Biotech Daily

Friday November 22, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PARADIGM UP 20%; MICRO-X DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: LTR PHARMA**

*** TRYPTAMINE DOSES 1st OBESE TRP-8803 I-V PSILOCYBIN PATIENT**

*** GENETIC SIGNATURES RECEIVES $5m FEDERAL R&D TAX INCENTIVE**

*** ISLAND RECEIVES $865k FEDERAL RDTI; REPAYS RADIUM LOAN**

*** ASX EXTENDS GENETIC TECHNOLOGIES SUSPENSION**

*** PATRYS AGM 30% REMUNERATION REPORT 1st STRIKE**

*** MEMPHASYS AGM 26% OPPOSE DIRECTOR MICHAEL ATKINS ELECTION**

*** ALTERITY AGM 24.4% REMUNERATION REPORT VOTE**

*** BIOXYNE AGM 22% OPPOSE REMUNERATION REPORT, DIRECTOR RIGHTS**

*** IMMUTEP AGM 20% OPPOSE EXECUTIVE DIRECTOR RIGHTS**

*** RESMED AGM 20% OPPOSE DIRECTOR RICHARD SULPIZIO ELECTION**

*** RESPIRI REQUESTS 'STRATEGIC ACQUISITION' TRADING HALT**

*** PERENNIAL TAKES 11.9% OF MEDADVISOR**

*** ARTRYA FOUNDER JOHN BARRINGTON REDUCES TO 7.65%**

*** PROF CHANDRA BALA REPLACES CAMBIUM'S PROF GRAHAM VESEY**

MARKET REPORT

The Australian stock market was up 0.85 percent on Friday November 22, 2024, with the ASX200 up 70.8 points to 8,393.8 points. Fifteen of the Biotech Daily Top 40 companies were up, 20 fell, three traded unchanged and two were untraded. All four Big Caps rose.

Paradigm was the best, up 5.5 cents or 20.4 percent to 32.5 cents, with five million shares traded. Resonance rose 9.4 percent; Actinogen climbed 8.3 percent; Immutep improved seven percent; Dimerix was up 6.15 percent; Imugene was up 5.4 percent; Syntara rose 4.8 percent; Pro Medicus was up 3.3 percent; 4D Medical, Cochlear, CSL, Impedimed, Mesoblast, SDI and Telix were up one percent or more; with Aroa, Cyclopharm, Orthocell and Resmed up by less than one percent.

Micro-X led the falls, down 0.5 cents or 7.35 percent to 6.3 cents, with 494,596 shares traded. Atomo lost five percent; Clarity and Curvebeam fell more than four percent; Alcidion, Medadvisor, Nova Eye and Opthea were down three percent or more; Amplia, Emvision, Genetic Signatures, Nanosonics, Prescient and Proteomics shed more than two percent; Avita and Medical Developments were down one percent or more; with EBR, Clinuvel, EBR, Neuren and Polynovo down by less than one percent.

DR BOREHAM'S CRUCIBLE: LTR PHARMA

By TIM BOREHAM

ASX code: LTP

Share price: $1.215

Shares on issue: 153,901,979

Market cap: $187.0 million

Executive chair: Lee Rodne

Board: Mr Rodne, Dr Julian Chick, Maja McGuire

Financials (year to June 30, 2024): revenue nil, loss of $9.95 million ($1.45 million deficit previously), cash of $3.1 million (up 79%) ahead of $10.5 million capital raising

Identifiable major shareholders: Mr Rodne 34% interest, Strategic Drug Solutions 3.8%, Trexapharm 2.7%.

When we were kids eyeing an unobtainable treat or the not-so-imminent arrival of Santa, Mum used to tell us to be patient. Patience, indeed, is a virtue and an admirably quality to exhibit throughout one's adult life.

But there are circumstances when even a Job-like quotient of patience will not suffice - and one of them is waiting for the effect of erectile dysfunction tablets to kick in.

According to LTR Pharma, oral drugs such as Viagra and Cialis can take more than an hour to have their desired effects.

Yes, there's such a thing as foreplay but in such a time span the amorous vibe is likely to be surpassed by the imperative of vacuuming the hall or emptying the dishwasher.

LTR Pharma is developing a nasally-delivered variant of the same drug class which, on evidence to date, hits peak bloodstream levels within nine to 15 minutes.

LTR founder and executive chair Lee Rodne says 50 percent of men stop taking the current tablets within a year, because of the timing problem and side effects.

"A lot of guys don't realize that Viagra is very variable as a tablet because of the delivery mechanism," Mr Rodne says.

"It has to go through your gut and your liver; sometimes it is effective but sometimes it is not effective at all."

The rise and rise of LTR

Mr Rodne founded LTR based on technology acquired from California's Strategic Drug Solutions, with pharmacologist Prof Moses Chow credited as the inventor.

Then an executive with iron-ore producer Fortescue Metals, Mr Rodne was hand-picked by Fortescue founder Dr Andrew 'Twiggy' Forrest to lead the company's health spin-off Allied Medical.

Mr Rodne led Allied for 10 years, merging it with Biomd to become Allied Healthcare and then Admedus and now heart transcatheter play Anteris Technologies.

Mr Rodne's Allied experience led him to a group of medical researchers and manufacturers who asked him for help with a project to make erectile dysfunction treatments more effective and consistent.

Under the deal with Strategic Drug Solutions, LTR Pharma can use the technology in any way, but its current sole focus is on erectile dysfunction (ED).

LTR Pharma listed on December 11 last year, having raised $7 million at 20 cents apiece.

Mr Rodne owns 59 percent of the company, with fellow director Dr Julian Chick accounting for 19.7 percent.

Dr Chick has been involved in no fewer than 16 start-ups and helmed the ASX-listed Avexa, which tried to develop an HIV drug but eventually went coal mining in Alabama instead. He is the chair of pot play Cann Group and is behind the proposed ASX listing of a nerve regeneration company called Renerve.

About Spontan

Spontan - as in spontaneous - is a drug and device combination to deliver vardenafil, the basis of Levitra and Staxyn.

Vardenafil is a PDE5 inhibitor, which target receptors that relax muscles and increase blood flow to the penis.

Other PDE5 inhibitors are behind Pfizer's Viagra (sildenafil), the first to market in 1998, Cialis (tadalafil) and Stendra (avanafil).

All these PDE5s are pretty much same-same, but vardenafil was deemed the most suitable for nasal reformulations.

Mr Rodne says current side-effects include heartburn and joint pain, which are all the result of the oral tablets going through the gastro-intestinal tract.

Spontan, of course, goes straight to the blood stream.

Why not earlier?

Mr Rodne says Spontan currently faces no competition, but the lingering question is why big pharma - notably trailblazer Pfizer with its 'Pfizer riser' - didn't crack the nasal channel.

Cialis, Viagra and Levitra, the three biggest-selling erectile dysfunction drugs are now off-patent and subject to generic competition. Stendra's patent expires in April 2025.

"Pfizer looked into it [nasal delivery] but it's very hard to work because of the [PDE5] chemical structure," he says. "It tends crystallize when in liquid form, so you can't just crush up a chemical tablet, put it in a bottle and expect to be able to spray it."

The nub of LTR's smarts is the ability to keep the drug soluble and enhance drug interaction.

Where's the evidence?

LTR Pharma's proof of efficacy to date is a small local trial and 'real world' usage evidence.

On June 7 this year the company said an 18-man bio-availability trial showed Spontan hit peak bloodstream levels in nine to 15 minutes – an average of 12 minutes – compared with an average 56 minutes and as much as 150 minutes for oral vardenafil.

The healthy adults were given two single 5.0mg doses of Spontan, as well as a 10mg dose of the oral version after a respectable crossover period.

Given the drug is known to be effective once it reaches the bloodstream, that's all the trial had to prove. In other words, the subjects weren't being assessed on the quality of erections and lovemaking by a white-coated researcher at the end of the bed.

Early in the piece, LTR became eligible for the local Therapeutics Goods Administration's special access scheme and then the authorized prescriber scheme. These allow unapproved treatments to be administered.

Initially, Spontan was prescribed by two men's health doctors, but has spread to a broader cohort. A notable prescriber is urology expert Prof Eric Chung of the University of Queensland.

Taking it slowly

Mr Rodne says the company won't reveal current patient use - which is on the rise - because it doesn't want investors to focus on sales for what is still a research and development-stage company transitioning to commercial phase.

“Before we do that fully, we want specific feedback on patient use, such as whether they are using it in combination with other products,” he says. “We also want to produce education videos on how to use the product and we have some more packaging work to do and ensure patients can follow the instructions clearly.”

That said, the company hopes the trial and the real-world data will support an application to the TGA initially; and then the US Food and Drug Administration, under the 505(b)(2) route, for a change in route of administration for an already approved drug, by mid-2025.

“We expect to use the data packages for both agencies, but our home market is important for us,” Mr Rodne says.

While the requirement for further trials is unclear, the company expects more investigator-led studies here, with a standard requirement for an animal toxicology study.

Take your partners

In the meantime, LTR is in confidential licencing and partnering discussions with pharmaceutical companies.

“We will run these discussions until [mid] 2025 and see what sort of value we can create,” Mr Rodne says. “They would not waste their time if they were not interested.”

In August, LTR entered a co-development agreement with New York’s Aptar Pharma, a developer of nasal spray medicines used by Pfizer and Johnson & Johnson.

“They [Aptar] don’t partner with everyone: it needs to be a differentiated product with a big market and significant data.”

As LTR’s device partner, Aptar will carry out market and regulatory readiness work, such as meeting with the agencies and formulation studies.

“Aptar has more than 25 products approved with the FDA, so we don’t have to prove [the device works] in the same way we don’t have to prove the drug works, because it has already been approved in oral form.” The PDE5 tablets have been tested on hundreds of thousands - if not millions - of patients and cost more than $US1 billion to develop.

Telehealth

Earlier this month, LTR entered a joint venture with a West Australian men's health group, the Restorative Sexual Health Clinic, for an online healthcare platform.

“The online platform will provide a discrete and convenient channel for men to access professional healthcare services and prescribed treatments,” Mr Rodne says.

The platform is expected to launch in the March quarter of next year.

Finances and performance

Shortly after the positive trial results, LTR bolstered its $7 million of IPO funds with a $10.5 million placement, struck at 73 cents apiece (a 19 percent discount).

Mr Rodne says LTR has sufficient cash – three years - beyond the likely timelines for regulatory approval and commercial partnering.

The company intends to devote some of the funds to building an online sales channel, to avail of the rapid rise in digital prescriptions (in fact, the lion's share of erectile dysfunction scripts is written remotely).

LTR Pharma's annual report shows a contingent liability of $US3 million, by way of potential milestone payments to Strategic Drug Solutions.

LTR Pharma shares have always traded above their 20 cents listing price, bottoming at 27 cents two days after the IPO and peaking at $2.06 on October 10 this year.

Dr Boreham's diagnosis:

Mr Rodne says that as a company focused on a single re-purposed drug, LTR Pharma is a simple story to understand.

Spontan also addresses a high unmet need, with an estimated 322 million of the world's blokes estimated to suffer erectile difficulties. Of these, close to half are in China, which might explain the nation's sagging birth rate. Australian blokes can't exactly stand proud, either, with the condition affecting more than 60 percent of over 45s.

The value of the erectile dysfunction market is estimated at $US4.52 billion, with the US accounting for 30 percent despite having less than 10 percent of the sufferers.

The market is expected to grow to $US6 billion by 2028, despite what Mr Rodne describes as a complete lack of erectile dysfunction treatment innovation.

While LTR Pharma is an easy-to-understand proposition, there's no plan B if Spontan fails to gain market approval or flops at launch.

An unexpected rival could also emerge, but Mr Rodne believes the coast is clear.

The endgame for LTR is unclear - it might go all the way to market on its own-– but it would be stiff for the company to fail at this point. After all, Spontan would seem to be a great way for, say, Pfizer, to re-establish patent life on its famed blue pill.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He doesn't have a Job-like quotient of patience, so will ensure the dishwasher stays off at the crucial moment.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has dosed and discharged the first of three obese participants in its phase Ib study of 140 minutes of intra-venous psilocybin-based TRP-8803.
Last month, Tryptamine said its 11-healthy volunteer, phase Ib trial showed TRP-8803 was “generally safe and well-tolerated” (BD: Oct 18, 2024).
On Tuesday, the company said the phase Ib study confirmed the required dose for a phase II trial, but did not state the specific dose (BD: Nov 19, 2024).
Today, Tryptamine said the open-label phase Ib study would enrol three obese participants “to determine if there are any differences in pharmaco-kinetic parameters compared to previous studied non-obese patients”.
The company said the first obese participant was discharged shortly after dosing follow-up was completed with two additional volunteers to receive dosing “over the coming weeks”.
Tryptamine said the results were expected “to support TRP8803’s dosing within obese study participants and to provide valuable and cost-effective data to optimize dose selection for the company’s phase II clinical program using TRP-8803 in specific indications”.
The company said it expected the obese subject population interim results “this year”.
Tryptamine chief executive officer Jason Carroll said the study was “very capital efficient and will provide the company with valuable data to further refine TRP-8803 dosing rates across a broader cross section of the population, while also building on our comprehensive dataset”.
“The first patient dosing follows exceptional and positive results from an initial three patient cohorts, which have determined TRP-8803’s safety, optimal dose and infusion rates and highlighted TRP-8803’s ability to achieve improved health outcomes at scale,” Mr Carroll said.
“This dataset will be used to inform the company’s phase II trial planning, which will explore the application of TRP-8803 across specific indications,” Mr Carroll said.
“The board and management are assessing a number of opportunities in relation to phase II trials for TRP-8803,” Mr Carroll said.
Tryptamine was unchanged at 4.5 cents with 2.9 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has received $5,001,792 from the Australian Tax Office under the Federal Government’s Research and Development Tax Incentive program.
Genetic Signatures said the incentive related to research and development expenditure for the year to June 30,2024.
Genetic Signatures fell 1.75 cents or 2.4 percent to 70 cents.

ISLAND PHARMACEUTICALS

Island says it has received $865,230 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Island said the incentive related to research and development expenditure for the year to June 30, 2024, with the funds used to repay its Radium Capital loan in full.
Last year, the company said it had borrowed $386,000 from Melbourne’s Radium Capital as an advance on its Federal Research and Development Tax incentive at 16 percent interest a year and repayable at the time it receives its tax incentive, expected by November 2024 (BD: Dec 15, 2023).
Island was unchanged at 16.5 cents.

GENETIC TECHNOLOGIES

The ASX says Genetic Technologies "will continue to be suspended from quotation under Listing Rule 17.3", which relates to suspensions "not at [the] entity's request".
Last month, Genetic Technologies said that it had requested an extension to its suspension following a trading halt for its "operational review and progress on its fund raising" (BD: Jul 26; Oct 17, 21, 2024).
On Wednesday, FTI Consulting said its Ross Blakeley and Paul Harlond had been appointed as voluntary administrators of Genetic Technologies, effective from November 20, 2024 (BD: Nov 20, 2024).
Today the ASX said that following the company's November 20 announcement "of the appointment of voluntary administrators, the securities of [Genetic Technologies] will continue to be suspended from quotation under Listing Rule 17.3".
"The suspension will continue until [the] ASX is satisfied that [Genetic Technologies] is in compliance with the Listing Rules, including Listing Rule 12.2, and that it is otherwise appropriate for [its] securities to be reinstated to quotation," the ASX said.
Genetic Technologies last traded at 3.9 cents.

PATRYS

Patrys says its annual general meeting voted a 30.33 percent remuneration report first strike with 34.70 percent against the equity incentive plan.
Patrys said the remuneration report was opposed by 161,357,265 votes (30.33%) with 370,632,061 votes (69.67%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company that sustains a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill.
If passed, the directors must stand for re-election within 90 days.
The company said the equity incentive plan was opposed by 188,735,950 votes (34.70%), the election of director Dr Pamela Klein had 153,629,927 votes (23.25%) in opposition and the 10 percent placement capacity passed easily.
According to its most recent notice, Patrys had 2,057,447,335 shares on issue, meaning that the 188,735,950 votes against the equity incentive plan amounted to 9.2 percent of the company, sufficient to requisition extraordinary general meetings.
Patrys was up 0.05 cents or 12.5 percent to 0.45 cents.

MEMPHASYS

Memphasys says its annual general meeting passed all resolutions, with 25.77 percent of votes opposed to the election of director Matthew Atkins.
Memphasys said Mr Atkins' election was opposed by 141,486,483 votes (25.77%) with 406,707,930 votes (74.23%) in favor.
The company said the remaining resolutions were overwhelmingly approved by more than 99.2 percent of the meeting.
According to its most recent filing, the company had 1,763,081,433 shares on issue, meaning that the 141,486,483 votes against Mr Atkins' election amounted to 8.0 percent of the company, sufficient to requisition extraordinary general meetings.
Memphasys was unchanged at 0.6 cents with 1.9 million shares traded.

ALTERITY THERAPEUTICS

Alterity says investors narrowly missed a remuneration report first strike with 24.35 percent against and voted 24.58 percent against the prior issue of placement shares.
Alterity said the remuneration report was opposed by 87,766,213 votes (24.35%) with 272,623,588 votes (75.67%) in favor.
The company said the 10 percent placement capacity was opposed by 99,500,946 votes (22.90%) with 335,010,917 votes (77.10%) in favor.
Alterity said the prior issue of placement shares was opposed by 24.58 percent of votes, with the issue of director options opposed by about 17 percent of the meeting.
Last month, Alterity said investors would vote to issue 170,000,000 options to directors Geoffrey Kempler Lawrence Gozlan, Peter Marks and Brian Meltzer (BD: Oct 23, 2024).
According to its annual report, Alterity had 5,320,336,118 shares on issue, meaning that the 99,500,946 votes against the placement capacity amounted to 1.9 percent of the company, not sufficient to requisition extraordinary general meetings.
Alterity was unchanged at 0.3 cents with 6.9 million shares traded.

BIOXYNE

Bioxyne says its annual general meeting approved all resolutions with up-to 22.25 percent against the remuneration report and the issue of rights to two directors.
Last month, Bioxyne said the meeting would vote to issue 30,000,000 performance rights to managing-director Sam Watson and executive director Jason Hine and 5,000,000 options to chair Tony Ho (BD: Oct 23, 2024).
Today, the company said Mr Hine's rights were opposed by 135,086,642 votes (22.26%) with 471,781,881 votes (77.74%) in favor, Mr Watson's rights had 135,675,124 votes (22.21%) against, with the remuneration report opposed by 132,497,857 votes (21.85%).
The company said Mr Hine was re-elected with 11.0 percent dissent, with the ratification of the issue of shares and the placement capacity passed overwhelmingly.
According to its most recent notice, Bioxyne had 2,046,645,398 shares on issue, meaning that the 135,086,642 votes against Mr Hine's performance rights amounted to 6.6 percent of the company, sufficient to requisition extraordinary general meetings.
Bioxyne was unchanged at 1.3 cents with 1.85 million shares traded.

IMMUTEP

Immutep says its annual general meeting passed all resolutions with up-to 20.06 percent against the issue of performance rights to two executive directors.
Immutep said Mr Voigt's 3,600,000 rights were opposed by 132,951,234 votes (19.93%) and had 534,232,087 votes (80.07%) in favor, with Prof Triebel's 2,700,000 rights opposed by 132,108,683 votes (20.06%) and approved by 526,421,011 votes (79.94%).
Immutep said the termination benefits were opposed by 12.13 percent, the issue of performance rights under the executive incentive plan had 9.10 percent opposition, the remuneration report and election of Prof Triebel as a director were opposed by 7.37 percent and 7.30 percent of the meeting, respectively, and the prior issue of shares and the proportional takeover provisions were passed easily.
According to its annual report, Immutep had 1,452,612,290 shares on issue, meaning that the 132,951,234 votes against Mr Voigt's rights amounted to 9.15 percent of the company, sufficient to requisition extraordinary general meetings.
Immutep was up two cents or seven percent to 30.5 cents with 5.25 million shares traded.

RESMED

Resmed says its annual general meeting passed all resolutions but with up-to 20.0 percent against the election of director Richard Sulpizio.
Resmed said 22,003,356 votes (20.00%) opposed Mr Sulpizio's election, with 88,007,747 votes (80.00%) in favor.
The company said 15.70 percent opposed the executive officers' compensation, with the independent accountant opposed by 8.77 percent and the election of Ronald Taylor as a director opposed by 13.35 percent with the remaining nine directors elected more easily.
According to its most recent filing, Resmed had the equivalent of 146,747,766 US shares on issue, meaning Mr Sulpizio's opposition to amounted to 15.0 percent of the company.
Resmed was up 20 cents or 0.5 percent to $37.28 with 578,937 shares traded.

RESPIRI

Respiri has requested a trading halt "pending an announcement by the company to the market regarding a strategic acquisition".
Trading will resume on November 26, 2024, or on an earlier announcement.
Respiri last traded at eight cents.

MEDADVISOR

Perennial Value Management Ltd says it has increased its substantial shareholding in Medadvisor from 57,326,354 shares (10.40%) to 65,656,394 shares (11.91%).
The Sydney-based Perennial said that it bought and sold shares on market between September 13 and November 20, 2024, with the single largest purchase 1,332,442 shares on October 31 for $320,490, or 24.05 cents a share.
Medadvisor fell one cent or 3.3 percent to 29 cents.

ARTRYA

Artrya co-founder and former managing-director John Barrington says he has reduced his holding in the company 7,526,095 shares (9.62%) to 6,933,146 (7.65%).
The Perth-based Mr Barrington said that on May 13 and 16, 2022 he bought 67,000 shares on market for $62,688, or 93.6 cents a share and between October 16 and 29, 2024 he transferred 250,500 shares for $115,695, or 46.2 cents a share.
Artrya fell 1.5 cents or 3.3 percent to 43.5 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it has appointed Prof Chandra Bala as a director, replacing founding director Prof Graham Vesey, effective immediately.
Cambium said Prof Bala was an ophthalmologist, the senior partner at Personaleyes and a surgeon at Macquarie University Hospital.
In April, the then Regeneus said it would merge with Atlanta, Georgia's Cambium Medical Technologies to develop Elate Ocular for dry eye disease (BD: Apr 28, 2023).
Today, the company thanked Prof Vesey for his since 2007.
Cambium was unchanged at 52 cents.