Zacks Small-Cap Research

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VIVUS, Inc. (VVUS - NASDAQ)

Never In a Straight Line

Based on our 2023 earnings and EBITDA forecasts, we apply a 18x P/E and 10x EBITDA multiple to these values and discount the result to present at a 15% rate. We equally weight these approaches to generate a valuation of approximately $9.00 per share. We anticipate adding a valuation component for VI-0106 following a successful IND and launch of the trial.

Current Price (11/5/2019)	$3.20
Valuation	**$9.00**

OUTLOOK

VVUS is a specialty pharmaceutical company developing and commercializing a portfolio of products for PAH, EPI, obesity and ED. The in-development product is designated VI-0106, generically named tacrolimus and previously approved for the prevention of transplant rejection. Pancreaze for EPI was purchased from Janssen in June 2018 to leverage the company's expense base. Qsymia is an established asset for obesity with a new direct to patient strategy that should increase penetration with modest impact on net revenues. Stendra/ Spedra is a royalty generating PDE5 inhibitor differentiated by its rapidity of action and improved side effect profile compared to others in the class.

Vivus' appreciation potential stems from management's execution on converting the company into a cash generating entity with an ability to layer on new products and employ an efficient growth strategy utilizing technology and traditional sales and marketing efforts unique to each individual product's characteristics and market. The company recently turned EBITDA positive and we believe can successfully address the debt hurdle before 2020, providing for reasonable leverage and positive cash earnings.

SUMMARY DATA

52-Week High	**5.78**
52-Week Low	**2.15**
One-Year Return (%)	**-19.6**
Beta	**2.59**
Average Daily Volume (sh)	**128,790**
Shares Outstanding (mil)	**10.6**
Market Capitalization ($mil)	**34.1**
Short Interest Ratio (days)	**9.0**
Institutional Ownership (%)	**18.1**
Insider Ownership (%)	**8.5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$11.9 A	$15.0 A	$18.1 A	$20.1 A	$65.1 A
2019	$16.1 A	$18.4 A	$18.0 A	$19.3 E	$71.8 E
2020					$78.5 E
2021					$88.7 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$1.00 A	-$1.06 A	-$0.53 A	-$0.08 A	-$2.67 A
2019	-$0.41 A	-$0.22 A	-$0.10 A	-$0.25 E	-$0.97 E
2020					-$0.93 E
2021					-$0.20 E

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WHAT'S NEW

Third Quarter 2019 Results

Vivus, Inc. (NASDAQ: VVUS) released quarterly results on November 5, 2019 and provided an update of financial and operational results for the third quarter. During the three month interval topline growth declined less than 1%, while adjusted earnings improved more than anticipated due to lower cost of goods sold and lower SG&A. During the third quarter and fourth quarter to date, Vivus has advanced its Qsymia Advantage and Vivus Health Platform, extended its contract manufacturing agreement for Pancreaze, announced approval of Qsymia in South Korea, repaid debt and experienced management and board turnover. A study was also published demonstrating the efficacy of using Qsymia in conjunction with gastric sleeve surgery for weight loss which may help support increased penetration into this combination approach.

Revenues lagged our expectations in the second quarter as Qsymia saw a sequential decline and Pancreaze increased slightly over 2Q:19. $2.5 million of license revenue from Alvogen related to the approval of Qsymia in South Korea offset lower product revenues. With the shift of Pancreaze to Vivus' control, Canadian revenues are now recognized as product rather than royalty revenues and represented $0.1 million. Royalty revenues for Pancreaze are now zero. Stendra and Spedra supply revenues fell to $64,000 and this was matched by a similar decline of the associated cost of goods sold for this product. Stendra/Spedra royalties were $557,000, up 1.3% compared to the prior year. Total revenues were $18.0 million, a 0.7% decline over the prior year and a 2.3% decline sequentially.

Cost of goods sold was $3.0 million, a sharp fall both year over year and sequentially due to the lack of Stendra and Spedra contribution. Gross margin for Qsymia was 85%, down from 90% in 3Q:18 and down sequentially from 91% in the second quarter. Gross margin for Pancreaze improved from 70% in 3Q:18 to 73% in 3Q:19 and was also better sequentially by 750 basis points.

SG&A of $9.2 million was up 9% over the prior year as expenses for commercialization and promotional efforts for Pancreaze were partially offset by the absence of acquisition related costs for Pancreaze. Research and development expenditures were $3.3 million up 55% on additional expense for the adolescent trial for Qsymia and spending related to post-marketing requirements for Pancreaze. Spending on VI-0106 declined as stability testing continues.

Vivus reported adjusted EBITDA of $3.0 million in the third quarter, up from $2.1 million in the prior quarter. Removing the $2.5 million in milestones and fees related to the debt buy down, non-GAAP recurring EBITDA, as calculated by Vivus was $2.2 million. Despite the positive EBITDA, operating burn was ($5.6) million, due to interest expense and prepayment premiums of $9.9 million.

Reported loss per share was ($1.04). After removing amortization and prepayment premiums, adjusted net loss was ($0.10) which compares to our estimate of ($0.28) with the difference attributable to lower SG&A and lower cost of goods sold partially offset by lower revenues.

Cash and equivalents on the balance sheet totaled $40.1 million, down from $94.4 million at the end of the second quarter and $111.2 million at the end of 2018. During the third quarter, Vivus paid down $48.6 million of its 2024 senior secured notes. Debt, as carried on the balance sheet, stands at $242.7 million as of September 30, 2019.

Vivus has initiated its Qsymia Advantage Program and its Vivus Health Platform which we see an innovative ways to connect to the patient using mobile and connective technology. This was followed by the June start of the e-medicine platform which enables patients to purchase the medication online and receive home delivery. The program has flattened the pricing structure for the drug and lowered total cost which is expected to improve penetration and extend the duration of use for Qsymia. The telemedicine component has also been launched with four physicians currently participating and eleven more expected in 1Q:20. Eventually the platform could have thousands of doctors participating that are focused on obesity and endocrinology. Qsymia is also advancing on other fronts including the launch of a Phase IV study in adolescents, which was started in May. The study is expected to enroll 200 patients at 20 US clinical sites. The duration of treatment is 56 weeks and will be combined with a reduced-calorie diet, increased physical activity and support. A successful outcome could expand the addressable population into younger populations.

The weight-loss medication was also approved by the South Korean Ministry of Food and Drug Safety (MFDS) in early August and first revenues are expected in 1Q:20. The approval resulted in a $2.5 million milestone payment by Alvogen to Vivus, which was received in the third quarter. We discuss the approval in a past note. In other overseas efforts, Vivus expects to submit a Marketing Authorisation Application (MAA) in Europe and seek decentralized approval in six countries. The decision by the regulatory agencies is expected in 2H:20.

The results of a study[1] examining the use of Qsymia in combination with sleeve gastrectomy in patients with a BMI of 50 or above were presented in the July issue of Surgery for Obesity and Related Diseases. For super obese patients, surgery alone may be insufficient to reduce weight sufficiently and combination therapy with a weight loss drug may result in improved outcomes. The research in the study demonstrated that patients receiving Qsymia before and after laparoscopic sleeve gastrectomy (LSG) surgery lost more weight and had a greater likelihood of achieving a BMI of less than 40 compared with patients undergoing surgery alone without anti-obesity medicine. The results of the study and the use of the combination approach suggest that the use of Qsymia along with a low calorie diet can reduce surgical risk and use of Qsymia after the procedure may help obese patients avoid a second surgery. Patients in the combination arm lost more than twice the weight with an average of 28.1 kg during the pre-operative period compared with an average of 12.3 kg for those in the control group. Two years after surgery, the experimental group lost 11.2% more body weight than the control group, with a p-value of 0.007. The combination approach was able to bring 61.5% of participants from above a 50 BMI to below a 40 BMI by the end of the study. This compares to 47.5% of the control group reaching this goal. Additional summary of data is included in the press release.

Pancreaze distribution in Canada was shifted from Janssen to Vivus in the second quarter which led to a 10-week transition period from approximately mid-June to mid-August. There was a build in distribution prior to the transition to ensure sufficient product was available, which positively impacted 2Q royalty revenues by an estimated $400,000. Management anticipates shipments under Vivus to begin in the second half of August. The change in distribution was accompanied by a change in reporting for the product where revenues will be presented as part of product sales and product costs will appear in cost of goods sold. Third quarter Canadian sales for Pancreaze totaled $0.1 million.

VI-0106 may still see a 4Q:19 investigational new drug (IND) submission; however, this will depend on the generation of necessary stability data for the once-daily extended release formulation. If results on in-process testing are favorable in December, the IND is prepared and ready to submit. If the stability test is not successful, then we anticipate a delay in the filing until next year. The science team anticipates that the formulation will provide therapeutic drug levels while minimizing immunosuppressive effects for pulmonary arterial hypertension (PAH) patients.

Departures

Vivus lost two executive management team members and two board members in October. Ken Suh, President and Scott Oehrlein, COO left the company effective October 31, 2019. Both had come aboard with CEO John Amos to acquire and transition Pancreaze and launch the turnaround. Ken and Scott were asked to take on different roles in the company as the environment around Pancreaze evolved and instead they decided to move on to other opportunities. The two board members who stepped down, Eric Roberts and Allan Shaw decided to pursue other business interests and felt they could not devote the necessary time to properly fulfill their board commitments. Vivus does not plan to replace any of the positions that were vacated.

Corporate Milestones

Vivus is in the fifth quarter of its ten quarter turnaround and has shown sales improvement for both Qsymia and Pancreaze; however, the third quarter did not continue on the trajectory we had anticipated. As any seasoned investor knows, turnarounds do not move in a linear fashion and slowdowns appear while placing the ship back on course. We have confidence in Vivus' strategy and see the push into the Vivus Health Platform and Qsymia advantage as an innovative way to respond to the changing environment and the specific setting for the way in which weight loss drugs are addressed. The telehealth program is especially interesting to us as we believe it can provide access to many patients who may not want to discuss weight loss face to face with their provider and also provides incentive for physicians to participate. We anticipate continued improvement as the changes in marketing for Qsymia have more time to take hold and as Pancreaze sales efforts yield results.

[1] Ard, Jamy D. et al. Use of phentermine-topiramate extended release in combination with sleeve gastrectomy in patients with BMI 50 kg/m^2 or more. Surgery for Obesity and Related Diseases. 15 (2019) 1039–1043.

We would be remiss to not mention Vivus' debt overhang. About $50 million was paid down from cash in the quarter, but net debt is essentially unchanged. Operational performance between now and the first quarter and the state of capital markets will determine the capital structure and the cost of new funding. Management engaged a financial advisor to assist in the refinancing and we think that ultimately the convertible debt will be replaced with a mix of debt and equity. Management could sell off non-core assets to raise a few dollars as well; however, we think it is likely that some of the refinancing will be done with equity.

Between now and when refinancing occurs, the team's objective is to improve the company's profile with respect to revenues and earnings sufficiently to justify the best terms possible. Third quarter results were behind the anticipated trajectory; however, there are a number of favorable elements in place, especially on the international front, that may drive improved revenue growth. Below we list the key items related to the turnaround effort and to the development of VI-0106.

- Addition of new management team and CEO – mid-2018
- Relaunch of Pancreaze – February 2019
- Marketing approval of avanafil in United Arab Emirates – February 2019
- Conversion of Qsymia to direct to patient model – 2019
- Marketing approval of avanafil in Russian Federation – March 2019
- Launch of online payment system for Qsymia – June 2019
- Approval of Qsymia by South Korea Ministry of Food and Drug Safety – August 2019
- $48.6 million of senior secured debt repaid – October 2019
- MAA for Qsymia in Europe – October 2019
- Launch of telemedicine – 4Q:19
- Increase licensing agreements for avanafil – 2019/2020
- Submit IND for VI-0106 – 4Q:19 / 1Q:20
- Improvement of analytics and profits for Qsymia and Pancreaze – 2019/2020
- Introduce Qsymia Health Platform to managed care and large self-insured employers – 1H:20
- Reduce, refinance and repay debt - 2020

Summary

We are in the fifth quarter of the ten quarter turnaround effort and have seen evidence of improvement that can convert Vivus into a profitable enterprise. The management team has the knowledge and experience to execute on its identified priorities and has provided detailed specifics on necessary steps to drive topline sales and improve its leverage position. Progress will be easy to monitor in the coming quarters as a ramp up in revenues is expected from the improved sales strategy the company has announced. While we saw a slowdown in revenue progression in the third quarter, we understand than turnarounds do not follow straight path. Management noted that Vivus is "two quarters behind expectations" and we reflect this in an update to our revenue projections. We reduce our target price on Vivus following third quarter results due to the longer than anticipated ramp in sales; however, we maintain our optimism that Vivus will achieve positive earnings in the later quarters of 2021. Our target moves to $9.00.

PROJECTED FINANCIALS

VIVUS, Inc. - Income Statement

VIVUS, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E	2022 E
Total Revenues	**$65,062**	**$16,146**	**$18,390**	**$17,970**	**$19,275**	**$71,781**	**$78,528**	**$88,659**	**$98,543**
	-0.5%	35.7%	22.9%	-0.7%	-4.2%	10.3%	9.4%	12.9%	11.1%
Cost of Product Sales	$14,704	$4,308	$4,377	$3,016	$5,005	$16,706	$19,029	$19,186	$22,424
Gross Margin	*77.4%*	*73.3%*	*76.2%*	*83.2%*	*74.0%*	*76.7%*	*75.8%*	*78.4%*	*77.2%*
Amortization of Intangibles	$8,549	$3,638	$3,638	$3,638	$3,638	$14,552	$14,552	$14,552	$14,552
SG&A	$37,941	$9,818	$10,070	$9,207	$9,700	$38,795	$39,060	$40,180	$41,000
R&D	$7,347	$2,469	$2,352	$3,266	$2,365	$10,452	$8,700	$8,000	$8,000
Operating Income	($3,479)	($4,087)	($2,047)	($1,157)	($1,433)	($8,724)	($2,813)	$6,741	$12,567
Operating Margin	*-5.3%*	*-25.3%*	*-11.1%*	*-6.4%*	*-7.4%*	*-12.2%*	*-3.6%*	*7.6%*	*12.8%*
Interest & Other Expense	$33,419	$3,870	$3,880	$9,911	$4,900	$22,561	$21,850	$23,500	$23,500
Pre-Tax Income	($36,898)	($7,957)	($5,927)	($11,068)	($6,333)	($31,285)	($24,663)	($16,759)	($10,933)
Taxes & Other	$52	($8)	$8	$4	$0	$4	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($36,950)	($7,949)	($5,935)	($11,072)	($6,333)	($31,289)	($24,663)	($16,759)	($10,933)
Reported EPS	**($3.48)**	**($0.75)**	**($0.56)**	**($1.04)**	**($0.59)**	**($2.94)**	**($2.27)**	**($1.53)**	**($0.99)**
Adjusted EPS	**($2.67)**	**($0.41)**	**($0.22)**	**($0.10)**	**($0.25)**	**($0.97)**	**($0.93)**	**($0.20)**	**$0.33**
Shares Outstanding	10,621.0	10,637.0	10,640.0	10,643.0	10,700.0	10,655.0	10,850.0	10,925.0	11,050.0

Source: Company Filing // Zacks Investment Research, Inc. Estir

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HISTORICAL STOCK PRICE

VIVUS, Inc. – Share Price Chart



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