Zacks Small-Cap Research

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Valeritas Holdings, Inc. (VLRX- NASDAQ)

VLRX: Q3 Record On Strong Rx Traction, Accelerating Into Q4

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 $12/share. P/GI using PODD as comp values VLRX at $17/share.

Current Price (11/14/17)	$3.00
Valuation	**$15.00**

OUTLOOK

As management highlighted on the earnings call, Q3 was the first quarter since Q1 2016 that revenue grew on both a yoy and qoq basis. Importantly, that relative strength appears to be a direct result of fundamental improvement in prescription trends – from both targeted and non-targeted territories. And while continued Rx growth of targeted accounts was encouraging, the apparent stabilization of prescription trends from non-targeted territories, which had experienced relatively massive script attrition over the recent past, may be nearly as significant of a harbinger towards an upward inflection in revenue growth.

The recently implemented direct-to-patient marketing/activation campaign, high-touch sales strategy and growth and initial seasoning of the sales force appear to be paying dividends in the form of double-digit growth of total and new prescriptions of targeted accounts. Meanwhile, apparent greater success from inside sales and a supporting marketing strategy not only reduced total prescription attrition among non-targeted accounts in Q3, it also was credited with (sequentially) increasing new prescriptions. These trends are expected to continue.

SUMMARY DATA

52-Week High	**$38.00**
52-Week Low	**$2.00**
One-Year Return (%)	**-90.78**
Beta	**3.94**
Average Daily Volume (sh)	**14,016**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
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	5065 A	5414 E	19,878 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	-$1.62 A	-$1.80 E	-$8.59 E
2018					-$6.67 E
2019					-$3.94 E

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

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WHAT'S NEW…

Q3 Results: Rx Growth Continues to Ramp in Targeted Territories, Stabilizing in Non-Targeted:

Valeritas reported Q3 financial results and provided a business update. As management highlighted on the earnings call (which we missed due to a timing conflict), this was the first quarter since Q1 2016 that revenue grew on both a yoy and qoq basis. Importantly, that relative strength appears to be a direct result of fundamental improvement in prescription trends – from both targeted and non-targeted territories. And while continued Rx growth of targeted accounts was encouraging, the apparent stabilization of prescription trends from non-targeted territories, which had experienced relatively massive script attrition over the recent past, may be nearly as significant of a harbinger towards an upward inflection in revenue growth.

The recently implemented direct-to-patient marketing/activation campaign, high-touch sales strategy and growth and initial seasoning of the sales force appear to be paying dividends in the form of double-digit growth of total and new prescriptions of targeted accounts. Meanwhile, apparent greater success from inside sales and a supporting marketing strategy not only reduced total prescription attrition among non-targeted accounts in Q3, it also was credited with (sequentially) increasing new prescriptions. These trends are expected to continue.

Revenue was not the sole financial highlight in Q3 as gross margin appears to be at the highest level in history and net loss was the lowest so far in 2017. Management reiterated full-year 2017 revenue guidance of ~$20M, which implies a Q4 top-line of $5.5M. This would not only represent sequential and yoy growth of 9% and 15%, respectively, it would also mark a new high in quarterly revenue. With expectations of continued success of the recently implemented marketing strategies (some of which will be rolled out across all territories) along with incremental additions to the sales force, VLRX indicated that they expect the revenue growth rate will further steepen in 2018.

Other potential future revenue catalysts include overseas expansion as well as launch of complementary products including V-Go Link. VLRX continues to evaluate international markets and distributors, although has yet to commit to any OUS endeavors – although we think that may be a future strategy. In the meantime, they do expect to bring V-Go Link to market. V-Go Link will provide communication between V-Go and smart phones, enabling the patient to track in real-time dosing information. It is anticipated that the patient and physician can then use this information for daily dosing needs. Management hopes to launch V-Go Link in the U.S. by the end of next year.

Revenue, at $5.1M was up 4% yoy, up 6% sequentially and slightly ahead of our $5.0M estimate. As noted, results reflect strong prescription growth in targeted territories (including particularly robust new Rx growth) as well as greater relative stabilization of non-targeted accounts. Management also indicated that results may have been even stronger had it not been for the two recent major hurricanes which effected approximately 12% of the company's sales territories.

Revenue has now grown sequentially for the last two quarters, which we think indicates more sustained traction from the new direct-to-patient marketing programs as well as productivity gains from newer members of the sales force (over 50% of which has less than 6 months tenure with VLRX). Meanwhile the yoy growth is likely also a product of expansion of the size of the sales force over the last several quarters – which grew from about 28 in Q3 2016 to 48 through the end of Q3 2017. This level is expected to be maintained through the end of 2017 which, coupled with Q4 revenue guidance that implies continued very robust revenue growth, suggests to us that gains in sales rep productivity and patient activation have continued to grow.

Gross margin was also a noteworthy highlight in Q3. At 39.8%, it was 210 and 420 basis points wider than the quarter and year-earlier periods, respectively. It was also slightly better than our estimate (38.5%) and looks to be the best in company history (based on publicly available financials since Q1 '15). GM improvement has been the result of manufacturing efficiencies and pricing gains. Management has guided for GM to crest above 40% in Q4. We think additional cost efficiencies and volume related scaling could further benefit margins going forward.

Q3 **operating expenses** were $11.9M, while this is up from $9.2M in Q3 2016, it is down from $12.9M in Q2 and $12.0M in Q1 of this year. While in previous quarters OpEx had grown faster than we had expected, which was a concern, the Q3 number came in well below our $13.6M estimate. Also encouraging, as it

relates to expenses, is management's guidance that they do not expect significant changes in operating expenses over the next several quarters. As such, and combined with expectations of stable-to-growing gross margin and accelerating revenue growth, VLRX could see significant improvement in operating loss.

Cash used in operating activities was $8.0M and $24.3M ($7.7M and $25.3M, ex-changes in working capital) in the three and nine months ending 9/30/2017. Cash balance was $34.1M at quarter end, which represents approximately 12 months' worth of operating capital at the current burn rate. Additional liquidity is available through a share purchase agreement which VLRX entered into with Aspire Capital Fund, LLC in September. Per terms, Aspire has committed to purchase up to $20M of VLRX common shares (at Valeritas' request) during the 30 months following acceptance by SEC of the already filed S-1 registration statement. The total shares that can be issued under the agreement cannot exceed 19.99% of total o/s shares if issued at an average price of less than $3.10. Minimum price which VLRX can sell shares under the agreement is $1.00.

Rx Traction: Double-Digit Growth in Targeted Territories, Stabilizing Trends in Non-Targeted

Prescription trends continue to indicate that VLRX's newly implemented sales strategies, including direct-to-patient activation and high-touch sales and marketing model, are paying dividends in the company's targeted territories. Additionally, and also encouraging, is that there also appears to be a positive correlation between the amount of time that accounts have been targeted and prescription growth. Specifically, total prescription growth has been particularly strong in those territories that have been detailed by the same rep for six months or longer (i.e. non-disrupted targeted territories) while new prescription growth has recently been exceptionally robust in less tenured areas (i.e. disrupted targeted territories). And, again, some of VLRX's sales territories fought the headwind from hurricanes Irma and Maria.

In Q3 total prescriptions (TRx) and new prescriptions (NRx) in **non-disrupted** accounts grew on a yoy basis by 17% and 15%, 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.

Meanwhile, in the **disrupted** territories TRx and NRx increased 10% and 34% on a yoy basis. This compares to Q2 which saw yoy growth of 0% and 9% in TRx and NRx, respectively. 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. Additionally, as these less-tenured reps account for more than 50% of the total sales force, additional productivity gains may result in somewhat of a multiplier benefit. As we noted in our update following Q2 results, we think that this will be an important metric to watch as continued efficiency and productivity improvement among these newer reps (in previously neglected territories) could be a particularly potent catalyst towards accelerating revenue growth.

Relative to the vacated, or non-targeted territories, while TRx fell 19% yoy, more recent metrics indicate that attrition has significantly leveled off. In fact, TRx fell just 2% sequentially in Q3 and NRx actually increased 2% from the prior quarter. The NRx growth, while only incremental, is particularly encouraging in our opinion as it may be harbinger to complete stabilization of TRx trends and could potentially represent the front end of future growth (albeit likely moderate growth, at best) in these territories. VLRX uses a combination of 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 or incremental growth among non-targeted accounts) continues, coupled with growth of the targeted accounts, total revenue growth should accelerate.

Success of Direct-to-Patient Pilot Program Prompts Footprint-Wide Roll Out…

VLRX used the first few quarters of 2017 as somewhat of a litmus test to assess the impact of their recently implemented multi-channel and direct-to-patient activation program. Given the early successes in ramping prescription volumes as well as positive feedback from both physicians and patients, VLRX is moving into "phase II" of this program. VLRX will now expand their DTP campaigns to all of their territories by the end of 2017 as well as initiate launch of some new marketing materials.

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. This seems to have resonated with both patients and physicians. In fact, management noted on the Q3 call that some clinicians have asked VLRX to do more DTP campaigns to help educate patients which would facilitate the patient training and learning curve. Early successes of the programs are evident in the Rx growth but also based on the fact that ~90% of patients which received a V-Go demonstration kit planned to talk to their physician about 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 quarters. Most recently, this included data from a new study which was presented at the ADT Annual Meeting in November.

ADT Annual Meeting (Nov 3rd): study showed V-Go, combined with a simple insulin titration algorithm, was associated with significant reductions in A1C and insulin requirements. Fifteen patients were evaluated after 4 months of V-Go use. Changes to insulin titration were done weekly and based on four daily self-monitoring measurements. Basal doses were adjusted as needed following the optimization of prandial dosing. Insulin dose adjustment was mostly done during the first 3 weeks. Results showed that A1C target was achieved in 67% of patients and a mean significant A1C reduction of 1.6% (8.7 to 7.1%; $p<0.001$) was observed with a significant decrease in the mean total daily dose of insulin (144 to 60 U/day; $p=0.002$). Hypoglycemia prevalence decreased from 23% at baseline to 7% of patients by month 4.

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.

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).

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

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

Our assumptions imply U.S. revenue will grow from $19.9M in 2016 to approximately $130M (< 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 $12/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 (~40%) 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 15x and 12x analysts' consensus 2017 and 2018 gross income estimates – the average of which implies VLRX fair value of $17/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	Q3A	Q4E	2017 E	2018 E	2019 E
Total Revenues	$19,550.0	$4,611.0	$4,788.0	$5,065.0	$5,414.1	$19,878.1	$26,532.2	$35,047.5
YOY Growth	8.0%	-7.9%	-2.0%	4.2%	12.9%	1.7%	33.5%	32.1%
Cost of Goods Sold	$12,606.0	$2,878.0	$2,985.0	$3,048.0	$3,194.3	$12,105.3	$15,335.6	$19,135.9
Gross Income	$6,944.0	$1,733.0	$1,803.0	$2,017.0	$2,219.8	$7,772.8	$11,196.6	$15,911.6
Gross Margin	35.5%	37.6%	37.7%	39.8%	41.0%	39.1%	42.2%	45.4%
R&D	$4,842.0	$1,588.0	$1,650.0	$1,861.0	$1,788.0	$6,887.0	$6,394.3	$5,817.9
% SG&A	24.8%	34.4%	34.5%	36.7%	33.0%	34.6%	24.1%	16.6%
SG&A	$33,481.0	$10,447.0	$11,231.0	$10,020.0	$11,624.1	$43,322.1	$48,315.2	$51,589.9
% R&D	171.3%	226.6%	234.6%	197.8%	214.7%	217.9%	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)	($9,864.0)	($11,192.3)	($42,436.3)	($43,512.8)	($41,496.3)
Operating Margin	-172.8%	-223.4%	-231.4%	-194.7%	-206.7%	-213.5%	-164.0%	-118.4%
Total Other Income (Expense)	($12,594.0)	($1,504.0)	($904.0)	($714.0)	($852.0)	($3,974.0)	($3,211.0)	($3,210.0)
Pre-Tax Income	($46,367.0)	($11,806.0)	($11,982.0)	($10,578.0)	($12,044.3)	($46,410.3)	($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	$557.0	$565.0	$1,719.0	$2,200.0	$2,200.0
Net Income	($46,367.0)	($11,854.0)	($12,531.0)	($11,135.0)	($12,609.3)	($48,129.3)	($48,923.8)	($46,906.3)
YOY Growth	-31.0%	-	-	-	-	3.8%	1.7%	-4.1%
Net Margin	-	-	-	-	-	-	-	-133.8%
EPS	($39.23)	($6.95)	($1.83)	($1.62)	($1.80)	($8.59)	($6.67)	($3.94)
YOY Growth	-20.1%	-	-	-	-	-78.1%	-22.4%	-40.9%
Diluted Shares O/S	1,182	1,706	6,843	6,859	7,010	5,604	7,340	11,900

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