



Bearpac Medical launches Novel Drainage Device to Improve Patient Care



Jay Zimmerman
President

Bearpac Medical, LLC.

Interview conducted by:
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CEOCFO Magazine

CEOCFO: *Mr. Zimmerman, what is the overall vision behind Bearpac Medical?*

Mr. Zimmerman: The overall vision is to offer a new technology to a space that has not evolved for the past twenty years. Bearpac is developing the next generation of drainage therapy for palliative care patients. Our entire team has many years of experience with thoracic drainage products, so we were able to develop this technology to treat patients with a pleural effusion diagnosis, or allow patients to treat themselves at home. Pleural effusion is a buildup of fluid around the lungs and that fluid needs to be drained intermittently. Patients with this condition are usually under palliative care for stage 4 lung or breast cancer with no other treatment options. Therefore, it is more of a comfort care treatment.

CEOCFO: *What has been the traditional way to treat this?*

Mr. Zimmerman: The traditional method of treatment for the last twenty plus years is a catheter placed in between the outer chest wall and the lungs where fluid has accumulated. The catheter is known as a tunneled pleural catheter which allows the patients go home from the hospital and be in the comfort of their own home while under care. The leading technology available is a vacuum bottle which attaches to that catheter when fluid needs to be drained. Think of a mayonnaise jar that contains vacuum pressure and once vacuum is accessed, it evacuates the fluid from the patient's chest.

That is the primary technology that has been on the market for years with no improvements to the product. We realized after speaking with customers and patients that there was an opportunity to develop a better way of performing drainage therapy than is currently available.

CEOCFO: *What have you created at Bearpac?*

Mr. Zimmerman: What we have done is add technology to the therapy along with a method of controlling the flow. By that I mean that we have developed a handheld digital control unit with a pump system called Passio™ that offers four speeds of flow to evacuate fluid out of the chest. Either the patient or the caregiver can control the handheld unit, which is smaller than a TV remote.

With the simple push of a button, they can speed up, slow down or pause the pump as they are evacuating the fluid out of their chest, depending on their comfort level. Passio puts complete control of the therapy in the hands of the patient going through the drainage therapy.

CEO CFO: *What is it about the evacuation process that someone would care whether it just goes out continually? Is it painful; is it annoying?*

Mr. Zimmerman: That is a great question and where our market positioning of Passio™ really comes into play. To take a step back a bit, the employees of Bearpac have many years of experience working with a different type of chest drainage device, so we understand the thoracic space. The technology available today for pleural effusion patients generates very high vacuum levels to evacuate fluid. As a baseline, the competitor's numbers are very high, but that unfortunately is the level of vacuum required to fill a vacuum bottle. Our experience in developing chest drainage products tells us that chest drains operate very well between -20 to -40 cm H₂O after a procedure in the chest cavity, so that is the level of vacuum we were targeting.

We have developed a digital handheld control unit with a pump system that can evacuate patient fluid into a collection bag using between -45 and -70 cm H₂O of pressure, so at exponentially lower levels of vacuum pressure than what the competition is utilizing. Anecdotally, what we are seeing in our trial patients is that we are not creating the pain that is typically caused by high levels of vacuum. To clarify, as I said earlier, this is palliative care. There is no other treatment strategy. Unfortunately, these patients may not survive long, so why subject them to more pain than necessary?

CEO CFO: *Where are you in the development and commercialization process of Passio?*

Mr. Zimmerman: We have had FDA clearance since July of 2019 and like most other companies, COVID impacted much of our commercialization strategies. However, with FDA clearance, we can now commercialize. We have had twenty-plus patients and hundreds of drainage therapies using Passio. Therefore, we have a significant amount of drainage therapies that have confirmed to us that we are going down the right path.

Commercially, we are currently in the process of putting our manufacturing, sales and distribution channels in place and building up inventory so that we can launch the product in the first quarter of 2021.

**"Bearpac is developing the next generation of drainage therapy for palliative care patients."
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CEO CFO: *About how many people in the US could use this product in a year?*

Mr. Zimmerman: The number of patients in the US diagnosed with Malignant Pleural Effusion (MPE), which is the diagnosis of the actual fluid building up around the chest, is approximately 125,000 people. Right now, however, only about a half of those patients are actually getting a catheter placed.

Truly there is an opportunity to go after the other half of that market with the novel device and platform that we have designed. Therefore, between 100,000 and 125,000 patients per year in the US could utilize Passio.

CEO CFO: *Are doctors that would be prescribing this paying attention to really making the patient more comfortable? Is it a focus? Is it becoming more of a focus?*

Mr. Zimmerman: That is a very valid question and I think, if you look at healthcare today, a portion of reimbursement for hospitals is based on patient satisfaction, so patient satisfaction is what hospitals are looking at to differentiate themselves from other hospitals in the market. It follows that patient satisfaction, comfort and quality of care is definitely something that physicians in turn look at as they are treating their patients.

If you can have either a better outcome or a more satisfied "customer," because their patients are their "customers," the hospital will receive a better review, which directly correlates to the reimbursement that hospitals are receiving from payers. The opportunity is there to offer physicians technologies like Passio that make it easier to treat their patients and minimize questions and follow-up not related to patient care. This all equates to a better return on investment for the hospital.

CEO CFO: *Where were the challenges in creating the product or is it that no one thought about it enough to come up with something?*

Mr. Zimmerman: The biggest challenge if you look at it from a large company's perspective is that there is just not a large enough market opportunity for big companies to invest their resources to innovate. Also, in order to innovate, you

have to offer something of value to the end user. New products have to offer improved outcomes, be less expensive, and/or be easier for the patient to use. Our strategy of offering improved technology, utilizing lower vacuum to potentially create less pain for the patient, is the reason for the hospital or the physician to want to switch to Passio. The system of regulatory approval in the U.S. stymies development and intellectual investment for larger companies and in many cases, we settle for "good enough", not better.

For a smaller company like Bearpac, we have the opportunity to utilize our resources and react faster than a large organization can in development and bringing technology to market sooner. It does not come without challenges, do not get me wrong! We still have the same regulatory challenges, FDA and all of that that comes with developing a medical device. However, we do not have all of the politics and the bureaucracy of a large organization and we can go after a smaller market that large companies aren't necessarily interested in pursuing.

CEOCFO: *Are you funded for your next steps? Are you seeking investment or partnerships?*

Mr. Zimmerman: Yes. We are very fortunate to have a principal investor who we worked with at our previous company, who is funding the organization. Having said that, we are always open to new partnerships.

CEOCFO: *What is the timetable? What is your go to market strategy for Passio?*

Mr. Zimmerman: Our go-to market strategy is to develop an infrastructure of manufacturer representatives and distributor networks throughout the US. We will also look at the European market. There are other markets that we can pursue, but a controlled rollout is a good thing when you are at this stage.

Our sales network across the U.S. will be trained and up and running to introduce Passio to the hospital market. The challenge for us continues to be the pandemic. Getting into the hospitals to demonstrate Passio is not as easy as it used to be because of restrictions, so our sales strategy and sales calls look very different today than they did two years ago.

CEOCFO: *Do you see working with any of the patient organizations to encourage doctors to take a look?*

Mr. Zimmerman: There is definitely a dual prong approach to selling, top down and bottom up. Top down would be calling on the physicians, since the physician implants the Passio catheter that works with our device. The bottom-up strategy would be marketing directly to the patient, and I believe there is an opportunity for that. However, I think another opportunity that we have, and which plays a very important role, is the homecare market. Many of our patients get supported with a visiting nurse that comes to their home and either trains them on the device or performs the therapy for them. The homecare nurses play a very important role in supporting these patients, either at hospice or at home.

There is some opportunity for social media getting directly to the patient, but it still really comes down to making sure that the physicians and the clinicians are comfortable with Passio. Without that comfort level there is small likelihood that the product will be utilized.

CEOCFO: *What is the takeaway for our readers?*

Mr. Zimmerman: The takeaway is that a small, nimble company like Bearpac can develop some really novel technologies that can change underserved or ignored markets. There is plenty of opportunity to take our technology and apply it to other healthcare spaces and hope that we can continue to grow the organization with it.