Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.49 percent on Friday July 25, 2025, with the ASX200 down 42.5 points to 8,666.9 points.

Eight of the Biotech Daily Top 40 companies were up, 22 fell, eight traded unchanged and two were untraded. The four Big Caps were mixed.

Botanix was the best, up one cent or 6.25 percent to 17 cents, with 29.5 million shares traded. Emvision and Universal Biosensors climbed four percent or more; Nova Eye was up 3.45 percent; Dimerix rose 2.7 percent; Medadvisor, Syntara and Telix were up more than one percent; with Pro Medicus and Resmed up by less than one percent.

Atomo led the falls, down 0.2 cents or 10.5 percent to 1.7 cents, with 4.2 million shares traded.

Amplia and Avita lost more than seven percent; Orthocell was down five percent; Alcidion and Clarity fell four percent or more; 4D Medical, Aroa, Curvebeam and Imugene were down more than three percent; Mesoblast, Polynovo and Prescient shed more than two percent; Actinogen, EBR, Medical Developments, Neuren and Starpharma were down one percent or more; with Clinuvel, Cochlear, CSL, Cyclopharm, Nanosonics and SDI down by less than one percent.

DR BOREHAM'S CRUCIBLE: QBIOTICS GROUP

By TIM BOREHAM

Chief executive officer: Stephen Doyle

Qbiotics is a public unlisted company

Shares on issue: 489,026,611

Financials (half year to December 31, 2024): revenue $1.16 million (up 6%), government grants $3.89 million (-4%), loss of $9.3 million (previously an $8.5 million loss), cash on hand $39.2 million (down 15%).

Board: Mark Fladrich (chair), Mr Doyle, Dr Victoria Gordon (co-founder), Dr Paul Reddell (co-founder), David Phillips, Sergio Duchini

Major shareholders: TDM Growth Partners 11%, founders and staff 13%, other Top-20 shareholders 24%, remaining shareholders 52%

Like other IPO candidates – and the list is growing - private oncology drug developer Qbiotics has been closely watching the trajectory of Virgin Australia since the airlines June 24 ASX listing.

The biggest float since fast food chain Guzman y Gomez spiced up things in June last year, Virgin's initial public offer (IPO) has been seen as a barometer of broader investor appetite for new offerings.

With Virgin shares holding nicely at cruising altitude, is it time for the Brisbane-based Qbiotics to debut?

Qbiotics chief Stephen Doyle says IPO timing has never been right in the past, but the company now is positioned to crawl through the window of opportunity when it opens.

In March the company appointed Jeffries and Bell Potter as joint lead managers for the putative float, and it is getting its financial reporting into shape.

"We have done the due diligence and prospectus drafting … all the things you need to do for an IPO," Mr Doyle says. "At the end of the day it's picking the right time with the right catalysts to create value for shareholders."

Tapping nature's pharmacy

The company may have found such a catalyst, having last month reported encouraging results from its phase II soft tissue sarcoma (STS) trial.

The study road tests Qbiotics tigilanol tiglate (EBC-46), which derived from the depths of the Daintree rainforest.

The company says tigilanol tiglate has a “multi-factorial mode of action”, including activating the protein kinase C.

This leads to the disruption of the tumor’s blood supply, while also stimulating a local inflammatory response.

Separate from this, tigilanol tiglate can directly kill cancer cells within the tumor, in a way that promotes the development of anti-tumor immunity.

This is like how a vaccine works.

Qbiotics has phase II programs for both soft tissue sarcoma and head and neck cancers (HNCs).

It also has less advanced programs in venous leg ulcers and anti-microbial and anti-inflammatory applications.

Dogged effort wins canine approval

Qbiotics has an approved product, Stelfonta, to treat canine mast cell tumors.

The current standard of care is surgery - but anaesthesia is dangerous for older dogs and brachycephalic breeds (short snouted ones such as bulldogs, boxers, pugs and shih tzus). Stelfonta is administered by injection directly into the tumor mass.

The European Medicines Agency approved Stelfonta in January 2020, followed by the US Food and Drug Administration in November 2020 and the Australian Pesticides and Veterinary Medicines Authority in July 2021.

Stelfonta is distributed by the French group Virbac, which is responsible for all sales and marketing, while Qbiotics provides the finished product at a suitable margin.

Mr Doyle says the veterinary drug showed Qbiotics could take a product all the way from discovery to commercialization.

“It was also a derisking strategy,” he says.

“The canine is a good surrogate for the human setting and that has been the case.

“We have some good safety and efficacy data in well over 20,000 dogs”.

Stelfonta recently won a label expansion in the UK, for use in resectable mast tumors (not just inoperable ones).

The story to date

Qbiotics was co-founded by research scientist Dr Victoria Gordon and husband and forest ecologist Dr Paul Reddell.

Both founders were employed by the Commonwealth Scientific and Industrial Research Organisation, but in 2000 Dr Gordon busted out to form Ecobiotics.

The duo then formed Qbiotics - into which Ecobiotics was merged - in 2017.

The pair stumbled on tigilanol tiglate when fossicking in rainforest in the Atherton Tablelands of Far North Queensland.

They observed that animals spat out the seed of the blushwood tree, pointing to a non-toxic deterrent preventing the critters from eating and thus destroying the seed.

Qbiotics isolated tigilanol tiglate and tests for anti-cancer activity in animals proved safe and effective.

Mr Doyle was appointed in early September 2024 after Dr Gordon stepped down, but she remains on the board.

At the time, Mark Fladrich and David Phillips were appointed, while Andrew Denver and Prof Bruce Robinson stepped down.

The company's chair, Dr Susan Foden died suddenly in early November and Mr Fladrich assumed the chair role.

The board previously included former ASX and Cochlear chair Roderic Holliday-Smith, Cochlear chief financial officer Neville Mitchell and erstwhile Macquarie Bank CEO Nicholas Moore.

Taking the low road and the high road

A Scottish pharmacist, Mr Doyle has a long history with big pharma companies in medical and commercial roles.

Since peregrinating to Australia at the end of 1999 on a working holiday visa, Doyle has held roles with Janssen, Novartis, Sanofi and Boehringer Ingelheim.

He had lengthy stints in Paris, Singapore and Shanghai, before being poached by the smaller Aslan Pharmaceuticals (based in the Lion City).

"I liked the idea of roll up your sleeves and multi-tasking, whereas with big pharma you tend to get pigeon-holed," he said.

Mr Doyle joined Qbiotics partly because he liked the idea of returning to Australia, notably Brisbane, but also because of the buzz of developing a drug.

“The risk of biotech is quite exciting,” he says.

“It’s not for everyone. If you want a nice stable job ... get a job at Pfizer.”

Soft tissue sarcoma

Soft tissue sarcoma (STS) is a rare cancer that generally forms as a painless tumor in any bodily soft tissue.

The company says there were 128,000 new cases of STS globally in 2023, with the incidence growing at about half a percent per year.

The US Food and Drug Administration has granted tigilanol tiglate orphan drug status for this indication.

Conducted at New York’s Memorial Sloan Kettering Cancer Centre, stage one of the phase IIa trial covered 10 evaluable patients with advanced STS.

The study achieved an objective response rate of 80 percent in injected tumors, with eight patients having a complete ablation or partial ablation (reduction of 30 percent or more).

Of the injected tumors, 22 out of 27 (81 percent) showed complete or partial ablation (14 complete).

“None of the 14 completely ablated tumors recurred at six months, indicating tigilanol tiglate may provide durable responses,” the company says.

The trial moves to an expanded second stage, with another 40 patients targeted.

Mr Doyle says there around 80 to 120 STS sub types, but the company intends to narrow its work to the most common varieties.

Head and neck cancers (HNC)

Qbiotics currently is recruiting in Australia and UK for the HNC phase II trial.

As with the STS trial, it is single-arm and open label.

An earlier 19-patient phase I/II trial met safety and tolerability goals.

Head and neck cancers are a portfolio of cancers afflicting the mouth, nose, throat, voice box, sinuses, and salivary glands.

Mr Doyle says HNCs are challenging in at least two ways.

For a start, they occur close to vital organs and vessels.

Secondly, patients tend to be from lower socio-economic areas.

For instance, mouth cancer is quite prevalent in India and may result from chewing betel nut.

Smoking and chewing tobacco and alcohol are key risk factors with mouth and voice box cancers.

Oro-pharyngeal cancers are linked to the human papillomavirus.

The company hopes to release top-line data later his year.

Here, there and everywhere …

Mr Doyle says tigilanol tiglate is an “interesting molecule” because it has multiple modes of action. This includes some evidence of an abscopal effect, over and above the drug’s direct effect on the tumor.

The abscopal effect is when localized cancer therapies lead to the shrinkage or even disappearance of tumors elsewhere in the body.

Not surprisingly, the immune system is thought to transmit the tumor kill signals.

In an ‘off study’ observation the abscopal effect was seen in a melanoma patient, in an earlier phase I ‘all comers’ study.

(The company carried out two melanoma studies, one of them a dose-escalation effort in combo with Keytruda and the other a monotherapy).

The company is carrying out exploratory work on the abscopal effect in the STS and HNC programs and hopes to present data at an upcoming congress of learned peers.

In the background, the company is also undertaking a dose escalation and safety study for venous leg ulcers, which remain stubbornly hard to treat.

A semi-synthetic variant, this one would be a drug rather than a device, which would be rare in wound healing.

Finances and performance:

Qbiotics’ unlisted status hasn’t prevented the company from raising large wads of money: $194 million since inception, plus $60 million of tax incentives and government grants.

In early 2021, the company raised a hefty $85 million, with investment firm TDM Growth Partners accounting for $50 million (existing holders took up the rest).

At the end of December 2024, the company had cash of $39 million.

“We have enough money to deliver on our outlined programs, including part two of the STS trial and a venous leg ulcer study,” Mr Doyle says.

In the December half year, the company generated $1.16 million from Stelfonta sales, which “continued to be lower than expected”.

With its level of disclosure, Qbiotics’ annual report looks more like the work of a listed company.

With no listed mechanism - or not yet anyway - buyers and sellers can trade separately via www.wholesaleinvestor.com.

Dr Boreham’s diagnosis:

Mr Doyle says Qbiotics’ strategy has been to generate data in multiple tumors, including melanoma, to broaden the company’s commercial appeal.

“For us it is about creating proof of concept and evidence in multiple solid tumor types, to make us attractive for partnering.

“Our sweet spot is phase II or IIb, but we need to find a big partner … with the necessary infrastructure and resources to run multiple registration studies targeting multiple solid tumor types.”

He says Qbiotics is not yet at the point of having to hone its indications of interest.

“We are small nimble and get to wear multiple hats, but ultimately we are limited by resources.”

In its 25th year, Qbiotics offers enough goings-on to maintain the interest of the company’s circa 2,600 shareholders ahead of the listing.

For the record, Grandview Research values the STS market at $US1.26 billion in 2023 and reckons the HNC sector will be worth $US5.2 billion by 2030.

The vet market is estimated at $US100 million.

That’s decent enough, but a morsel compared to the human oncology opportunities.

Disclosure: Dr Boreham is not a qualified medical practitioner or veterinarian and does not possess a doctorate of any sort. Nor does Dr Google, but that doesn’t stop him from being the most trusted doctor in town.

DIMERIX

Dimerix says customer receipts for the year to June 30, 2025 were $54,562,000 from licencing agreements for its DMX-200 for focal segmental glomerulosclerosis (FSGS).
Last year, Dimerix said that it had received $10,872,000 in receipts from customers for the year to June 30, 2024 related to a EUR6.5 million ($A10.8 million) payment under its licence of DMX-200 with Advanz Pharma (BD: Jul 23, 2024).
Earlier this year, Dimerix said Osaka's Fuso Pharmaceuticals had paid it the JPY300 million ($A3.2 million) upfront fee as part of its licencing deal of DMX-200 for FSGS in Japan; and later, said Fuso had paid a further JPY400 million ($A4.2 million) for opening the first phase III trials site in Japan (BD: Jan 19, Mar 4, May 30, 2025).
Later, Dimerix said it received a $US30 million payment from Princeton, New Jersey's Amicus Therapeutics for the US licence of DMX-200 for FSGS (BD: May 6, 2025).
Today, the company said that it had signed four licencing deals for DMX-200 in multiple territories and continued "to pursue licencing opportunities with potential partners in territories not already licenced".
Dimerix said it would "assess what it may apply any excess capital towards which may include new spend on the company's research and development pipeline".
Dimerix said it was $45,585,000 cash flow positive for the three months, with cash and equivalents of $68,284,000 at June 30, 2025 compared to $22,141,000 at June 30, 2024.
Dimerix was up 1.5 cents or 2.7 percent to 56.5 cents with four million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has filed a formal response to the US Food and Drug Administration "to resolve the NUZ-001 clinical hold" including pharmaco-kinetic data in rats and dogs.
Last year, the then Pharmaust said Massachusetts General Hospital had accepted the then monepantel, now NUZ-001, into its phase II/III 'Healey' amyotrophic lateral sclerosis (ALS), or motor neuron disease (MND) platform trial (BD: Jul 15, 2024).
Later, the company said it filed an investigational new drug application to the FDA to conduct a phase II/III trial of NUZ-001 for ALS "within the 'Healey' ALS platform trial framework"; and earlier this year, the FDA put its application on clinical hold due to "certain concerns about the sufficiency information" (BD: Dec 18, 2024; Jan 19, 2025).
Later, Neurizon said the FDA requested "additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001"; and in March, said it had requested advice from the FDA on lifting the clinical hold (BD: Feb 17, Mar 17, 2025).
Earlier this month, the company said the FDA had confirmed it would lift the clinical hold on NUZ-001 pending two pre-clinical pharmaco-kinetic studies (BD: Jul 10, 2025).
Today, Neurizon said the clinical hold complete response included "bridging pharmaco-kinetic data from 28-day studies in rats and dogs … designed to address the FDA's request for more comprehensive animal exposure data to support the safety margins of NUZ-001 and its primary sulfone metabolite".
The company said the data showed "greater than 10-fold safety margins based on projected human plasma exposure levels for both NUZ-001 and its active sulfone metabolite … [and] enhanced confidence in dose selection and systemic tolerability to support progression to phase II/III clinical evaluation".
Neurizon managing-director Dr Michael Thurn said the filing "underscores our disciplined execution and ability to deliver critical development milestones ahead of schedule".
Dr Thurn said he expected resolution of the clinical hold in August and joining the 'Healey' trial this year.
Neurizon was up 1.5 cents or 9.7 percent to 17 cents with 2.8 million shares traded.

OPYL (FORMERLY SHAREROOT)

Opyl says its extraordinary general meeting passed all resolutions, with 98.70 percent in favor of its change of company name to 'Pathkey.AI'.
Last month, Opyl said investors would vote to change its name to 'Pathkey.AI' and ticker code to 'PKY', "primarily to better align the company's legal name with its evolving brand identity and strategic direction", as well as issue 10,000,000 rights to chair Saurabh Jain (BD: Jun 24, 2025).
Today, the company said the issue of performance rights to Mr Jain had 26,235,359 votes (99.95%) in favor and 13,559 votes (0.05%) in opposition.
Opyl fell 0.1 cents or 3.85 percent to 2.5 cents.

ATOMO DIAGNOSTICS

GZ Family Holdings Pty Ltd says it has increased its substantial holding and been diluted in Atomo from 113,359,869 shares (16.52%) to 116,922,671 shares (14.84%).
The Oakville, New South Wales-based GZ said it bought 3,562,802 shares between May 9 and June 25, 2025 for $57,606, or 1.6 cents a share and was diluted in a placement and share purchase plan between June 27 and July 24, 2025.
On Monday, Atomo said it had placed $260,000 of the $727,613 shortfall from its share purchase plan at 1.85 cents a share, taking the total raised with the $2,113,000 placement and $272,388 share plan to $2,645,388 (BD: Jun 27, Jul 21, 2025).
Atomo fell 0.2 cents or 10.5 percent to 1.7 cents with 4.2 million shares traded.

ADHERIUM

Sydney's Regal Funds Management says its 364,651,488 share-holding in Adherium was diluted from 23.18 percent to 20.29 percent due to a share issue on July 22, 2025.
Last week, Adherium said it raised $3,092,395 at 0.5 cents a share in an institutional rights offer and $1,400,000 in a partially-underwritten retail rights offer (BD: Jul 17, 2025).
Adherium was unchanged at half a cent with 1.4 million shares traded.

ORTHOCELL

Orthocell says it has appointed Michael McNulty as a director, replacing former Deputy Prime Minister and Labor Opposition Leader Kim Beazley who has resigned.
Orthocell said Mr Beazley had resigned "for health reasons" and would continue to act in an advisory capacity.
The company said Mr McNulty's appointment was effective from September 1, 2025 and he had been a director of several listed companies and not-for-profit organizations, managing partner of Deloitte's Perth office and was a director of Deloitte Australia.
According to his Linkedin profile, Mr McNulty held a Bachelor of Commerce from Perth's University of Western Australia.
Orthocell said that in addition to directors' fees, Mr McNulty would be issued 2,000,000 options, exercisable at $1.53 within three years of the issue date and vesting two years from the date of issue.
The company said following Mr McNulty's appointed it had five directors and that US-based director Dr Ravi Thadhani had been promoted to "lead independent director".
Orthocell chair John Van Der Wielen said extended the company's "sincere gratitude to Mr Beazley for his contributions to the board".
Orthocell fell seven cents or five percent to $1.33.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Dr Catherine Cole as its chief medical officer, effective immediately.

Neuroscientific said Dr Cole had been head of haematology and oncology at Perth's Princess Margaret Hospital for Children, inaugural professor of paediatric haematology and oncology at the University of Western Australia, director of laboratory haematology Pathwest and co-director of the Children's Cancer Centre Telethon Kids Institute.

The company said Dr Cole's appointment was "at a key development stage for the Company as the special access scheme (SAS) program in fistulas in Crohn's [disease] is underway, with interim results anticipated later this year".

Last month, Neuroscientific said it acquired Perth's Isopogen WA and its Stemsmart mesenchymal stromal cell technology and had begun a special access program for fistulizing Crohn's disease (BD: Jun 27, 2025).

Neuroscientific fell one cent or 4.35 percent to 22 cents with 2.6 million shares traded.