Biotech Daily

Friday June 9, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: STARPHARMA UP 11%; PRESCIENT DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: NOVA EYE MEDICAL**

*** TELIX OPENS $21m BELGIUM RADIO-PHARMACEUTICAL FACTORY**

*** IMUGENE TAKES VAXINIA TRIAL TO IV COMBINATION COHORT**

*** PHARMAUST STARTS MONEPANTEL FOR MND COHORT 3**

*** NYRADA REPLACES NYR-BI02 WITH NYR-BI03 FOR BRAIN INJURY**

*** ARTRYA, FDA 'Q-SUBMISSION' MEETING YIELDS SALIX 501(k) PATH**

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*** AUCKLAND'S MILFORD TAKES 5% OF IMMUTEP**

*** SANDON TAKES TO 17% OF IDT**

*** DONALD GIBSON, GLOBAL CR TAKE 10% OF BIOXYNE**

*** KEFFORD FAMILY TAKES 8.8% OF VECTUS BIOSYSTEMS**

*** PLANET INNOVATION DILUTED TO 22% IN LUMOS**

*** CSIRO: PROF BRETT SUTTON HEALTH, BIOSECURITY DIRECTOR**

*** STARPHARMA TO LOSE 16-YEAR CEO DR JACKIE FAIRLY**

*** ANSHUL THAKRAL REPLACES OPTHEA DIRECTOR MICHAEL SISTENICH**

*** LIVING CELL APPOINTS DR JAMES MCKENNA CSO**

MARKET REPORT

The Australian stock market was up 0.32 percent on Friday June 9, 2023, with the ASX200 up 22.8 points to 7,122.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Starpharma was the best, up four cents or 10.8 percent to 41 cents, with 378,215 shares traded. Antisense climbed 8.6 percent; Imugene improved 7.5 percent; Cynata was up 3.45 percent; Compumedics rose 2.6 percent, Avita, Emvision and Orthocell were up more than one percent; with Medical Developments, Mesoblast, Pro Medicus and Volpara up by less than one percent.

Prescient led the falls, down 0.6 cents or 6.7 percent to 8.4 cents, with 955,560 shares traded. Universal Biosensors lost 6.25 percent; Next Science fell 4.6 percent; Atomo and Cyclopharm were down more than three percent; Actinogen, Alcidion and Paradigm shed more than two percent; 4D Medical, Amplia, Immutep, Nanosonics, Polynovo, Proteomics and Telix were down one percent or more; with Clinuvel, Cochlear, CSL, Neuren and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: NOVA EYE MEDICAL

By TIM BOREHAM

ASX code: EYE

Market cap: $54.2 million

Share price: 28.5 cents

Shares on issue: 190,327,893

Chief executive officer: Tom Spurling

Board: Victor Previn (chair), Mr Spurling, Rahmon Coupe, Mike Southard

Financials (December half 2022): revenue $8.39 million (up 28%), net loss of $6.6 million ($3 million deficit previously).

Identifiable major holders: Australian Ethical 19%, Jancay Capital 7%, Sedico Pty Ltd (Victor Previn) 5%.

On his second CEO stint at the Adelaide-based eye diseases devices house, Tom Spurling sums up his mission statement in simple terms: "We are preserving the most valuable asset in the world - eyesight".

Having just raised $8 million in a placement, Nova Eye is in a more financially secure position to save glaucoma sufferers from blindness - one eyeball at a time.

Nova Eye is also about to mount a concerted push into the US market, having won US Food and Drug Administration (FDA) assent for Itrack Advance, a tweaked version of its Itrack catheter device for flushing out the eye.

Commercialized in 2008, Itrack was the pioneering device canaloplasty, a non-penetrating eye canal procedure to reduce the intraocular eye pressure that causes glaucoma.

Indeed, Mr Spurling describes glaucoma as "failure of the plumbing in the eye" (see below).

Itrack has been used in 120,000 surgeries to date.

Nova Eye also has a second string to its bow, a device in development to tackle the equally debilitating age-related macular oedema.

Both conditions are leading causes of blindness.

Eye see they've changed their name

Nova Eye was formed from the 'remains' of the ASX-listed Ellex Medical Lasers, which sold off most of its business (lasers and ultrasounds) to French multinational and laser specialist Lumibird for $100 million.

In April 2020, Ellex shareholders voted overwhelmingly in favor of the deal, which resulted in Ellex distributing $60 million to shareholders. The Australian Competition and Consumer Commission launched a public review, but in the end waved the acquisition through.

The sale also includes three of the group's biggest earning products - lasers used in the treatments of glaucoma, cataracts and diabetic eye disease.

These products accounted for about 80 percent of Ellex's sales, but the offer of a $100 million for the subdivision "was bigger than the then market cap for the whole company".

On completion of the deal, Ellex then changed its name to the downsized Nova Eye.

At the time, chair Victor Previn said Nova Eye would focus on the Itrack business and developing the 2RT (retinal rejuvenation therapy) age-related macular degeneration tool.

Mr Spurling joined (or effectively re-joined) the company in April 2021 as an executive, having previously headed Ellex between 2011 and 2019.

He was anointed to the top job in August 2021. Mr Spurling was also a director of the Adelaide-based green energy innovator Sparc Technologies but resigned in March 2022.

Nova Eye retains a research and development and manufacturing base in Adelaide. But most of company's business is in the US, where it has a direct sales team and a manufacturing facility in Fremont, San Francisco.

In Germany, the company sells directly to eye doctors, while elsewhere in Europe the company avails of distributors.

In China - an attractive market because of the expansive and ageing population - the company uses a well-established distributor. "There, we are relatively small but growing fast," Mr Spurling says.

What's the problem?

The ocular irrigation system at the front of the eye circulates nutrients, but with time and age - typically 40 years and over - blockages occur.

The optic nerve is crushed, the pressure builds and eventually patients lose their sight.

"It's painless and asymptomatic and the first sign is the loss of peripheral vision," Mr Spurling says.

In case you're wondering, that's why optometrists do the mildly uncomfortable 'air puff' eye-pressure test.

Mr Spurling says glaucoma typically has been treated with daily drops, which doesn't sound too arduous a task in return for the gift of sight.

Or does it? In reality, adherence is poor with 15 to 25 percent of patients not even renewing a second prescription.

"For someone aged 40 to 50 with a lifespan of another 30 years it's actually quite hard," Mr Spurling says, adding that older patients can have trouble self-administering the drops.

The poor adherence has sparked interest in earlier, minimally invasive surgical intervention and that's where Nova Eye comes into sight.

Just like clearing the gutters

Nova Eye report renewed interest in canaloplasty as part of the "glaucoma treatment armamentarium".

Itrack is used to perform a 360-degree clean-out of Schlemm's canal, the eye's natural ocular drainage system.

The FDA approved Itrack Advance on April 1, 2023.

Looking somewhat like a portable reading light, the devices are a catheter consisting of a light, a pipe and a wire.

The pencil-like handpiece enables surgeons to use their fingers to move the catheter through the canal. This optical waterway is then flushed out with bio-compatible fluid.

"It's like clearing the leaves from you gutter and then flushing with a hose," Mr Spurling says.

"Nothing is left behind."

Better dr-eye-vability

The key difference between the devices is 'driveability'. The original Itrack required the surgeon to navigate the micro-catheter around the canal with forceps, which Mr Spurling likens to pushing a "wet slippery noodle".

Itrack Advance incorporates a handpiece, enabling surgeons to guide the catheter with a thumb or forefinger.

“This design makes it more appealing and available to a wider range of surgeons,” Mr Spurling says.

Currently, the company sells Itrack to around 200 US surgeons but the tweaked device opens up access to about 1,200. In effect, the extra 1,000 are the surgeons lacking the finesse to chase the “wet slippery noodles”.

In the US, the company has started converting its existing Itrack customers and in April made the first sale among the wider surgeon cohort.

“We have direct evidence of good support for this product,” Mr Spurling says.

Management expects Itrack Advance sales in the US to drive “significant sales during the current and future fiscal years”.

The company is also developing Molteno3, for late stage severe and complex glaucoma.

At 0.4 millimetres wide, Molteno3 is a plate that slides between the tissue planes and adjacent extraocular muscles.

While no part of the Itrack is left in the eye, Molteno3 stays in the peepers.

Targeting cataract surgeons

Beyond glaucoma, there’s a broader market of 9,800 cataract surgeons.

Cataract removals are commonplace and Itracks are not directly relevant for the procedure. But about 20 percent of patients who present for cataract operations also have glaucoma.

“The idea of Itrack is it provides patients with the option of a minimally-invasive surgery at the same time as cataracts to solve their glaucoma,” Mr Spurling says.

“This reduces or eliminates the need to take drops every day.”

… and AMD

The second string to Nova Eye’s bow relates to treating aged-related macular degeneration – AMD - which is more prevalent than glaucoma.

The company is developing Alpha RET, a novel proprietary ophthalmic laser based on so-called 2RT (retinal rejuvenation therapy) platform and the world’s first AMD laser therapy.

2RT stabilises the degeneration if caught early enough, but may have to be repeated after five years.

While the device has Conformité Européenne (CE) mark approval, it essentially is in development and subject to a vaunted pivotal trial pitched at US approval.

The company's stated intention is not to use the proceeds from the Itracks to fund a trial, but to tap money from "global participants" interested in backing the trial.

Mr Spurling says the laser has the potential to delay progression of disease from intermediate to late stage and "materially disrupt the AMD treatment paradigm."

In other words: it could be bigger than the Itracks.

Finances and performance

With $2.63 million of cash in the bank at the end of December 2022, Nova Eye needed to raise some cash.

Announced on March 2, the placement was struck at 18 cents - a 22 percent discount to the prevailing 'undisturbed' price - with sophisticated and professional investors participating.

Already the company's biggest shareholder, Australian Ethical boosted its stake to just below the allowable 19.9 percent.

The directors also chipped in $270,000.

The funds are earmarked for expanding the rollout of the Itracks in the US, Europe and China.

In the six months to December 31, 2022, the company generated revenue of $8.39 million, 28 percent higher than the previous corresponding period and mainly from the Itracks.

The loss of $6.6 million compared to the previous $3 million deficit.

In the pandemic-affected year to June 2022, the company posted revenue of just under $13.4 million and lost $7.5 million.

The company reported a bounce in US Itrack revenues, as surgeons trialing rival devices returned to the fold.

The company is coy about pricing but Mr Spurling says there is a "healthy reimbursement structure" for physicians, hospitals and insurers.

The eye facilities buy the devices and Nova Eye also takes a per-procedure cut of reimbursement.

Over the last year Nova Eye shares have varied between 19 cents (March 7 2023) and 32 cents (December 21 2022). The shares hit a record high of 85 cents in January 2020.

Sizing the rivals

While many healthcare device companies claim to have the market to themselves, Mr Spurling describes the glaucoma landscape as “very competitive”.

Naturally, Itrack is superior to its peers.

“Our tech goes around 360 degrees of the canal; our competitors only do 180 degrees in a single pass,” Mr Spurling says.

“Our catheter has a light, which gives the doctor a better understanding of where the catheter is in the canal; a surgeon using our competitor products is guessing where it is.”

The owner of the Omni device, the Nasdaq-listed Sight Science trades on a market capitalisation of $US450 million and last year generated $US45 million in revenue.

“They are only four times bigger than us in revenue but ten times bigger than us in terms of market capitalization,” Mr Spurling says.

The private New World Medical markets a device called KDB Glide.

Dr Boreham’s diagnosis:

Over time, the age-related macular degeneration business could prove to be bigger and more lucrative than the glaucoma segment.

But it’s best to showcase the toys one already has and Mr Spurling notes there are 140 million people with glaucoma in the world. The surgical intervention market is valued at $US600 million now and growing at 15 percent a year.

Including the drugs, the total glaucoma market is worth $US6 billion.

“We see a very strong landscape and as one of the top three companies in this space we have a very good opportunity,” Mr Spurling says.

“We have a good product in the consumable surgical device market, one of the fastest in ophthalmology and in an absolute sense.”

With Itrack advance only just starting to be sold in the US, the company should have a good bead on sales by the end of December.

Early indications are promising, although we’re a little wary of the level of competition and the risk of pricing being eroded.

Otherwise, there’s potential with this one as far as the eye can see.

Disclosure:* Dr Boreham *is not a qualified medical practitioner and does not possess a doctorate of any sort … that he can find. Hang on, where are my glasses?

TELIX PHARMACEUTICALS

Telix has opened the first stage of its $21.2 million radio-pharmaceutical factory in Brussels South, to assist patient access to its radiotherapies.

In an announcement to media and social media, not released to the ASX, Telix said the 2,800 square metre (30,139 square feet) factory was in Belgium's 'Radiopharma Valley' and would be the primary manufacturing site for radio-isotopes and commercial and clinical products for patients in the Europe Middle East and Africa (EMEA) region.

Telix EMEA chief executive officer Raphael Ortiz said that patients needed to have access radio-pharmaceuticals and "given the just-in-time manufacturing and complex logistics required for radiopharmaceuticals this is vital to building a foundation for long-term, commercial success in our field and delivering to the needs of patients".

The company said it bought the 35,000sqm (8.65 acre) site in 2020, redeveloped it, decommissioned and removed two cyclotrons and renewed its radio-isotope licence.

Telix managing-director Dr Christian Behrenbruch said that suitable sites were "a rarity … [with] very few places in the world where a site of this scale could be constructed and secure a licence to produce the array of isotopes that our licence allows".

Telix said it was preparing to install the first of two planned cyclotrons, with the first stage of the buildout complete, including of nine manufacturing lines, two research and development laboratories, quality control laboratories and warehousing space with capacity to support its operations.

The company said that Belgium's Wallonia regional government provided grant funding and the Wallonia Export & Investment Agency provided access to financing.

Telix said that Wallonia was home to five major airports, including Liege Cargo, with most European destinations under two hours away by train or air travel, providing "an efficient supply chain for medical radioisotopes and equipment".

Telix fell 18 cents or 1.7 percent to $10.28 with 1.3 million shares traded.

IMUGENE

Imugene says it will dose the intra-venous monotherapy and combination cohorts of its phase I trial of CF33-hNIS, or Vaxinia, for metastatic or advanced solid tumors.

Last year, Imugene said it had US approval for a phase I, dose-escalation trial of Vaxinia for metastatic or advanced solid tumors in up to 10 patients (BD: Mar 23, 2022).

Today, the company said the monotherapy component had progressed from cohort 3 to cohort 4, with the pembrolizumab combination, moving from cohort 1 to cohort 2.

Imugene said the oncolytic virus had been shown to shrink "colon, lung, breast, ovarian and pancreatic cancer tumors in preclinical and animal models".

The company said that it hoped to recruit up to 100 patients at 10 trial sites in the US and Australia, escalating doses in cohorts of three to six patients.

Imugene was up 0.7 cents or 7.5 percent to 10 cents with 37.5 million shares traded.

PHARMAUST

Pharmaust says it has begun dosing the third cohort for its monepantel for motor neuron disease trial at 6.0mg/kg.

Earlier this week, Pharmaust said interim results from the monepantel trial for motor neuron disease showed the tablets to be well-tolerated and reached bloodstream therapeutic levels, and said the trial safety committee had approved the dose escalation of cohort one patients to cohort three (BD: June 7, 2023).

Pharmaust was up 0.1 cents or 1.3 percent to 7.6 cents.

NYRADA

Nyrada says it will evaluate its brain injury drug NYR-BI03 in an efficacy study and a stroke model study in the second half of 2023, in tandem with pre-clinical studies.
Nyrada said it had chosen to test NYR-BI03 instead of NYR-BI02 in preclinical studies, due to its “superior potency and safety profile”.
The company said that during pre-clinical development NYR-BI02 had shown to block transient receptor potential ion channels, limit excito-toxicity and secondary brain damage following traumatic brain injury or stroke but that good laboratory practice studies demonstrated a “sub-optimal safety profile” for continuous dosing.
Nyrada said it reviewed more than 200 available compounds and decided to use NYR-BI03, a closely related analogue of NYR-BI02, instead.
The company said it had paused the pre-clinical good laboratory practices while it manufactured quantities of NYR-BI03.
Nyrada was up 0.9 cents or 11.4 percent to 8.8 cents.

ARTRYA

Artrya says a meeting with the US Food and Drug Administration agreed a regulatory path for its Salix coronary anatomy system for coronary plaque identification.
In May, Artrya said the ‘Q submission’ was a “key enabling step” in the US regulatory process and it expected a meeting with the FDA to present its approach to the Salix product’s development and clinical reader study, with the meeting to provide feedback on its regulatory strategy, product definition, indications for use and product testing and clinical validation requirements (BD: May 3, 2023).
At that time, the FDA could not explain what the “Q” represented but said a ‘Q-Submission’ or ‘Q-Sub’ “refers to the system used to track the collection of interactions” and were opportunities for submitters to share information with the FDA and receive input beyond the submission of an application.
Today, Artrya said the FDA agreed on a pathway to 510(k) regulatory clearance for Salix and discussed the multi-reader, multi-site study, receiving feedback on the study design in preparation for their 510(k) submission.
The FDA website said that a 510(k)-pre-market submission was “to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device”.
Artrya said that its 510(k) application would be updated to include feedback and guidance from the FDA, and would be submitted to the FDA “in due course”.
Artrya chief executive officer Mathew Regan said the meeting was “a significant moment for Artrya”.
Artrya was unchanged at 20.5 cents.

CRESO PHARMA

Creso Pharma says it has a letter of intent to import 3,4-methylene-dioxy-meth-amphetamine and psilocybin from Switzerland’s Apotheke Dr Hysek AG.
Creso said the commercial terms had not been decided but both parties would enter into a detailed agreement on or before August 31, 2023, unless the deal fell through.
The company that the letter of intent proposed it would provide the infrastructure to import, warehouse and distribute the products through its wholly-owned subsidiary Health House International.
Creso was unchanged at 0.9 cents with 2.8 million shares traded.

IMMUTEP

The Auckland, New Zealand-based Milford Asset Management says it has become a substantial shareholder Immutep with 61,555,077 shares or 5.339 percent.
The Milford substantial shareholder notice said that the registered holder was NNL custodians and between May 24 and June 8, 2023 it bought shares with the single largest transaction 16,658,988 shares for $4,331,337 or 26 cents a share.
Last week, Immutep said that a placement and institutional entitlement offer had raised $67.9 million at 26 cents a share (BD: Jun 2, 2023).
Immutep fell half a cent or 1.7 percent to 29 cents with 2.7 million shares traded.

IDT AUSTRALIA

Sandon Capital says it has increased its substantial shareholding in IDT from 32,774,525 shares (13.6%) to 51,331,149 shares (16.9%).
The Sydney-based Sandon said that it acquired 17,643,964 shares through IDT's recent placement for a total of $1,146,858 or 6.5 cents.
Earlier this week, IDT said it had firm commitments for a placement to raise $5.0 million at 6.5 cents a share (BD: Jun 5, 2023).
IDT was unchanged at 6.5 cents.

BIOXYNE

Donald Gibson and Global CR Holdings say they have become substantial shareholders in Bioxyne with 182,661,044 shares or 9.6 percent.
Auckland's Global CR director Mr Gibson said the company became substantial on May 19, 2023.
In late May, Bioxyne said it had completed its acquisition of Breathe Life Sciences issuing 1,230,000,000 shares to Breathe Life shareholders (BD: May 22, 2023).
Bioxyne was untraded at 2.5 cents.

VECTUS BIOSYSTEMS

The Kefford Family says it has increased its substantial shareholding in Vectus Biosystems from 3,948,321 shares (7.62%) to 4,650,000 shares (8.83%).
The Brisbane-based Kefford Family Trust said it bought shares between January 3 and June 8, 2023, with the single largest purchase 340,000 shares for $154,757 or 45.5 cents a share.
Vectus fell 1.5 cents or 3.2 percent to 45 cents.

LUMOS DIAGNOSTICS

Melbourne's Planet Innovation Holdings says its 68,021,060 share-holding in Lumos has been diluted from 23.34 percent to 21.98 percent.
Planet Innovation said it had been diluted by the issue of shares in respect of the conversion of a convertible note by SBC Global Investment on June 2, 2023.
Lumos was up 0.1 cents or 8.3 percent to 1.3 cents with two million shares traded.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says it has appointed former Victoria chief health officer Prof Brett Sutton as its director of health and biosecurity, starting in September 2023.

The Organisation said Prof Sutton had provided "expert advice on matters relating to the health and well-being of Victorians, including playing a critical leadership role in the public health response to Covid-19 in Victoria".

CSIRO said Prof Sutton would assist research and development for Australia's health and bio-security preparedness and responsiveness, digital health, and health and wellbeing, and play a "leading role" in developing its broader health challenge strategy, focusing on human health and the impact of animal and environmental factors on human health.

The Organisation said Prof Sutton was a public health physician with extensive experience and clinical expertise in public health and communicable diseases, and had working in government, emergency medicine and field-based international work.

CSIRO executive director Kirsten Rose said "the magnitude of the challenges Prof Sutton faced as Victoria's chief health officer in guiding the public health response to Covid-19, together with his specialized knowledge in tropical medicine and infectious disease, gives him a unique and compelling skill set to continue to drive CSIRO's leadership in health and biosecurity research".

According to his Linkedin page, Prof Sutton held a Bachelor Medicine, Bachelor of Surgery from the University of Melbourne and a Masters of Public Health and Tropical Medicine from Queensland's James Cook University.

STARPHARMA

Starpharma says that 16-year chief executive officer Dr Jackie Fairley intends to retire during 2024 and will continue until a successor is ready to begin.

Starpharma said Dr Fairley would remain available under a consultancy agreement for up to 12 months after her successor begins.

Starpharma chair Rob Thomas said that Dr Fairley had shown "a remarkable dedication".

"Under her leadership and vision, Starpharma has successfully transformed from a start-up with promising technology to a mature organization with multiple commercial partnerships, marketed products around the world, and a strong portfolio of pre-clinical and clinical-stage assets," Mr Thomas said.

"She has also built a stable and highly skilled workforce and positive organizational culture which will serve the company well into the future," Mr Thomas said.

"I sincerely thank Jackie for her vision, leadership, drive, personal support and contribution throughout her time with Starpharma as chief executive officer," Mr Thomas said.

Starpharma said it had begun a search for a new chief executive officer.

Starpharma was up four cents or 10.8 percent to 41 cents.

OPTHEA

Opthea says Anshul Thakral has been appointed as a non-executive director, following the resignation of seven-year director Michael Sistenich.

Opthea said Mr Thakral was Launch Therapeutics chief executive officer and previously was an executive with PPD Biotech and the Gerson Lehrman Group.

According to his Linkedin page Mr Thakral held a Bachelor of Science and a Master of Biomedical Engineering from Baltimore's Johns Hopkins University and a Master of Business Administration from the University of Pennsylvania's Wharton School.

Opthea was unchanged at 57.5 cents.

LIVING CELL

Living Cell says it has appointed Dr James Mckenna as its chief scientific officer, effective from June 19, 2023.

Living Cell said Dr Mckenna had been a research scientist for 23 years, was currently employed at La Trobe University as a research scientist, and was previously with Hexima.

The company said that Dr McKenna had managed teams working on pre-clinical and clinical research and development programs.

Living Cell said Dr Mckenna held a Bachelor of Science and a Doctor of Philosophy from the University of Melbourne.

Living Cell was up 0.1 cents or 9.1 percent to 1.2 cents.