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FastWave Taking The Fast Way To Intravascular Lithotripsy

by Barnaby Pickering

FastWave is developing an intravascular lithotripsy platform that will be differentiated from incumbent Shockwave Medical's IVL platform and hopefully land its founders and investors a healthy return.

Being the first to bring an innovative medical device to market is one way of making millions of dollars – if payors cooperate.

Shockwave Medical, developer of the first widely approved intravascular lithotripsy (IVL) system, is an example. Its sonic-wave-based, calcium busting technology has led the company to a valuation of almost $8.5b; not bad considering its total fundraising prior to IPO summed to just $148m.

Sometimes though, one company's success can provide opportunities for others. It was rumored for a while that Boston Scientific, which has a market cap of more than $90bn, was looking to acquire Shockwave Medical, however analysts have since implied that it may be too big a meal for it to fully chew. Larger strategic players like Boston are also likely to look at Shockwave as a potential acquisition – however they may also be considering alternatives.

Enter FastWave Medical. The company is hoping to bring an alternate line of products to the highly valuable IVL market, setting themselves up for direct competition against Shockwave.

FastWave is led by Scott Nelson, who brings with him almost two decades of experience working for Medtronic, Boston Scientific and CR Bard, as well as expertise from his prior venture, red-light therapy developer Joovv.

Nelson told *Medtech Insight* that, right from the company's start, he and his team held a "fundamental belief" that "IVL utilization would only increase," and that because Shockwave

was the only incumbent player, an opportunity was present.

He also noted that, three years ago, "there weren't many start-ups working on IVL."

"Looking at the structural heart space as an example – or renal denervation – there were a ton of start-ups. Medtronic's acquisition of Ardian is an example," he said. "We just didn't see that same level of activity in IVL."

Another beneficial factor for FastWave Medical is the action taken by CSI against Shockwave. Shockwave was attempting to revive two patents related to its IVL technology, however CSI appealed and won.

"When the US Patent Office overwhelmingly ruled in CSI's favor, we saw that as an inflection point – a strong reason to allocate more resources to FastWave in our early days," Nelson explained.

"Analysts thought Shockwave's appeal process would last over 12 months," he continued. "The fact that they lost in just three was definitely a sign that FastWave would likely have more freedom to operate within the IVL space."

Filling Key Gaps

Nelson said that, for interventionalists, IVL is a "nice tool" to have in their arsenal when dealing with "challenging calcific plaque," but current offerings leave "gaps."

"Shockwave has a big, bulky balloon that is hard to traverse and navigate through torturous anatomy that is burdened by calcium build-up," he explained. "That's probably the biggest complaint we hear."

> *"At FastWave, we've really focused on improving the balloon catheter – reducing the crossing profile, optimizing the shaft for better deliverability, and making it more rupture-resistant." – Scott Nelson*

"Because Shockwave is the incumbent, they aren't necessarily incentivized to innovate quickly. IVL would be a lot different if there were more competitors. At FastWave, we've really focused on improving the balloon catheter – reducing the crossing profile, optimizing the shaft for better

deliverability, and making it more rupture-resistant." Nelson said.

"For lack of a better description, we just want to be more nimble and innovate faster," he continued.

According to Nelson, the underlying technology within FastWave's balloon was developed in-house – it was not licensed from a university like many other medtech inventions.

The company is also developing a next-generation IVL system. It will supposedly use a "different energy" source, instead of electric current, to create the cavitation necessary for calcium modification.

This will bypass certain "design limitations" present in current electric-based IVL technology.

"Inside the angioplasty balloon, the aim is to create vapor bubbles, which rapidly collapse, producing shockwaves that fracture calcium," Nelson explained. "But to deliver more pulses, or develop longer balloons, you need more emitters and therefore wires – which leads to a larger balloon that is harder to maneuver."

Moreover, the emitters "degrade."

"I think the maximum number of pulses in Shockwave's devices range from 120 to 300– we're targeting a bigger number," Nelson explained.

When asked how FastWave's technology will create the necessary cavitation pulses – specifically whether it would involve passing fluid through a small gap (one way of creating cavitation) – Nelson said the company would not be disclosing the specific method just yet.

Current Progress

On 17 January, FastWave announced the completion of enrollment in the first-in-human trial of its technology. The study enrolled eight patients and collected 30-day outcomes data. (Also see "*IPM 2024 Roundup: Abbott And Medtronic Push Diabetes Tech, Edwards Updates Tricuspid Progress, Shockwave Bets On R&D*" - Medtech Insight, 22 Jan, 2024.).

Nelson described it as a "really valuable experience" for the company, adding that the device performed "very well."

He also noted that based on dialogue with the FDA, no FIH feasibility studies were required; it could have gone straight to a pivotal trial.

"We pondered that decision with advice from investors and advisors. We really felt that this FIH

study would help de-risk the future pivotal trial," he explained.

"So far, we've had some really nice learnings that we will carry forward. It was a great experience."

FastWave's (Potential) Impact

Right now, IVL is a well-reimbursed technology and Shockwave provides relevant reimbursement codes on its website.

Nelson admits that IVL competitors could add pricing pressure in the future. He compared it to the drug-eluting stents market, where prices have tumbled over the years.

He did argue, though, that this would take "at least five years," and the pressure would merely "force companies to be better."

"When there is only one company selling a technology, they don't have to improve it. FastWave will force the field to progress and serve as an overall good for health care systems."

Pricing pressure could be accelerated, he suggested, if a larger strategic "like a Medtronic, or a Boston Scientific, or even a J&J" waded into the IVL marketplace.

"If one of these companies could include IVL in their portfolio, I think it would pose a big challenge for Shockwave. They would be forced to compete as a standalone company against organizations that can offer bundled plays – I'm sure Shockwave is working on plans for that," he said.

"But with respect to IVL, strategic interest is so high, so we naturally sit in a really good position. If we continue to execute and meet our development and regulatory milestones, the natural byproduct would be an exit to one of these strategics. That said, we certainly won't put all our eggs in one basket."

Timing The Exit

FastWave is wary of growing too big. Shockwave's current market cap has made it difficult for strategics to acquire, and Nelson does not know when his company might be acquired by a larger medtech company.

"Just like any smart start-up that is moving along and making good progress, we are keeping all options on the table. But I do think that any strategic which wants to get involved in IVL would be interested in what we are building," he said.

Nelson pointed towards the company's trial ambitions as possible inflection points. FastWave is

currently testing its system in peripheral artery disease, however, hopes to move over to coronary applications “later this year.”

These trials would be larger in scale – between 350 and 400 patients according to Nelson – and will likely come with more risk and greater capital requirements.

“I think most strategics would want to be fairly involved in large pivotal trials of our technology. So, I think 12-18 months, factoring in loads of things I cannot control, could be a reasonable exit timeframe.”