



# Biotech Daily

Tuesday April 9, 2024

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: SYNTARA UP 6%; MICRO-X DOWN 11.5%**
- \* **SOMNOMED RIGHTS OFFER FOR \$23m**
- \* **NUHEARA PLACEMENT TO RAISE \$1.85m, 'STRATEGIC REVIEW'**
- \* **PACIFIC EDGE RECORD 33k CXBLADDER TESTS**
- \* **FISHER & PAYKEL: 'SMALLEST, LIGHTEST NASAL PILLOW MASK'**
- \* **TELIX COMPLETES \$12.5m ISOTHERAPEUTICS ACQUISITION**
- \* **NEXT SCIENCE: 'BLASTX TREATS PRESSURE ULCERS'**
- \* **ATMO 'PIVOTAL' GAS-SENSING CAPSULE MEETS TRIAL ENDPOINTS**
- \* **ANATARA PHASE II GARP IBS TRIAL STAGE 2 ENROLMENT OPEN**
- \* **FIVEPHUSION DEFLEXIFOL COLORECTAL CANCER TRIAL APPROVED**
- \* **SPEEDX PLEXPLUS PCR 'DOUBLES STANDARD TARGET OUTPUT'**
- \* **PATRY'S: 'PAT-DX1, PAT-DX3 REDUCE VASCULITIS, IN MICE'**
- \* **ONCOSIL WINS UK REIMBURSEMENT**
- \* **IMRICOR: 2.1m CEO OPTIONS, 315k DIRECTORS STOCK AGM**
- \* **ANTERIS REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **GREGORY GEORGE, G TO THE FOURTH TAKE 13% OF MESOBLAST**
- \* **BLINKLAB YULIA UVAROVA 8.6%, CEO DR HENDRIKUS BOELE TAKE 6.8%**
- \* **BLINKLAB CTO CORNELIS BOELE, CSO DR SEBASTIAAN KOEKKOEK 5.8%**
- \* **REGENEUS LEO LEE, BARRY SECHOS, PROF GRAHAM VESEY BELOW 5%**
- \* **OPTHEA APPOINTS DR JOHN HAN HEAD OF MEDICAL AFFAIRS**

## MARKET REPORT

The Australian stock market was up 0.45 percent on Tuesday April 9, 2024, with the ASX200 up 35.1 points to 7,824.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 were down, six traded unchanged and two were untraded. All three Big Caps fell.

Syntara was the best, up 0.1 cents or 5.6 percent to 1.9 cents, with 134,550 shares traded. Amplia and Resonance climbed four percent or more; Actinogen, Emvision and Next Science were up three percent or more; Impedimed, Medical Developments, Nova Eye and Pro Medicus improved more than one percent; with Opthea and Proteomics up by less than one percent.

Micro-X led the falls, down 1.5 cents or 11.5 percent to 11.5 cents, with 48,578 shares traded. Nanosonics and Prescient fell more than four percent; Compumedics, Dimerix and Starpharma lost more than three percent; Clinuvel, Cochlear, Orthocell, Percheron and Universal Biosensors shed more than two percent; 4D Medical, Avita, Clarity, Immutep, Mesoblast, Neuren, Paradigm and Resmed were down one percent or more; with CSL, Genetic Signatures, Polynovo and Telix down by less than one percent.

## SOMNOMED

Somnomed says it hopes to raise about \$22.6 million at 21.0 cents a share in a pro-rata, non-renounceable, fully underwritten, one-for-1.01 entitlement offer.

Last week, Somnomed requested a further extension to its suspension relating to an entitlement offer and earnings guidance downgrade (BD: Mar 27, Apr 2, Apr 5, 2024).

Today, the company said the funds would be used for a “more aggressive restructuring plan that will materially reduce costs with effect from [2024-'25]” as well as to clean its balance sheet and invest in its manufacturing capacity and Rest Assure scalability.

Somnomed said the offer included an institutional and retail component, with both fully-underwritten by lead manager Wilsons Corporate Finance Ltd.

The company said the retail offer was for shareholders on the record date of April 11, would open on April 16, and close on May 1, 2024.

Somnomed was in a suspension and last traded at 38.5 cents.

## NUHEARA

Nuheara says it has “firm commitments” to raise \$1.85 million in a placement at six cents a share to support a review “to evaluate and determine its future strategic options”.

Nuheara said the offer was a 23 percent discount to the 15-day volume weighted average price, with one option for every three shares bought, exercisable at 11 cents within 90 days, with Intuitive Pty Ltd managing the placement and to receive a fee of 3.5 percent.

Nuheara said following the launch of its US Food and Drug Administration-approved over-the-counter hearing aid, it was “positioned to evolve to its next phase”.

The company said it would require significant investment, would restructure its investments and prioritize the completion of agreements with Realtek and Hewitt Packard.

Nuheara said following the completion of the capital raise, it intended to seek to secure a return of its shares to trading on the ASX, subject to satisfying the ASX's requirements.

Last month, the ASX said it had suspended Nuheara under Listing Rule 17.5 for “not lodging the relevant period report by the due date” (BD: Mar 1, 2024).

Nuheara was in a suspension and last traded at 8.1 cents.

## PACIFIC EDGE

Pacific Edge says it processed 32,633 Cxbladder tests for bladder cancer for the year to March 31, 2024, up 3.4 percent compared to the prior corresponding period.

Last year, Pacific Edge said revenue from sales of 31,565 Cxbladder non-invasive urine tests for bladder cancer for the year to March 31, 2023 was \$NZ19,616,000 (\$A18,540,000) (BD: May 25, 2023).

Today, the company said the result was achieved with a smaller sales force which had “benefited from previously reported improvements in sales force efficiency and a growing contribution of tests from kaiser Permanente following the incorporation of Cxbladder tests into its electronic medical records system”.

Pacific Edge said that US sales volume for the three months to March 31, 2024 were up one percent to 6,099 tests, with Asia Pacific sales down 2.7 percent to 1,111 tests due to the impact by the “traditional slowdown in New Zealand post the Christmas period”.

Pacific Edge was up 0.1 cents or 1.3 percent to 7.9 cents.

## FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says it has released its Nova Micro “smallest and lightest” nasal pillow mask for obstructive sleep apnoea in New Zealand.

Fisher & Paykel said the mask weighed less than 40gm and included “minimal, easy-adjusting headgear and a soft micro-pillow cushion that nestles gently within the nostrils and inflates to conform to the patient’s nose”.

The company said the design provided “stability and freedom of movement, allowing patients to sleep in their preferred position”.

Fisher & Paykel said sales of the Nova Micro had begun in New Zealand and were expected to begin in Canada “in the coming months”, with Australia, Europe and the US to follow “later this calendar year”.

Fisher & Paykel head of products and technology Andrew Somervell said: “Nova Micro was created for patients wanting a mask that doesn’t compromise on comfort and performance.”

“‘Less is best’ was the mantra for our teams throughout the development process, and the result is our smallest and lightest mask yet,” Mr Somervell said.

Fisher & Paykel was up 18 cents or 0.8 percent to \$23.63 with 215,298 shares traded.

## TELIX PHARMACEUTICALS

Telix says it has completed the acquisition of the Angleton, Texas-based Isotherapeutics following the upfront payment of \$US8.1 million (\$A12.5 million).

In February, Telix said it would acquire radiochemistry and bio-conjugation manufacturer Isotherapeutics for up-to \$US13.6 million (\$A20.7 million) (BD: Feb 27, 2024).

Today, the company said it had paid \$US6.0 million through the issue of shares and a further \$US2.1 million in cash, with a further \$US5.0 million to be paid in cash for performance-related milestones still to be paid, as well as a two-year revenue share of about \$US600,000.

Telix managing-director Dr Chris Behrenbruch said the acquisition was “a significant milestone in Telix’s continued focus on vertical integration of development, supply and manufacturing and is highly complementary to Sacramento, California’s Optimal Tracers Vancouver, British Columbia’s ARTMS, and our extensive commercial manufacturing infrastructure in Belgium”.

Telix fell nine cents or 0.7 percent to \$12.42 with 549,965 shares traded.

## NEXT SCIENCE

Next Science says a 20-patient study shows its Blastx anti-microbial gel can treat pressure ulcers in combination with negative pressure wound therapy.

Next Science said the study met its primary objective of showing that an anti-microbial agent increased the efficacy of negative pressure wound therapy and decreased both planktonic and biofilm bacteria in a wound.

The company said the results showed that 45 percent of the pressure ulcers reduced in size in the four-week study with “a resolution of bacterial fluorescence in the negative pressure wound therapy dressing and wound bed seen in an average of three weeks”. Next Science said the study concluded that the combination of Blastx with negative pressure wound therapy dressing “reduced bacterial levels and improved wound healing in recalcitrant pressure ulcers”.

The company said the study, titled ‘A Diagnostic-Driven Prospective Clinical Study Evaluating the Combination of an Antibiofilm Agent and Negative Pressure Wound Therapy’ was published in the peer-reviewed journal Diagnostics with a full article available at: <https://www.mdpi.com/2075-4418/14/7/774>.

Next Science managing-director Harry Hall said the study showed that Blastx “should be considered when treating pressure ulcers with negative pressure wound therapy”.

Next Science was up one cent or three percent to 34.5 cents.

## ATMO BIOSCIENCES

Atmo says its more than 200-patient study of its gas-sensing capsule technology for suspected gastro-intestinal motility disorders met its primary endpoint.

Last year, Atmo said it expected to recruit about 100 patients with gastro-intestinal symptoms and dysmotility for a “pivotal” trial of its gas-sensing capsule against Medtronic’s Smartpill, with results to be used for a US Food and Drug Administration 510(k) application (BD: Aug 10, 2023).

Later, the company said it had recruited its target of more than 200 patients in its ‘pivotal’ trial of its gas-sensing capsule for diagnosing motility disorders such as gastro-paresis and constipation (BD: Dec 14, 2023).

Today, Atmo said the study met its primary endpoints of gastric emptying time, or emptying from the stomach, and colonic transit time, or transit time in the large bowel, to assist with the diagnosis of gastro-paresis and slow transit constipation.

The company said the data would be used to support a regulatory submission with the FDA for an initial indication in gastrointestinal motility disorders by July 2024.

Atmo said more than 200 subjects from 12 trial sites in the US and Australia ingested its gas-sensing capsule and a wireless motility capsule predictive device in the trial to test the comparative ability of its technology.

The company said its gas-sensing capsule was currently an investigational device exclusively for use in clinical investigations and was not available for sale in the US.

Atmo chief executive officer Mal Hebblewhite said the company was “thrilled to have reached the pivotal study’s primary endpoints”.

“This result gives us confidence as we complete our current capital raise, prepare a US regulatory submission, and plan for subsequent market launch” Mr Hebblewhite said.

Last week, stock-brokers Ord Minnett said that Melbourne’s Atmo hoped to raise \$15 million at \$1.65 a share to “complete product development and develop its US market opportunity” for its gas-sensing gut capsule, with \$10.5 million committed by existing investors (BD: Apr 5, 2024).

Atmo is a public unlisted company.

## ANATARA LIFE SCIENCES

Anatara says it has opened five sites for stage two of its up-to 140-patient phase II trial of gastrointestinal reprogramming, or Garp, for irritable bowel syndrome (IBS).

Last year, Anatara said stage one of the trial, met its primary endpoints reducing irritable bowel syndrome by 56 percent, meeting safety objectives and was statistically significant for anxiety and depression but not quality of life (BD: Oct 6, 17, 2023).

Earlier this year, the company said stage two would begin recruiting in March and would confirm statistical significance for primary and secondary endpoints through greater numbers of patients (BD: Feb 29, 2024).

Today, Anatara said the trial was open at five sites in Melbourne, Sydney and Brisbane, following ethics approval, with participants to be randomized equally to receive either Garp or placebo for about three months.

The company said it the data from the 60 to 100 patients in stage two would be in addition to stage one and that the overall study remained blinded to ensure the trial was sufficiently powered to deliver statistically significant results.

Anatara was up 0.3 cents or four percent to 7.8 cents.

## FIVEPHUSION

Fivephusion says it has ethics approval for an up-to 50-patient, phase Ib trial to study Deflexifol as a first-line treatment for unresectable metastatic colorectal cancer.

Fivephusion said Deflexifol was a physiological pH (potential of hydrogen) formulation designed to co-administer the chemo-therapeutic treatment 5-fluorouracil (5-FU), and the bio-modulator leucovorin (LV) which enhances 5-FU's anti-cancer activity.

The company said it had ethics approval for the multi-centre, phase Ib, dose-escalation trial which would study the optimal dose of Deflexifol for use in a planned phase III registration study.

Fivephusion managing-director Dr Christian Toouli told Biotech Daily that the company expected to enrol between 40 and 50 patients in the phase Ib trial, which would evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of Deflexifol in combination with oxaliplatin and bevacizumab as a first-line treatment in colorectal cancer patients.

Fivephusion said, subject to phase Ib trial outcomes, the phase III study would show "the superiority of Deflexifol over standard-of-care 5-FU/LV 'backbone' therapy in unresectable metastatic colorectal cancer]".

The company said the phase Ib trial design was based on US Food and Drug Administration advice and would be its fourth clinical study investigating Deflexifol as a treatment for solid tumors, and the first to study Deflexifol in combination with other standard-of-care drugs.

Fivephusion said the trial would be conducted by its Morrisville, North Carolina-based US partner Syneos Health.

Dr Toouli said there was "a significant unmet medical need to optimize standard-of-care 5-FU/LV therapy for solid tumor treatment".

"This ... approval endorses the feedback we have received from oncologists and the US FDA on the appropriateness of investigating Deflexifol as an optimized replacement of 5-FU/LV in the standard-of-care for the first line treatment of [metastatic colorectal cancer],"

Dr Toouli said.

"We intend to initiate this trial as soon as possible," Dr Toouli said.

Fivephusion is a private company.

## SPEEDX

Speedx says its Respiv Plexplus polymerase chain reaction (PCR) technology can “double the standard target output” on standard PCR laboratory instruments.

In 2021, Sydney’s Speedx said the Australian Therapeutics Goods Administration had approved its Covid-19 Plex-PCR test which expanded its portfolio of tests for the detection of influenza A and B, and respiratory syncytial viruses A and B (BD: Aug 13, 2021).

Today, the company said it had developed Respiv Plexplus, which could detect 14 respiratory viral targets at once, including influenza viruses A and B, Sars-Cov-2, respiratory syncytial viruses A and B, adenoviruses B and C, human para-influenza viruses 1, 2, 3 and 4, human meta-pneumovirus, rhinovirus and human enterovirus. Speedx said current PCR laboratory solutions could “be expensive, sometimes cover unnecessary targets and are often ill-suited to meet high testing demands”.

The company said it had developed Respiv Plexplus as a “highly multiplexed, scalable technology that is affordable” and allowed the detection of multiple target readouts within each test channel during quantitative polymerase chain reaction while increasing the multiplexing capacity and enabling higher sample throughput.

The company said the test used “specialized universal probes, which fluoresce in a temperature-dependent manner, with their fluorescence acquired at two temperatures across multiple wavelengths in real-time”.

Speedx said the test simplified “analysis for laboratories, removing the need for complex algorithms to ascertain contributions from different targets measured at the same wavelength ... [and it was] the first product to harness this ... multiplexing technology”.

Speedx co-founding chief technical officer Dr Alison Todd said the company saw “endless possibilities for Plexplus applications”.

Speedx is a public unlisted company.

## PATRY'S

Patry's says its PAT-DX1 and PAT-DX3 deoxymabs reduce inflammation from vasculitis without negatively affecting the immune system, in mice.

In March, Patry's said PAT-DX1 had been shown “to ameliorate the underlying processes associated with auto-immune diseases such as ... vasculitis”, in mice (BD: Mar 4, 2024).

Today, the company said the studies of anti-neutrophil cytoplasmic antibody vasculitis were conducted by Melbourne’s Monash University’s Dr Kim O’Sullivan and presented at a conference in Barcelona on April 8, 2024.

Patry's said that PAT-DX1 and PAT-DX3 were able to inhibit the formation of neutrophil extracellular traps, structures of DNA strands and proteins that maintain and spread cancer cells and regulate inflammation, in mice.

The company said the results showed that both deoxymabs reduced the level of inflammation and kidney injury in mice and that neither deoxymab had “any detrimental effect on neutrophils” and did not suppress the immune system.

Dr Campbell said “there may be opportunities to develop deoxymabs as a therapeutic for ... vasculitis, and potentially for other related autoimmune diseases”.

“[Anti-neutrophil cytoplasmic antibody] vasculitis is a challenging condition and, while current treatments have transformed it into a relapsing and, or remitting disease, they are associated with increased drug-related toxicities and organ damage,” Dr Campbell said.

“We believe a therapeutic that is able to reduce the inflammation associated with this disease without suppressing the immune system could provide a very attractive therapeutic option for patients,” Dr Campbell said.

Patry's was up 0.05 cents or 5.9 percent to 0.9 cents with 8.8 million shares traded.

## ONCOSIL MEDICAL

Oncosil says an unnamed UK insurance company will reimburse its device for pancreatic cancer at London's Imperial College Healthcare National Health Services Trust.

Oncosil did not name the private health insurer, not state the material terms of the reimbursement of the use of its device for treating locally advanced pancreatic cancer.

The company said with the "significant reimbursement achievement, the Oncosil team was poised to collaborate with additional insurers, aiming to broaden reimbursement options and enhance patient accessibility to treatments not only at Imperial College Healthcare NHS Trust but also at other private healthcare facilities".

Oncosil managing-director Nigel Lange said with a health insurance provider "now committed to covering the costs of the Oncosil device, patients dealing with locally advanced pancreatic cancer can now avail themselves of this ground-breaking treatment at Imperial College Healthcare NHS Trust".

"We eagerly anticipate collaborating with other healthcare facilities across the UK, as well as further private insurers, to ensure broader accessibility to the Oncosil device for all individuals who could potentially benefit from its innovative approach," Mr Lange said.

"This endeavor stands as a pivotal focus for our company, and we are actively pursuing reimbursement initiatives in other regions as well," Mr Lange said.

Oncosil fell 0.1 cents or 16.7 percent to 0.5 cents with three million shares traded.

## IMRICOR MEDICAL SYSTEMS

Imricor says its annual general meeting will vote to issue 2,113,342 options to chief executive officer Steve Wedan and 315,946 restricted stock units to directors.

Imricor said the meeting would vote to approve 1,161,420 long-term incentive options for Mr Wedan, worth 70 percent of his \$US464,900 (\$A703,000) yearly salary and subject to performance milestones, as well as 1,000,000 special grant options, both exercisable at the Chess depository interest (CDI) closing price of the day prior to their exercise as soon as the performance goal was achieved.

The company said investors would vote to issue directors Peter McGregor, Anita Messal and Mark Tibbles 107,556, 100,834 and 107,556 restricted stock units, respectively.

Imricor said the restricted stock units would vest in quarters over a four year period, and were in addition to Mr McGregor's \$80,000, Ms Messal's \$75,000 and Mr Tibbles' \$80,000 yearly salaries.

The company said the meeting would vote to elect Ms Messal as a director, approve its equity incentive plan and increase its reserved shares, ratify the appointment of its accounting firm and approve its 10 percent placement facility.

The meeting will be held online on May 15, 2024 at 8am (AEST).

Imricor fell five cents or 9.1 percent to 50 cents.

## ANTERIS TECHNOLOGIES

Anteris has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on April 11, 2024, or on an earlier announcement.

Anteris last traded at \$23.00.

## MESOBLAST

Gregory George and G to the Fourth Investments say they have increased their Mesoblast holding from 136,435,560 shares (11.99%) to 150,183,635 shares (13.20%).

The Tampa, Florida-based Mr George said that with James George, Grant George, Citicorp and JP Morgan, they bought American depository receipts and Australian shares from April 1, 2024 to April 5, 2024, with the single largest purchase 3,618,295 shares on April 3, 2024 for \$2,022,905, or 55.9 cents a share.

Mesoblast fell 1.5 cents or 1.6 percent to 91 cents with 17.6 million shares traded.

## BLINKLAB

Perth's Yulia Uvarova as trustee for Techinvest Nominees says she has become a substantial shareholder in Blinklab with 8,500,000 shares, or 8.57 percent.

Ms Uvarova said that on August 17, 2021 she bought 2,788 shares and 8,322,212 escrowed shares for \$120,435, or 1.4 cents a share, and on March 27, 2024 purchased 175,000 shares for \$35,000, or 20 cents a share.

Last week, Blinklab said its initial public offer at 20 cents a share raised \$7 million to develop its autism and neurological disorder test, with co-inventors Dr Anton Uvarov and Dr Henk-Jan Boele appointed directors (BD: Apr 4, 2024).

In its prospectus, the company said Dr Uvarov held 8,325,000 shares indirectly by Ms Uvarova, and that Techinvest Nominees was "an entity associated with Dr Uvarov".

Blinklab was up 0.5 cents or 2.2 percent to 23.5 cents with 1.5 million shares traded.

## BLINKLAB

Blinklab chief executive officer and director Dr Hendrikus Boele says he has become substantial in the company with 6,750,000 shares, or 6.81 percent (see above).

Dr Boele said as sole director and shareholder of the Leiden, Netherlands-based Cason Holding BV, he bought 2,261 shares and 6,747,739 escrowed shares on August 17, 2021 for \$465.00, or 0.007 cents a share.

## BLINKLAB

Blinklab chief technical officer Cornelis Boele says he has become substantial in the company with 5,775,000 shares, or 5.82 percent (see above).

Mr Boele said that as sole director and shareholder of the Leiden, Netherlands-based Bello Holding BV he bought 1,934 shares and 5,773,066 escrowed shares for \$370, or 0.006 cents a share.

## BLINKLAB

Blinklab chief scientific officer Dr Sebastiaan Koekkoek says he has become substantial in the company with 5,775,000 shares, or 5.82 percent (see above).

Dr Koekkoek said that as sole director and shareholder of the Nispen, Netherlands-based Inacea Holding BV he bought 1,934 shares and 5,773,066 escrowed shares for \$385, or 0.007 cents a share.



## REGENEUS

Regeneus director and former chief executive officer Leo Lee says his 15,890,893 shareholding has been diluted below five percent due to a capital raise and merger. Last month, Regeneus said its investors voted for its merger with the Atlanta, Georgia-based Cambium Medical Technologies LLC for its Elate Ocular for dry eye disease and to rename the company to 'Cambium Bio'; and last week, said it had raised \$3.48 million in a placement at 0.6 cents a share (BD: Mar 28, Apr 5, 2024). According to its most recent notice, Regeneus had 1,193,067,757 shares on issue, meaning that the Chiba, Japan-based Mr Lee's 15,890,893 shares amounted to about 0.013 percent of the company. Regeneus was up 0.3 cents or 33.3 percent to 1.2 cents with 5.8 million shares traded.

## REGENEUS

Regeneus chair Barry Sechos says as secretary of Kirman 2 Pty Ltd his 15,760,892 shareholding has been diluted below five percent due to a capital raise and merger (see above). According to its most recent notice Regeneus had 1,193,067,757 shares on issue, meaning that Mr Sechos and Kirman 2's 15,760,892 shares amounted to about 0.013 percent of the company.

## REGENEUS

Regeneus executive director and chief scientific officer Prof Graham Vesey says he has ceased his substantial shareholding following a share sale and dilution. The Hornsby, New South Wales-based Prof Vesey said with Vesey Investments Pty Ltd he sold 1,108,944 shares on March 14, 2022 for \$150,522, or 13.6 cents a share and on April 2, 2024 was diluted due to the company's merger and capital raise (see above). Biotech Daily calculates that Prof Vesey's remaining 14,771,024 post-merger shares amount to about 0.012 percent of the company.

## OPTHEA

Opthea says it has appointed Dr John Han as head of medical affairs to support the phase III trial of sozinibercept, formerly OPT-302, effective from April 8, 2024. Opthea said Dr Han had worked at Regeneron Pharmaceuticals, ISTA Pharmaceuticals, Chiron Corp, Amgen Inc and Bayer AG, as well as his most recent role as head of medical affairs at Adverum Biotechnologies. The company said Dr Han held a Bachelor of Arts from the University of California, Berkely and a Doctor of Pharmacy from the University of California San Francisco. Opthea was up 0.5 cents or 0.7 percent to 75 cents.