

V-Go a go! VLRX rides Type 2 diabetes patient adoption wave to 10 Millionth Device Sold

Valeritas Holdings, Inc. shows steady growth as market awareness grows for its unique insulin delivery device.

LOS ANGELES, CA, UNITED STATES, December 6, 2016 /EINPresswire.com/ -- With a growing number of patients with Type 2 diabetes being diagnosed every year, the correlating rise in need for treatment options provides investment opportunities for small cap investors.

For commercial-stage medical technology developer Valeritas Holdings, Inc. [OTCQB: VLRX], the opportunity was easy to spot. Valeritas is the maker of the only FDA cleared and EU-approved single-use, wearable, disposable basal-bolus insulin delivery device: called V-Go®. In fact, it is the only non-electronic basal-bolus insulin delivery device on the market.

Since hitting the U.S. market in the second half of 2012, V-Go has steadily increased its base of users among the growing number of patients with Type 2 diabetes in the United States. As of the end of October 2016, the company has dispensed more than 10 million devices, and anticipates double-digit revenue growth in the coming year.

So just how large is the market opportunity for Valeritas? Currently there are approximately 6 million patients with Type 2 diabetes prescribed daily insulin injections, with approximately 80%-, or roughly 4.6 million patients, who do not reach their target A1C glucose goal.

When glucose levels are note controlled, patients are at a higher risk for diabetes complications - a serious health problem and a major incremental cost for their health insurance provider. These 4.6 million patients represent an addressable \$15 billion annual market for V-Go in the U.S. alone.

Compliance with multiple daily injections is low. Studies show a significant cause of low compliance is the social stigma surrounding Type 2 diabetes, where by patients are simply too embarrassed or self-conscious to administer an insulin injection in public. Additionally, there is a significant amount of inconvenience for patients with Type 2 diabetes who need multiple daily injections and must carry around insulin vials, syringes or insulin pens for mealtime dosing.

The 24-hour wearable V-Go provides a solution that addresses both of these issues. Patients no longer need to carry vials, syringes or insulin pens. Because it is worn under the patient's clothing, V-Go is an easy-to-use device that's so discreet, that without anyone noticing, the patient can simply reach down and click a button on V-Go to administer an insulin dose before mealtime, eliminating embarrassment. And it's not just theory clinical data is validating V-Go's ability to deliver clinically relevant reductions in A1C levels while lowering the total daily amount of insulin the patient needs.

So far the V-Go device is sold only in the U. S., with no specified timeline in place for EU sales. However, it is reasonable to believe that Valeritas could pull the trigger on a strategic deal that would launch the product into the European Union. Importantly, even though V-Go is a device, it is distributed and reimbursed more like a drug in the United States., including for Medicare, where V-Go is reimbursed under Medicare Part D. Approximately 95% of all V-Go devices were disbursed to patients at retail or mail order pharmacies over the last year.

In late September 2016, B. Riley analyst Greg Chodaczek initiated research on Valeritas with a "BUY" rating and a price target of \$7.50. He reiterated both the rating and price target in an update published on November 11, 2016 after Valeritas released its Q3 numbers, highlighting that Valeritas's new capital-efficient commercial strategy is beginning to show results.

Zacks Investment Research maintains a price target of \$12 per share.

V-Go's uniqueness stems from its ease-of-use, design, and patient preference over having to administer multiple daily injections of insulin. Unlike the insulin pen, or conventional vials and syringes, V-Go is discreetly adhered to the body underneath the patient's clothing (typically just above the waistline), giving the patient a simple and discreet solution when he or she needs insulin. Because V-Go delivers a continuous basal rate of insulin (replacing the need to take basal insulin injections), it allows for the patient to discreetly provide themselves with additional insulin when he or she eats a meal or snack (replacing the need to take multiple daily bolus or meal time injections).

Although using V-Go is simple, and an advancement over multiple daily injections, there is still a transitional period for the market to gain awareness of the product.

2017 AND BEYOND

In the coming year, Valeritas expects to see steady double-digit revenue growth. It will still take some time to gain the widespread adoption enjoyed by the much higher valued peer companies, Insulet and DexCom. However, given its higher patient retention rates compared to needle/pen insulin therapy, it appears that V-Go is going to continue gaining loyal users going forward, while further reducing its manufacturing costs, and increasing its gross profit margins.

Keep in mind that while Valeritas reduced its sales team to start the year in order to better allocate its resources, the company still has plenty of blue sky out in front of it. Gradually restocking its sales team will open up new territories in the United States. And the company still has the ability to increase revenue and accelerate gross margin gains with V-Go's European Union approval, where the potential of a strategic European partnership exists should the right circumstances come about.

Patients with Type 2 diabetes are warming up to the concept of a discreet wearable device. As the Company rolls out more direct patient promotion in rep-covered geographic areas and as word-of-mouth grows between patients and physicians alike, there is a big opportunity for V-Go to grow its adoption by patients with Type 2 diabetes.

Total cash and cash equivalents were \$15.5 million at September 30, 2016.

Valeritas's V-Go addresses a \$15 billion annual market in the U.S. It is still early and there's still plenty of blue sky for V-Go adoption by a major block of the Type 2 insulin injectors, which translates in the potential for considerable stock valuation for VLRX.

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