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Vanquishing Prostate Cancer Without Debilitating Side Effects – Francis Medical CEO On Water Vapor Ablation

Company's Vanquish System On Track For Potential Market Launch In Q4 2025

by Ryan Nelson

Francis Medical believes it will be the first-line treatment of choice for prostate cancer patients and physicians by offering high efficacy and significantly reduced prospects for life-altering side effects. The company is halfway through a pivotal trial guided by US FDA feedback as part of the agency's Breakthrough Devices Program.

Medtech Insight speaks with industry experts about trends and innovations with potential to transform cancer care.

Francis Medical, Inc. says its Vanquish Water Vapor Ablation treatment for prostate cancer will have cancer kill rates on par with radical prostatectomy and radiation while also causing "close to zero urinary incontinence and very, very minimal ED."

The Minneapolis, MN-based company is seeing encouraging results in its half-completed pivotal clinical trial for the Vanquish system, which the US Food and Drug Administration designated a Breakthrough Device in August 2023.

According to Francis president and CEO Mike Kujak, who spoke with *Medtech Insight* on 25 July, the company will use the pivotal trial findings to support both a 510(k) notification and a

premarket approval submission to the FDA. The 510(k) targets an "ablation of prostate tissue" indication, while the PMA is aimed at securing a unique label in the market, "management of prostate cancer."

Per Kujak, "Nobody else has that."

Kicked off in July 2023, Francis' VAPOR 2 is a prospective, single-arm study designed to treat 235 patients with intermediate-risk, localized prostate cancer at up to 30 clinical sites around the US. The study will evaluate 100 patients for one year with six-month biopsies to support 510(k) clearance, in accordance with *FDA guidance*, and then follow a total of 235 patients for three years and submit that safety and efficacy data for its PMA.

Key Takeaways

- The Vanquish system could be a compelling alternative to other ablation techniques, which can lead to urinary incontinence and erectile dysfunction similar to radiation and radical prostatectomy.
- Francis is targeting a unique indication, "management of prostate cancer," through a planned PMA submission after seeking 510(k) clearance for "ablation of prostate tissue," which could bring Vanquish to market in late 2025.
- Kidney cancer is next in the company's crosshairs, followed by bladder cancer.

That puts Francis on track to file its 510(k) in June 2025 and potentially go to market in the 2025 fourth quarter for ablating prostate tissue, while PMA application for the upgraded cancer label is targeted for June 2028. The company currently is finalizing an $80m Series C round to fund the remainder of its pivotal trial and build a commercial organization to support launch activities.

Francis scored FDA Breakthrough Device status for Vanquish on the strength of its VAPOR 1 Early Feasibility Study, *published* in the Journal of Endocrinology in November 2022, and the company shaped its pivotal trial based on FDA feedback over five pre-submission meetings. "We approached it a lot of different ways because we knew we wanted to be differentiated in the marketplace and wanted to have a cancer label," Kujak said.

Importantly, in VAPOR 2, Francis will be able to retreat patients if cancer reappears at any point in the study. "So we should, in essence, at three years have a very low number of patients who have cancer somewhere else in the prostate based on three-year biopsies. That's the beauty of our study and our technology, because procedure time is 30 to 60 minutes on average right now."

According to Kujak, that can compare with two or more hours for a prostatectomy, up to 28 separate sessions for radiation, and 90 minutes to two hours for high-intensity focused

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FRANCIS MEDICAL CEO MIKE KUJAK *Source: Francis Medical*

ultrasound (HIFU). Further, the Vanquish procedure can be performed in an outpatient environment, typically in an ambulatory surgical center, the CEO said.

'Tough On Cancer. Gentle On Patients'

The Vanquish Water Vapor Ablation System uses phase shift energy stored in sterile water vapor to convectively transfer thermal energy to cancerous tissue, causing cell death. Unlike HIFU, cryotherapy and other ablation techniques, which use conductive energy, Francis' system minimizes or avoids damage to surrounding structures by respecting the prostate's natural boundaries, the company says.

Kujak explained, "With conductive energy – which is most of the other ablative therapies, cold or hot – you put a needle in and you make it either cold or hot, and that thermal energy moves away from cell to cell from the energy source. The problem is that the energy source does not respect the prostate capsule, so you will ablate through the capsule."

That can lead to the same life-altering side effects as radiation and radical prostatectomy.

"Unfortunately, when God made man, he designed the prostate to not come out of the body," Kujak said. "Because you have the urethra running through the middle; then on the top of the prostate, which is right next to the bladder, you have an internal urinary sphincter; and on the bottom of the prostate you have an external urinary sphincter, and that's what keeps the urine in your bladder. If you didn't have those sphincters, urine would constantly run right through you."

He continued, "You also have nerves and blood vessels that run up the capsule wall to the tip of the penis. And those are the nerves and the blood vessels that control and give a man an erection upon stimulation. So when you're taking the prostate out, you're actually damaging the sphincter and you're damaging the nerves, and that's why there's high incidence of urinary incontinence and ED."

The same issues can occur with radiation, if to a lesser degree, he said.

Not so with Vanquish. Francis' approach is unique in that its thermal energy suffuses the prostate capsule in vapor form, destroying cancer cells, but residual energy is not transferred beyond the capsule's walls. "It's like wind at a sail," Kujak said.

That's why Francis describes its technology as "Tough on cancer. Gentle on patients."

Kujak noted, "I'm a guy, I have a prostate, right? I always say to the man, 'Look in the mirror and ask yourself the question, do you want to take a chance with RP or radiation, or do you want to try this first and have a good quality of life?'"

Reimbursement Work Underway

The American Cancer Society estimates that one in eight men will be diagnosed with prostate cancer in their lifetime. In 2024, the organization anticipates 299,010 new cases and 35,250 deaths from prostate cancer.

Francis says its Vanquish therapy could benefit any patient whose prostate cancer has not migrated outside of the prostate capsule, which is 85% of newly diagnosed cases.

Based on its safety and efficacy results to date and reported perceptions among patients and physicians, Francis is confident that Vanquish will be the first-line therapy of choice for treating prostate cancer.

As for reimbursement, Francis got off to a rapid start compared with many medtech companies, starting the process with the American Medical Association and Centers for Medicare & Medicaid Services even before initiating clinical research, Kujak said.

"Back in 2019, we went to AMA and got our own CPT [Current Procedural Terminology] code. And then after that we filed a New Tech APC [Ambulatory Payment Classification] application with CMS to get some idea around payments, and we heard back from CMS in 2019 on what the likely payment would be once this product is on the market. So we've done a lot of early work," he said.

Next up in Francis' development pipeline is water vapor ablation for kidney cancer, a project expected to commence in 2026, followed by bladder cancer in 2028.

To date, Francis has raised $80m in funding in Series A and Series B funding rounds led by investors including Solas BioVentures and Abortetum Ventures, with contributions from H2Oey Ventures, Tonkawa, and Coloplast A/S.

Boston Scientific was an early investor as well.

Boston Scientific in 2018 acquired NxThera, the developer of an FDA-cleared, minimally invasive therapy to treat lower urinary tract symptoms associated with benign prostatic hyperplasia via convective water vapor energy. NxThera's Rezūm System was developed by Michael Hoey, who went on to found Francis Medical and continues to serve as its chief technology officer.

Kujak was general manager of prostate health solutions at American Medical Systems before joining NxThera in January 2016, where he served just shy of three years as chief marketing officer and senior vice president of international commercialization.