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VIVUS, Inc. (VVUS - NASDAQ)

Qsymia Responds to New Approach

Based on our 2022 earnings and EBITDA forecasts, we apply a 20x P/E and 8x 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 $11.00 per share. We anticipate adding a valuation component for VI-0106 following a successful IND and launch of the trial.

Current Price (8/6/2019)	$3.34
Valuation	**$11.00**

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	**6.90**
52-Week Low	**2.15**
One-Year Return (%)	**-49.4**
Beta	**2.79**
Average Daily Volume (sh)	**24,373**
Shares Outstanding (mil)	**10.6**
Market Capitalization ($mil)	**35.5**
Short Interest Ratio (days)	**12.37**
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	$19.1 E	$20.6 E	$74.2 E
2020					$82.7 E
2021					$93.1 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	-$0.28 E	-$0.17 E	-$1.08 E
2020					-$0.65 E
2021					$0.10 E

WHAT'S NEW

Second Quarter 2019 Results

Vivus, Inc. (NASDAQ: VVUS) released second quarter results on August 6, 2019 and provided an update of financial and operational results for the April to June period. During the three month interval the company achieved topline growth of 23%, launched online payments for Qsymia, assumed full responsibility for Pancreaze in Canada from Janssen and launched its Phase IV Qsymia study in adolescents. Following the end of the quarter, Vivus announced the approval of Qsymia in South Korea.

Revenues and earnings exceeded our expectations in the second quarter. Sales of $18.4 million compared to our forecast of $16.9 million due to better Qsymia product revenue and Pancreaze royalty revenue partially offset by lower than expected Pancreaze product revenue. Adjusted net loss of ($0.22) compares to our estimate of ($0.47) with the difference attributable to better revenues, better gross margin and lower than anticipated R&D.

Total cost of goods sold was $4.4 million. When broken down by product, this represents a gross margin of 91% for Qsymia, 65% for Pancreaze and 6% for Stendra/Spedra supply revenue. The sequential improvement in Qsymia gross margin was attributable to improved revenues for the product and timing of inventory in allocation of overhead. Pancreaze margin of 65% was as expected given the assumption of responsibility by Vivus from Janssen. SG&A of $10.1 million was down 14% over the prior year as expenses related to the Pancreaze acquisition were not repeated.

Research and development expenditures were $2.4 million and while lower than our estimate, represented a 15% increase over prior year levels. Contributors to the increase include the launch of the adolescent trial for Qsymia and spending related to post-marketing requirements for Pancreaze.

Vivus reported adjusted EBITDA of $2.1 million in the second quarter, up from $0.1 million in the prior quarter. Despite the positive EBITDA, cash used in operations in the second quarter was ($10.5) million, predominantly due to an inventory build related to required minimums for avanafil purchase. Partners Menarini and Metuchen also have minimum purchase requirements which are expected to reverse this inventory build as the year progresses.

Cash and equivalents on the balance sheet totaled $94.4 million, down from $104.7 million at the end of the first quarter and $111.2 million at the end of 2018. While adjusted EBITDA has been positive year to date, inventory builds, which we expect to reverse, and interest payments have consumed cash, reducing the quarter to quarter balance. We anticipate that if current trends hold, improved revenues and product margin contribution combined with favorable cash flow items will add to the cash balance in the second half. Debt is carried at $292.4 million on the balance sheet

The key driver for performance was the advance in the Qsymia Advantage Program which was launched early in the year. 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. A third component of the program will add telemedicine before year end. As we discussed in our initiation, the new approach is able to eliminate substantial costs from distribution, allowing for a similar gross margin in terms of dollars per prescription, but with a more attractive $98 price for patients. Initial results show that more patients are moving to the higher dose and the number of 90-day scripts has improved markedly. We anticipate continued improvement in metrics in 3Q as the program has more time to take hold and the program is fully implemented.

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 adolescents.

The weight-loss medication was also approved by the South Korean Ministry of Food and Drug Safety (MFDS) in early August. The approval will result in a $2.5 million milestone payment by Alvogen to Vivus, which is expected to be received in the third quarter. We discuss the approval in our recent note. In other overseas efforts, Vivus expects to submit a Marketing Authorisation Application (MAA) in Europe and seek decentralized approval in six countries.

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 also 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 will be 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.

VI-0106 remains on track for a 2H:19 investigational new drug (IND) application. Vivus' IND is in process and generating necessary stability data for the once-daily extended release formulation. The science team anticipates that the formulation will provide therapeutic drug levels while minimizing immunosuppressive effects for pulmonary arterial hypertension (PAH) patients.

Corporate Milestones

Vivus is in the fourth quarter of its ten quarter turnaround and is demonstrating early success, especially in its Qsymia efforts. We anticipate continued improvement as the changes in marketing for Qsymia have more time to take hold and as Pancreaze sales efforts yield results. One of the dominant issues facing Vivus is the debt overhang related to its convertible debt. Management does not want to assume new debt prior to the expiration of the current debt in order to avoid concurrent interest expense. The team's current objective is to improve the company's profile with respect to revenues and earnings sufficiently to justify better debt deal terms by 2Q:20. Second quarter results have shown evidence of execution on the corporate turnaround which are will help with this goal. 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
- Launch of telemedicine – 2H:19
- MAA for Qsymia in Europe – 2H:19
- Increase licensing agreements for avanafil – 2019/2020
- Submit IND for VI-0106 – 2H:19
- 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 and repay debt - 2020

Summary

We are in the fourth quarter of the ten quarter turnaround effort and are starting to see 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 relatively quick ramp up in revenues is expected from the improved sales strategy the company has announced. While our valution only accounts for the performance of Qsymia, Pancreaze and Stendra/Spedra, the company also has an attractive development asset VI-0106 which could enter the clinic next year. Management also has extensive experience with M&A which could layer on a new asset to existing infrastructure to provide additional growth opportunities. We will add a valuation component for these eventualities when they occur. We increase our target price on Vivus following second quarter results due to anticipated sales in South Korea in 2020 and better than expected Qsymia revenue. Our target moves from $10.00 to $11.00.

PROJECTED FINANCIALS

VIVUS, Inc. - Income Statement

VIVUS, Inc.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E	2022 E
Total Revenues	**$65,062**	**$16,146**	**$18,390**	**$19,125**	**$20,575**	**$74,236**	**$82,747**	**$93,117**	**$103,292**
Cost of Product Sales	$14,704	$4,308	$4,377	$5,188	$5,460	$19,333	$20,222	$20,319	$23,543
Gross Margin	*77.4%*	*73.3%*	*76.2%*	*72.9%*	*73.5%*	*74.0%*	*75.6%*	*78.2%*	*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	$9,700	$9,700	$39,288	$39,060	$40,180	$41,000
R&D	$7,347	$2,469	$2,352	$2,350	$2,365	$9,536	$8,700	$8,000	$8,000
Operating Income	($3,479)	($4,087)	($2,047)	($1,751)	($588)	($8,473)	$213	$10,066	$16,196
Operating Margin	*-5.3%*	*-25.3%*	*-11.1%*	*-9.2%*	*-2.9%*	*-11.4%*	*0.3%*	*10.8%*	*15.7%*
Interest & Other Expense	$33,419	$3,870	$3,880	$4,900	$4,900	$17,550	$21,850	$23,500	$23,500
Pre-Tax Income	($36,898)	($7,957)	($5,927)	($6,651)	($5,488)	($26,023)	($21,637)	($13,434)	($7,304)
Taxes & Other	$52	($8)	$8	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($36,950)	($7,949)	($5,935)	($6,651)	($5,488)	($26,023)	($21,637)	($13,434)	($7,304)
Reported EPS	**($3.48)**	**($0.75)**	**($0.56)**	**($0.62)**	**($0.51)**	**($2.44)**	**($1.99)**	**($1.23)**	**($0.66)**
Adjusted EPS	**($2.67)**	**($0.41)**	**($0.22)**	**($0.28)**	**($0.17)**	**($1.08)**	**($0.65)**	**$0.10**	**$0.66**
Shares Outstanding	10,621.0	10,637.0	10,640.0	10,690.0	10,700.0	10,666.8	10,850.0	10,925.0	11,050.0

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

HISTORICAL STOCK PRICE

VIVUS, Inc. – Share Price Chart

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