



Biotech Daily

Friday December 8, 2023

Daily news on ASX-listed biotechnology companies

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- * **AUSBIOTECH NSW WOMEN IN LIFE SCIENCES REGISTRATION OPENS**

MARKET REPORT

The Australian stock market was up 0.3 percent on Friday December 8, 2023, with the ASX200 up 21.6 points to 7,194.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and two were untraded.

Impedimed was the best, up 1.5 cents or 11.1 percent to 15 cents, with 4.55 million shares traded. Clarity climbed 6.1 percent; Medical Developments and Proteomics were up more than five percent; Avita and Nova Eye were up more than four percent; Imugene improved 3.2 percent; Next Science rose 2.2 percent; Alcidion and Orthocell were up more than one percent; with Cochlear, CSL and Neuren up by less than one percent.

Mesoblast led the falls, down three cents or 9.5 percent to 28.5 cents, with 20.7 million shares traded. Genetic Signatures lost 8.65 percent; Prescient and SDI were down more than five percent; both Compumedics and Micro-X fell four percent; Antisense, Dimerix, Immutep, Starpharma and Syntara (Pharmaxis) were down more than three percent; Atomo, Clinuvel, Polynovo, Telix and Universal Biosensors shed more than two percent; Envision and Paradigm were down one percent or more; with Cyclopharm, Nanosonics and Resmed down by less than one percent.

[DR BOREHAM'S CRUCIBLE: BOTANIX PHARMACEUTICALS](#)

By Tim BOREHAM

ASX code: BOT

Share price: 15 cents; **Shares on issue:** 1,541,144,642; **Market cap:** \$231.2 million

Chief executive: Dr Howie McKibbon

Board: Vince Ippolito (executive chair), Matt Callahan (founder and executive director), Dr William Bosch, Dr Stewart Washer, Danny Sharp

Financials (September quarter 2023): receipts \$302,000, operating outflows \$2.2 million, investing outflows \$13.6 million, cash of \$20.3 million (following last month's \$13.5 million placement and July's \$12.5 million placement)

Major identifiable holders: Shenasaby Investments (Callahan family) 5.2%, Caperi Pty Ltd 3.7%, Dr Henry William Bosch 1.3%

As with rapper and enthusiastic lifetime cannabis consumer Snoop Dog, Botanix has renounced the weed.

A current inhabitant of 'Cannabis Corner', Botanix focused on developing synthetic cannabinoid treatments for skin diseases including acne, atopic dermatitis and psoriasis, and is looking to partner or licence the programs.

Results were patchy, but no sweat! The company has moved on to pursue US approval for the non-cannabis indication primary axillary hyperhidrosis (PAH).

When diagnosed with this exotic-sounding malady, unwitting patients could be excused for thinking they have been given a death sentence. In reality, PAH is excessive sweating well beyond what the body needs to excrete to maintain a normal temperature.

Many of those affected become reclusive, lest they die of embarrassment.

"They are silent sufferers," says Botanix chief Dr Howie McKibbon. "They plan their day around when they think it will happen and go out as little as possible."

In May last year Botanix obtained the rights to the substance sofipronium bromide, renamed Sofdra, which addresses the problem by suppressing underarm receptors (see below).

After being rebuffed by the US Food and Drug Administration over concerns about the wording of instructions, the company is ready to front the regulator again and is confident of getting to market by mid-2024.

Meanwhile, the company has raised a further \$13.5 million via an institutional placement, having gathered \$12.5 million in July.

More than skin deep

Botanix listed in July 2016 via the back door, using the shelf of Perth-based biotech Bone Medical. The accompanying capital raise raised \$3.5 million at two cents apiece.

Botanix's US-based management has launched more than 30 dermatological drugs, so its experience is more than skin-deep. Headquartered in Perth, but based in Philadelphia, Botanix was founded by parties including current executive director Matt Callahan, Caperi (a financial investor) and scientist and non-executive director Robert Bosch.

Aptly, the Philadelphia-based Mr Callahan is a lawyer. He also founded Iceutica Inc and Churchill Pharma, having co-invented Iceutica's drug delivery platform.

Following the death of chair Graham Griffiths in 2019, Vince Ippolito was appointed as executive chair. Mr Ippolito had been chief commercial officer with the Nasdaq-listed inflammatory diseases house Anacor, which Pfizer acquired for \$US5.2 billion in 2016.

The company's chief operating officer since May 2019, Dr McKibbon was anointed CEO in August this year. Based in Phoenix, Arizona, Dr McKibbon was a former vice prez at Dermavant Sciences and held senior positions at Anacor and Medicis.

In May last year, Botanix acquired sofipronium bromide for primary axillary hyperhidrosis (PAH) from the Nasdaq-listed Brickell Biotech, now Fresh Tracks Therapeutics, for \$US4 million upfront and various other milestones and royalties (see below).

Brickell had taken the program to pivotal stage, successfully completing a 700-patient trial. And then decided it wanted to adopt an unrelated early-stage discovery program. In September 2020, Brickell's (and now Botanix's) Japanese partner Kaken Pharmaceuticals won approval to sell a 5.0 percent formulation of the drug, which it calls Ecclock, with sales off to a flying start.

No sweat

Caused by physiological rather than psychological factors, PAH often becomes apparent in youths aged 12 to 17 years - the time in their lives they really don't want to be whiffy.

The excessive sweating comes in three iterations: primary axillary (under the arms), cranio-facial (head and face), palmar (hands and palms) and plantar (feet). The company is seeking FDA approval for the first.

Sofdra works by inhibiting M3 muscarinic receptors in eccrine glands at the application site. Found throughout the body, these receptors induce a 'fight or flight' response, including sweating and salivating, lactation and even urination.

With 16 million sufferers, primary axillary hyperhidrosis is the third biggest dermatological condition behind acne and dermatitis (with rosacea vying for third).

Last year, Botanix applied for FDA consent, but in September this year the agency responded with a 'complete response letter' - a.k.a as 'do some more work and try again'.

The knock-back wasn't as bad as it seemed at first blush, as the objections pertained to the instructions in the box rather than a demand for more trials or clinical work. For example, the regulator demands the addition of the term "applicator" as well as reformatting the instruction sheet so it didn't fold. Patients also needed to be told to wash their hands after use.

Sofdra is intended to be sold in the US at 15 percent strength.

The company has been assured by the FDA that no work needs to be done and it plans to re-lodge the entreaty by the end of March next year, with approval targeted for mid-2024 and launch shortly thereafter.

The company estimates a market of 16 million sufferers in the US, only 3.2 million of whom have sought treatment. Treatments to date include a double lashing of the Old Spice, Drysol (aluminium chloride) or - more radically - Botox or surgery (nerve cutting, which can result in over compensatory sweating in other areas).

Aluminium chloride is used cauterizing wounds and can cause burns. Botox requires 30 needles in each arm pit once every three months and invasive surgery is - well - invasive.

Dial-a-drug

Meanwhile, the company can access US dermatologists with a small force of 20-30 sales representatives. While there are 50,000 general practitioners in the US, there are about 10,000 dermatologists, of which only 3,500 write scripts for medical conditions.

But the company's market research shows that it is partly because of the patients' reclusive nature, and most can be accessed via digital channels and in October, Botanix signed a deal with US telehealth pioneer Upscript Health, offering direct-to-consumer access to one million patients.

Dr McKibbon adds that telehealth is the way of the future, given the rapid contraction of the physical footprint of US pharmacies.

More than skin deep

Botanix also has an exclusive licence to a device called Permetrex, a dermal delivery device allowing 10 to 20 times more of the active ingredient to get through the skin, which it was originally using with its marijuana products.

"We haven't applied Permetrex to [the program] yet because we would have to study it separately," Dr McKibbon says.

"But down the line it could extend the products technology life or into other dermatological indications."

Usual topical treatments contain chemicals (permeation enhancers) that open the skin pores just enough for a drug to sneak through.

Where's the evidence?

Botanix inherited a completed two-stage pivotal phase III trial from Brickell, dubbed 'Cardigan'.

Cardigan is a synonym for sweater - get it? - which shows that even medical researchers are not devoid of a sense of humor.

When the highway cops tell them to 'pull over' they're the guys who respond: 'it's a jumper, actually'.

Anyway, the heartening results showed an average two-point improvement in the HDSM-Ax (hyperhidrosis disease severity measure - axillary) scale of patient-reported sweating severity.

"Almost nine in 10 patients had a one-point improvement, which is important because it is only a four-point scale," Dr McKibbon says.

"At four, you are sweating through your shirt to the point past plain embarrassment, to the inability to interact with people.

"At three, your shirt is drenched to the point where it is very noticeable."

Other programs

Meanwhile, Botanix has parked its cannabinoid-based programs for rosacea, acne and atopic dermatitis (severe eczema), but they remain on the books for possible partnering deals.

The most advanced secondary program is for rosacea, which affects about five percent of the population. Rosacea causes broken veins and strong redness.

So, the next time you see an older person with a bulbous nose and ruddy cheeks, don't assume that they have been hitting the sherry too hard.

Acne needs no introduction as the enemy of many an adolescent's love life. Or looking on the bright side - a preventative of many a teenage pregnancy.

In October 2019, the company's pimple hopes were popped when a phase II trial of its synthetic cannabinoid did not meet its primary endpoint, but a phase Ib atopic dermatitis study showed better results.

Finances and performance

Having raised \$23 million in the 2022-'23 financial year, Botanix went to the well in July to raise \$12.5 million in a placement at 12 cents apiece (a three percent discount to the previous day's closing price).

Last month the company raised a further \$13.5 million at 13 cents apiece (a 16 percent discount).

The first raising was mainly to fund the \$8 million repurchase of milestones and royalties payable to Fresh Tracks Therapeutics (formerly Brickell).

The liabilities - including \$US4 million payable on European or UK approval - far exceeded this amount.

But Fresh Tracks entered the seemingly unfavorable deal because it wanted to invest in separate early-stage programs.

Post raising, the company has cash of \$20 million "more than enough" to get to commercialization.

Botanix shares peaked at 27 cents in mid-September 2019 and over the last 12 months have been as low as 6.9 cents (mid-January 2019).

Dr Boreham's diagnosis:

Botanix cites industry estimates of a current \$US1.6 billion worth for the primary axillary hyperhidrosis market.

Of course, every drug developer outlines Big Numbers, but in this case Botanix has evidence in the form of promising Japanese sales, from which the company derives a royalty.

In the September quarter, Kaken reported Ecclock sales of 700 million yen (\$A7.3 million), up 71 percent and updated its full-year sales target to 2.1 billion yen.

Broker Euroz Hartleys extrapolates annual US Sofdra revenues of \$US239 million, based on an average (reimbursed) price of \$US540 a month.

The firm values Botanix shares at 31 cents - more than twice their current worth.

"If you believe only half the numbers it is still a good story," Dr McKibbon chimes.

He adds that US dermatology products are regularly - and widely - used off label.

Indeed - that's why strabismus (cross-eyed) treatment Botox is used for cosmetic enhancement, diabetes drug Ozempic has been hijacked for weight loss and hypertension drug Viagra is used for ... you know what.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He tries not to sweat the small stuff but has a bottle of Brut 33 on hand just in case.

CHILDREN'S MEDICAL RESEARCH INSTITUTE

Sydney's Children's Medical Research Institute (CMRI) says it has developed APOD53 that "impairs cancer cell growth, while sparing non-cancerous cells".

The Children's Medical Research Institute said the compound used 'alternative lengthening of telomeres' and telomerase to maintain DNA protective telomere structure. The Institute said telomeres were at the end of chromosomes and formed a looped structure guarded by an array of proteins that protect DNA, and that one of the most important telomeres was telomere repeat factor-2 (TRF2).

CMRI said when the telomere structure was disrupted there were "catastrophic effects on cells, causing them to die" and the ability of cancer cells to proliferate was depended on telomere maintenance.

The Institute said that due to the connection between telomeres and the development of cancer cells, factors that control telomeres were attractive chemotherapeutic targets. CMRI said unlike the use of radiation and most chemotherapies, telomere-focused cancer drugs were expected to have lower side effects and improve long-term outcomes.

The Institute said the research showed the effectiveness of APOD53 could be increased with other chemicals affecting other parts of the protective structure on telomeres.

CMRI said the peptide compound, APDO53, was permeable which allowed it to easily enter cells and making it a "good candidate for future anti-cancer drug development".

The Institute said the study, titled 'Irreversible inhibition of TRF2TRFH recruiting functions by a covalent cyclic peptide induces telomeric replication stress in cancer cells' was published in Cell Chemical Biology today, with a summary available at:

[https://www.cell.com/cell-chemical-biology/pdf/S2451-9456\(23\)00423-3.pdf](https://www.cell.com/cell-chemical-biology/pdf/S2451-9456(23)00423-3.pdf).

CMRI's Prof Hilda Pickett said the results were "promising and have future potential to improve long term health outcomes for all types of cancer".

VICTORIA GOVERNMENT, LA TROBE UNIVERSITY

The Victoria Government says with Germany's Biontech it will open a factory at La Trobe University to produce mRNA-based vaccines and treatments.

A media release from Victoria Premier Jacinta Allen said the facility would manufacture Biontech's existing drugs and vaccines and research and develop additional mRNA and RNA vaccines, treatments and materials for clinical trials.

The State Government said Biontech was a German biotechnology company that co-developed an mRNA-based Covid-19 vaccine with Pfizer.

The Government said the facility would allow researchers and companies to use Biontech's resources for developing immunotherapies.

Victoria said the agreement included Biontech's clinical cancer program, which hoped to deliver therapies for hard-to-treat cancers for up-to 4,000 Australians in the next 10 years.

The Government said the Peter MacCallum Cancer Centre would co-ordinate the program with Melbourne's Austin Health, Alfred Health and Monash Health.

The Victoria Government said treatments would target pancreatic, neck, cervical, oesophageal and colorectal cancers and include other hard-to-treat cancers.

Victoria said Biontech would establish an innovation centre in Parkville to support the commercialization of local research and help deliver therapies from laboratory to patients.

Victoria said part of the agreement included Biontech opening an Australian head office for its artificial intelligence-based pandemic early warning system Instadeep.

The Government said the artificial intelligence capability would aid La Trobe University's Centre for Artificial Intelligence in Medical Innovation, which was to be established under the agreement.

LBT INNOVATIONS

LBT says it has placed the remaining \$500,000 shortfall from its four-for-one rights offer at 0.5 cents a share, taking the total raised in the offer to the target \$4.5 million.

In October, LBT said it hoped to raise \$4.5 million in a rights offer, and later said it had raised \$1,030,228 from shareholders, \$2,549,772 from the underwriter and placed \$420,000 of the initial shortfall (BD: Oct 13, Nov 15, Nov 20, 2023).

Today, the company said the funds would allow it to accelerate market development activities for Apas Pharma QC as well as complete its financial restructure including refinancing its \$1.7 million South Australian Government loan and terminate its share placement facility.

LBT fell 0.1 cents or 6.7 percent to 1.4 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its one-for-2.35 entitlement offer at seven cents a share has raised about \$2.1 million of a hoped-for \$10 million, leaving a shortfall of about \$7.9 million.

In October, Radiopharm said it hoped to raise up-to \$10 million in a non-renounceable, non-underwritten, entitlement offer (BD: Oct 31, 2023).

Today, the company said a shortfall of 114,190,261 shares worth about \$8.0 million remained, had not been issued and might be placed.

Radiopharm managing-director Riccardo Canevari said “the funds raised will go towards supporting our prioritized programs”.

Radiopharm fell 0.4 cents or 5.3 percent to 7.1 cents.

ALCIDION GROUP

Alcidion says its up-to \$1 million share plan at 7.5 cents a share raised \$378,000 leaving a \$622,000 shortfall and taking the total raised with the placement to \$5,378,000.

Last month, the company said it had raised \$5 million in a placement and hoped to raise a further \$1 million in a share purchase plan (BD: Nov 1, 2023).

Today, Alcidion managing-director Kate Quirke said “the funds raised under the placement were sufficient to ensure Alcidion maintained a strong balance sheet, with additional funds in the [share purchase plan] only further adding to that strong balance sheet position”.

“The company is now well capitalized as it continues to execute on the significant market opportunities ahead,” Ms Quirke said.

Alcidion was up 0.1 cents or 1.4 percent to 7.1 cents with 1.8 million shares traded.

ONCOSIL MEDICAL

Oncosil says the first two patients in Greece have been treated with its radiation device for pancreatic cancer in combination with chemotherapy at Athens' Agios Savvas Hospital.

Oncosil said the treatments delivered “another milestone in the commercialization strategy for this innovative device, which is intended for the treatment of locally advanced unresectable pancreatic cancer”.

The company said Greece was the third European country after Italy and Spain where commercial treatment using its device for locally advanced pancreatic cancer had been completed.

Oncosil managing-director Nigel Lange said the company remained “confident that other countries across Western Europe will join the list”.

Oncosil was up 0.1 cents or 12.5 percent to 0.9 cents with seven million shares traded.

[NOVA EYE MEDICAL](#)

Nova Eye says all five US Medicare administrative contractors proposing changes to glaucoma surgery reimbursement have deferred their decision until January 29, 2024. In October, Nova Eye said the Wisconsin Physician Service Insurance Corp proposed to limit or deny coverage for several minimally invasive glaucoma surgery procedures, effective from December 24, 2023; and earlier this month, said the reimbursement changes had been proposed by four more contractors (BD: Oct 31, Nov 14, 2023). Last week, the company said one-of-five contractors, the National Government Services Medicare contractor, deferred the decision until March 23, 2024 (BD: Nov 28, 2023). Today, Nova Eye said the update superseded the National Government Services previous deferral decision, and that all five contractors had updated their deferral by about one month.

The company said the deferral was a positive outcome for near-term sales of its Itrack canaloplasty devices and that reimbursement coverage in the thirty-eight states covered by the five contractors beyond January 29, 2024 would still depend on whether the proposed changes were implemented.

Nova Eye said the deferral gave it more time to execute its near-term initiatives designed to overcome the challenges imposed by the proposed local coverage determination changes and reduce the expected impact on sales revenue in the medium and long-term, subject to the changes being implemented.

Nova Eye was up half a cent or 4.35 percent to 12 cents with 1.1 million shares traded.

[NYRADA INC](#)

Nyrada says it has received \$3,541,731 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Nyrada said the rebate related to expenditure for the year to June 30, 2023.

Nyrada was up 0.6 cents or 30 percent to 2.6 cents.

[UNIVERSAL BIOSENSORS](#)

Richmond Hill Capital Pty Ltd says it has increased its holding in Universal Biosensors from 15,080,709 shares (7.10%) to 17,304,622 shares (8.15%).

The Melbourne-based Richmond Hill said that with Ovens Valley Pty Ltd and E & M Odza Pty Ltd it bought 2,223,913 Chess depository shares on market between May 1 and December 7, 2023 for \$472,220, or 21.2 cents per CDI.

Universal Biosensors fell half a cent or 2.4 percent to 20 cents.

[CRYOSITE](#)

Cryosite says it has appointed Mark Kerr chair and chief executive officer John Hogg managing-director, with directors Steven Waller, Nicola Swift and Luis Antonio resigning. Cryosite said Mr Kerr was the founding chair of Nido Early School and according to his LinkedIn page, Mr Kerr was currently a director of Berkeley Consultants Pty Ltd, a board member of ISS Institute, and held a Bachelor of Laws from the University of Melbourne. The company said "the only variation Mr Hogg's employment agreement is to reflect his new office with the company".

Cryosite said the board thanked the three retiring directors "for their outstanding contribution to the company over a number of years".

Cryosite was up four cents or 7.1 percent to 60 cents.

[AUSBIOTECH](#)

Ausbiotech says registration is open for its annual New South Wales Women in Life Sciences Luncheon, to be held on March 8, 2024.

Ausbiotech said the event would “celebrate women’s achievements and support the removal of barriers to build a better future for us all”.

The industry organization said it expected more than 550 attendees, including chief executive officers, researchers, intellectual property specialists and industry luminaries.

Ausbiotech said the event included speakers and networking opportunities and was an “opportunity to be inspired, share insights and forge valuable connections”.

Ausbiotech said the event will be held at the Doltone House, Darling Island Wharf, Sydney on March 8, 2024 from 12pm to 3.30pm (AEDT), with bookings at:

<https://www.ausbiotech.org/events/event/nsw-women-in-life-sciences-luncheon-2024>.