Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Saluda Medical

By TIM BOREHAM

ASX code: SLD

Share price: 22.5 cents

Shares on issue: 252,023,810

Market cap: $56.7 million

Chief executive officer*: Mike Mathias

Board: Doug Godshall (chair), Mr Mathias, Robert Palmisano, Robert Faulkner, Quentin Blackford, Catherine Livingstone, Dr Geoff Brooke.

* Barry Regan resigned as of September 24, 2026

Financials (year to June 30, 2026): operating revenue $US90.2 million (up 28%), loss of $US149.6 million ($US149.3 million deficit previously)

September quarter 2026: revenue $US23.5 million, cash burn $US42.7 million, cash balance $US73.6 million.

Identifiable major shareholders: FMR (Fidelity) 7.53%

Sector-wide clinical studies failing their primary endpoints are not the only issues to have spooked investors this year, resulting in cruel sell-offs.

On October 21 shares in Saluda plunged 20 percent after the back pain device company unveiled a "voluntary field action" for its Evoke spinal cord stimulators.

Saluda didn't mention the 'R' word – as in 'recall' – and said the problem stemmed from a "low-incidence issue related to a third-party manufacturing process change".

The complaints affected less than one percent of devices and the problem has been corrected (see below).

But the share price damage has been done, thus perpetuating a wretched period for the stock since Saluda listed on the ASX, last December.

The voluntary field action aside, the company has exceeded the expectations outlined in last year's initial public offer (IPO) prospectus.

We're talking about measures such as revenue and underlying earnings.

Let's not forget Saluda is a substantive, commercialized company, having generated more than $US90 million of revenue last financial year.

What a pain

Defined as lasting for more than three months, chronic pain is increasing because of an ageing population, better survival from catastrophic injury and more pain-inducing surgery.

Saluda focuses on developing treatments for chronic neurological conditions via its closed-loop spinal cord stimulation (SCS) platform, Evoke.

SCS works by suppressing pain using electrical pulses generated by electrodes, to activate the spinal cord's dorsal columns.

This inhibits the body's pain signals before they travel up the spinal cord to the brain.

SCS leads are positioned in the epidural space and anchored to spinal fascia.

The first product, Evoke, is indicated for chronic intractable pain of the trunk and/or limbs.

The chronic pain could stem from spinal related nerve injuries, botched back surgeries or peripheral nerve injuries from orthopaedic surgery.

Evoke senses and measures neural responses to stimulation and automatically adjusts therapy based on real-time neuro-physiological feedback.

"We have technology that can objectively measure a patient's neural response to stimulation and automatically adapt therapy based on that response and we have clinical evidence demonstrating durable outcomes over time," CEO Mike Mathias says.

Cochlear roots

Saluda draws on 15 years of research and development.

The company was founded by John Parker, a device inventor and researcher at Cochlear.

Saluda gained US Food and Drug Administration approval for Evoke in February 2022; and launched the device in the US in July 2023, having won reimbursement.

In April 2023, a Delaware incorporated US entity acquired all the shares of Saluda Medical Pty Ltd.

The company debuted on the ASX at $2.65 a share, ascribing a $670 million market cap.

Mr Mathias joined in November 2024 after more than 30 years in medical technologies, mainly at Medtronic.

“What attracted me to Saluda was ultimately the technology, the patients it can help, and the opportunity to build a very different business in neuro-modulation,” he says.

Saluda has been well backed in the past, with Boston Scientific and Redmile Group chipping in $US75 million ($A113 million) in 2019.

In 2023, Saluda raised a further $US150 million of equity, from parties led by Wellington Management.

Where’s the proof?

Saluda’s therapeutic claims are backed by the Evoke study, a 41-patient, prospective, multi-centre, parallel-arm, double blinded, randomized and controlled pivotal trial.

The trial showed that all of the treated patients “were clinically significant responders”, with half of them showing such on all five measures (such as reduced opioid usage).

The company says the study showed the “clinical superiority of our system over the fixed-output, open-loop therapy [used] in most commercially available SCS devices”.

The trial showed that 2.6 percent of Evoke implant recipients needed a reprogramming follow-up visit within six months of the procedure, compared with the sector average of 3.1 percent.

Within seven to 18 months the revisit rate fell to 1.4 percent compared to the standard six percent. After 18 to 30 months the rate declined to 0.8 percent.

As for efficacy, 83 percent of patients had ongoing pain relief after 36 months.

Paddling along

On October 5, Saluda said it would release its closed loop surgical paddle lead, CAP24, in the US, having had FDA approval in June.

CAP24 is the “first and only FDA-approved surgical paddle lead purpose-built for physiologic, dose-controlled, closed-loop therapy”.

CAP24 enables the Evoke System to measure each patient’s neural response and adapt stimulation with every pulse.

The idea is that by providing real-time feedback, CAP24 can enable clinicians to adjust the stimulation as neural responses change.

Following a limited market release in the US, CAP24 is being made available more broadly to neurosurgery and orthopaedic spine practices. Saluda says CAP24 opens a $US670 million-a-year US market.

What’s the problem?

Saluda says the voluntary recall relates to a “defined population” of previously manufactured Evoke closed-loop stimulators.

The third-party manufacturing issue “has been corrected and devices manufactured and distributed following the corrective action are unaffected”.

The fault caused “temporary unintended stimulation associated with charging, or an inability to charge the implanted device”.

Mr Mathias said the corrective actions were “progressing well”, with a focus on communicating clearly with physicians and patients.

“While these situations are never ideal, we're focused on doing the right thing for patients and customers.”

Saluda said the action stemmed from 26 complaints over the 3,900 implanted devices – a problem rate of 0.66 percent over two years. Management estimates 29 more devices could have the same problem over their remaining life.

“Given the very low complaint rate, Saluda is not recommending prophylactic replacement or explanation of potentially affected implanted devices.”

The company recommends physicians continue routine patient management and can decided whether device replacement or “another intervention” is appropriate.

Saluda “does not expect the action to disrupt product supply or its ability to meet customer demand”

Finances and performance:

Saluda reports a “solid start” to the 2026-’27 financial year.

September quarter revenue rose 26 percent year on year, to $US23.1 million.

Of that, US revenue accounted for $US17 million, up 34 percent.

But revenue declined from $US27 million in the June quarter, for seasonal reasons and because the previous stanza included $US600,000 of one-off revenues.

In the US, patient implants rose from 769 to 838, with the average number of implanting physicians rising from 311 to 374.

Product pricing was “relatively stable”.

The company ended the quarter with $US73.6 million of cash, 36 percent lower than the June quarter.

“We don’t believe the September quarter cash use [of $US42.7 million] represents the remaining quarters of the 2026-’27 year,” chief financial officer Jim Erickson says.

“We expect cash usage over the remaining three orders to reduce the levels similar to prior quarters.”

Nonetheless, with the current cash runway lasting until only June next year, “We recognize that our path to profitability will require additional capital.”

The company has long term debt of $US96 million, with $US25 million undrawn.

Saluda reported revenue of $US90.2 million for the 12 months to June 30 2026, up 28 percent and a steady net loss of $US149.6 million.

Management has guided to current year revenue of $US113-122 million, up 25 to 35 percent.

The company says that it expects an adjusted earnings before interest, taxation, depreciation and amortization (Ebitda) loss of $US95 million to $US101 million.

The cost of the field action should not “materially affect” earnings.

Saluda shares have pulsed between $1.53 on December 10 last year and 22.5 cents today.

Reflecting the 86 percent share decline since listing, Saluda was ejected from the S&P/ASX All Ordinaries index on September 21 this year.

Size of the prize

SCS devices generated $US2.67 billion in the 2023-'24 year but have only penetrated six percent of the market.

Globally, Saluda estimates 1.2 million new patients a year could be eligible for the Evoke System, including 560,000 with failed back pain after surgery and 400,000 with non-surgical back pain.

Saluda is targeting the US population of 5,700 interventional spine physicians, initially the 2,700 who have performed at least one a month. The tally includes 2,100 neurosurgeons, who generally prefer the implantation of a paddle lead, rather than percutaneous leads.

Saluda also plans to seek FDA approval to label the Evoke System for other conditions, such as non-surgical back pain and diabetic peripheral neuropathy.

Chair Doug Godshall says Saluda is in the "early stages" of US commercialization in the US$18 billion a year market. The company values the global opportunity at US$23 billion.

Eyeing the competitive landscape

Saluda claims current SCS devices have limitations that the Evoke System seeks to address.

"We believe our [device] is the only SCS system that can adjust therapy in real time with every stimulation pulse to maintain a target level of neural activation," Saluda says.

Rivals include Abbott Laboratories, Medtronic and the aforementioned frenemy Boston Scientific Corporation - players with much greater resources than Saluda.

For example, Medtronic won FDA approval of its Inceptiv SCS System in April 2024. Saluda believes is the only other SCS therapy with evoked compound action potential (ECAP) sensing capabilities or "the sum of responses from the activation of multiple nerves and … a direct measure of the spinal cord's response to stimulation".

As well as competing with standard SCS devices, Saluda vies with other "interventional techniques". These include steroid injections, nerve blocks or nerve ablation, peripheral neuro-stimulation and opioids.

Dr Boreham's diagnosis:

Saluda cites US sales traction and "well established" US reimbursement codes.

The company also reports a growing share in high volume ambulatory surgery centre procedures.

So, what's not to like? Clearly, investors have not warmed to the story from day one, with the IPO clearly being valued too ambitiously.

We posit that, in the current climate, investors have little tolerance for medical technology companies that have excelled with their rollouts but expect ongoing heavy losses.

Saluda' s opportunities are clear, but the company needs to show more discipline than a bondage madam in its Evoke execution.

"The focus is increasingly on productivity and reducing territory selling costs as a percentage of the revenue those territories generate," Mr Erickson said.

"Reducing time for therapy adjustment is an important part of the therapy we can provide," Mr Mathias says.

"Patients don't get SCS because they want another medical device to manage. They want to get back to living their lives."

With 24 percent of Americans suffering chronic pain, evidently there's a lot more living to be done.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Luckily, he doesn't suffer from a chronic pain, but knows a few (Hey, whose paying your wages? – Ed.)