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# Incontinence failure puts Viveve under stress

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**With little cash in the bank and creditors soon to start pressing, a trial failure is a disaster for Viveve.**

Sham-controlled trials are the acid test for medical devices, and are thus fraught with risk. Losing this gamble today is Viveve Medical, whose device for regrowing collagen has failed in the Liberate-International trial, intended to allow approval of the product for stress urinary incontinence.

The Viveve 2.0 device is already approved in the US for electrocoagulation and haemostasis in general surgery, but SUI, a huge market, was the big hope. The company's stock was down as much as 65% in early trading today, and the group is casting about for a financial lifeline. With another, larger trial looking at the system's ability to improve sexual function in women due to report next year, the company needs a miracle, and soon.

The Viveve 2.0 system emits radiofrequency from an electrode placed inside the vagina; the company says this causes new collagen to grow, tightening the vagina and urethra. The Liberate-International trial randomised 99 patients in a 2:1 ratio to the active or sham groups.

The primary endpoint was change from baseline in the one-hour pad weight test six months after the therapy, with a hit being a 20% higher response rate in the treatment than the sham arm. In a note published on July 11, Stifel analysts wrote that when they asked a group of doctors who used Viveve to treat SUI patients whether this would be hit, 86% of respondents said they were confident or very confident of success.

In the event the median decrease from baseline at six months post-treatment was 8.0g in the active group and 8.0g in the control group.

### Rents and debts

The company will get hold of the full dataset, including information on secondary endpoints, in early August, and will evaluate that before deciding whether to can development for SUI. But it will also have one eye on the Viveve II study, testing the system against sham in 250 patients who experience vaginal laxity following childbirth. Data are expected in April 2020.

The trouble is, even if Viveve II is on course for a hit, it might not get there since Viveve is having difficulty keeping the lights on.

In June the Colorado-based company changed its US business model from capital sales to rental, to attract customers with lower up-front costs and gain itself a recurring revenue stream. The group said today that this had indeed boosted adoption rates, with 27 Viveve systems changing hands last month – a higher monthly productivity rate per rep than it had yet seen.

Unfortunately, the change to rental was the main cause of its second-quarter revenues being, at $5.5m, lower than expected. Viveve is now going to reset its revenue guidance for 2019.

More importantly it has initiated a strategic analysis of its business to preserve cash and explore financing and strategic alternatives. But the writing looks to be on the wall: at March 31 Viveve had $18m in cash and $30m of debt, on which material principal payments are scheduled to begin in 2021.

With its stock now languishing at around 15 cents the group has little hope of raising cash on the public markets, and any potential acquirer would have to be optimistic to a fault.