



Biotech Daily

Friday July 5, 2024

Daily news on ASX-listed biotechnology companies

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- * **DR BOREHAM'S CRUCIBLE: STARPHARMA**
- * **CLINUVEL: 'AFAMELANOTIDE REDUCES U-V LIGHT DNA DAMAGE'**
- * **GENETIC SIGNATURES RETAIL RIGHTS RAISE \$8.5m; TOTAL \$30m**
- * **INOVIQ 'OVERSUBSCRIBED' SHARE PLAN RAISES \$2.4m; TOTAL \$9.4m**
- * **NHMRC, MRFF CLOSER COOPERATION; ADVISERS WANTED**
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- * **PARTICIA VANNI REPLACES BLUECHIIP CO SEC CHELSEA SHERIDAN**

MARKET REPORT

The Australian stock market fell 0.12 percent on Friday July 5, 2024, with the ASX200 down 9.5 points to 7,822.3 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 12 were down and six traded unchanged. All three Big Caps were up.

Syntara was the best for the second day in a row, up 0.5 cents or 20.0 percent to three cents, with 2.8 million shares traded.

Clinuvel climbed 14.6 percent; Medical Developments and Next Science were up more than seven percent; Nova Eye climbed 6.25 percent; Immutep and Mesoblast improved more than five percent; Atomo and Compumedics were up more than four percent; Cyclopharm, Prescient and Starpharma increased more than three percent; Curvebeam, Impedimed, Medadvisor and SDI rose two percent or more; Cochlear, Nanosonics, Opthea, Pro Medicus, Proteomics and Telix were up one percent or more; with CSL, Polynovo and Resmed up by less than one percent.

Amplia led the falls, down 0.3 cents or 4.7 percent to 6.1 cents, with 310,955 shares traded; followed by Clarity, down 22 cents or 4.2 percent to \$4.98 with 925,206 shares traded.

Dimerix, Imugene, Resonance and Universal Biosensors lost more than three percent; 4D Medical, Alcidion and Genetic Signatures shed two percent or more; Paradigm and Percheron were down more than one percent; with Emvision down by 0.25 percent.

[DR BOREHAM'S CRUCIBLE: STARPHARMA](#)

By TIM BOREHAM

ASX code: SPL

Share price: 9.9 cents; **Shares on issue:** 412,372,598; **Market cap:** \$40.8 million

Chief executive officer: Cheryl Maley

Board: Rob Thomas (chair), Ms Maley, David McIntyre, Lynda Cheng, Dr Jeff Davies, Dr Russell Bassar

Financials (March quarter 2024): receipts \$371,000, net cash outflows \$5.327 million, cash balance \$26.5 million, quarters of available funding 5.1 (with access to undrawn loan facilities of \$591,000)

(December half 2023): revenue \$8.025 million (up 400%), adjusted revenue \$1.472 million (down 8%), loss of \$1.034 million (previous loss \$8.277 million), adjusted loss \$7.587 million (the adjusted figures exclude the impact of \$6.55 million received in August 2023, as settlement of an agreement with Mundipharma)

Major shareholders: Allianz SE 11.8%, Allan Gray 7.91%, UIL Ltd 6.69%, ICM Investment Management 5.2%

With Starpharma shares having lost losing three-quarters of their value over the previous year when new CEO Cheryl Maley reported for duty on January 8 this year, the former big drug company exec knew that maintaining the status quo wouldn't cut it.

With the freedom to make changes enjoyed by an incoming chief, Ms Maley began a review involving management, the board, external experts and some shareholders. Unveiled in May, the soul-searching effort concluded that the dendrimer technology specialist was confusing investors with its array of early to late-stage programs, notably in cancer.

"Over the years, the broad portfolio from early assets to commercial assets ... has been a strength for Starpharma," Ms Maley says.

"But we have learned that having those broad options perhaps has led to a loss of identity, or some confusion about what is Starpharma's core value proposition."

That said, the new guard is not exactly chucking out the baby with the bath-water, with the clinical cancer programs reduced from three to two (see below).

The company is also honing its approach to partnerships, one example being an equity involvement in a drug development joint venture with the London-based life sciences investor Medicxi Ventures.

And – yes - investors can also expect a nip and tuck of the cost base.

Star(pharma) gazing over time

Starpharma listed in September 2000 as a Paul Keating-era pooled development fund (PDF). Despite these PDFs being valuable - they confer tax advantages at revenue stage - the company shed the structure.

Starpharma sold its agricultural chemical division to Canadian agri-giant Agrium in 2017 for \$35 million, in favor of focusing on two-legged beings.

Starpharma used to sell Vivagel-coated condoms to the ASX-listed Ansell, before Ansell sold its 'sexual health' arm to Chinese interests in 2016. But Starpharma still has - er - things covered with Japan's Okamoto Industries.

Formerly a practising veterinarian, Dr Jackie Fairley became CEO in July 2006 and held the role for an almost record-breaking 17 years.

Holding a science degree majoring in human physiology, Ms Maley started out in a research role at CSIRO and then had 25 years in the pharmaceutical sector, including at Novartis, Abbvie/Abbott, Servier Laboratories and Wyeth Pharmaceuticals. At Novartis she was Australia and New Zealand head of oncology.

"I have launched many products in different regions and countries and I can bring that experience to Starpharma," she says.

Dendrimers

Starpharma's reason for being is its dendrimer enhanced product (DEP) platform, with the company laying claim to being the only one to commercialize a DEP product (the bacterial vaginosis treatment Vivagel).

Before you ask, dendrimers are nanoscale polymers aimed at improving drug efficacy and reducing side effects (such as bone marrow toxicity and hair loss).

The company broadened to a series of oncology programs that combine the dendrimer with three existing drugs.

They are irinotecan (colorectal cancer), cabazitaxel (prostate cancer and others) and docetaxel (breast, head and gastric cancers).

While all programs have completed phase II trials, work on the last has been paused.

"It would be fantastic to progress all of the assets ... but we need to prioritize to allow us to be successful in a partnering and licencing deal," Ms Maley says.

The cabazitaxel program adds DEP to Jevtana, a Sanofi-Aventis drug.

The irinotecan program tricks up Pfizer's drug Camptosar. A phase II program showed efficacy in multiple tumor types including colorectal, breast, ovarian, pancreatic, lung and oesophageal.

Medicxi deal heralds corporate renaissance

As with E-harmony, Starpharma is all about partnering.

In April, the company said it would co-found a UK company, Petalio Therapeutics with Medicxi Ventures, which will develop one of Starpharma's molecules for an unnamed dendrimer drug conjugate target. Medicxi will chip in up to \$US25 million (\$38 million) and Starpharma will contribute "certain intellectual property" for a 22.5 percent Petalio stake.

The Medicxi moolah will be trickled out via a "tranche investment plan with defined scientific and technical milestones". Starpharma will provide research and development services on a fee-for-service basis and own the background intellectual property.

"We had looked at a specific target, which gives us a specific asset," says Medicxi principal Shyam Masrani. "We went around the world to find the right platform and that brought us to Melbourne and Starpharma. We are standing on the shoulders of giants."

The former global head of medicine at Boehringer Ingelheim, Petalio CEO Dr Mehdi Shahidi says Medicxi focuses on specific drug targets and indications.

The Starpharma deal is Medicxi's second Australian technology foray, having invested in a Pfizer vaccine developed by the University of Queensland.

Dr Shahidi says it's hoped that the project can get to proof-of-concept stage within two to four years, with "real value" emerging in three to four years when the clinical efficacy is proven.

Keep up!

Meanwhile, Starpharma has research partnerships with Genentech and Merck Inc (Merck Sharp and Dohme outside the US) and a quiescent one with Astrazeneca.

Ms Maley says management has been reminded - possibly rudely - that the Starpharma programs are only "one of many" for the big pharma partners.

"We will attempt to be agile but the partners ... may not be moving as quickly as we can," she says. Meanwhile, the dendrimer technology is in its fifth generation.

Fuelling the funnel

Ms Maley says the company has done well with early research and experimentation and is keen to feed the "funnel" of new projects, which could be off the company's own bat, through partnerships or other forms of non-dilutive funding.

"Across any drug development ... there are losses and failures along the way," she says. "Our aim is to increase our shots at goal and advance them where we could add significant value."

Ms Maley calls out the company's special interest in improving the efficacy of both radio-diagnosis and radio-therapy.

"Dendrimers allow a treatment that is fast-in to tumor and fast-out of blood, reducing exposure to non-target tissues such as kidneys and increasing accumulation in the target tumor," Ms Maley says.

The company aims to be in phase I next year.

Another area of interest is the HER2 target, a validated marker in many forms of cancer including breast. Ms Maley says a number of HER2 treatments are emerging, but many have toxicity issues.

"This increases the importance of accurate diagnostics to ensure the right patient gets the right treatment at the right time."

Vivagel

Vivagel is an alternative to the out-of-favor, prescription-only treatments for bacterial vaginosis (BV). The company claims the over-the-counter product both treats and prevents the odiferous bacterial condition.

Sold under the Fleurstat brand, Vivagel was launched in Australia in April 2019 and roll-outs in Europe and Britain ensued. The product is approved and licensed in 160 countries.

In Europe, Vivagel was distributed by Mundipharma under the moniker Betadine BV, but the tie-up was dissolved last year and Starpharma is scouring for a new partner.

A notable exception to Vivagel's global reach is the US, with the US Food and Drug Administration (FDA) unconvinced about the product's benefit for the nation's 125 million women. The company has signed a license with Irom Pharmaceutical Group to distribute in the Middle East, also a former Mundipharma geography.

A Vivagel variant, Viraleze is an anti-viral nasal spray sold in 35 countries, mainly online.

Finances and performance

In the March 2024 quarter, Starpharma had revenue of \$371,000 and net outgoings of \$5.32 million. At quarter's end the company had \$26.6 million in cash and expects a \$5 million Federal Research and Development Tax Incentive in September 2024.

In the December half year, the company reported adjusted revenue of \$1.47 million, derived from product sales, royalty and licensing payments and research revenue from commercial partners and \$828,000 of interest income.

The company's 'official' half-year revenue was \$8,025,000, including a \$6.55 million payment from Mundipharma as a termination settlement.

Starpharma reported a loss of \$1,034,000, but excluding the Mundipharma settlement the deficit was \$7,587,000.

Ms Maley says with the phase II trials wrapping up, the company's research and development expenses - \$3.3 million in the March quarter - are abating. Expense wise, management has identified \$2 million of savings in fixed costs for the 2024-'25 year.

Over the last year, Starpharma shares have gyrated between 50 cents in mid-September last year and the current sub-10 cents lows.

The share slump resulted in Starpharma being chucked out of the S&P ASX All-Ordinaries index on March 18 this year.

The five-year chart shows a high of \$2.36 in February 2021.

According to Commsec data, the current nine cents price is the lowest in Starpharma's 24-year history.

Dr Boreham's diagnosis:

Ms Maley notes the Starpharma register has tilted toward retail shareholders, which means the company will have to "change the way in which we communicate and engage".

Indeed! Since the May 22 strategy manifesto, Starpharma shares have fallen a further 23 percent and the company has an enterprise value (market cap less cash) of a mere \$12 million.

Ms Maley acknowledges that investors are awaiting tangible results from the tighter focus.

"There is a strong belief in the value of the dendrimer technology, but there is also an increasing urgency to see a return on that value," she says.

"But we have significant work to do to make sure that value proposition is recognized by the market and for our shareholders."

Having been around for two decades, Starpharma shows that drug development is a tortuously long process.

It doesn't help that sales of Vivagel - once the company's prime focus - have underwhelmed.

Success with the Medicxi partnership will help to show whether Starpharma has entered a true renaissance, or is in danger of returning to the dark ages of large expenditures for little progress.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Like the Medici family he likes to think of himself as a cultured fellow but without the tendency to murder, conspire and corrupt.

CLINUVEL PHARMACEUTICALS

Clinuvel says a seven-patient trial shows afamelanotide reduces differentially expressed gene numbers after skin is exposed to ultra-violet (UV) irradiation ($p < 0.05$).

Clinuvel said the study, conducted at Manchester, England's Salford Royal Hospital, analyzed biopsies from seven patients with "fair skin types" taken prior-to and six days after treatment with afamelanotide, the active ingredient in Scenesse.

The company said it used RNA sequencing to study the differentially expressed genes, and that the genes evaluated "were found as being crucial in the regulation of DNA repair and inflammatory reactions following solar and UV exposure".

Clinuvel said that without afamelanotide, ultra-violet-irradiation resulted in 625 differentially expressed genes in comparison to non-irradiated skin.

The company said that with afamelanotide there were 183 differentially expressed genes in irradiated patients compared to non-irradiated, or a factor of 3.4 fewer differentially expressed genes ($p < 0.05$).

In 2023, the company said a nine-patient trial of 16mg afamelanotide showed it reduced skin damage, ultra-violet light-erythema response, increases pigmentation and supported DNA repair, and later said the second set of results from the trial showed it reduced DNA photo-damage (BD: Feb 2, Aug 15, 2023).

Today, Clinuvel said the results indicated that "critical genes expressed after UV-damage can be positively affected with afamelanotide treatment".

The company said for the general population and specifically people with a fair skin type who easily sun burn, the results indicated that afamelanotide could "reduce oxidative damage and inflammatory reactions after sun exposure and skin damage".

Clinuvel said the results were presented at the British Association of Dermatology Meeting held in Manchester, England between July 2 and 4, 2024.

Clinuvel chief scientific officer Dr Dennis Wright said the results from RNA sequencing complemented the earlier results seen "from immune-histochemistry, in that afamelanotide consistently seems to assist repair of UV-damaged DNA in the skin".

"The significance of these results evaluating the use of afamelanotide in reducing oxidative and inflammatory damage caused by UV is high for those at high risk of solar damage, sunburn and skin cancers, hence we will repeat and confirm these results in a final study," Dr Wright said.

Clinuvel was up \$2.21 or 14.6 percent to \$17.38 with 363,254 shares traded.

GENETIC SIGNATURES

Genetic Signatures says its one-for-5.82 retail rights offer at 75 cents a share raised \$8.5 million, taking the total with its placement and institutional offer to \$30 million.

In June, Genetic Signatures said it had raised \$21.5 million at 75.0 cents a share through a \$6.0 million institutional placement and the institutional component of its one-for-5.82, fully-underwritten rights offer (BD: Jun 4, 6, 2024).

At that time, the company said that the issue price was a 11.6 percent premium to the five-day volume weighted average price of 67 cents up-to and including May 30, 2024.

Today, Genetic Signatures said the retail component of the entitlement offer had raised about \$700,000 from investors, with the remaining \$7.8 million shortfall allocated to the underwriters.

The company said Bell Potter Securities and Taylor Collison were joint lead managers and underwriters to the offer.

Genetic Signatures fell 1.5 cents or 2.1 percent to 71 cents.

INVIQ

Inoviq says it has raised \$2,379,000 in an “oversubscribed” share purchase plan at 50.0 cents a share which received applications totalling about \$7,293,000.

Last month, Inoviq said it had raised about \$7 million at 50 cents a share in a placement and hoped to raise up-to \$2.4 million in a share plan (BD: Jun 12, 2024).

At that time, the company said the issue price was a 25.1 percent discount to the 10-day volume weighted average price of 66.8 cents a share, and an 11.5 percent discount to the last traded price.

Today, Inoviq said it had the capacity to accept up-to \$400,000 in oversubscriptions and due to “the strong support resulting in significant oversubscription” it had exercised its right to limit oversubscriptions to \$379,000.

The company said that all share purchase plan applicants would receive a minimum application of \$1,000, scaled back on a pro-rata basis based on the applicant’s shareholding at the record date.

Inoviq said investors would receive an option for every two shares issued, exercisable at \$1.00 until July 8, 2026.

The company said that its directors had “opted not to participate in the [share purchase plan] given their earlier participation in the placement, thereby enabling greater uptake in the [share purchase plan] by unrelated shareholders”.

Inoviq said following the share plan raised a total of \$9.379 million with the placement and would have a cash balance of about \$14.489 million.

Inoviq was up five cents or 8.7 percent to 62.5 cents.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, MEDICAL RESEARCH FUTURE FUND, FEDERAL GOVERNMENT

The National Health and Medical Research Council (NHMRC) says it “will work more closely” with the Medical Research Future Fund and appoint new advisory committees. A media release from the NHMRC said the advisory committees would “better harmonize and promote collaboration by key government funders in Australia’s health and medical research sector and make it easier for researchers to engage with funders”.

The Council said that “better alignment and coordination of the NHMRC’s Medical Research Endowment Account (MREA) and MRFF will achieve the best of both and strengthen Australia’s world-leading research capability to change and improve the health and lives of Australians”.

The NHMRC said the committees included a research committee to advise on quality and scope of Australian health and medical research, an MRFF consumer advisory group to advise on consumer and community involvement in health and medical research and to strengthen consumer involvement in MREA and MRFF grant programs.

The Council said the other committees included an industry, philanthropy and commercialization committee, a public health and health systems committee and an indigenous advisory group.

The NHMRC said it would open nominations for the committees “shortly, including new joint committees and a number of existing committees with new joint responsibilities”.

The Council said it was seeking nominations from individuals “including, but not limited to, consumers and community members, industry representatives, philanthropy representatives, physicians and other clinicians, [and] researchers in all areas of health and medical research and at all career stages”.

The NHMRC said nominations would close on July 31, 2024, with further information and nomination forms available at: <https://bit.ly/3LwBaFn>.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Prof Carolyn Ellaway as its chief medical officer on a part time basis, effective from August 1, 2024.

Neurotech said Prof Ellaway was lead investigator of its phase I/II Rett syndrome trial, a professor at the University of Sydney, a consultant at Westmead's Children's Hospital and Sydney Children's Hospital Randwick and provided paediatric clinical genetics services at Sydney's Lumina Kids' Brain and Mind Clinic.

According to her LinkedIn page, Prof Ellaway held a Bachelor of Medicine and Bachelor of Surgery from the University of Melbourne and a Doctor of Philosophy from the University of Sydney.

Neurotech was unchanged at 7.3 cents.

BLUECHIIP

Bluechiip says financial services firm Automic Group's Patricia Vanni will replace company secretary Chelsea Sheridan, effective immediately.

Bluechiip said Ms Sheridan had "tendered her resignation from Automic Group" and thanked her for her services.

Bluechiip was up 0.3 cents or 100 percent to 0.6 cents with two million shares traded.