTS $19.2m**

*** MACH7 H1 RECEIPTS UP 3% TO $15.9m**

*** NOVA EYE EXPECTS FULL-YEAR REVENUE UP 18-25% TO $27.5m-$29m**

*** IMEX RECEIPTS UP 17% TO $24.4m**

*** GENETIC SIGNATURES H1 RECEIPTS UP 85% TO $10.3m**

*** VISIONEERING RECEIPTS UP 5% TO $14.7m; 3 MONTHS CASH**

*** CANN H1 RECEIPTS DOWN 28% TO $7.2m; 1.5 MONTHS CASH**

*** IMPEDIMED H1 RECEIPTS UP 3% TO $6.1m**

*** MESOBLAST H1 RECEIPTS DOWN 23% TO $4.9m**

*** LUMOS H1 RECEIPTS UP 23% TO $4.8m**

*** CONTROL BIONICS RECEIPTS UP 6% to $2.7m; 1.5 MONTHS CASH**

*** NOVA EYE RAISES $6.6m**

*** TELIX COMPLETES $372m IMAGINAB ACQUISITION**

*** MESOBLAST US RYONCIL GvHD LAUNCH**

*** AMPLIA ENROLS AMP 945 PANCREATIC CANCER TRIAL; 10 RESPONSES**

*** PYC BEGINS 2nd PYC-001 ADOA DOSE ESCALATION COHORT**

*** PARADIGM APPOINTS ADVANCED CLINICAL PHASE III TRIAL CRO**

*** NEUROTECH RECEIVES $2.4m FEDERAL R&D TAX INCENTIVE**

*** OPTISCAN RECEIVES $1.8m FEDERAL R&D TAX INCENTIVE**

*** MICRO-X REQUESTS CAPITAL RAISING' TRADING HALT**

*** BIO101 TIM LUSCOMBE REPLACES PROTEOMICS CO SEC KAREN LOGAN**

MARKET REPORT

The Australian stock market was up 0.45 percent on Friday January 31, 2025, with the ASX200 up 38.6 points to 8,532.3 points. Sixteen of the Biotech Daily Top 40 companies were up, 14 fell, eight traded unchanged and two were untraded.

Medical Developments was the best (see below), up 22.5 cents or 51.1 percent to 66.5 cents, with 1.8 million shares traded. Curvebeam climbed 10 percent; Opthea was up 9.6 percent; Atomo rose 8.3 percent; Amplia and Cynata were up seven percent or more; Orthocell was up 6.1 percent; Paradigm improved 5.4 percent; Alcidion and SDI were up more than four percent; Mesoblast was up 3.6 percent; Emvision and Pro Medicus rose more than two percent; Prescient and Telix were up more than one percent; with 4D Medical, Cochlear, CSL and Neuren up by less than one percent.

Nova Eye led the falls (see below), down 2.5 cents or 15.15 percent to 14 cents, with two million shares traded. Compumedics and Nanosonics lost more than three percent; Impedimed, Imugene, Proteomics and Universal Biosensors shed more than two percent; Aroa, Clarity, EBR, Immutep, Polynovo and Resonance were down more than one percent; with Clinuvel and Resmed down by less than one percent.

RESMED

Resmed says revenue for the six months to December 31, 2023 was up 10.7 percent to $US2,506,598,000 ($A4,035,883,000) with net profit after tax up 31.9 percent to $US683,699,000 ($A1,100,848,000).

Resmed said the increased revenue was “driven by increased demand for our sleep devices and masks portfolio, as well as solid growth across our residential care software business”.

The company cited both US generally accepted accounting principles (GAAP) and non-GAAP data, saying it used non-GAAP information because it provided “investors better insight when evaluating … performance from core operations and provides consistent financial reporting”. This report quotes the non-GAAP data.

Resmed said sales of sleep and respiratory products rose 10.7 percent for the six months to $US2,193,300,000, with software-as-a-service up 10.2 percent to $US313,300,000.

Resmed managing-director Michael Farrell said the company was “well-positioned to capitalize on the once-in-a-generation opportunities we have with the recent introduction and adoption of consumer wearables that track sleep health, as well as use of [glucagon-like peptide-1] therapies,” Mr Farrell said.

“We believe these developments will drive increased patient flow as we continue to educate people on the benefits of healthy sleep and breathing, with care delivered right in their own home,” Mr Farrell said.

The company said that research and development expenses were up 7.6 percent to $US160,897,000, or 6.4 percent of total revenue as compared to $US149,590,000 or 6.6 percent of total revenue in the prior corresponding period.

Resmed said it would pay an unfranked dividend of 53 US cents to shareholders at the record date of February 13, payable on March 20, 2025.

The company said non-GAAP diluted earnings per share rose 31.9 percent to $US4.63 for the six months to December 31, 2024.

Resmed said that it had cash and equivalents of $US521,944,000 at December 31, 2024 compared to $US210,247,000 at December 31, 2023.

Resmed fell 32 cents or 0.8 percent to $40.18 with 1.55 million shares traded.

DR BOREHAM'S CRUCIBLE: MESOBLAST

By TIM BOREHAM

ASX code: MSB

Nasdaq code (American depository shares): MESO

ASX shares on issue: 1,270,527,187; **Share price:** $3.17

Market cap: $4.03 billion

Chief executive: Prof Silviu Itescu

Board: Jane Bell (chair), William Burns, Prof Itescu, Dr Eric Rose (chief medical officer), Philip Facchina, Dr Philip Krause

Financials (December half 2024): receipts $US3.1 million (down 21%), cash outflows $US20.65 million ($US26.57 million previously), cash on hand circa $US200 million ($A322 million) after January's $US160 million placement

Identifiable major shareholders: G to the Fourth Investments LLC (Dr Gregory George) circa 18%, Prof Silviu Itescu 6.2%

Fresh from its landmark US regulatory approval for its stem-cell product for paediatric graft-versus-host disease (GvHD), Mesoblast plans to waste no time pursuing consent for the much bigger indications of heart disease and back pain.

Other inflammatory diseases such as irritable bowel syndrome (IBS) are also on the cards, along with adult GvHD.

For those who might have forgotten after a hazy summer, in December the US Food and Drug Administration (FDA) approved Mesoblast's Ryoncil for children two years and older who are resistant to the standard-of-care steroids.

The treatment is based on mesenchymal stromal cells (MSCs), a program Mesoblast acquired in 2013 (see below).

Ryoncil is the first GvHD stem cell therapy approved by the agency and the first of any sort of mesenchymal stem cell therapy.

Mesoblast founder and CEO Prof Silvio Itescu says the "historic" approval paves the way for Mesoblast to pursue the other indications.

"We have created a benchmark for the whole industry," he says.

Not wasting the moment, in January the company executed a $US160 million ($260 million) capital raising, by way of a placement.

Try and try again

Graft-versus-host disease affects about half of all allogeneic (off-the-shelf) bone marrow transplant recipients, affecting the skin, liver and gastrointestinal tract.

There are more than 30,000 bone marrow transplants annually, with about 1,500 childhood cases in the US. About half of them will develop GvHD.

In the case of patients resistant to the standard-of-care of steroids, mortality rates are as high as 90 percent.

GvHD is commonly treated with steroids, but this treatment is ineffective for many patients.

The approval marks third time lucky for Mesoblast.

In August last year, the FDA knocked back the so-called biologics marketing application and told the company to do another phase III trial. The same thing happened in 2020.

About Mesoblast

Mesoblast is using its proprietary mesenchymal lineage cell technology platform to develop allogeneic cellular medicines, to treat complex inflammatory diseases resistant to the standard of care.

These cells “respond to tissue damage, secreting mediators that promote tissue repair and modulate immune responses” the company says/

Mesoblast selects precursor and stem cells from the bone marrow of healthy adults, creating a master cell bank. This cell kitty is then expanded into thousands of doses for off-the-shelf use, without the need for tissue matching.

The cells can be administered to patients without the need for donor–recipient matching or suppressing the recipient’s immune system.

The company’s phase III product candidates are Remestemcel-L (Ryoncil), Revascor (advanced chronic heart failure) and MPC-06-ID (for chronic low back pain due to degenerative disc disease).

A slow-burn story

Mesoblast was founded by stem-cell expert Prof Itescu, based on technology developed over 10 years by the Institute of Medical and Veterinary Sciences (now South Australia Pathology) and the Hanson Institute in Adelaide.

Mesoblast listed on the ASX in December 2004, having raised $21 million at 50 cents apiece and then on the Nasdaq in late 2015.

In 2013, Mesoblast bought the intellectual property of US pharma group Osiris Therapeutics in 2013, for around $US100 million.

The company receives royalties or milestones on two non-US approved products: for GvHD in Japan (Temcell, marketed by JCR Pharmaceuticals) and for peri-anal fistulas in Europe (Alofisel, marketed by Tigenix). Perianal fistulas are a common complication of Crohn's disease.

In 2016, partner Teva walked away from a deal by which it would have funded the heart program (sending Mesoblast shares down 42 percent in a day).

Sod it! Let's approve it …

Ultimately, the FDA consent was achieved without any additional trials – but we're sure it wasn't a case of the agency saying 'Yes' simply so the company would go away.

In 2020, the FDA rejected the therapy despite an expert panel recommending the approval on a majority of nine votes to one.

"It's hard to say anything about that, other than those are the difficulties faced when you are first in class." Prof Itescu says. "For new products, the bar is higher than for traditional products."

Just released, a lengthy FDA document notes the 70 percent response rate was "significantly superior" to data generated from the approved non-stem-cell adult GvHD drug, ruxolitinib (Jakafi).

Prof Itescu says the FDA asked no fewer than 70 questions in the lead-up to approval and the company answered them promptly.

He adds the FDA has been clearer "in terms of their expectations and what we and others need to do (in terms of acceptable data."

Roll up, roll up for the Ryoncil rollout

Given the "tremendous unmet medical need", Mesoblast will waste little time making Ryoncil available in the US.

The quest is made easier because 45 percent of the top US transplant centres account for 77 percent of the potential market.

Half of the transplants are done at 15 sites – an even more modest footprint.

Investors should expect an update “in the next few weeks” on revenue and reimbursement expectations.

Earlier, broker Bell Potter estimated peak sales of $US137 million annually.

Prof Itescu says that given Ryoncil’s benefit of almost 50 percent survival after four to five years, reimbursement should be like that of other recent US-approved stem-cell therapies.

The company has plenty of inventory at its Singapore factory, with targeted delivery to the centres within 48 hours “if not 24 hours”.

Heart approval next?

In 2020, a 537-patient heart trial missed the primary endpoint of reducing heart failure in chronic patients.

But a follow-up study identified strengthened heart function at 12 months among the “largest unmet needs and best responders”.

As reported recently in the European Journal of Heart Failure, a single injection into the left ventricle reduced the risk of heart attack, stroke and mortalities over a median 30 months and for as long as three years.

The company is hoping for FDA accelerated approval for patients with left ventricle assist devices (LVADs), which means it would be able to sell the product ahead of a confirmatory trial.

More than 100,000 US patients each year progress to end-stage heart failure, with a one-year mortality exceeding 50 percent.

Given the size of the market, the company expects to seek a commercialization partner.

Don’t forget the kids

Mesoblast is also targeting the children’s disorder hypoplastic left heart syndrome, for which it has rare paediatric disease designation.

“Spectacular” results of a randomized trial at the Boston Children’s Hospital showed an increase in the size and function of the children’s under-developed left ventricles.

“By doing that, we enabled a surgeon to create a permanent circulation by which the left ventricle supports he whole body,” Prof Itescu says.

The agency is likely to require another trial for the disease, which accounts for up to 40 percent of neonatal cardiac fatalities.

We've got your back

With lower back pain, the company is undertaking a phase III study to confirm the results of a 2021, 404-patient phase III trial, showing the therapy to be "safe, durable and effective".

Specifically, the program is for chronic low back pain due to inflammatory degenerative disc disease, of less than five years' duration.

The 2021 study showed a reduction in pain from a single injection with a duration of 12 months to three years.

"The FDA demanded a trial with the same endpoint – pain reduction at 12 months – so we have started second trial," Prof Itescu says.

The company has begun enrolling a 300-patient randomized, placebo-controlled study at 40 US sites. The placement enabled the sites to be expanded from the envisaged 15.

Key secondary measures include improvement in quality of life and function, with a focus on reducing opioid use.

"That is a huge blockbuster, multi-billion-dollar opportunity in the US alone," Prof Itescu says.

In Europe, the company is partnered with Germany's Grunenthal and will seek a US buddy.

Finances and performance

Subscribed for by a mix of new and existing shareholders, the placement was struck at the going market rate of $2.50 per share.

The company now has cash on hand of around $US200 million ($322 million), enough for the next three years.

In the December 2024 half Mesoblast reported receipts of $US3.1 million, (down 21%) and cash outflows $US20.65 million, compared with a $US26.57 million deficit previously.

In the year to June 2024, the company lost $US88 million compared with a $US82.4 million deficit previously, on customer receipts of $US5.9 million (down 21 percent).

The company has raised equity on numerous occasions.

As of June 2024, the company also had just over $US113 million of debt, of which $US100 million was classed as long-term. This is by way of debt facilities with Oaktree Capital Management and Nova Quest Capital Management, with varying terms and conditions (some of which have been adjusted along the way).

In December, the company was added to the Nasdaq biotechnology index.

Mesoblast shares have given investors more ups and downs than a Coney Island rollercoaster ride, having climbed from their record low of 25.5 cents in early February 2024, to $3.37 after December's approval.

The shares peaked at $9.57 on October 2011.

About 35 percent of Mesoblast's register is US based – and growing – while offshore investors account for about half of the shares.

Dr Boreham's diagnosis:

Mesoblast's long-suffering investors will be pinching themselves after the Ryoncil approval but – hey! – it's for real.

Prof Itescu dubs GvHD as the tip of the iceberg.

"I see it as a halo product for our mechanism of action, which is broad," he says. "The FDA has acknowledged we understand the mechanism and we can use this product to expand into other diseases."

The placement takes the funds raised by Mesoblast since listing to well over $1 billion, but management won't reveal about the exact amount.

"The fact we have taken our products to phase III - and beyond - means we have retained the full value to date on all of our pipeline," Prof Itescu says.

"Whatever the type of [partnering] transaction, it will be on terms very favourable to us."

Prof Itescu says such truckloads of dosh are typical of those required to bring a drug to market – and the company also has two advanced ones to show for the money.

"No matter how much we have raised, investors can be very proud with what we have done with the capital."

He adds that investors need to be better educated about the risks and funding requirements of a drug development program.

"Less than one percent of all publicly listed companies are ever going to get a product approved by the FDA," he says. "Getting our approved was a huge hurdle to overcome."

Now that Mesoblast has won back the faith of shareholders, it needs to walk the walk with its ambitious plans - something the company has not always achieved.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He tries to walk the walk, blisters permitting.

MEDICAL DEVELOPMENTS

Medical Development says customer receipts for the six months to December 31, 2024 were down 0.8 percent to $19,219,000, compared to the prior corresponding period.
Last year, Medical Developments said it had receipts from customers of $19,368,000 for the six months to December 31, 2023 (BD: Feb 29, 2024).
Today, in an Appendix 4C, the company said revenue for the three months was $7.1 million, up $1.1 million on the prior period, driven by higher pricing and increased demand in Europe and the UK for its Penthrox methoxyflurane analgesic.
The company said it was $1,921,000 cash flow positive for the three months, with cash of $17,618,000 at December 31, 2024, compared to $15,699,000 at December 31, 2023.
Medical Developments was up 22.5 cents or 51.1 percent to 66.5 cents with 1.8 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says receipts from customers for the six months to December 31, 2024 were up 2.8 percent to $15,919,000, compared to the previous corresponding period.
Mach7 said licencing receipts for its medical imaging management software for the three months to December 31, were up 34.2 percent to $9,603,000, compared to the prior year.
The company said it reaffirmed expectations that revenue for the year to June 30, 2025 would be up 15-to-25 percent on the prior corresponding period to between $33.5 million and $36.4 million (BD: Aug 28, 2024).
Mach7 said it had a cash burn of $944,000 for the three months, with cash of $23,597,000 at December 31, 2024 compared to $22,729,000 at December 31, 2023.
Mach7 was up four cents or 10.8 percent to 41 cents with 1.6 million shares traded.

NOVA EYE MEDICAL

Nova Eye says it expects revenue for the year to June 30, 2025 to be up 17.9-to-24.8 percent to between $27.5 million and $29.1 million.
Last year, Nova Eye said revenue for the year to June 30, 2024 from sales of its Itrack Advance glaucoma consumable surgical device was $23,325,000 (BD: Aug 26, 2024).
Today, the company said unaudited revenue for the six months to December 31, 2024 was up 26.6 percent to $US8,384,000 ($A13,475,000) compared to the prior period.
Nova Eye said its increased sales reflected “the continued success of the US direct sales force and the early benefits of commercial investments in international markets”.
The company said it had a cash burn of $1,285,000 for the three months, with cash and equivalents of $2,196,000 at December 31, 2024 compared to $2,612,000 the prior year.
Nova Eye fell 2.5 cents or 15.15 percent to 14 cents with two million shares traded.

IMEX HEALTH SERVCES

Imex says receipts from customers for the year to December 31, 2024 was up 16.9 percent to $24,432,000, compared to the previous corresponding period.
Imex said receipts for its cloud-based medical imaging software and radiology services for the three months to December 31, 2024 fell 8.2 percent to $6,632,000, compared to the prior corresponding period.
The company said it was $90,000 cash flow positive for the three months, with cash and equivalents of $2,072,000 at December 31, 2024, compared to $2,362,000 the prior year.
Imex was unchanged at 35 cents.

GENETIC SIGNATURES

Genetic Signatures says receipts for the six months to December 31, 2024 were up 84.6 percent to $10,308,000, compared to the prior corresponding period
Genetic Signatures said customer receipts for its Easyscreen respiratory pathogen detection kits and enteric detection kits for infection control for the three months to December 31, 2024 fell 59.6 percent to $3,302,000, compared to the prior period.
The company said the “strong cash receipts in the quarter were primarily attributable to Australian sales due to higher respiratory testing rates in Australia in the quarter”.
Genetic Signatures said it had a cash burn of $302,000 for the three months, with cash and equivalents of $40,793,000 at December 31, 2024 compared to $18,124,000 at December 31, 2023.
Genetic Signatures was untraded at 62 cents.

VISIONEERING TECHNOLOGIES

Visioneering says customer receipts for the year to December 31, 2024 were up 4.7 percent to $US9,174,000 ($A14,750,000) compared to the prior corresponding period.
Visioneering said receipts from sales of its Naturalvue multi-focal one-day contact lenses for the three months to December 31, 2024 were up 36.2 percent to $US2,204,000, compared to the previous corresponding period.
The company said it had a cash burn of $US623,000 for the three months, with cash and cash equivalents of $US649,000 at December 31, 2024 compared to $2,999,999 at December 31, 2023, leaving it with 1.04 quarters cash.
Visioneering said it was evaluating future cash needs.
Visioneering was unchanged at 6.8 cents.

CANN GROUP

Cann says receipts from customers for the six months to December 31, 2024 fell 27.9 percent to $7,155,000, compared to the previous corresponding period.
Cann said receipts from sales of marijuana products for the three months to December 31, 2024 were down 34.7 percent to $3,518,000, compared to the prior corresponding period.
The company said that it had a $990,000 cash burn for the three months, with cash and cash equivalents of $60,000 at December 31, 2024 compared to $1,636,000 at December 31, 2023, meaning it had 0.46 quarters of funding available.
Cann said it had recently raised $2.03 million in an entitlement offer, had continued support from its main financer the National Australia Bank (NAB).
Cann Group fell 0.3 cents or 8.3 percent to 3.3 cents with 3.7 million shares traded.

IMPEDIMED

Impedimed says receipts from customers for the six months to December 31, 2024 were up 3.1 percent to $6,137,000, compared to the prior corresponding period.
Impedimed said that receipts from customers for the sale of 49 units of its Sozo bio-impedance spectroscopy devices in the three months to December 31, 2024 were up 18.4 percent to $3,419,000, compared to the previous corresponding period.
The company said it had a cash burn for the three months of $2,471,000, with cash and cash equivalents of $17,693,000 at December 31, 2024 compared to $36,905,000 at December 31, 2023.
Impedimed fell 0.15 cents or 2.7 percent to 5.35 cents with 1.2 million shares traded.

MESOBLAST

Mesoblast says customer receipts for the six months to December 31, 2024 fell 22.9 percent to $US3,063,000 ($A4,933,000) compared to the prior corresponding period.
Mesoblast said that receipts were from royalties on sales of its Temcell for graft-versus-host-disease in Japan, for the three months to December 31, 2024 fell 2.0 percent to $US1,693,000.
The company said it had a cash burn for the three months of $US10,128,000, with cash and cash equivalents of $US38,029,000 at December 31, 2024 compared to $US77,554,000 at December 31, 2023.
Mesoblast was up 11 cents or 3.6 percent to $3.17 with 7.3 million shares traded.

LUMOS DIAGNOSTICS

Lumos says customer receipts for the six months to December 31, 2024 were up 23.4 percent to $US3,009,000 ($A4,838,000) compared to the prior corresponding period.
Lumos said receipts, mostly from sales of its Viradx respiratory infection test as well as its Febridx bacterial infection test for the three months to December 31, 2023 were up 76 percent to $US1,936,000.
The company said it had a cash burn of $US3,741,000 for the three months, with cash and cash equivalents of $US5,532,000 at December 31, 2024 compared to $US1,379,000 at December 31, 2023.
Lumos fell 0.7 cents or 17.5 percent to 3.3 cents with 10.2 million shares traded.

CONTROL BIONICS

Control Bionics says receipts from customers for the six months to December 31, 2024 were up 5.8 percent to $2,744,000, compared to the previous corresponding period.
Control Bionics said receipts from sales and software licensing of its Neuronode wireless sensors for speech and computer-controlled functions for the three months to December 31, 2024 were up 29.1 percent to $1,403,000.
The company said it had a cash burn of $1,698,000 for the three months, with cash and cash equivalents of $972,000 at December 31, 2024 compared to $1,314,000 at December 31, 2023, meaning it had 0.6 quarters of cash.
Control Bionics said it expected increased cash flows as the National Disability Insurance Scheme funding approvals improved, it had implemented cost saving measures and believed it would be able to raise capital if required in the short term.
Control Bionics fell 0.3 cents or 4.9 percent to 5.8 cents.

NOVA EYE MEDICAL

Nova Eye says it has “binding firm commitments” to raise $6.6 million at 12 cents a share in a placement to institutional and sophisticated investors.
Nova Eye said the issue price was a 30.7 percent discount to the 15-day volume weighted average price and a 29.1 percent discount to the five-day volume weighted average price.
The company said the funds would be used to expand its Itrack Advance sales team in the US and Germany, product development and production efficiencies as well as working capital.
Nova Eye said Taylor Collison was lead manager and would be paid six percent of the funds raised in cash.

TELIX PHARMACEUTICALS

Telix says it has completed its up-to $US230 million ($A372 million) acquisition of the Los Angeles-based antibody engineering company Imaginab Inc.

Earlier this month, Telix said it would acquire Imaginab for $US45 million up-front and up-to $US185 million in milestones (BD: Jan 19, 2025).

Today, the company said it paid Imaginab $US10 million up-front in cash and $US31 million through the issue of 2,053,311 shares at $24.3745 a share, with a further $US185 million payable subject to development and commercial milestones.

Telix said with its purchase of Imaginab it would receive “a pipeline of drug candidates against validated cancer targets including DLL3 and integrin alpha-v-beta6, as well as a panel of other agents against novel targets in early discovery stage”.

The company said it believed “that these next generation drug candidates fit synergistically with Telix’s therapeutics pipeline, enabling expansion to future therapy areas with unmet clinical need”.

Telix said the transaction added Imaginab’s Los Angeles research facility to its US operations, complementing its existing radio-chemistry platform at Optimal Tracers in Sacramento, California, isotope production at ARTMS in Vancouver, Canada and bio-conjugation chemistry at Isotherapeutics in Angleton, Texas.

The company said Imaginab’s discovery, protein engineering and radio-pharmaceutical development team would join Telix’s early development team to further improve “in-house capabilities in antibody engineering, protein characterization and pre-clinical development”.

Telix chief scientist Dr Michael Wheatcroft said the addition of an early-stage pipeline of promising therapeutic and diagnostic assets and a novel biologics platform added “new optionality for Telix to create the next generation of precision medicine and therapeutic products, beyond the current clinical-stage pipeline”.

Telix was up 53 cents or 1.8 percent to $29.34 with 991,625 shares traded.

MESOBLAST

Mesoblast says it expects to commercially launch its Ryoncil for steroid-refractory acute graft-versus-host disease (GvHD) in the US by April 2025.

Last year, Mesoblast said the US Food and Drug Administration approved Ryoncil for children aged two months and older for graft versus host disease (BD: Dec 19, 2024).

The company said commercialization would start when it had National Drug Codes from the FDA “enabling subsequent publication of product pricing in the US Price Compendia”.

Mesoblast said its commercial launch strategy would “initially target those centers with greatest experience using the Ryoncil product and highest volume”.

The company said that half of all pediatric transplants in the US were performed at just 15 centers and that its team would “be heavily engaged in these centers of excellence along with another 30 sites, which together account for almost 80 percent of pediatric transplants”.

Mesoblast said it had manufactured commercial inventory of Ryoncil and had a distribution network with Philadelphia, Pennsylvania’s Cencora, a specialty pharmaceutical services and distribution company that would allow for the “efficient and secure delivery of cryo-preserved product to US treatment centers”.

The company said Cencora would manage its patient access hub, called Mymesoblast, to facilitate patient enrolment, shipment and logistics and would provide support for patients in the in-patient and out-patient setting.

AMPLIA THERAPEUTICS

Amplia says it has enrolled 53 pancreatic cancer patients in its phase Ib/IIa trial of narmafotinib, or AMP945, and reported an additional confirmed partial response.
Last year, Amplia said six of 26 enrolled patients in its 50-patient, phase IIa, trial of AMP945 for pancreatic cancer showed reduced tumor size with no new lesions, allowing it to begin recruitment of the remaining 24 patients (BD: Sep 23, 2024).
Later, the company said it had nine confirmed partial responses in the 26-patient, phase IIa trial of narmafotinib, formerly AMP945 (BD: Dec 11, 2024).
Today, Amplia said it had enrolled three additional patients "to replace patients who came off study prior to any assessment of drug efficacy having been undertaken".
The company said a further patient had a confirmed partial response, bringing the total to 10 which was "an objective response rate of 38.5 percent, significantly better than the 23 percent reported for the historical trial being used as the benchmark for this study".
Amplia said the drug continued "to be well-tolerated by patients, and for the first 26-patient group, the median duration on trial is 197 days which is a 68 percent improvement over the historical data of 117 days".
The company said that the total number of patients remaining on study was 35.
Amplia managing-director Dr Chris Burns said that completing recruitment of the trial "well ahead of schedule is a direct result of the focused and diligent effort of the Amplia team and our clinical partners".
"Safety and efficacy data for the patients on study continues to be collected … with top-line data from the study to be available [by September 2025]," Dr Burns said.
Amplia was up 0.6 cents or 7.4 percent to 8.7 cents.

PYC THERAPEUTICS

PYC says it has safety review committee approval to begin dosing the second cohort in its dose escalation trial of PYC-001 for autosomal dominant optic atrophy (ADOA).
Last year, PYC said it had approval for a nine-patient, single-ascending dose study of PYC-001 for the blinding-eye disease ADOA; and later, said it had dosed the first of three patients in the study (BD: Aug 15, Nov 1, 2024).
Today, the company said the safety review committee approved escalation of the PYC-001 treatment dose from 3.0 micrograms per eye in cohort one to 10 micrograms per eye in cohort 2, following evaluation of the safety and tolerability data for patients in cohort one through four-weeks of follow-up.
PYC did not disclose the number of patients it expected to dose in the second cohort.
The company said it would "engage the regulator to discuss the inclusion of an additional dosing cohort in the … study", with results on the safety, tolerability and initial efficacy profile of PYC-001 expected in "the course of 2025".
PYC was unchanged at $1.22.

PARADIGM BIOPHARMACEUTICALS

Paradigm says Advanced Clinical will be the clinical research organization in its 466-patient, phase III trial of pentosan poly-sulfate sodium (PPS) for knee osteo-arthritis.
Last year, Paradigm said it was approved to begin its 466-patient, randomized, phase III trial of injectable PPS for knee osteo-arthritis pain (BD: Nov 28, 2024).
Today, the company said with the appointment of Chicago's Advanced Clinical, it was preparing site activation, with the first patient expected to be recruited by July 2025.
Paradigm was up three cents or 5.4 percent to 58.5 cents with three million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has received $2.44 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Neurotech said the incentive related to research and development expenditure for the year to June 30, 2024.
Neurotech was unchanged at 4.7 cents.

OPTISCAN IMAGING

Optiscan says it has received $1,775,733 from the Australian Taxation Officer under the Federal Government's Research and Development Tax Incentive program.
Optiscan said the incentive related to research and development for the year to June 30, 2024 and included an advance and overseas finding.
Optiscan was unchanged at 16 cents.

MICRO-X

Micro-X has requested a trading halt pending an announcement "in respect of a material capital raising".
Trading will resume on February 4, 2025, or on an earlier announcement.
Micro-X last traded at 7.8 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says Bio101 Financial Advisory director Tim Luscombe will replace its resigning company secretary Karen Logan, effective from today.
Proteomics fell 1.5 cents or 2.3 percent to 64.5 cents.