



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Botanix Pharmaceuticals

By TIM BOREHAM

ASX code: BOT

Share price: 30 cents

Shares on issue: 1,960,869,049

Market cap: \$588.3 million

Chief executive officer: Dr Howie McKibbon

Board: Vince Ippolito (executive chair), Dr William Bosch, Dr Stewart Washer, Danny Sharp (founder and executive director Matt Callahan stepped down on May 23 to attend to a medical issue)

Financials (March quarter 2024): receipts from product sales \$326,000, receipts from royalties \$218,000, operating outflows \$19.96 million, cash of \$28 million (ahead of \$40 million capital raising and this month's \$US20 million debt drawdown)

Major identifiable holders: Insignia Financial 8.3%, Shenasaby Investments (Callahan family) 4%, Caperi Pty Ltd 2.9%, Zenith Pacific 1.2%, Dr Henry William Bosch 1%

Botanix CEO Dr Howie McKibbon says investors shouldn't just rely on management's assertion that its anti-sweating drug Sofdra has – and we paraphrase – “the potential to be the world's most successful dermatology drug”.

Ask Blackrock. With \$US11.5 trillion in assets, Blackrock can afford extensive due diligence. The world's biggest asset manager has extended a \$US30 million (\$48 million) debt package via its venture capital funder, Kreos Capital.

Dr McKibbon says Botanix doesn't need the dosh - one-third of which is not drawn down immediately - for its current Sofdra roll-out in the US.

"But if an acquisition opportunity emerges, it does not have to hinge on a capital raising," he says. "It allows us to be nimble."

"We will look to leverage that relationship in future as other opportunities emerge," Dr McKibbon says.

Meanwhile, three months after the US Sofdra launch, prescriptions have exceeded management's expectations.

Sweating bullets

Sofdra tackles primary axillary hyperhidrosis (PAH), or excessive underarm sweating, to the extent that it affects a person's daily lives.

With around 16 million sufferers in the US, hyperhidrosis is the third most common skin condition behind acne (40-50 million sufferers) and atopic dermatitis (20-25 million).

About 10 million Americans have PAH, of which seven million have been diagnosed. The condition accounted for 3.7 million doctor visits last year.

The condition is defined as sweating beyond the body's need to cool itself. Sufferers can sweat through multiple layers of clothing in mid-winter.

"It doesn't have to be severe; it has to be enough to affect your daily life," Dr McKibbon says.

PAH is caused by sweat glands becoming overstimulated by acetylcholine binding to M3 receptors, thus triggering the excessive sweat.

Sofdra selectively binds to - and blocks - the M3 receptors to reduce sweat at the source.

Current treatments include strong topical anti-perspirants and aluminium chloride. In severe cases there's invasive Botox or surgery (nerve cutting, which can result in over compensatory sweating in other areas).

About Botanix

Nominally headquartered in Perth but based in Philadelphia, Botanix was founded by parties including Matt Callahan, Caperi (a financial investor) and scientist and non-executive director Dr William 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.

The company back-door listed in July 2016, using the shelf of Perth-based biotech Bone Medical.

At the time, Botanix aimed for synthetic cannabinoid treatments for skin diseases including acne, rosacea, atopic dermatitis (eczema) and psoriasis.

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.

Renouncing the weed, in 2022 the company acquired Sofdra (sofpironium bromide) from the cash-strapped Nasdaq-listed Brickell Biotech, now Fresh Tracks Therapeutics.

The price - an upfront \$US4 million plus various other milestones and royalties – hardly reflected the \$US120 million Brickell had invested to get the drug beyond phase III stage.

“It was during Covid and they basically ran out of money, which was their loss and our benefit,” Botanix founder Matt Callahan said.

After earlier prevarication the US Food and Drug Administration approved Sofdra as a topical treatment in June 2024 - and it's been off the races for the company since then.

Wealth of experience

Given they have been involved in developing around 30 approved drugs, the Botanix top brass can't claim ignorance about the gritty realities of drug development.

Taking over as (executive) chair from the late Graham Griffiths in February 2019, Vince Ippolito was 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 McKibbin was anointed CEO in August 2023.

Based in Phoenix, Arizona, Dr McKibbin was formerly an executive at Dermavant Sciences and held senior positions at Anacor and Medicis.

Mr Callahan, meanwhile, co-founded the ASX-listed nerve regeneration play Orthocell and eye drug developer Dimerix as well as the psychotropic play Emyria.

On May 23, Mr Callahan stepped down from the Botanix board temporarily for health reasons.

“He's OK and he will be back sooner rather than later,” Dr McKibbin says.

Roll up! Roll up! for the roll-out

In mid-April the company said by the end of the first week of the US launch, 125 doctors had written a script. Four months later, subscriber numbers had grown to 500.

One tube of Sofdra lasts for 30 days.

“These doctors are very easily activated,” Dr McKibbon says. “They didn’t have to hear the message multiple times, it happened immediately.”

“Most importantly, our refill rates are well above industry standards,” Dr McKibbon says. “After three months we are getting 3.1 [repeat] fills [per script] which surpasses the average topical dermatology prescription of two per year.”

Dr McKibbon says six refills are “definitely in sight” but naturally the company is aiming for 12, which signifies full ongoing patient compliance.

Who pays?

Not the patients, who are covered by Medicaid or - in most cases - insurers.

US reimbursement is complex, but typically a refill attracts a payment of \$US400 to \$US500. The first tube might not be reimbursed, in which case the company will provide it for nothing.

In theory, patients need to use Sofdra for the term of their natural lives. But full compliance is rare with any drug. Patients are more likely to use Sofdra when they are younger and care more about being whiffy, such as in courtship stage.

Reaching out

Botanix is expanding its 27 strong sales force to 33. The company doesn’t need a huge army of sales representatives because prescriptions are issued by about 5,000 dermatologists. (Unlike Australia, US nurse practitioners can prescribe).

Put in perspective, the acne treatment Solodyn (minocycline) - the most widely prescribed dermatology drug - at peak had 1,900 prescribers issuing 1.3 million prescriptions a year.

Dr McKibbon was intimately involved with Solodyn’s development when he was at Dermavant.

“In dermatology it’s amazing how much you can do with so few doctors,” Dr McKibbon says. “As a specialty, it is very attractive because it is concentrated.”

Meanwhile, the company accesses physicians by means such as leaflets in waiting rooms.

Finances and performance

In its initial US sales period, Botanix generated \$326,000 of receipts from product sales in the March 2024 quarter. The company also reported revenue of \$4.99 million, with \$47,000 of sales in February stiffening to \$3.26 million in March, and banked \$218,000 of royalty receipts, courtesy of a licencing deal with Japan's Kaken which sells a different formulation of the product, Ecclock.

In mid-April, Botanix raised \$40 million of equity, via an institutional placement at 33 cents apiece (a 7.0 percent discount). Post last year's FDA approval, Botanix went to market for \$70 million in an institutional placement - as you do – at 30 cents a share.

Last week the company unveiled a US\$30 million (\$A48 million) 9.9 percent interest debt facility with Kreos Capital, providing \$US20 million to be drawn now, with the remainder to be tapped by October 1, 2026 (Botanix does not have to avail of these funds).

Under certain conditions, Kreos can convert 20 percent of the loan into Botanix shares, at 33 cents apiece. Kreos also pockets just over three million warrants to acquire Botanix shares, also at 33 cents, within the next five years.

Botanix has cash of more than \$60 million - enough to fund the Sofdra rollout - and Dr McKibbon says the company strives to be cash flow positive “within the next 12 to 15 months”.

Without too much perspiration, Botanix shares climbed from their 12-month low of 31 cents on November 19 last year, to a record 52 cents on February 19 this year, with Botanix promoted to the ASX300 index, on March 23 this year.

In its ‘Alan Bond’ moment, in July 2023 bought-back up to US\$172 million of potential milestones and royalties payable to Fresh Tracks, for a mere US\$8.25 million.

Return to SendRx

Unusually, Botanix created its own platform, SendRx as a captive distribution partner (‘Rx’ as in medicinal prescription - geddit?). Every Sofdra script is sent to Senderx, a concierge service that gains reimbursement and ships the drug to the patient.

“This yields a better net price because we skip the wholesaler (and their typical 20 percent cut),” Dr McKibbon says. “We pay Senderx a flat fee of about three percent, so we save 17 percent and make more money than we normally would.”

The platform also provides Botanix real-time data on frequency of physician visits, shipping times and such. Most importantly, Senderx automatically sends the repeats, which Dr McKibbon says could be used as a springboard for an acquired therapy.

“In future we could take an underperforming drug and it would be five times as valuable in our hands.”

Dr Boreham's diagnosis:

As outlined at the start of this piece, Dr McKibbin makes the seemingly outlandish claim that Sofdra could become the world's most successful dermatology drug.

Come to think of it, the gap between Sofdra's 500 prescribers and Solodyn's 1900 isn't that wide - and Sofdra has only been selling for a few weeks.

"Physicians seem to be clamouring for the product," Dr McKibbin says.

He notes that Botanix is an early mover in hyperhidrosis and "sometimes the pioneers catch the arrows".

Botanix certainly is in rarefied company, given the FDA approved 50 drugs last year.

In terms of ASX drug developers, only a handful have won US approval and have gone on to be commercialized.

Despite the company's progress, Botanix shares have fallen 34 percent in the year to date, which we will attribute to the slings and arrows of outrageous fortunes.

Biotech valuations generally have been under pressure because of US President Donald Trump's edicts on tariffs and Most Favoured Nation drug pricing mechanisms (which don't affect Botanix).

However, Botanix hasn't been immune from the increase in short selling activity across the sector. Currently, 3.66 percent of the Botanix register is 'shorted', compared with none at the start of February.

The next few months will show whether Botanix can fire off a few arrows from its own quiver as the US roll-out intensifies.

While it's early days for the roll-out, the company looks to be able to generate early meaningful revenues without too much – er - sweat.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he's got a few other feathers to his bow and won't quiver at a challenge – or sweat bullets