

Vensica Medical Opportunity

Friends and colleagues

Just like many of you in our medical profession, we are pitched new products and devices routinely. But every once in while one comes across a technology that is particularly interesting and I am presenting one of these to you now. The company is Vensica Medical and they make a device that will potentially change the way we treat OAB (over active bladder) and other irritative bladder symptoms.

We all know that Botox injections into the bladder works. But there are limitations to this technology:

- Patients don't like the idea of having their bladder injected multiple times to place the toxin.
- The procedure generally requires an anesthetic and a surgical or ASC room for delivery. This may also involve the additional aggravation of pre-admission testing.
- This leads to patients unwilling to take the leap to have the procedure done since their symptoms are annoying but not typically debilitating or life threatening.
- Surgeons have to spend time performing the procedure including travel time.
- There is a risk of retention.

Vensica uses their "Vibe" catheter and their neurotoxin "Venoxin" to address all the above issues. They have a catheter device that is a needle free alternative to deliver their neurotoxin. This catheter has an ultrasound transducer situated between two balloons that provides uniform distribution of their neurotoxin. Early data shows this 10-15 minute procedure to be painless and can be done by office personnel while the doctor is still seeing patients. The Venoxin toxin is a purer form of Botulism toxin that does not have any foreign body proteins (so no allergens) and can be shipped and stored at room temperature.

Vibe delivers Venoxin® into the bladder wall using ultrasound cavitation. Venoxin is delivered uniformly for substantial bladder wall coverage.

Ultrasound acoustic pressure creates small gas bubbles, called cavitation bubbles, in the drug solution. These bubbles are highly energetic, and this energy is utilized to deliver drugs into tissues.

In the standard Botox procedure, needle injections deliver the toxin deep into the bladder muscle, mainly affecting motor nerves, causing the retention risk that we see. Vibe delivers the toxin to the mucosa, submucosa, and into the muscle, thereby targeting both sensory and motor nerves. The targeting of sensory and motor nerves may show superior efficacy, and lower retention rates. But this has yet to be proven.

Most of the data proving the efficacy of this procedure is on pig bladders. They have completed a Phase 1 safety trial on 10 human subjects proving that it is safe and tolerable in the office setting.

This is an early stage company and therefore should be viewed as a very risky investment. There is a very real possibility that you can lose your investment completely. Specifically, the company doesn't yet have phase 2 human data showing that this device works. Thus far they only have compelling pig studies

and the early Phase 1 results. However, there is a company called Carthera that uses an ultrasound device to get chemo products past the blood brain barrier and ultrasound technology is universally utilized in healing for its effects on tissues. Additionally, there is the issue of potential competition, but we are unaware of any other companies trying intravesicle Botox placement. Urogen (the maker of Jelmyto) did try this but recently announced that even though their technology kept their drug in contact with the bladder wall for 10 hours, it did not impact OAB symptoms likely because the neurotoxin could not permeate through the urothelium.

In my opinion, this device has significant potential to not only take significant market share away from Allergan (the standard injection Botox procedure) but I think the ease of use and the ability to simply put patients on this device in the office will prompt far more patients to seek neurotoxin treatment than would have ordinarily considered it. Currently, this treatment is considered 3rd line treatment after behavioral therapy and meds, but I can certainly see a very quick move to this modality of treatment when someone has even mild side effects from the meds (which is a large number). If indeed the data shows that it is easy and comfortable with no retention risk, I can see the indications increasing to include patients with only mild symptoms, nocturia, IC etc.

The economics seem favorable as well. Ultimately, they would probably get their own CPT code, but for now Mark Painter (a urology coding expert) has identified CPT codes of 51700 (bladder instillation) + 64646 (chemodenervation) + 76999 (unlisted ultrasound procedure) as payable codes. Assuming a cost for the Vibe disposable catheter of \$30 and office expenses of \$30 there is a net payment of \$315 - \$60 = \$255 to the office. This is more than the \$180 currently paid for Botox injections.

We would be investing through an investment company called MedPro which is a group of physician investors that evaluate early stage offerings in healthcare and relies heavily on the expertise of their investors in their respective fields for their opinions.

Attached please find the important information about the company and product. We will be holding two meetings with MedPro and the company (Vensica) to help you make an informed decision about investing in this opportunity.

Obviously, this has nothing to do with NJU, and I have limited this correspondence to people who I personally know. However, if you know of someone that would be interested in investing with us (especially if they are urologists who I believe are uniquely qualified to understand how valuable this technology could be) please feel free to invite them.

Marty Goldstein