Zacks Small-Cap Research

August 24, 2017

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Valeritas Holdings, Inc. (VLRX- NASDAQ)

VLRX: Strong Growth In Targeted Accounts Indicates Marketing Strategy Is Working

Based on blended DCF and P/GI comp, we value VLRX at $15/share. Our 15-year DCF, which uses a 10.5% discount rate and 2% terminal growth rate values VLRX at $14/share. P/GI using PODD as comp values VLRX at $16/share.

Current Price (08/24/17)	$3.50
Valuation	**$15.00**

OUTLOOK

While indications are that prescription growth in the 'targeted territories, or those that are actively detailed by the recently expanded direct sales force, has responded favorably from the newly implement high-touch marketing strategy, this has been largely offset by greater than expected weakness in the de-prioritized (i.e. non-targeted) territories. VLRX has rapidly re-expanded the size of their sales force in order to capitalize on the initial success that they have seen with their high-touch sales and marketing strategy. This includes what appears to be a positive correlation between the amount of time that accounts have been targeted and prescription growth. Specifically, prescription growth has been relatively strong in those territories that have been detailed by the same rep for six months or longer. And among the de-prioritized, there has been strong sequential growth. Noteworthy is that the majority of the newly hired reps were assigned to these disrupted territories – which implies that their relatively short tenure and inexperience with these accounts could translate into outsized productivity gains over the next few quarters. Also encouraging is a slowing rate of decline in TRx from non-targeted accounts.

SUMMARY DATA

52-Week High	**$50.00**
52-Week Low	**$2.90**
One-Year Return (%)	**-92.65**
Beta	**N/A**
Average Daily Volume (sh)	**17,445**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	5009 A	4885 A	4860 A	4796 A	19,550 A
2017	4611 A	4788 A	5013 E	5414 E	19,826 E
2018					26,532 E
2019					35,048 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$47.33 A	-$8.76 A	-$5.78 A	-$6.19 A	-$39.2 A
2017	-$6.95 A	-$1.83 A	-$1.90 E	-$1.86 E	-$9.00 E
2018					-$6.85 E
2019					-$4.01 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 Results Rx Decline From Deprioritized A Headwind But Subsiding. Strong Growth in Targeted Accounts:

Valeritas reported Q2 financial results and provided a business update. While indications are that prescription growth in the 'targeted territories, or those that are actively detailed by the recently expanded direct sales force, has responded favorably from the newly implemented patient-centric and high-touch marketing strategies, this has been largely offset by greater than expected weakness in the de-prioritized (i.e. non-targeted) territories. This contributed to revenue coming in below our Q2 estimate as well as reduction in the company's full-year guidance from double-digit growth to (what is effectively) 2% growth.

Revenue, at $4.79M, was down 2% yoy, up 4% sequentially and about 7% below our $5.14M estimate. In addition to a significant decrease in prescriptions from non-targeted accounts, which resulted in a 4.4% yoy decline in V-Go prescriptions, overall weakness in the insulin market was also cited as headwind to sales growth in Q2. The decline in prescriptions was partially offset by a 2.5% net (yoy) increase in average pricing.

VLRX has rapidly re-expanded the size of their sales force in order to capitalize on the initial success that they have seen with their high-touch sales and marketing strategy. Specifically, the sales force went from 30 to 48 at the end of Q2 – a level that is expected to be maintained through the remainder of 2017. The additional manpower, coupled with prescription growth from targeted accounts, particularly those in non-disrupted territories (i.e. those serviced by the same rep for six months or more), was responsible for the sequential revenue growth (more on this below).

But while revenue has not been much of a highlight as of late, **gross margin** has. At 37.7%, gross margin was the widest since VLRX publicly reported their financials and was up slightly from 37.6% in Q1. Importantly, management is guiding for GM to continue to expand as a result of manufacturing efficiencies and other expense containment measures. And while they had previously guided for GM to contract considerably in Q3 (due to certain LIFO/FIFO-related) accounting treatment, that is no longer expected to be the case. Moreover, management is also now guiding for Q4 GM to be above 40%. As such, we have since made some meaningful upward revisions to our gross margin estimates.

Q2 **operating expenses** were $12.9M, up from $12.0M in Q1. Operating expenses continue to climb faster than we have modeled – some of which relates to accelerated expansion of the sales force, but also from higher R&D expense related to development their V-Link and Prefill devices. Stock compensation has also been a meaningful contributor and accounted for $3M, or about 12% of OpEx in 1H 2017.

But while we had previously been modeling OpEx to remain at around the Q1 level with expectations that an anticipated reduction in average stock comp would offset growth in expense related to the sales force (and R&D would remain flattish), we now think that it is more likely than not that we will see incremental growth in the expense base throughout the remainder if 2017.

Importantly, we still expect to see some obviously scaling in OpEx in the late-2018 / early-2019 timeframe – which approximately corresponds to when the newly-hired reps (which are mostly detailing disrupted territories) can be expected to be at a much higher level of productivity.

Cash used in operating activities was $8.3M and $16.3M ($9.1M and $17.6M, ex-changes in working capital) in Q2 and 1H 2017. Cash balance was $42M at quarter end which VLRX expects to be sufficient to fund operations until at least August 2018.

Growth of Targeted Territories, Coupled With Slowing Attrition of Deprioritized Accounts Could Create Upward Revenue Inflection…

On the Q2 call management detailed some trends that indicate their patient-activation and high-touch sales and marketing model is producing anticipated results. This includes what appears to be a positive correlation between the amount of time that accounts have been targeted and prescription growth. Specifically, prescription growth has been relatively strong in those territories that have been detailed by the same rep for six months or longer. In Q2 total prescriptions (TRx) and new prescriptions (NRx) in these **non-disrupted** accounts grew on a yoy basis by 13% and 18%, respectively. Management expects this

trend to continue and this early success is what prompted them to rapidly grow the sales force in order to overlay the same strategy in those territories that had previously been de-prioritized.

And among the de-prioritized, or **disrupted territories** (i.e. those in which a sales rep has been in place for six months or less, many of which were vacated in early 2016 as a result of the restructuring), TRx and NRx increased 11% and 14% on a sequential basis. And while TRx fell 3% as compared to Q2 2016, we think the yoy comparison is less relevant given that these accounts have not had stable detailing yet for even six months. Noteworthy is that the majority of the newly hired reps were assigned to these disrupted territories – which implies that their relatively short tenure and inexperience with these accounts could translate into outsized productivity gains over the next few quarters. This will be an important metric to watch, in our opinion, as continued efficiency and productivity improvement among these newer reps (in previously neglected territories) could be a particularly potent catalyst towards accelerating revenue growth.

Meanwhile the vacated territories, or what VLRX now refers to as **'non-targeted'** accounts, saw TRx fall 21% yoy. These represent accounts that had been detailed in the past but are no longer serviced by outside reps. Management indicated that greater-than-expected prescription attrition from these accounts pressured revenues in 1H 2017. But while the decline in prescriptions from the comparable prior-year period was substantial, encouraging is that the rate of attrition may be slowing as evidenced by the fact that on a sequential basis, prescriptions fell by just 3%. VLRX will continue to use more cost-effective sales and marketing methods to target these accounts such as multi-channel marketing as well as inside sales representatives. Assuming this trend (i.e. flattening prescription attrition among non-targeted accounts), coupled with growth of the targeted accounts, total revenue growth should accelerate.

Build On Early Success, Roll-Out Phase II of New Marketing Strategy…
VLRX used the 1H of 2017 to assess the impact of their recently implemented multi-channel and direct-to-patient activation program and noted on the Q2 call that they will now be moving into "phase II" of this program. That includes using the most effective parts of this strategy across all of their targeted accounts (i.e. where they have a direct rep).

As a reminder, the goal of this marketing strategy, which is aimed directly at the patient (as opposed to the physician), is to prompt individuals currently using MDIs to inquire to their clinician about V-Go. As it is often challenging to change physician prescribing habits, marketing directly to the patient can be much more effective and efficient. The difficulty in motivating physicians is that they have limited time to meet with patients and engaging in discussions about new and novel therapies is often time consuming (particularly if there is a training component involved). VLRX's marketing strategy is essentially aimed at doing an end-around the physician and straight to the patient which has the influence to prompt discussion about new therapies such as V-Go.

These patient-activation strategies are a complement to the high-touch servicing model that VLRX also recently implemented. Based on increased patient awareness of V-Go and resultant relatively significant prescription growth in targeted (vs. non-targeted) territories, early indications are that this strategy has already had some success. However, the full benefits may not be realized for several more months because many type-2 diabetes patients see their clinician only once every three months. As such, management is guiding for a much greater steepening of the revenue curve beginning in Q4 of this year.

Clinical Data Continues To Support Health Benefits of V-Go vs. Pens/Needles
Valeritas remains very active in adding to their clinical evidence database supporting the clinical and economic benefits of V-Go, particularly as compared to traditional insulin delivery methods. **Clinical evidence continues to show V-Go more effectively controls A1C than insulin pens/needles and does so with lower insulin doses and associated cost.**

V-Go was the subject of several presentations related to a host of clinical studies over the last few months. This includes three abstracts at the American Diabetes Association's (ADA) Annual meeting in June as well as presentations in May at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and at the American Association of Clinical Endocrinologists' (AACE) annual meeting.

Two abstracts were presented at AACE (May 5th). The first, a retrospective study using medical records of patients (n=103) who switched from insulin pens/syringe to V-Go showed switching to V-Go resulted in significant and sustained A1C reductions among the entire patient population and reductions in total daily insulin dose. The second assessed the ability of V-Go to better control A1C as compared to insulin

pens/syringe among type-2 diabetes patients (n=89) with uncontrolled A1C (i.e. A1C > 8%). Success was defined by patients achieving A1C less than 8% and/or a reduction in A1C of at least 1% after switching to V-Go. After an average of 15 weeks on V-Go, 70% of patients achieved these A1C goals. In addition, average daily insulin dose was significantly reduced across the patient population

Two abstracts were presented at ISPOR (May 23rd). One study showed that among 86 patients who had difficulty controlling A1C and switched from MDI to V-Go, average A1C levels fell by 1.2%, daily insulin dose fell 44% and average monthly costs fell by $146. The other study compared treatment outcomes and costs between study sites using V-Go versus those using other type 2 diabetes therapies. Results showed that the V-Go study sites had a larger decrease in average A1C (-1.015% vs. -0.377%) and lower average per patient cost ($30.59 vs. $32.60).

Three abstracts were presented at ADA (June 11th), two of which were poster presentations. Cluster randomization, where study sites rather than patients were randomized to V-Go or standard optimization control (STO), was used to evaluate V-Go versus conventional insulin deliver in a real-world setting. Type-2 diabetes patients (n=415) were treated with V-Go (n=169) or STO (n=246) over a four-month period across 52 sites. Significant decreases in A1C from baseline were observed with V-Go (-0.95%, p<0.001), STO (-0.46%, p<0.001) and for V-Go vs. STO (p<0.002). While total daily insulin dose (vs. baseline) remained unchanged (72 units/day) for STO patients, it declined from 71.3 to 54.0 units/day for V-Go patients. Additionally, patient satisfaction scores improved with V-Go and 93.5% of patients used V-Go as directed.

The second abstract was of a retrospective study evaluating clinical and economic outcomes of type-2 diabetes patients who switched to and used V-Go for five months or longer as compared to those who discontinued V-Go use and went back to conventional insulin therapy for five months or longer. Results showed that patients that remained on V-Go had; significantly greater reductions in A1C compared to those who switched back to conventional insulin therapy (-1.42 vs. -0.46, p=0.018) and had a greater reduction in the amount of daily insulin that was used (-8.11 vs. +9.50 units/day, p=0.003). This also resulted in V-Go treatment being more cost-effective than conventional insulin delivery.

The third abstract, based on a subset from a larger prospective study, compared V-Go to MDI in A1C reduction and insulin required over a four-month treatment period. Results showed A1C reduction was greater among V-Go patients (-1.00% vs. -0.35%, p=0.006) and while daily insulin dose remained unchanged in the standard of care arm, it was reduced from 75 to 55 units/day in the V-Go arm.

Valuation: Blended P/S and DCF Values VLRX at ~$15/share

Our assumptions imply U.S. revenue will grow from $19.6M in 2016 to approximately $145M (< 2% market share) in 2031. Gross margin expansion and improvement in operating leverage could result in Valeritas reaching a point of cash flow break-even by approximately 2024. Using these inputs as well as a 10.5% discount rate and 2% terminal growth rate, our 15-year DCF values VLRX at approximately $14/share.

We also use Insulet Corp (PODD), manufacturer of the OmniPod System as a comp for valuation purposes. PODD similarly generates operating losses and given the difference in average gross margin between VLRX (~38%) and that of PODD (~59%), comparable price to gross income (P/GI) multiple is more appropriate for valuation purposes than is price to sales (P/S). PODD currently trades at 13x and 11x analysts' consensus 2017 and 2018 gross income estimates – the average of which implies VLRX fair value of $16/share.

Our blended DCF and P/GI methodology values VLRX at $15/share.

FINANCIAL MODEL

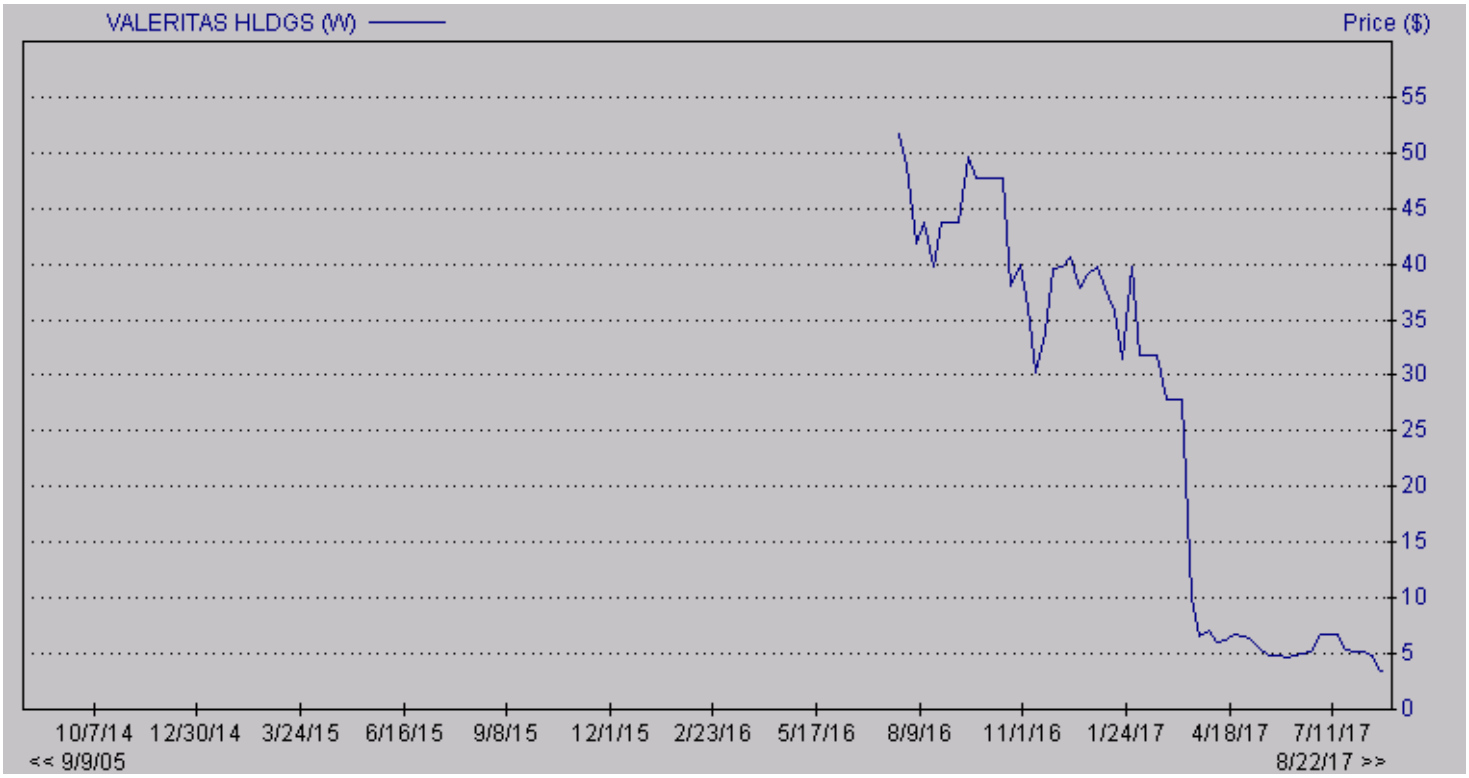
Valeritas Holdings, Inc. (figures in 000s of $)

Valeritas	2016 A	Q1A	Q2A	Q3E	Q4E	2017 E	2018 E	2019 E
Total Revenues	$19,550.0	$4,611.0	$4,788.0	$5,013.1	$5,414.1	$19,826.2	$26,532.2	$35,047.5
YOY Growth	*8.0%*	*-7.9%*	*-2.0%*	*3.1%*	*12.9%*	*1.4%*	*33.8%*	*32.1%*
Cost of Goods Sold	$12,606.0	$2,878.0	$2,985.0	$3,083.0	$3,194.3	$12,140.4	$15,335.6	$19,135.9
Gross Income	$6,944.0	$1,733.0	$1,803.0	$1,930.0	$2,219.8	$7,685.8	$11,196.6	$15,911.6
Gross Margin	*35.5%*	*37.6%*	*37.7%*	*38.5%*	*41.0%*	*38.8%*	*42.2%*	*45.4%*
R&D	$4,842.0	$1,588.0	$1,650.0	$1,690.0	$1,721.0	$6,649.0	$6,394.3	$5,817.9
% SG&A	*24.8%*	*34.4%*	*34.5%*	*33.7%*	*31.8%*	*33.5%*	*24.1%*	*16.6%*
SG&A	$33,481.0	$10,447.0	$11,231.0	$11,916.0	$12,212.0	$45,806.0	$48,315.2	$51,589.9
% R&D	*171.3%*	*226.6%*	*234.6%*	*237.7%*	*225.6%*	*231.0%*	*182.1%*	*147.2%*
Other	$2,394.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($33,773.0)	($10,302.0)	($11,078.0)	($11,676.0)	($11,713.2)	($44,769.2)	($43,512.8)	($41,496.3)
Operating Margin	*-172.8%*	*-223.4%*	*-231.4%*	*-232.9%*	*-216.3%*	*-225.8%*	*-164.0%*	*-118.4%*
Total Other Income (Expense)	($12,594.0)	($1,504.0)	($904.0)	($779.0)	($767.0)	($3,954.0)	($3,211.0)	($3,210.0)
Pre-Tax Income	($46,367.0)	($11,806.0)	($11,982.0)	($12,455.0)	($12,480.2)	($48,723.2)	($46,723.8)	($44,706.3)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred dividends	$0.0	$48.0	$549.0	$550.0	$550.0	$1,697.0	$2,200.0	$2,200.0
Net Income	($46,367.0)	($11,854.0)	($12,531.0)	($13,005.0)	($13,030.2)	($50,420.2)	($48,923.8)	($46,906.3)
YOY Growth	*-31.0%*	-	-	-	-	*8.7%*	*-3.0%*	*-4.1%*
Net Margin	-	-	-	-	-	-	-	*-133.8%*
EPS	($39.23)	($6.95)	($1.83)	($1.90)	($1.86)	($9.00)	($6.85)	($4.01)
YOY Growth	*-20.1%*	-	-	-	-	*-77.1%*	*-23.9%*	*-41.5%*
Diluted Shares O/S	1,182	1,706	6,843	6,845	7,010	5,601	7,140	11,700

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