Zacks Small-Cap Research

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# VIVUS, Inc. (VVUS - NASDAQ)

***New Ideas for Established Portfolio***

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 $10.00 per share. We anticipate adding a valuation component for VI-0106 following a successful IND and launch of the trial.

| | |
|---|---|
| Current Price (5/1/2019) | $3.70 |
| **Valuation** | **$10.00** |

## 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** | **9.90** |
| **52-Week Low** | **2.15** |
| **One-Year Return (%)** | **-31.5** |
| **Beta** | **3.66** |
| **Average Daily Volume (sh)** | **76,572** |
| **Shares Outstanding (mil)** | **10.6** |
| **Market Capitalization ($mil)** | **39.4** |
| **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 | $16.9 E | $19.2 E | $20.5 E | $72.7 E |
| 2020 | | | | | $80.9 E |
| 2021 | | | | | $90.2 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 | -$0.47 E | -$0.27 E | -$0.18 E | -$1.33 E |
| 2020 | | | | | -$0.79 E |
| 2021 | | | | | -$0.13 E |

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## INITIATING COVERAGE

We are initiating coverage of VIVUS, Inc. (NASDAQ: VVUS) with a $10.00 price target based on our revenue forecasts for approved products. In addition to a portfolio of weight loss, exocrine pancreatic insufficiency (EPI) and erectile dysfunction (ED) solutions, Vivus maintains a development program for pulmonary arterial hypertension (PAH). Existing product Qsymia and recently acquired product Pancreaze are expected to be the main revenue drivers over the next several years. Qsymia has distinguished itself as the most effective approved product in a limited number of approved pharmaceutical options for weight loss and Pancreaze has a substantial opportunity to increase its low penetration levels into the billion dollar plus market for pancrelipase.

Vivus will implement a new strategy called the Vivus Health Platform which will combine technology, nutritional science and Amazon-era distribution to improve patient experience, penetration and loyalty. Following several pilot studies to measure elasticity, the company has found that selling Qsymia directly to patients at a flat price and passing on the associated savings increases sales volumes with limited impact on profit dollars. Additional exploration is advancing to measure the benefits of internet connected biometric readers, telemedicine, wearable health monitors and scales.

In June 2018, Vivus acquired U.S. and Canadian commercial rights to Pancreaze and its U.S. sales force began making calls on target physicians in February 2019. Under previous ownership, the product was only a small contributor to revenues and was not actively commercialized, resulting in a loss of market share as other competitors put more effort behind their own brands. We expect an improvement in market share as the sales force meets with payors and physicians and as the company implements a patient support program and expands the available dosages of the digestive enzyme.

Stendra/Spedra was originally approved in 2012 for erectile dysfunction and was a late comer to the market as Viagra and Cialis were approved years earlier. Now that generic versions of first movers are available, we anticipate licensing partners will focus on patient populations that are willing to pay for the faster action of the drug. Despite the competitive market, the product does offer a more rapid onset of action in the label, an improved side effect profile, and the ability to use with food and alcohol.

VI-0106 leverages an active pharmaceutical ingredient already approved in organ transplantation, ulcerative colitis and atopic dermatitis and has a well-understood safety profile. Early stage clinical work has shown a dramatic improvement on symptoms in Pulmonary Arterial Hypertension (PAH) patients with the use of VI-0106 and low doses of the drug are thought to remodel the pulmonary artery wall. Vivus plans to file an investigational new drug (IND) application with the FDA this year and is also seeking a partner to develop the product. Both the FDA and EMA have granted an orphan designation to VI-0106 for PAH and the company intends to design forthcoming trials to qualify for Fast Track or Breakthrough Therapy designations.

Debt stands at $291 million as of March 31, 2019, $181 million of which is convertible debt due May 2020. Vivus has a plan in place to pay down a portion of the convertible debt with cash on hand and use new funds raised through debt and/or equity financings to balance the difference. The company recently turned EBITDA positive and with the addition of topline growth and potentially new products, net debt leverage is expected to decline as the company advances the topline.

We see Vivus as an attractive investment as the current management team continues to progress in its ten quarter turnaround effort to improve sales, applying established techniques to marketing products, reorganizing debt and layering on new assets complementary to the company's strategy. Management experience in turning companies around is extensive.

As of March 31, 2019, Vivus held approximately $105 million in cash on its balance sheet and $291 million of debt. 1Q:19 sales were $16.1 million and non-GAAP recurring EBITDA in 1Q:19 was $0.1 million. After a volatile second quarter as the new initiatives take hold, we expect 3Q:19 revenues and EBITDA to show the beneficial efforts of the Vivus sales team and its direct sales model followed by a rise in subsequent quarters.

Our thesis for Vivus is supported on three sides that support the turnaround. Improved performance with current products, a restructuring of the debt and the addition of new products which are expected to improve the cash flow generation capability of the company and development projects. Other drivers include regional expansion of existing products and further development of VI-0106.

## INVESTMENT THESIS

Vivus is a turnaround story with a portfolio of three approved products, one development asset and capacity to layer on additional products that can be acquired within reasonable valuation parameters. Corporate strategy calls for a multilateral and direct sales approach for Qsymia and relaunch of recently acquired Pancreaze. Additional partners will be sought to license Stendra/Spedra in unpenetrated geographies and an orphan designation in the US and EU will help advance VI-0106 through the clinic either alone or with a partner. The experienced management team, with numerous turnarounds and transactions under its belt will seek to layer on opportunities with available products focusing on attractive valuations and problems that can easily be fixed to yield growth.

One of the key assets for the company is Qsymia, which has differentiated itself as a class leader compared to other weight loss medicines with high efficacy and a favorable side effect profile. The new marketing approach will directly target physicians and patients and incorporate monitoring technology, diet and counseling to achieve weight loss goals. Pricing elasticity will also play a role and Vivus' reduction in price is expected to markedly expand the addressable market. Due to a shift to direct marketing, there is expected to be a minimal impact on unit profits but a dramatic increase in units sold.

The other key asset, Pancreaze, was acquired from Johnson & Johnson (JNJ) subsidiary Janssen in mid-2018. The pancrelipase product intended for exocrine pancreatic insufficiency (EPI) patients maintains only three percentage points of market share in the US. With additional sales focus and direct work with KOL's and patient groups, the company will work to increase market share to six or nine percentage points over the next two to three years.

Stendra/Spedra provides faster action, an ability to be used with food and alcohol, and lesser side effects compared with competitors which can target an attractive niche; however, generic versions are available in the PDE-5 inhibitor class which may limit growth. Vivus will only license rights to this drug, but does have opportunities in various global geographies where it is not being sold.

A new management team was hired in 2018, and is headed by CEO John Amos to convert Vivus into a cash flow positive enterprise. One of the largest hurdles the company must overcome is the debt and debt service. The company carries $291 million of debt which will be partially paid down and refinanced in the next year. The company shifted to generating positive EBITDA in the latter half of 2018 and we expect the magnitude of cash generation to improve as new strategies are implemented, expenses are rationalized and revenues are grown.

We anticipate management's disciplined focus on cash flow and commercialization fundamentals will allow for both an improvement in leverage statistics and profitability over the next few years. We are also optimistic on development success for VI-0106 in PAH, a condition that lacks an effective disease modifying therapy. While our target price is generated based on current approved products, we will add a component to reflect success of the development portfolio following a successful IND and enrollment in clinical trials for VI-0106.

Key reasons to own Vivus' shares:

- **Current portfolio of revenue generating products**
- **Disciplined focus on cash flow and debt refinancing**
- **Implementing proven sales strategies to improve Pancreaze market share**
- **Direct sales approach and rationalized pricing to drive Qsymia revenue growth**
- **Additional regions available for Stendra/Spedra penetration**
- **Rights to development asset for PAH**
- **M&A efforts prioritize valuation and turnaround opportunities**
    - **ROIC Limits**
    - **Market Barriers**
    - **Significant Clinical Following**
    - **Identifiable Turnaround Strategy**

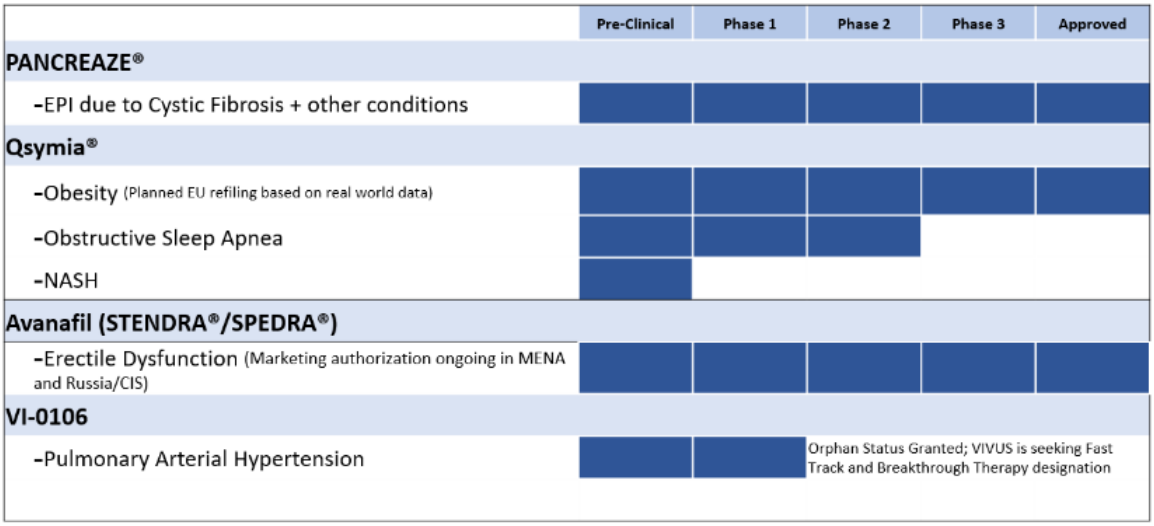
In the following sections we review the each of Vivus' marketed, owned and development products and examine the targeted indication and therapeutic area. We also discuss the company's approach to bring the company's leverage to normal levels and their acquisition philosophy. We see a renewed focus on the proven portfolio assets as a positive driver for growth and cash generation. Our review of earnings potential and financial analysis generates a target price of $10.00 per share.

## VIVUS Portfolio and Indications

VIVUS holds three approved and one in-development asset in their portfolio. All three approved products are currently generating revenues and include Qsymia, which is a combination of phentermine and topiramate extended-release indicated for chronic weight management, Stendra, a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction and Pancreaze, a recently acquired asset intended for the treatment of exocrine pancreatic insufficiency (EPI). Vivus is developing a product for pulmonary arterial hypertension (PAH) designated VI-0106 that is currently in Phase II development.

Qsymia and Pancreaze both have an identified growth strategy that the company is executing. Below we discuss each of the portfolio members, their historical background, mechanism of action, commercialization strategy and other relevant factors that will drive their performance.

**Exhibit I – Vivus' Product Pipeline**

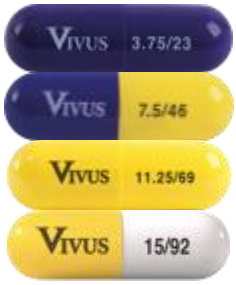



### Qsymia

Qsymia was approved by the FDA in July 2012 and VIVUS began commercializing the drug in September 2012. It was denied marketing authorization in Europe, but was approved in the US for obesity and for those overweight with at least one comorbidity. As a condition of approval for Qsymia, the FDA required additional studies to be conducted including a post-approval cardiovascular outcomes trial (CVOT). During the 2000s, there had been several weight loss products pulled off of the market due to adverse side effects, which raised the perceived risk for all products in this class.[1] Vivus is in discussions with the FDA to obtain the desired CV outcomes data in a more efficient manner that would satisfy the agency's concerns. Management is considering further development of Qsymia for a range of other diseases, including obstructive sleep apnea, nonalcoholic steatohepatitis (NASH) and nonalcoholic fatty liver disease (NAFLD). However, favorable resolution of the CVOT requirement is needed before the company will pursue other indications. Vivus expects to resubmit its market authorisation application (MAA) request in the EU on a decentralized basis during the second half of 2019, initially focusing on six countries.

[1] Rimonabant was approved in 2006 and withdrawn in 2008 due to serious psychiatric side effects. Sybutramine by Abbott was withdrawn in 2010 due to stroke and myocardial infarction. Mediator was an amphetamine that was used extensively in France, but later was found to cause heart valve damage and was taken off the market in 2009.

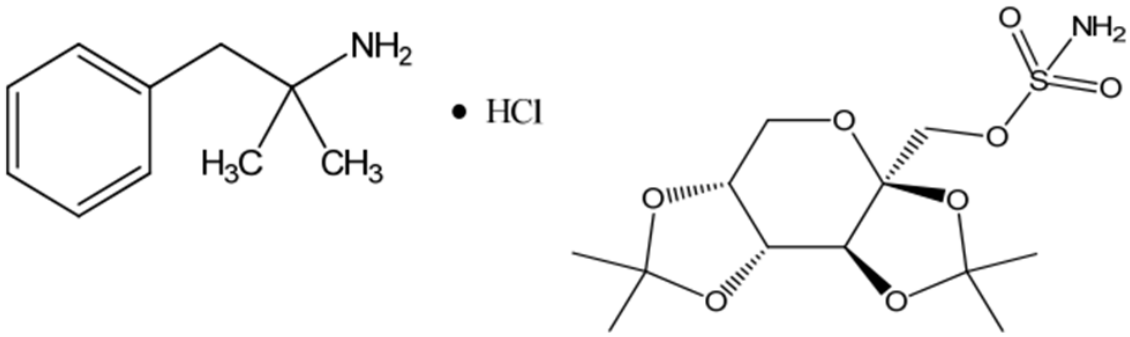
**Exhibit II – Qsymia Capsules**




Qsymia incorporates low doses of active ingredients from two previously approved drugs, phentermine[2] and topiramate. Phentermine is a psychostimulant drug of the substituted amphetamine chemical class which has been used to suppress appetite. Topiramate is an anticonvulsant and was originally used as a treatment for epilepsy in children and adults. Other uses for topiramate include prevention of migraines, and treatment of bipolar disorder, alcoholism and obesity. Together they provide an effective weight loss combination that suppresses appetite and increases satiety via alternate pathways.

Qsymia is a capsule and prescribed in conjunction with a reduced-calorie diet and increased physical activity for chronic weight management. It is prescribed for patients with a body mass index (BMI) in excess of 30 kg/m$^2$ or 27 kg/m$^2$ with at least one weight related comorbidity including hypertension, type 2 diabetes or dyslipidemia. Recommended dosage is one Qsymia 3.75 mg/23 mg (phentermine 3.75mg/topiramate 23 mg extended-release) tablet daily for 14 days; then increase to 7.5 mg/46 mg daily until weight loss targets are achieved. Administration is recommended in the morning to avoid insomnia.

**Exhibit III – Chemical Composition of Phentermine (Left) and Topiramate (Right)**




Contraindications for Qsymia include pregnancy, glaucoma, hyperthyroidism, the use of monoamine oxidase inhibitors and sensitivity to sympathomimetic amines. The drug can have toxic effects or cause birth defects in pregnant women and is not recommended for nursing mothers or pediatric use. Qsymia was approved with Risk Evaluation and Mitigation Strategy (REMS)[3] requirements related to the risk of fetal exposure to the drug in the first trimester of pregnancy. There is an association of topiramate with orofacial clefts in babies of pregnant women and the REMS program serves to inform women of reproductive potential of the risks and requirements if pregnancy occurs. To date, no orofacial clefts have been reported in connection with Qsymia use.

Commercialization

Qsymia is commercialized in the US with Vivus' own 21 person specialty sales force. The strategy to increase penetration is multi-faceted including targeting prescribers with educational efforts and investment in digital medial to augment the message to consumers seeking weight loss. The company also offers a patient savings plan at the pharmacy to encourage patient loyalty. Commercialization efforts will also focus on self-insured employers and Medicare Advantage (MA) members in 2020.

[2] Readers may recall the drug fen-phen which was marketed in the 1990s by American Home Products. The combination drug included phentermine and fenfluramine. It was the latter drug, fenfluramine that was associated with the potentially fatal pulmonary hypertension and heart valve problems that led to the drug being taken off of the market. Phentermine was not associated with harmful effects.
[3] REMS is an FDA program that monitors regulated products with a high potential for serious adverse effects.

In September 2017, Vivus licensed the right to commercialize Qsymia in South Korea to Alvogen Malta Operations in return for a $2.5 million upfront and additional milestones as they are achieved.

During 2018, Vivus management developed a new plan to increase sales of Qsymia based on research performed into consumer behavior and sensitivity to price. The company conducted several studies that examined willingness to pay and elasticity of the drug. Management also identified barriers to seeking a weight loss solution which led to efforts to develop an online pharmacy and offer telemedicine services.

Market Elasticity Studies

Vivus commissioned a study with A.C. Nielsen to measure the demand elasticity for Qsymia. The study found that at a price between $150 and $200, about 11% of the addressable market would be willing to take a pill to improve their weight loss. If the price was reduced to ~$100, then over 70% of the addressable market would be willing to remain on the therapy. The data from this research was used to refine the pricing strategy for Qsymia.

The company tested the findings of the Nielsen research and commissioned two pilot studies to examine the impact of price on usage for Qsymia. When the drug was launched in 2012, the government and industry considered obesity to be a lifestyle choice, which limited reimbursement by payors and transformed it into a cash pay product. Qsymia was also priced based on dose level, which deterred patients from shifting up to the next higher tier due to the cost. This limited patients' commitment to the therapy, the size of the addressable market and ultimate efficacy of the therapy. To learn more about consumer behavior, the company studied the elasticity of consumer demand for Qsymia at its historical price point of approximately $200 per month of treatment and at $100 per month of treatment in two pilot studies conducted in Texas and Georgia. The results demonstrated a significant increase in demand for Qsymia from 50% to over 100%, depending on market. Another element of the previous administration protocol included an initial two weeks of drug to evaluate tolerability at no charge. This was insufficient time for the drug to provide measurable weight loss, which left patients hesitant to continue on the therapy. As a result, many patients did not stay on drug long enough to benefit from its effect during a 15-day trial period, and never became customers. To address this, Vivus combined the initial two week trial with the first month of therapy and charges $98 for it. Succeeding months are also priced at $98. The elasticity research and additional exploration found that patients were hesitant to shift up to the next, more expensive, higher dose,[4] and as a result were not able to achieve weight loss goals and they gave up the therapy. Therefore, low, medium, three-quarter and high doses are all now set at $98, in contrast to the earlier approach which was based on dose level. The adjustments are expected to increase penetration into the addressable market and increase the duration of therapy.

The Qsymia program will also be switched from the traditional retail channel to a direct to patient model using an online pharmacy for distribution. The effect of this change will reduce distribution costs by 40% resulting in a similar profit to Vivus for each month of therapy despite the drop in patient cost. Vivus has contracted with Medvantx to deliver Qsymia to the patient within a day of the first order. In the future, Vivus anticipates adding a telemedicine component to the program which will allow patients to obtain a prescription to Qsymia and receive it online from home, substantially improving the ease with which overweight and obese patients can receive treatment.

Cardiovascular Studies

In January, a study evaluating the cardiovascular safety of Qsymia was made available online and later published in *The Journal of Clinical Endocrinology & Metabolism*. The trial was motivated by data in previous trials that found an elevated heart rate in the high dose active arm trials with Qsymia compared to the placebo arm. There was concern that this could signal a higher incidence of major adverse cardiovascular events (MACE) in patients taking Qsymia. The 500,000-patient retrospective study found that the risk of MACE was not statistically higher in patients taking Qsymia; however, there was a wide range of values inside the 95% confidence interval. While this did not satisfy the Cardiovascular Outcomes Trial (CVOT) requirement, it did provide additional data in support of cardiovascular health while using Qsymia.

As a condition of approval for Qsymia, the FDA required a CVOT to be conducted as a post-marketing study. The rationale for the requirement was related to cardiovascular issues with other approved drugs during the 2000s and the higher heart rate in the high dose. None of the studies conducted for Qsymia have demonstrated any increase in adverse cardiovascular events. Due to the anticipated prohibitive cost of conducting a CVOT study for Qsymia, Vivus is in dialogue with the FDA to identify an alternative strategy to gather the necessary information.
Vivus proposes that the FDA examine real world data and notes that Qsymia is frequently used only for short periods rather than the chronic use that is indicated on the label. A change in the label to indicate short-term use for Qsymia and the favorable findings of the cardiovascular study released in January 2019 may provide sufficient

[4] Under the former pricing regime, higher doses could cost an additional $50 to $60 per month.

justification to eliminate the need for a CVOT; however, the eventual requirement is yet to be determined. The company submitted a supplementary NDA (sNDA) to modify the label to indicate short term use, which may provide the constraints necessary for the FDA to remove the CVOT requirement.

Mechanism of Action[5]

While the exact mechanism of action for phentermine is not known, it is postulated that the effect of the drug on weight management is mediated by the release of catecholamines in the hypothalamus, resulting in reduced appetite and decreased food consumption. Other metabolic effects may be involved. The mechanism of action for topiramate is not known either; however, the drug's effect on weight management may be attributed to its effects on both appetite suppression and satiety enhancement induced by a combination of pharmacological effects. These effects include increasing the activity of the neurotransmitter gamma-aminobutyrate, modulation of voltage-gated ion channels, inhibition of AMPA/kainite excitatory glutamate receptors, or inhibition of carbonic anhydrase.

Side Effects and Adverse Reactions

Adverse reactions of greater than 5% observed in clinical trials include paresthesia, dry mouth, constipation, upper respiratory tract infection, headache, nasopharyngitis, insomnia, dysgeusia and dizziness.

Registrational Studies

Two Phase III clinical studies were conducted to obtain approval of Qsymia designated the EQUIP (Study 1) and CONQUER (Study 2) trials. EQUIP examined patients with a BMI equal to or greater than 35 and enrolled 1,267 individuals in a 2:1:2 ratio for placebo, Qsymia 3.75 mg/23 mg and Qsymia 15 mg/ 92 mg. The CONQUER trial enrolled 2,487 patients with a BMI of 27 to 45 kg/m$^2$ and two or more obesity-related co-morbid conditions such as high blood pressure, elevated triglycerides or fasting blood glucose and excessive waist circumference. A reduced-calorie diet was recommended to patients and nutritional and lifestyle counseling were offered in both studies. We summarize the primary endpoints below.

**Exhibit IV – Weight Loss in Studies 1 and 2[6]**

| | Study 1 | | | Study 2 | | |
|---|---|---|---|---|---|---|
| | Placebo | Low Dose | High Dose | Placebo | Low Dose | High Dose |
| N | 498 | 234 | 498 | 979 | 488 | 981 |
| % of Pt >5% loss | 17% | 45% | 67% | 21% | 62% | 70% |
| % of Pt >10% loss | 7% | 19% | 47% | 7% | 37% | 48% |

Future Studies

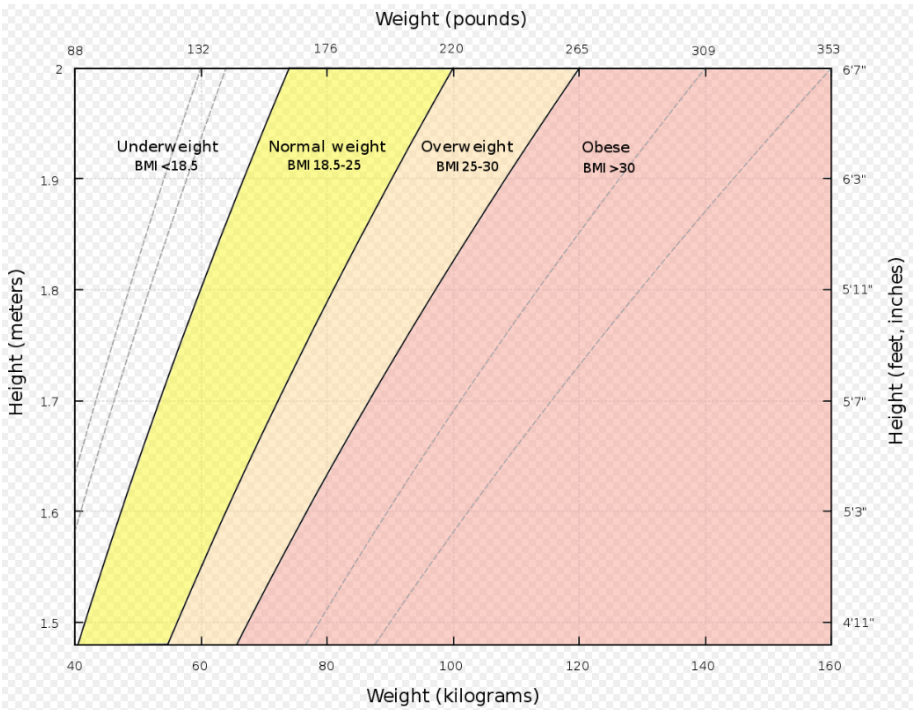
In 1Q:19 the company launched a Phase IV study in obese adolescents, ages 12 to 17. The study was required as a condition of Qsymia approval in 2012 and is anticipated to enroll 200 patients at 20 clinical sites in the US. Treatment will last 56 months and seek a primary endpoint of mean percentage change in body-mass index as compared to a placebo. Timing for the topline readout is 2H:20.

**Obesity**

The Body Mass Index (BMI) metric is frequently used to determine whether or not a person is overweight or obese. The data point is calculated based on height and weight measurements. Individuals with a BMI between 25 and 30 are considered overweight and a BMI above 30 considered obese.

[5] Prescribing Information for Qsymia. FDA Label, July 2012.
[6] Summarized from Prescribing Information for Qsymia. FDA Label, July 2012.

**Exhibit V – BMI Graph[7]**




According to the National Center for Health Statistics (NCHS), almost 40% of the US adult population is considered obese based on data collected in a 2015/2016 survey. This is equivalent to approximately 130 million persons. The condition is associated with diabetes, hypertension, high cholesterol, cardiovascular disease, sleep apnea, stroke, arthritis and certain cancers. Losing weight, even just 5 to 10% can prevent or delay these conditions and dramatically improve the health of the person.

As with many diseases, there is a correlation between obesity and age with about 43% of those from 40 to 59 classified as obese compared to 36% for adults aged 20 to 39. The rate has been increasing over time as the prevalence of the condition was 15% in 1990. The NCHS further estimates that medical obesity costs were $147 billion in 2008, and found that obese individuals incurred medical costs $1,429 greater than their non-obese counterparts.

Diet adjustments and an increase in physical activity are the first recommendations for individuals that are overweight or obese. However, diet and exercise are frequently not sufficient to lose weight and maintain weight loss. If these measures do not work, then drug therapy is appropriate. In cases where medication in combination with lifestyle changes fail to reduce weight, then bariatric surgery may be an option. In some cases, Qsymia may be used prior to and/or following bariatric weight loss surgery. The medication can help a patient get to a weight where bariatric surgery is safe and effective. It can also help a patient adapt to eating less after the surgery as they adjust to lower levels of caloric intake.

Treatment

Five prescription medications have been approved by the FDA for weight loss across a variety of drug classes. Their efficacy in terms of kilograms lost and relative ranking for adverse events (AE) are included in the following exhibit. The AE rank was based on surface area under the cumulative rankings (SUCRAs) and measures the probability of discontinuation due to adverse events and excludes placebo. Qsymia appears favorably in the comparison below with the greatest weight loss of the five drugs and position in the middle of the pack for AE.

[7] BMI chart.svg. (2018, April 27). Wikimedia Commons, the free media repository. Retrieved 12:56, March 20, 2019 from https://commons.wikimedia.org/w/index.php?title=File:BMI_chart.svg&oldid=298729507.

**Exhibit VI – FDA Approved Medications for Obesity[8]**

| Branded | Generic | Company | Class | Loss v Placebo | AE Rank |
|---|---|---|---|---|---|
| Xenical | orlistat | Roche/GSK | Gastric & pancreatic lipase inhibitor. 1/3 cut in fat absorption | 2.6 kg | 2 |
| Belviq | lorcaserin | Arena | activation of serotonin 5-HT2C receptors | 3.2 kg | 1 best |
| Qsymia | phentermine & topiramate | Vivus | Appetite suppressant & stimulant/anticonvulsant | 8.8 kg | 3 |
| Contrave | bupropion & naltrexone | Takeda & Orexigen | norepinephrine uptake inhibitor & opioid receptor antagonist | 5.0 kg | 4 |
| Saxenda | liraglutide | Novo Nordisk | GLP1 analogue/lower $HbA_{1C}$ concentration/improve β-cell function | 5.3 kg | 5 worst |

## Pancreaze

On May 1, 2018 Vivus announced its plan to acquire Pancreaze from Janssen Pharmaceuticals in a deal that closed June 11, 2018. U.S. and Canadian rights to the drug were purchased for $135 million. Pancreaze, generically known as pancrelipase, contains porcine-derived lipases, proteases and amylases in capsule form. The product is indicated for treatment of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis (CF), chronic pancreatitis (CP), pancreatic oncology, diabetes, pancreatectomy or other conditions that affect digestive enzymes.

**Exhibit VII – Pancreaze Capsule – 10,500 Lipase Units**




According to the Cystic Fibrosis Foundation, about 30,000 people are living with cystic fibrosis (CF) in the United States and over 70,000 worldwide. Chronic pancreatitis (CP) affects about five people in every 10,000, or about 0.05% of the population according to the Pancreas Foundation. In this United States, this equates to over 163,000 persons. Together, CF and CP sum to almost 200,000 individuals; however, the actual addressable market for Pancreaze may be larger including other conditions that may cause EPI such as diabetes, irritable bowel syndrome and other diseases. Sales of Pancreaze were recognized on Vivus' income statement starting in the second quarter of 2018 and Vivus relaunched the drug in the first quarter of 2019 with a new sales team.

Based on data provided by Symphony Health Solutions, full year sales of Pancreaze in the U.S. fell from about $43 million in 2012 to $29 million in 2018. Vivus management estimates that recent Pancreaze sales equate to about 3% of market share. The current revenue breakdown for Vivus' PERT therapy is 20% CF, 51% CP, 11% oncology with the remaining percentage allocated to other conditions. Vivus' strategy is to have an active sales team that will increase the visibility of the product with gastroenterologists, cystic fibrosis centers and pulmonologists, later combining the product with biometric (weight and potentially other) measurement and nutritional supplements.

### Commercialization

Vivus anticipates being able to commercialize Pancreaze with its existing infrastructure and ten additional sales representatives in the United States and up to two in Canada. The company relaunched Pancreaze in February 2019 and has simultaneously transitioned all activities from Janssen as of this date. Sales efforts will target gastrointestinal and cystic fibrosis specialists as well as pulmonologists. Calls will be focused on the top 40% of US physicians that prescribe treatment for exocrine pancreatic insufficiency (EPI). There are approximately 3,500

[8] Data for weight loss compared to placebo and adverse event rank are taken from: Khera, Rohan; et al. Association of Pharmacological Treatments for Obesity With Weight Loss and Adverse Events A Systematic Review and Meta-analysis. JAMA. 2016;315(22):2424-2434. doi:10.1001/jama.2016.7602

physicians in the target group areas and sales representatives will target from eight to twelve interactions per day. We believe there will be a positive correlation between interactions with physicians and sales volume.

The evolving Vivus Health Platform will be used to support the use of Pancreaze with patient tracking, co-pay support, and vitamins and nutritional supplements. EPI patients have a difficult time obtaining sufficient essential nutrients, including fat-soluble vitamins. Almost all EPI patients require vitamin supplements, specifically A, D, E and K, because these levels are low. To provide a comprehensive solution to the EPI patient, Vivus will provide vouchers for vitamins that can be redeemed at the Amazon Marketplace.

Side Effects

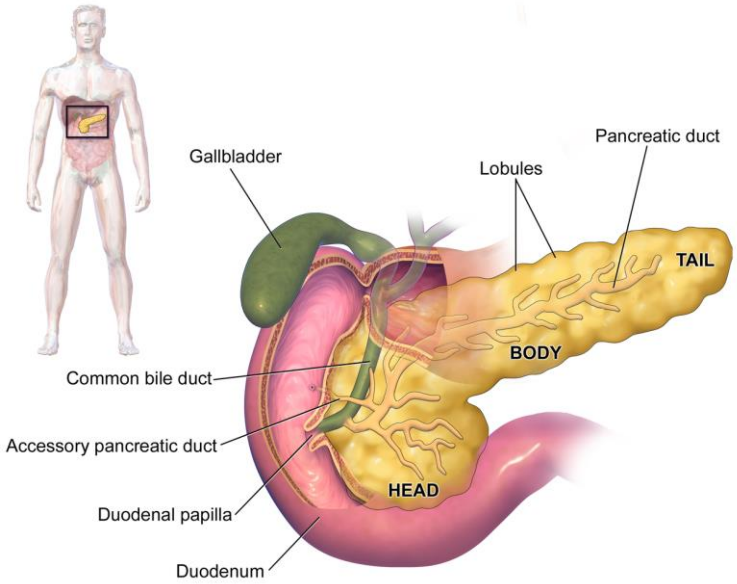
The most serious adverse events for pancrelipase include fibrosing colonopathy, distal intestinal obstruction syndrome, recurrence of pre-existing carcinoma and severe allergic reactions. Fibrosing colonopathy is a potentially significant event associated with high-dose enzyme therapy. It is a thickening of the bowel wall that can be improved by reducing enzyme levels, but may in some cases requires surgery.

## Exocrine Pancreatic Insufficiency (EPI)

### Chronic Pancreatitis

The pancreas is an "L" shaped organ located in the abdomen behind the stomach. It produces several important hormones (most notably insulin) and digestive fluids (enzymes) that support digestion and absorption of nutrients in the small intestine. These enzymes are critical to the digestive process and in some cases the gland may not be able to produce sufficient amounts. Excessive alcohol use and smoking are two of the most common risk factors for chronic pancreatitis (CP), but autoimmune conditions and genetic mutations from cystic fibrosis can also precede the disease. The pancreatic ducts may also become blocked due to trauma, stones or tumors which decreases the organ's functionality. When CP manifests itself, the pancreas is unable to secrete the necessary digestive enzymes required to break down the carbohydrate, protein and lipid components of food. CP causes an inflammation of the pancreas that does not improve. Pancreatic ducts may become blocked, limiting the secretion of pancreatic enzymes and hormones resulting in malnutrition and diabetes. Sufferers of CP may experience symptoms such as pain in the upper abdomen, diarrhea, fatty stools, nausea, vomiting, weight loss and excessive thirst and fatigue. The pain may become intense and trigger a visit to the hospital.

**Exhibit VIII – The Pancreas[9]**




[9] "Blausen gallery 2014". Wikiversity Journal of Medicine. DOI:10.15347/wjm/2014.010. ISSN 20018762. - Own work, CC BY 3.0, https://commons.wikimedia.org/w/index.php?curid=28909219

**Cystic Fibrosis**

Cystic fibrosis (CF) is an autosomal recessive disorder that involves the CFTR (cystic fibrosis transmembrane conductance regulator) gene which is responsible for creating the CFTR protein. This protein promotes the secretion of chloride ions into sweat, digestive fluids and mucus, thereby attracting water molecules into these secretions and thinning them. When the protein is absent, this reaction fails to take place in the pancreas, and pancreatic secretions become thick and congest pancreatic ducts, preventing digestive enzymes from entering the small intestine. Not only does this lead to malnutrition and a failure to properly break down foods, but the digestive enzymes may damage and degrade the pancreas causing cysts and fibrosis, hence the name cystic fibrosis. This damage can also prevent the pancreas from generating sufficient insulin, resulting in diabetes.

**Exocrine Pancreatic Insufficiency[10]**

Exocrine Pancreatic Insufficiency (EPI) can result from several disease states, most commonly CP and CF, but also diabetes, pancreatic cancer, Shwachman-Diamond Syndrome, inflammatory bowel disease and other conditions. EPI is caused either by the loss of cells (acinar cells) that create digestive enzymes or the blockage of the ducts that transport the enzymes to the intestines. Without sufficient enzymes, the body cannot sufficiently digest food. The pancreas synthesizes three key enzymes which we describe below along with their function.

**Exhibit IX – Pancreatic Enzymes**

| Enzyme | Breaks Down | Produces | Shortage of Enzyme Causes |
|---|---|---|---|
| Lipase | Fat | Fatty acids & Glycerol | Lack of needed fats and fat-soluble vitamins. Diarrhea and/or fatty stools. |
| Protease | Protein | Amino Acids | Allergies or the formation of toxic substances due to incomplete digestion of proteins. Increased risk for intestinal infections. |
| Amylase | Starch | Glucose | Diarrhea due to the effects of undigested starch in the colon. |

Under normal conditions, the pancreas has the ability to produce more enzymes than are needed and can continue to produce sufficient quantities of lipases to digest fat unless production declines below 10% of the organ's normal capacity. The digestion of fats is important as they provide the richest source of energy for the body. Fats average 9 calories per gram while carbohydrates and protein have less than half that level at 4 calories per gram. Without the contribution from fat, weight loss and malnutrition frequently result. There are mild and moderate levels of EPI that can result in periodic fatty diarrhea and weight loss; however, the symptoms are frequently not severe enough for patients to seek treatment. In severe cases, patients additionally suffer from frequent steatorrhea, malnutrition, and abdominal discomfort and swelling to an extent where diagnosis and treatment are necessary.

Diagnosis

Diagnostic testing, including blood panels[11] and scans using non-invasive and invasive ultrasounds[12] may be used to diagnose exocrine pancreatic insufficiency (EPI). Stool tests which seek to determine if there is an abnormal level of fat or elastase in the body's waste products are also used. EPI can have several levels of severity, from mild to severe. Mild and moderate levels show FE-1[13] fecal content from 100 to 200 µg/g, greater than 7 g/day of fat in the stool and a coefficient of fat absorption (CFA) measure of 50 to 90%. Severe cases of EPI evidence levels of FE-1 fecal content below 100 µg/g, greater than 15 g/day of fat in the stool and a CFA of below 50%.

Treatment

Treatment for chronic pancreatitis includes diet changes, the use of pain medications, and pancreatic enzyme supplements. In some serious cases, surgery may be needed. As a result of the pancreas not being able to provide the necessary enzymes to break down food, pancreatic enzyme replacement therapy (PERT) is commonly prescribed. Under normal conditions, the enzymes (specifically lipase) break down the undigested triglycerides into fatty acids and monoglycerides. Bile salts then solubilize these breakdown products to form micelles, which are vehicles for absorbing lipid breakdown products.

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132852/#!po=6.60377
[11] Blood tests can detect digestive enzymes that leak out of the pancreas into the bloodstream when the pancreas is inflamed.
[12] Imaging tests such as x-ray, ultrasound, CT scan, or MRI provide information about the structure of the pancreas, the ducts that drain the pancreas and gallbladder, and the tissues surrounding the pancreas. Other tests, such as endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic ultrasound, are tests that can outline the areas that drain the pancreas and gallbladder. These tests are performed by passing a tube through the mouth into the digestive tract.
[13] Fecal elastase-1 (FE-1) is an enzyme used to identify an exocrine deficiency.

From 25,000 to 40,000 international units (IU) of lipase are generally sufficient to digest a typical meal and from 20% to 60% of this amount is appropriate for a snack. From 50,000 to 150,000 IU of lipase per day will generally reduce steatorrhea by 45% to 70% when taken during or after meals.

Current enzyme replacement therapy is formulated into immediate release, enteric coated microspheres in a capsule with a bicarbonate buffer. There are currently six approved pancrelipase products approved for use.

**Exhibit X - Pancrelipase Delayed Release Capsule**

| Drug | Generic Name | Marketer | Format |
|---|---|---|---|
| Creon | Pancrelipase | AbbVie | Delayed Release Capsule |
| Pancreaze | Pancrelipase | Vivus | Delayed Release Capsule |
| Pertzye | Pancrelipase | Digestive Care | Delayed Release Capsule |
| Ultresa | Pancrelipase | Aptalis | Delayed Release Capsule |
| Viokase | Pancrelipase | Aptalis | Tablets, Non-enteric Coating |
| Zenpep | Pancrelipase | Aptalis | Delayed Release Capsule |

In the early days of PERT, due to instability of the enzymes and enzyme degradation, there had been marked variability in the enzyme content of the different formulations.[14] Part of the reason for the variability was that the products were not regulated as their availability preceded FDA oversight. In 2004, the FDA mandated that new drug applications be submitted for the PERT class and in April 2010, unapproved pancreatic enzyme products were required to cease manufacturing and distribution of product. As of 2018, based on market share estimates and available financial report data, US sales for the class are estimated to be around $1.1 billion and global sales from $1.4 to $1.5 billion.

**Stendra/Spedra**

Stendra (avanafil) is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (ED) similar in chemical structure to the well-known Viagra (sildenafil). Avanafil was originated by Mitsubishi Tanabe Pharma Corporation (MTPC), developed by Vivus and approved by the FDA in April 2012. MTPC maintained Asian rights to the drug and granted Vivus worldwide rights outside this area. Vivus licenses Stendra/Spedra for commercialization in its territories and has not used an internal sales force to commercialize the drug.

Stendra's safety and efficacy were evaluated in three double-blind, placebo-controlled clinical studies lasting up to three months. 1,267 patients were randomly assigned Stendra for up to 12 weeks at doses of 50 milligrams (mg), 100 mg or 200 mg, or a placebo as needed about 30 minutes before sexual activity with no restrictions on food or alcohol consumption. Primary endpoints for the studies included an erectile function score, whether or not vaginal penetration was achieved and if successful intercourse occurred. Results from the studies demonstrated a dose dependent response for all of these factors. The FDA and the EU granted approval for the drug in 2012 and 2013, respectively.

Side effects of the drug include headache, flushing, stuffy or runny nose, sore throat and back pain. In rare situations, priapism, and temporary vision or hearing loss may occur.

Stendra differentiates itself from some of the other PDE5 inhibitors with a lower side effect profile due to fewer off target effects and is approved for use 15 minutes before sexual activity. Stendra has high affinity for the PDE5 enzyme and low affinity for off target enzymes including PDE1, 3, 6 and 11 that are associated with a variety of side effects including impaired vision and low blood pressure. The drug is also effective when taken with food and up to three servings of alcohol.

Others in this class include Viagra (sildenafil), Cialis (tadalafil), Zydena (udenafil), Levitra (vardenafil). Approved PDE5 inhibitors outside of US: Helleva (lodenafil), Mvix (mirodenafil). Generic versions of sildenafil, tadalafil and vardenafil are available in the United States.

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132852/#!po=6.60377

Commercialization

In July 2013, Vivus signed a license and commercialization agreement with Menarini for avanafil (Spedra outside of the US) in over 40 countries. This includes the EU, Australia, New Zealand and others. The agreement allows for royalties on Spedra sales and milestones based on sales targets.

Commercialization rights were sold to Auxilium Pharmaceuticals in 2013 for US and Canada development but were terminated in September 2016. That same month, Vivus entered into a license and commercialization agreement with Metuchen Pharmaceuticals. Metuchen will develop, commercialize and promote Stendra in the US, Canada, South America and India. Vivus will supply drug product.

Vivus previously had a license and commercialization agreement with Sanofi which was terminated in March 2017. The territories granted in this agreement included Africa, the Middle East, Turkey and the Commonwealth of Independent States, including Russia. Vivus is in discussions with other potential collaborators to assume responsibility for these markets. In the last year, approval to commercialize Spedra was granted in Jordan, Saudi Arabia, Turkey and the United Arab Emirates. In March 2019, the Ministry of Health of the Russian Federation has approved the 50 mg, 100 mg and 200 mg doses of avanfil, where it will be called Razatus.

Mechanism of Action

Sexual arousal leads to penile erection through release of nitric oxide (NO) from non-adrenergic, non-cholinergic nerves to the corpora cavernosa. This action triggers the conversion of ATP to the second-messenger cyclic GMP (cGMP) in vascular smooth muscle cells of the corpora cavernosa, resulting in reduced intracellular $Ca^{+}$ levels and smooth muscle relaxation. As the smooth muscle cells relax, the blood vessels expand and the corpus cavernosum becomes engorged with blood creating an erection. In the corpora cavernosa, cyclic GMP is inactivated by phosphodiesterase enzymes, predominantly PDE5. By inhibiting the PDE5 enzyme, avanafil effectively amplifies the vasodilatory effect of NO, thus enhancing vasodilation of the cavernosal smooth muscle and erection.

Avanafil retains some subtle differences as compared to the other PDE5 inhibitors. Competing PDE5 inhibitors have demonstrated off-target activity associated with inhibition of other PDE isozymes including PDE6 (retinal photoreceptors), PDE11 (associated with pain and myalgia) and PDE1. Compared to other agents in this class, avanafil causes less inhibition of PDE6, PDE11 and PDE1, reducing the likelihood of common side effects such as temporary color blindness and discomfort. Avanafil also has a faster onset of action compared to others in the class, achieving $T_{max}$ within 30 to 40 minutes and exhibiting a half-life of three to five hours.

**Erectile Dysfunction (ED)**

Symptoms and Risk Factors

Symptoms of ED include difficulty in achieving or maintaining an erection sufficient to engage in sexual activity. There a number of causes of ED, with many stemming from vascular disorders. Some of the most common causes include smoking, excessive alcohol consumption, heart disease, diabetes, high blood pressure, high cholesterol, obesity and metabolic syndrome and neurological and other diseases.

Diagnosis

Diagnosing erectile dysfunction is performed during a physical exam which looks for underlying conditions that may be involved. Blood and urine tests may be conducted to check for signs of heart disease, diabetes and low testosterone. Ultrasounds may be conducted to examine blood flow and a psychological exam may be ordered to screen for depression, stress or anxiety.

Treatment

There are a variety of treatments which include injected vasodilator agents, vacuum erection devices, intraurethral suppository and surgical intervention. However, after the emergence of PDE5 inhibitors, these are all considered second-line therapies. Lifestyle modification, with an emphasis on smoking cessation, reduction of alcohol intake and improved diet and exercise are also recommended. In cases where these are insufficient, PDE5 inhibitors are prescribed. All products with the exception of Stendra are currently generic, which are listed in the subsequent exhibit.

**Exhibit XI – PDE5 Inhibitors**

| Branded | Chemical Name | Indication | Company | Generic |
|---|---|---|---|---|
| Cialis | tadalafil | ED | Sanofi | Available |
| Levitra | vardenafil | ED | Bayer | Available |
| Stendra | avanafil | ED | Vivus | No |
| Viagra | sildenafil | ED | Pfizer | Available |

**Tacrolimus (VI-0106)**

Vivus is developing a unique and proprietary formulation utilizing tacrolimus[15] for the treatment of pulmonary arterial hypertension (PAH) in a program designated VI-0106. Development and commercialization rights were acquired from Selten Pharma in 2017 for bone morphogenetic protein receptor 2 (BMPR2) activators, which covers the use of tacrolimus and ascomycin to treat the disease.

The company intends to design trials for this orphan indication with the intent to qualify for fast track or breakthrough therapy designation. If expedited pathways are pursued, VI-0106 could see approval in two or three years. An important factor that supports an efficient approval process is the familiarity the FDA and EMA have with this previously approved chemical entity. The candidate will also pursue the 505(b)(2) pathway, which will allow for a streamlined approval process.

Tacrolimus was discovered in 1987 and is produced by a soil bacterium *Streptomyces tsukubaensis*. It was originally approved for use as an immunosuppressant for liver transplantation in 1994, and has been applied more broadly in other transplant organs since then. For its initial indication, the drug's mechanism of action involves inhibition of T-lymphocyte activation. Experimental evidence suggests that tacrolimus binds to an intracellular protein, FKBP12. A complex of tacrolimus-FKBP12, calcium, calmodulin, and calcineurin is then formed and the phosphatase activity of calcineurin is inhibited. This effect, in turn may prevent the formation of lymphokines including interleukin 2 and gamma interferon, and subsequently, inhibit T-cell activation.

FKBP12 and calcineurin also have an inhibitory role in the regulation of BMPR2 signaling. With BMP ligand binding, interaction between the BMPR2 receptor and the affiliated type 1 receptor is initiated, resulting in the release of FKBP12 and calcineurin, followed by the phosphorylation of the type 1 receptor and initiation of downstream signaling. In PAH, where patients have dysfunctional BMPR2 signaling, whether due to either mutations or other causes, BMP ligand binding no longer results in the release of FKBP12 and calcineurin from the type 1 receptor, and downstream signaling fails to occur. Tacrolimus has been shown to restore BMPR2 signaling by effecting the release of FKBP12 from the type 1 receptor, and thereby provides an opportunity to address the loss of BMPR2 function related to PAH.

Vivus entered into a patent assignment agreement with Selten Pharma to receive worldwide rights for development and commercialization of BMPR2 activators for treatment of PAH and related vascular diseases. Selten assigned the related patents, which are owned by Stanford University, to Vivus for an upfront of $1 million and additional potential milestones of $39 million.

In October 2017, Vivus held a pre-IND meeting with the FDA and was provided detail on requirements to file an investigational new drug (IND) application. We expect to see an IND filed prior to the end of 2019. PAH is considered an orphan disease and tacrolimus has received an Orphan Drug Designation from the FDA and European Medicines Agency. This classification allows for certain development benefits and the candidate may qualify for Fast Track and/or Breakthrough Therapy designations. If approved under the designation, seven years of exclusivity is also granted.

**Clinical Studies**

A randomized, double-blind, placebo-controlled Phase IIa trial in PAH was conducted in 2012 to 2014 for tacrolimus (designated FK506 in this trial). The study enrolled 23 patients equally divided into four study arms over the 16-week duration of the work. Arms included placebo, low-level FK506, medium level FK506 and high level FK506. Patients were between the ages of 18 and 70 and were diagnosed with Group 1 PAH due to idiopathic, heritable or associated causes, verified with right heart catheterization.

[15] Vivus also has rights to Ascomycin, which is an ethyl analog of tacrolimus with strong immunosuppressant properties.

The primary objective of the trial was to show safety and tolerability of FK506. Secondary objectives examined changes in six minute walking distance, NYHA functional class and several other biomarkers for PAH.

The Phase IIa study observed that some of the 20 patients that completed the trial had a material increase in BMPR2 expression and improvements in six minute walking distance; however, other parameters were inconclusive. Select patients with end stage PAH that did not qualify for the trial were granted a compassionate use exemption due to the severity of their disease. The three patients under the compassionate use protocol were all NYHA class III/IV patients. After treatment with tacrolimus (FK506 in the study), all demonstrated material improvement in their symptoms, frequency of hospitalization, and six minute walk distance, and all improved by at least one NYHA functional class level. The results in this small group of end-stage subjects suggest a potential benefit of the drug in end-stage PAH.

Tacrolimus was well tolerated by patients in the study with the most frequent side effect being nausea and diarrhea, which were observed more frequently at the medium and high level doses of the drug. Only one patient developed a serious adverse event (hemoptysis) during the 2-week follow-up period off the study drug that required a brief hospitalization and imaging studies to verify the bleeding source. The investigators felt the event was related to the patient's streptococcal infection rather than the study drug.

Vivus plans to launch an additional Phase II study following the submission of an IND. The pathway for the tacrolimus program will depend on the success of the turnaround, interest by partners and availability of development capital. With limited solutions for PAH, and the dramatic improvement seen in a select subset of patients, we anticipate a valuable asset and will update our analysis as additional details are made available.

**Pulmonary Arterial Hypertension**

There are several types of pulmonary hypertension, which progresses due to a variety of causes.[16] PAH is a subtype where mean blood pressure in the pulmonary circulation is above 25 mm Hg. It usually develops as a result of congenital heart defects due to septal imperfections and results in excessive blood pressure in the pulmonary arterioles, while pressure in capillaries and pulmonary veins are normal. As a result of the excessive pressure, pulmonary edema and right ventricle hypertrophy can occur resulting in fatigue, shortness of breath, lightheadedness, fainting and a dry cough. Obesity, infections such as HIV, thyroid disorders and family history can also contribute to PAH. PAH occurs as a result of an imbalance of endothelin, prostacyclin and nitric oxide, which if present in the incorrect amounts can cause vessel contraction and the disease. Low levels of prostacyclin result in constricted vessels. Treprostinil as an analogue of prostacyclin is able to increase low levels and reverse the vessel constriction.

Treatment for PAH includes administration of prostaglandins, PDE-5 inhibitors, endothelin receptor antagonists and prostacyclins. Other drugs that have been approved for PAH include iloprost, bosentan, epoprostenol sodium and riociguat. Failure of medication to improve the condition may result in the need for a lung transplant.

PAH is considered a rare disease and prevalence is estimated to be between 15 and 50 persons per million adults and usually occurs between ages 20 and 60. The National Organization for Rare Disorders (NORD) reported from 500 to 1,000 new cases in the US per year with a total population from 10,000 to 20,000. Based on data provided by the EMA, PAH affects approximately 64,000 people in the EU. The disorder is twice as common in females as in males. Research by Vivus identified approximately 217,000 patients with the disease and a ~$4.5 billion market size worldwide.[17]

**Exhibit XII – Comparison of Healthy and Affected Vessel[18]**



[16] The WHO classified pulmonary hypertension into five groups. PAH is classified in Group 1.
[17] Source: Vivus corporate presentation.
[18] United Therapeutics' patient primer on PAH and Remodulin, "Remodulin Information for Patients with PAH" http://www.phaeurope.org/wp-content/uploads/Remodulin-Information-for-patients-with-PAH1.pdf

Symptoms of the disease usually begin with shortness of breath and difficulty in exertion. PAH may also cause chest pain, fatigue, unconsciousness and swelling of the lower extremities. Diagnosis of the disease requires diagnostic testing such as an echocardiogram, CT scan, ventilation-perfusion scan or chest X-ray. A stress test may also be administered to diagnose the condition. To verify the initial assessment, the physician may perform a heart catheterization which will measure the internal pressures of the chambers of the heart and the stiffness of the pulmonary arteries.

PAH is a subtype of pulmonary hypertension (PH). There are five groups of PH, as classified by the World Health Organization. Group 1, due to the availability of treatment, is best known and called Pulmonary Arterial Hypertension (PAH); however, it is considered a rare disease. Group 2 is the most common, occurring in about half of all PH patients and is related to patients with left heart disease. Group 3 is PH related to chronic lung disease or conditions that cause hypoxemia. Group 4 results from the obstruction of the pulmonary vascular bed with chronic, organized thromboemboli. Group 5 PH is a heterogenous group that initiated by several factors.

**Exhibit XIII – PH WHO Groupings[19]**

| TABLE 2. Clinical classification of pulmonary hypertension | |
|---|---|
| GROUP 1 | Primary pulmonary hypertension: idiopathic, familial, drug and toxin induced (appetite suppressant drugs), rare medical conditions |
| GROUP 2 | Secondary to left ventricular disease: mitral valve disease, left ventricular systolic or diastolic failure. |
| GROUP 3 | Secondary to pulmonary disease or hypoxia: COPD, sleep disordered breathing, obesity hypoventilation |
| GROUP 4 | Secondary to chronic thromboembolism |
| GROUP 5 | Unclear and multifactorial etiologies |

Symptoms

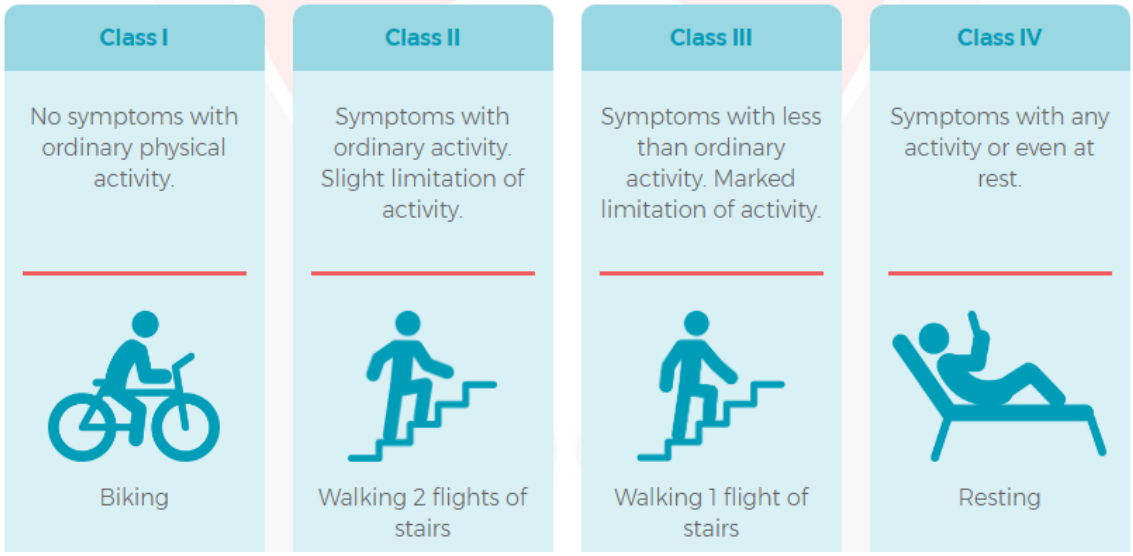
The primary symptoms of PAH include exhaustion, shortness of breath, chest pain, fainting, dizziness, presyncope, rapid heartbeat and edema. Insufficient gas exchange in the pulmonary arterioles may lead to a bluish color in the lips and skin. Further examination may show pulmonary edema, right ventricle hypertrophy and orthopnea.

Diagnosis

A proper diagnosis of PH requires catheterization; however, many times the diagnosis is made based on an echocardiogram, Doppler echocardiography or magnetic resonance imaging. A physician will first narrow down the likelihood of the condition with a physical exam and non-invasive diagnostic testing, then perform a right heart catheterization to accurately measure the pressure in pulmonary arteries and measure how well the heart is pumping blood. Other methods of determining the condition include chest x-rays, blood tests to rule out other causes, pulmonary function tests and six minute walk distance to measure severity. There are also four functional classes of PAH, ranging from Class I, with few signs or symptoms to Class IV, where even resting is difficult.

[19] http://bariatrictimes.com/wp-content/uploads/benottitable1-aug13.jpg

**Exhibit XIV – World Health Organization Functional Classes[20]**




Treatment

There are several approved treatments for PAH, depending on its cause which fall into three classes. The first class includes PDE5 inhibitors and soluble guanylate cyclase stimulators (sGCS) slow the breakdown of nitric oxide, allowing the smooth muscle in blood vessels to remain open. Endothelin receptor agonists are another class which prevents an excess from endothelin from constricting the blood vessels in the lungs. The third class includes prostacyclin class therapies, such as prostacyclin analogues or IP receptor agonists. All of these treatments come in oral form, and the prostacyclin class may also be administered through a pump or infused.

**Corporate Strategy**

Vivus will implement a turnaround strategy with increased focus on cash flow, rationalizing costs and implementing proven sales techniques for existing assets. The company will also pay down debt coming due and refinance it efficiently. Acquiring additional product candidates is another component of the strategy that targets assets with identifiable difficulties that can be remedied. Acquisitions will help improve overall leverage as they will be folded in at disciplined multiples and will provide revenue growth opportunity to further improve leverage ratios.

Vivus plans to improve operating performance to a level where the debt is industry appropriate and acquire new assets and refinance in a manner that provides additional cash flow that will support this goal. We see a 5.5x net debt to EBITDA ratio as ideal. Vivus has identified several assets in attractive therapeutic areas, including cardiovascular, oncology, dermatology and diabetes. The gating factor for the company is valuation of under 6.0x EBITDA. Assets that are suffering temporary difficulties in the market or can be improved with the implementation of established sales techniques are favored. Deals must achieve a 25% IRR over the first several years of ownership based on management assessments in order to be considered.

Senior management team members have extensive experience in consumer driven sales strategies, integrating technology with sales efforts and transactions. CEO John Amos has spent the last three decades in a variety of roles that required innovative strategies to improve information systems and adapt them for consumer use. In his eight years at McKesson (MCK) he held numerous responsibilities including the integration of McKesson's (MCK) acquisitions. During his tenure the company grew from ~$10 billion in revenues to ~$60 billion while simultaneously improving corporate information systems. While at ORIX, Mr. Amos also led the team that acquired dermatology drug tretinoin and grew EBITDA by a factor of seven over a multi-year period through implementing focused sales strategies and rationalizing costs.

President Kenneth Suh has a broad background of experience identifying a product's unique characteristics and developing a marketing plan around its strengths and weaknesses. His turnaround experience was evident in the optimization of anti-hypertensive aliskiren. The product had poor uptake in the market due to apathy from cardiologists who were focused on competitors with extensive cardiovascular mortality data. Ken and his team

[20] United PAH Support. https://www.unitedpahsupport.com/what-is-pah/who-functional-class/

recognized the unique benefit to the kidneys and potent anti-proteinuric effects of the drug which can delay kidney disease. With this data in hand, marketing was shifted towards nephrologists which helped drive penetration. CFO Mark Oki has held financial roles at a number of life sciences companies and has been integral to executing numerous asset transactions during his career at Alexza Pharmaceuticals and Pharmacyclics as well as the Pancreaze integration at Vivus.

The Vivus team has identified several strategies in its turnaround efforts. These include a focus on gaining share, understanding a product's unique characteristics, optimizing these attributes to address the needs of patients and making it easy for consumers.

**Vivus Health Platform**

Vivus is in the process of building and launching a platform that will integrate medical, pharmaceutical, nutritional and information technology to help patients and their medical care team identify and manage their ideal weight. This approach will employ wearable mobile devices such as medical wristwatches that are able to be monitored by the patient and managing physician in real time. Some of the inputs that will upload to the platform include sleep patterns, EKG, weight, BMI, blood pressure and diet.

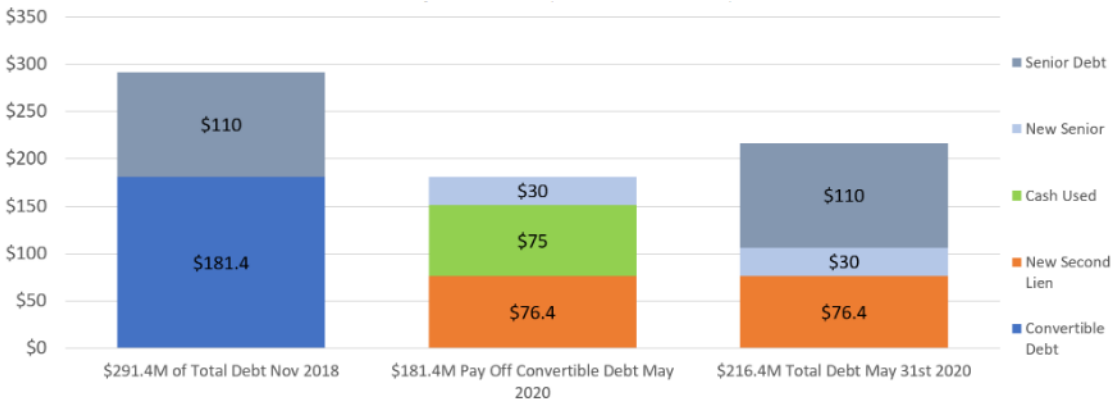
In addition to the technology related efforts, Vivus will also implement physician sampling programs to familiarize both doctors and patients with the products. Co-pay cards will also be provided which will reduce patient out-of-pocket costs and vitamins and nutritional supplements will be made available through an online portal and added as a complement to medication use.

Telemedicine is another component of the solution that Vivus will layer on its platform to improve the patient experience. Internal Vivus research has indicated that overweight and obese patients are hesitant to discuss weight control with their physicians, possibly due to embarrassment or shame. An article from a few years ago discusses some of the issues that doctors and patients face when trying to address weight during a checkup. Shifting to telemedicine can overcome many of these issues and will allow providers with a focus on weight management and allow patients to hold an appointment from the comfort of home, and receive their medication in the mail within a day. The addition of mobile monitoring to the mix will allow patients to track their weight through connected scales and vital signs through mobile devices for both Qsymia and Pancreaze patients. Yet another layer of benefit can include meal suggestions and nutritional supplement tracking on the mobile device, providing a virtual counselor. The combination of pharmaceutical, information and nutritional technology will not only simplify starting and maintaining the therapy but can also improve patient loyalty.

**Debt**

Vivus carries $291 million of borrowings on its balance sheet, consisting of senior debt and convertible bonds. $110 million of the total is senior debt held by affiliates of Athyrium Capital Management due in 2024. Interest on the securities is 10.375%. The remaining $184 million is 4.5% interest convertible notes due on May 1st, 2020. The conversion price is substantially out of the money and it is expected that the notes will be settled in cash. Vivus' strategy is to grow topline and EBITDA over the next year sufficient to materially reduce the leverage ratio. The company will also use cash on its balance sheet to repay $30 million of the convertible notes and raise additional funds in debt and/or equity financings to satisfy the remainder on similar terms as the senior secured debt. An alternative may arise if Vivus pursues an acquisition, which will provide additional borrowing capacity and cash flow. Management believes that a deal generating $40 million in EBITDA could provide sufficient capacity to refinance the entire convertible note amount. Total cash interest expense is currently $19.6 million. Based on the anticipated pathway presented by the company, cash interest will increase to $23.48 million under the proposed debt bridge, despite overall lower debt levels due to the refinancing of the 4.5% interest convertible bonds for an anticipated 10.375% interest senior notes.

**Exhibit XV – Debt Bridge: November 2018 to May 2020**




| | | |
|---|---|---|
| • Total Debt as of Nov 2018<br>• $181.4M of Convertible Debt at 4.5% Interest Rate<br>• $110M of Senior Debt at 10.375% Interest Rate with Athyrium Capital<br>• Total Annual Interest Expense of $19.6M | • Use $75M of $115M of VIVUS Cash<br>• Borrow $30M of Senior Debt Pari Passu to Athyrium Capital Terms<br>• Raise $76.4M of Second Lien at ~12% | • Total Debt as of May 31st, 2020<br>• $140M of Senior Debt at 10.375% Interest Rate<br>• Raise $76.4M of Second Lien at ~12% per annum<br>• Total Annual Interest Expense of $23.48M |

- As of May 2020, based on current internal projections of EBITDA, VIVUS should be able to support senior secured debt amounts between $165M and $210M and support second lien debt in the range of $75M to $125M based on industry standard credit metrics as of Nov 2018
- Thus, as of May 2020, VIVUS believes we will have a debt cushion of approximately $23M to $118M

**Manufacturing and Supply Chain**

Vivus uses the services of contract manufacturers to produce drug product on their behalf. Avanafil is manufactured in France with active pharmaceutical ingredient (API) manufactured by Sanofi Chimie and avanafil tablets manufactured by Sanofi Winthrop Industrie. Pancreaze is manufactured in Germany by Nordmark, which also supplies pancrelipase product to other PERT sponsors. Catalent manufactures Qsymia capsules from their Kentucky facility and is also providing development support for VI-0106 to produce a soft gel form for clinical testing.

Zacks continuously highlights the importance of ensuring good practices both internally and with partners who perform manufacturing, testing, packaging and other services. This emphasis is justified given the risk of regulatory agency action highlighting partner oversights and focus on partner compliance in spite of a phamaceutical product that is safe and effective. Vivus and its CMC team have a program in place to ensure that all manufacturing partners are in compliance with regulatory requirements and that there is sufficient supply of product and alternative manufacturing capacity in case of disruption.

**Intellectual Property**

Vivus maintains patent protection for Qsymia and Stendra and Pancreaze is essentially a branded form of a generic. We anticipate that, if approved, VI-0106 will receive seven years of exclusivity from an orphan designation.

As part of a settlement agreement, Actavis (TEVA), will be allowed to manufacture and commercialize a generic form of Qsymia beginning in December 2024. Stendra is expected to see competition in 2025, as generic company Hetero has the right to market avanafil that year. Pancreaze competes in a generic market and does not have any specific patent protection or exclusivity and there are currently several competitors in the market. However, any new animal based pharmaceuticals, such as Pancreaze, must undergo the full NDA approval process. Tacrolimus, if approved, will receive orphan protection, which prevents competition for the specific indication for seven years after approval.

**Vivus History**

Vivus was launched in 1991 as a company focused on both male and female sexual health. It was initially developing Muse[21] (transurethral alprostadil), which was launched in 1997 as the first minimally invasive treatment for erectile dysfunction. In 2010, Vivus sold Muse to Meda for $23.5 million. The company's second product was EvaMist (estridol transdermal spray) which was used to symptoms of menopause and female arousal. EvaMist was

[21] Affectionately known as "The Musket Loader"

sold to KV Pharma in 2007 for ~$140 million and funds from the sale were used to develop Qsymia. After initially being rejected by the FDA due to concerns over psychiatric and cardiovascular issues, Qsymia was later approved in July 2012. Initial hopes for sales were optimistic for Qsymia, given its strong safety and efficacy profile; however, the lack of committed coverage by payors led to mediocre sales. In an effort to pursue the PDE5 class, Vivus brought Mitsubishi Tanabe's avanafil through the FDA approval process and subsequently obtained approval in April 2012. After approval, Vivus outlicensed the product to Menarini in the EU, Australia and New Zealand, Auxilium in the U.S. Endo later acquired Auxilium and returned the U.S rights to Vivus. Upon the return of the U.S. commercial rights, Vivus licensed commercial rights for the U.S., Canada, South America and India to Metuchen.

In early 2017, the company acquired the rights to tacrolimus (VI-0106) from Selten and has launched stability studies in preparation for an IND submission. In 2018, Vivus added a new management team to breathe new life into the current portfolio of products and focus on topline growth, cash flow generation and debt pay down/ refinancing. In mid-2018, the new team launched a turnaround plan which is expected to show material topline improvements by 2H:19.

**Corporate Milestones**

Vivus is executing its corporate turnaround, improving its capital structure and seeking new product opportunities. We list below the key items related to this effort and to the development of VI-0106. Below we list recent milestones and anticipated events over the next several quarters.

- 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
- 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

## RISKS

All investments contain an element of risk which reflects the uncertainty of a business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level of perceived risk.

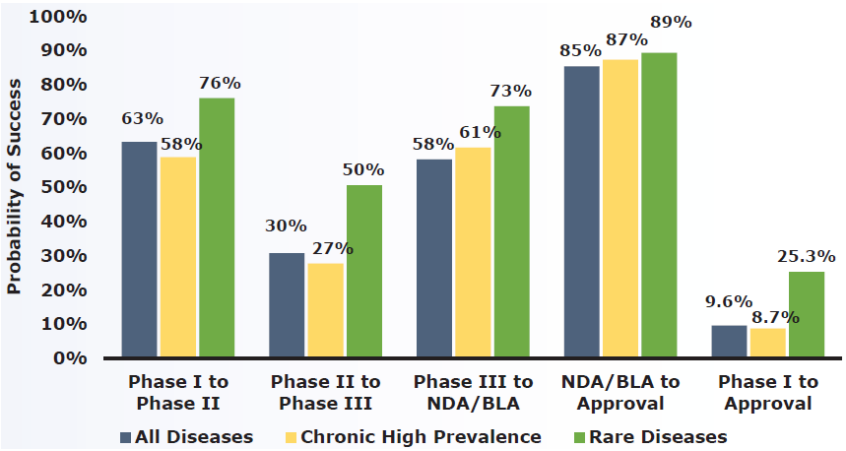
The biotechnology space includes companies at both ends of the spectrum, from mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products.

For smaller companies, with a limited portfolio of products, it can be difficult to leverage a limited salesforce and gain penetration into managed care and other payor formularies on favorable terms. A limited portfolio also means that success is more reliant on one or two products, and unfavorable changes in the environment in therapeutic areas specific to the company's portfolio can have dramatic impacts on revenues and profits. Even if a company has a strong, experienced team with a plan and a large addressable market, success may be elusive.

Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain operations and it is not readily available, the company may be forced to sell assets or equity at a substantial discount to previous valuations and dilute earlier shareholders.

All drugs must navigate the regulatory approval process in the US, EU and other countries before commercialization in those regions. This effort is a material uncertainty which may take years depending upon the needs and desires of the determining authority. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Isolating companies that have a long history of research success in drug development, with opinion leaders and experts in the field are important fundamentals that can help mitigate this risk. Companies that have had previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process. Some accelerated pathways to approval have been put forth such as the Orphan Drug Act, however, changes in sentiment or perceived safety for pharmaceuticals drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place. Approval for medicines indicated for rare diseases has demonstrated a much higher rate of success than for high prevalence diseases as indicated below. Vivus has secured an orphan indication for its sole development asset, VI-0106, and falls into this category. Below we show rare disease candidate success rates for the various phases.

**Exhibit XVI – Approval Success of Rare Disease vs. High Prevalence Diseases[22]**




[22]Clinical Development Success Rates 2006-2015. David Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

Vivus holds three approved and revenue generating products in its portfolio and is developing a fourth. The company may find a partner to advance its development candidate from Phase II to commercialization. The primary risks faced by Vivus are related to commercialization of approved products and competitive actions by other companies in the space. The company is now implementing strategies to stimulate revenue from mature products which may be met by a competitive response from others and from new products in development. While Vivus' management has identified several shortcomings in previous sales strategies and can implement proven techniques for increasing sales, the company's sales targets are not guaranteed.

Regulatory risk can impact both development and approved products. The FDA and other regulatory agencies may require additional studies after approval, such as the CVOT, which was a condition of approval. Commercialization is also difficult, especially for products where there are equivalent competitors and generic competition. New product acquisitions and launches require the hiring and training of a salesforce to market it to appropriate audiences. Each stage of the drug development and commercialization process presents high risk and many precedents of failure exist despite the best efforts of management teams and their employees.

Vivus employs contract manufacturers to produce drug product. Manufacturing facilities that produce drug for sale in the U.S. must acquire FDA approval of its processes and adherence to current good manufacturing processes. Risks of poor manufacturing processes, quality control issues and product delays may postpone ultimate production of a drug if facilities do not comply with regulatory agency requirements. Vivus has developed an internal system to ensure good practices and conformance to guidelines and has verified that sufficient inventory exists in case of production stoppage. For some products, alternate suppliers and supply sources are available if the main supplier is unable to fulfill their obligations. Despite these efforts, unexpected disruptions may occur that delay or halt production and delivery.

Drug price inflation has gained increased attention over the last several years and has contributed materially to the increase in health care costs over the last decades. As new therapies have been approved, drug prices have set new records and increased at a substantial rate. For example, in 1996, new cancer drugs cost roughly $54,000 for each additional year of life they provided. However, by 2013, this amount increased to over $200,000. The inflation rate for established drugs has also been very high. In a Forbes article, an author highlighted Novartis' leukemia drug Gleevec. This drug cost $24,000 in 2001 when it was first approved; and 14 years later, in 2015, had risen to a cost of $90,000. This represents a 10% compound annual growth rate over that period. Other price moves such as the 5,000% price hike for Turing Pharmaceutical's Daraprim and Valeant Pharmaceuticals 500% and 200% price increase for Isuprel and Nitropress combined with similar moves by other companies may create a situation where further increases are unsustainable. We also cite the broad response to Mylan's (NASDAQ: MYL) EpiPen price increases which have pressured the company to offer lower priced alternatives and brought a number of competitors into the market.

We highlight several risks that materialize from these pricing increases. Health care may become unaffordable for a broad segment of the population, reducing the market size to a level below current expectations. Pharmacy benefit managers and other third party payors may continue to remove drugs from their formularies due to price concerns and sharp price increases will attract the attention of elected officials and regulators who may create legislation and implement regulations that limit drug profitability. Additionally, the government may impose additional non-price related regulation and disclosure requirements that can increase costs for the industry. We note Vivus' pioneering efforts to move toward a lower priced direct model for Qsymia, which is expected to have a dramatic impact on volumes, stem generic competition and address the concerns raised in this section.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by both Vivus and its peers.

## COMPETITORS AND COMPETING THERAPIES

Vivus competes in several therapeutic areas including weight loss, EPI, ED and PAH. Some of these spaces are extremely competitive with other medicines, non-medical approaches and new products in development. Weight loss is one of the most competitive categories, with exercise and diet co-existing with a selection of medications and surgery that can address the condition. In the pancrelipase space, there are six approved products and other non-porcine products in development. The ED market has four competitors in the U.S. and additional ones outside the country. Additionally, three of the competitors offer generic options, a reality that is expected to create additional pricing and volume pressure. While there is no cure for PAH currently available, there are products that can treat the symptoms of the disease and there are competing products in development. Generics do or will play a role in the competitive environment that Vivus faces. We believe that management recognizes and understands this dynamic and is responding appropriately with pricing that is competitive with generics and a full program of support that holistically meets the needs of their patient population.

Below, we highlight several of the key companies that are competing and developing new products in the same therapeutic areas as Vivus. This list is not exhaustive and only represents select companies contributing that participate in the weight loss, EPI, ED and PAH spaces.

**Exhibit XVII – Peers and Competitors[23]**

| Ticker | Company | Price | MktCap (MM) | EV | Therapeutic Area |
|---|---|---|---|---|---|
| JNJ | Actelion (acq by JNJ) | $141.95 | $377,980 | $386,680 | Veletri, Opsumit, Tracleer, Ventavis/PAH |
| RHHBY | Roche | $33.05 | $231,010 | $225,990 | Xenical/Obesity |
| PFE | Pfizer | $40.77 | $226,350 | $249,110 | Viagra/ED |
| NVO | Novo Nordisk | $49.13 | $117,530 | $117,330 | Saxenda/Obesity |
| ABBV | AbbVie | $78.89 | $116,610 | $149,360 | Creon/EPI |
| SNY | Sanofi | $43.41 | $108,470 | $108,940 | Cialis/ED |
| GSK | GlaxoSmithKline | $40.41 | $100,650 | $99,470 | Xenical/Obesity |
| TAK | Takeda | $18.22 | $57,090 | $56,840 | Contrave/Obesity |
| BAYN.DE | Bayer | €59.34 | €55,120 | €95,560 | Levitra/ED;Adempas/PAH |
| 4523.T | Eisai | ¥6,454 | ¥1,850,000 | | Belviq/Obesity |
| UTHR | United Therapeutics | $99.30 | $4,340 | $3,290 | PAH |
| ARNA | Arena Pharma | $44.18 | $2,190 | $1,870 | PAH, Ulcerative colitis |
| ZGNX | Zogenix | $38.46 | $1,630 | $1,130 | Low dose fenfluramine for seizures |
| AZRX | AzurRx | $2.44 | $48.39 | $43.19 | Lipase for EPI |
| pvt | Digestive Care | | | | Pertzye/EPI |
| pvt | Aptalis | | | | Ultresa,Viokase,Zenpep/EPI |
| pvt | Nalpropion Pharma | | | | Contrave/Obesity |
| VVUS | Vivus | $3.70 | $39.4 | $226.1 | Stendra,Qsymia,Pancreaze,VI-0106 |

[23] Price and market capitalization data is as of May 1, 2019.

## MANAGEMENT PROFILES

**John Amos, Director and Chief Executive Officer**

John Amos has served as Chief Executive Officer and director of Vivus since April 2018. From May 2017 to April 2018, he served as the Executive Chairman of Willow Biopharma Inc. He served as the Chief Executive Officer of ORIX Healthcare Capital LLC, a private equity and venture capital investment company, from October 2012 to April 2017. Mr. Amos served as the Operating Partner and Portfolio Company Board Member of BioVeda China Fund, a financial investment company, from February 2008 to October 2012. He served as the Chief Executive Officer and President of the Oncology Therapeutics Network (acquired by McKesson Corporation in November 2007), a physician services company, from June 2005 to November 2007 and was a special advisor to McKesson Corporation, a public healthcare services company, from November 2007 to May 2008. Mr. Amos served as the President of the Oncology Therapeutics Network of Bristol Myers Squibb, a publicly traded biopharmaceutical company, from June 2003 to May 2005. He held executive roles in finance and technology in McKesson Corporation from March 1995 to April 2003. From 1991 to 2003, he served in the United States Air Force and the California Air National Guard in Tactical Fighter Operations. Mr. Amos has previously served on the board of directors of TD2, Navigating Cancer, CITIC Pharmaceuticals, Aesyntix Health, Prodigy Health, Apollo Health Street, Quinian Health, Oncology Therapeutics Network and Matawan Pharmaceuticals. Mr. Amos served as a member of the Scientific Advisory Board at MD Anderson Cancer Center Institute for Applied Cancer Science (IACS) and was a health policy advisor to Governor Jeb Bush's 2016 Presidential Campaign. He has been appointed as a Trustee of the Global Leadership Council of the University of California, Davis Foundation. Mr. Amos has been named to the Information Week Top 500 CIO's twice, won the Frost and Sullivan Award for Corporate Innovation. He studied Economics at the University of California, Davis and has a B.S. in General Business from the University of the State of New York.

**Kenneth Suh, President**

Kenneth Suh has served as Vivus' President since August 2018. Prior to that, Mr. Suh, founded Willow Biopharma Inc., and served as its President and Chief Executive Officer and as a director. In April 2018, Willow Biopharma Inc. became a wholly-owned subsidiary of Vivus, and Mr. Suh was re-appointed as the President and Chief Executive Officer at that time. He also founded KRIM Biopharma Inc. in 2013 and served as President and Chief Executive Officer from August 2013 to August 2015 and as a director from August 2013 to August 2015. Mr. Suh held the following roles for Novartis Pharma Canada: Franchise Lead from 2012 to 2013, Brand Manager from 2010 to 2012, Associate Brand Manager from 2009 to 2010 and Medical Representative from 2006 to 2009. He received a Bachelor of Commerce, Honors Program from the University of Guelph, Ontario.

**John L. Slebir, Esq., Senior Vice President, Business Development and General Counsel**

John L. Slebir, Esq. joined Vivus in September 2009. Since January 2014, Mr. Slebir has served as Senior Vice President, Business Development and General Counsel, and, since June 2012, he also has served as Secretary. From June 2011 until January 2014, Mr. Slebir served as Vice President, Business Development and General Counsel, from January 2011 until June 2011, he served as Vice President, General Counsel, and, from September 2009 until January 2011, he served as General Counsel on a part-time basis. From March 1999 to January 2011, Mr. Slebir served as an attorney at Wilson Sonsini Goodrich & Rosati, P.C., specializing in corporate securities and corporate governance. Prior to joining Wilson Sonsini Goodrich & Rosati, P.C., Mr. Slebir was an attorney at two prominent Bay Area law firms specialized in insurance defense litigation. Mr. Slebir holds a B.A. in Communications from San Diego State University and a J.D. from Santa Clara University School of Law.

**Scott Oehrlein, Chief Operations Officer**

Scott Oehrlein has served as Vivus' Chief Operations Officer since April 2018. From November 2017 to April 2018, he served as the Global Chief Operations Officer of Willow Biopharma Inc. He served as Vice President and Head of General Medicines Sales/Diabetes and CV Sales, US Sanofi, from April 2014 to June 2017. Mr. Oehrlein held various roles for Novartis Pharmaceuticals Corporation from August 2004 to April 2014 including Vice President, Head of Primary Care Sales US from April 2012 to April 2014, General Manager South Operating Unit from August 2011 to March 2012, and Vice President Primary Care Franchise, Novartis Canada Montreal from January 2009 to July 2011. He began his career as a sales representative with The Upjohn Company, a global pharmaceutical company, in 1989 before moving into multiple leadership roles in sales and marketing. He received a B.A. in Biology and Pre-Medicine from Franklin and Marshall College.

**Mark K. Oki, Senior Vice President, Chief Financial Officer and Chief Accounting Officer**

Mr. Oki has been Vivus' Senior Vice President, Chief Financial Officer and Chief Accounting Officer since February 2019 and was Vivus' Chief Financial Officer and Chief Accounting Officer from October 2015 through February 2019. Prior to joining the company, Mr. Oki served as Chief Financial Officer of Alexza Pharmaceuticals, Inc., a publicly traded pharmaceutical company, from July 2012 to October 2015, as Principal Accounting Officer from May 2010 to October 2015, as Principal Financial Officer and Secretary from December 2011 to October 2015, as Vice President, Finance and Controller from February 2010 to July 2012, and as Controller from April 2006 to February 2010. From June 2001 to April 2006, Mr. Oki served as the Controller of Pharmacyclics, Inc., a publicly traded development stage pharmaceutical company. From 1998 to 2001, Mr. Oki held several positions at Incyte Genomics, Inc., now Incyte Corporation, a publicly traded company, including most recently as Assistant Controller. From 1992 to 1997, he held several positions at Deloitte & Touche LLP, a public accounting firm. Mr. Oki received a B.S. in Business Administration with a concentration in Accounting from San Jose State University.

**Santosh T. Varghese, MD, Vice President, Chief Medical Officer**

Dr. Varghese has been Vivus' Vice President, Chief Medical Officer since January 2016. From October 2013 to December 2015, Dr. Varghese served as the company's Vice President, Medical & Regulatory Affairs, Pharmacovigilance, and QA. He joined the company in March 2012 as Vice President, Head of Medical Affairs. Prior to joining the company, Dr. Varghese was Senior Vice President, Medical Affairs at Élan Pharmaceuticals where he lead Medical Affairs teams responsible for the BioNeurology portfolio. He held the position of Vice President Primary Care & Cardiovascular in Global Medical Affairs at Schering-Plough/Merck, and also held senior roles at Aventis/Sanofi-Aventis where he contributed to both U.S. and global brand strategy and tactics. Dr. Varghese has served on the Board of Directors of the American Lung Association - New York, and was on faculty at Touro University College of Medicine. Dr. Varghese earned his M.D. from St. George's University School of Medicine, and B.S. in Biology from Pennsylvania State University. He completed his medical training in the Caribbean, United States and United Kingdom.

## Financial Results

Vivus announced first quarter 2019 results on April 30, 2019 in conjunction with the issuing of their Form 10-K. First quarter operational results captured the relaunches of both Qsymia and Pancreaze as they transition to more efficient and effective structures. During the period, the Qsymia Advantage Program was launched, which employs the direct model and was extended to ~450 providers. So far this year under the direct model, Qsymia prescriptions per day went from 9 in January to 30 in March and 45 in April, increasing sharply off of a small base. Total Qsymia shipments and prescriptions were down year over year and we expect continued volatility for the next few months as the new program takes hold. In Europe, Vivus expects to submit a Marketing Authorisation Application (MAA) and seek decentralized approval in six countries.

Pancreaze was transitioned to the Vivus salesforce in January 2019 with 10 representatives advancing the effort. New patient starts were up 13.4% sequentially in the first four weeks post launch. We see first quarter revenues as a baseline for future quarterly growth. Pancreaze will also assume additional distribution costs following the transition from Janssen. Vivus plans to assume direct control of the Canadian operations mid-year and will recognize Canadian Pancreaze revenues as product revenues in place of royalties at that time.

Total revenue for the first quarter was $16.1 million compared to $11.9 million in 1Q:18 with the growth entirely attributable to the acquisition of Pancreaze in June 2018. By segment, for the January to March period, Qsymia product revenues were $8.4 million, down 12.6% over the prior year, Pancreaze was $5.1 million compared to no recognized revenues in the prior year, and Supply/Royalty revenue was $2.6 million up 16.8%.

Total cost of goods sold was $4.3 million. When broken down by product, this represents a gross margin of 84% for Qsymia, 71% for Pancreaze and 9% for Stendra/Spedra supply revenue. SG&A of $9.8 million was down 2.5% over the prior year as declines in general and administrative expenses outweighed a rise in selling and marketing expenses. Research and development expenses were up 76% to $2.5 million. The increase was due to the Qsymia adolescent safety and efficacy study and post-marketing requirement spend for Pancreaze

The balance sheet held $105 million in cash and equivalents and $291 million of debt as of March 31, 2019. This compares to year end 2018 cash levels of $111 million and debt of $291 million. Cash burn for 1Q:19 was ($7.0) million compared to ($12.0) million in 1Q:18. Cash provided by financing was $43.8 million in 2018 as debt was refinanced and new debt was issued.

## VALUATION

Vivus is relaunching its Qsymia and Pancreaze products with a focus on increased provider interaction, technology and nutrition. Stendra/Spedra will continue to be partnered with an effort to expand into new territories. An IND is expected to be submitted on behalf of development candidate VI-0106 later this year with the pace of development dependent on the availability of discretionary cash and availability of a partner. Vivus has identified several opportunities to stimulate sales for both Qsymia and Pancreaze which we expect will be successful. The new direct pricing model for Qsymia recognizes the price elasticity for the product, and we forecast a sharp improvement in units as 2019 progresses. Pancreaze was a smaller asset at Janssen and was overlooked; however, increased attention by Vivus, physician interaction by the salesforce and tailoring the product as a solution to the patients' needs is expected to increase market share.

Qsymia generated $40.6 million in product revenues in 2018 and we expect a dip in the first half of 2019 as the transition to the direct model takes place then a quick ramp up in 2H:19. We anticipate that in 2020, the program will be in full swing and Vivus will be able to achieve a double digit sales increase over the next few years. Gross margins were 88% in 2018 and we anticipate a reduction to 85% as realized revenue for the product is slightly lower following the conversion to the direct model. The model does not reflect sales from Europe; however, these will be reflected if approval is obtained and commercialization partners are secured.

Pancreaze generated an estimated $29 million in revenues in 2018, and we expect first quarter revenues to represent a baseline for growth as the year progresses. On an annualized basis we see 2019 Pancreaze revenues as below 2018 levels; however, the impact from the new sales strategy is expected to drive double digit growth in 2020 and beyond at an accelerating pace. Gross margins for the product are estimated to be 66% in 2019, which is below the 68% gross margin recognized in 2018. We anticipate improvement in Pancreaze gross margin as sales increase and management identifies efficiencies.

Stendra/Spedra has suffered revenue declines following the shift to generics for several competitors. Revenues for both supply and royalty in 2018 were $7.2 million which yielded $2.4 million in gross profit. We anticipate double digit contraction in Stendra/Spedra royalties which may be partially offset by entry into new geographies. We do not anticipate any material management time to be spent on this product and frame it as a declining annuity.

Our valuation model does not reflect a component for VI-0106; however, we anticipate adding this following a successful IND and the start of a Phase II trial. Despite a small addressable population, we anticipate attractive pricing and a rapid trek to market upon the grant of an expedited approval pathway. Other factors that may add to our valuation include approvals for additional Qsymia indications and future Qsymia sales in Europe, a new acquisition and geographical expansion in other regions.

2018 expenses, excluding amortization, were $60 million. We anticipate an increase to $68 million in 2019 due to several factors. Higher cost of product sales from a full year of Pancreaze sales and an increase in the sales representative count will hike SG&A expense and the adolescent study for Qsymia will push up R&D. Expenses in 2020 are anticipated to fall slightly on better gross margins and lower R&D slightly offset by an increase in SG&A. As of December 31, 2018, Vivus held approximately $631 million and $274 million of net operating loss carryforwards to offset its future federal and state taxable income. Over the forecast period in our model we do not recognize any cash taxes.

Our target price is generated using a combination of valuation multiples applied to future earnings per share and EBITDA. We apply a 20x price to earnings multiple to 2022 adjusted earnings and discount the result at 15% to present. We apply an 8x EBITDA multiple to 2022 EBITDA and discount that value to present at the same rate. Our target price is generated by averaging the two values.

Based on the assumptions identified in our valuation approach we generate a target price of $10.00.

## CONCLUSION

Vivus has a portfolio of products that can achieve successful growth profiles with the application of basic sales fundamentals, augmented by the Vivus Health Platform. The platform combines pharmaceutical, nutritional and distribution technology that centers on solving and simplifying a patient's problem.

The management team has recognized some of the inherited shortcomings in both the Qsymia and Pancreaze sales strategies and is making the necessary adjustments to improve market penetration. After conducting several price elasticity studies and gaining greater understanding about obese patients' hesitancy to undergo treatment, Vivus has changed its pricing. It has moved to a lower, flat price for all dosages and will provide direct home delivery of Qsymia after an online visit with a physician specializing in obesity.

Pancreaze received little attention from Janssen and as a result only held three percent of market share. Vivus recognized that the product could achieve a sharp improvement with more attention given to physicians and patients. Recognizing that the application of basic sales strategies could substantially improve performance, Vivus bought the asset. Since the transfer, Vivus has launched a sales force which will call on physicians regularly. Patient support and access will be another goal of the program which seeks to make the patients' life easier. Some examples of specific efforts include education of new parents of a CF child about the importance of nutrition, the addition of vitamins to the prescription and co-pay support. These additions are expected to improve loyalty and increase brand recognition of Pancreaze.

While the company is facing a substantial debt cliff next year, we anticipate a successful resolution. With partial payment from cash on hand and favorable refinancing anticipated following an improvement in topline and profit margins, Vivus will be in good shape to address the convertible notes that come due in May 2020.

While we have not added a valuation component to recognize potential acquisitions, Vivus has a disciplined strategy that seeks an asset within their valuation constraints and is facing difficulties that management has experience resolving. Adding a new asset would have several benefits including an improvement in debt ratios, the leverage of corporate expenses and the opportunity to refinance existing debt at favorable rates and for a longer term.

Key reasons to own Vivus' shares:

- **Current portfolio of revenue generating products**
- **Disciplined focus on cash flow and debt refinancing**
- **Implementing proven sales strategies to improve Pancreaze market share**
- **Direct sales approach and rationalized pricing to drive Qsymia revenue growth**
- **Additional regions available for Stendra/Spedra penetration**
- **Rights to development asset for PAH**
- **M&A efforts prioritize valuation and turnaround opportunities**
    - **ROIC Limits**
    - **Market Barriers**
    - **Significant Clinical Following**
    - **Identifiable Turnaround Strategy**

In summary, we see a defined strategy to solve the primary difficulties that the company faces. The management team has the knowledge and experience to execute on these priorities and has provided detailed specifics on necessary steps to drive topline sales and improve the 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. Based on our analysis, forecasts and multiples applied to earnings and EBITDA, we initiate Vivus with a target price of $10.00.

## PROJECTED FINANCIALS

### VIVUS, Inc. - Income Statement

| VIVUS, Inc. | 2018 A | Q1 A | Q2 E | Q3 E | Q4 E | 2019 E | 2020 E | 2021 E | 2022 E |
|---|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$65,062** | **$16,146** | **$16,875** | **$19,175** | **$20,500** | **$72,696** | **$80,927** | **$90,214** | **$100,574** |
| Cost of Product Sales | $14,704 | $4,308 | $4,725 | $5,150 | $5,449 | $19,632 | $19,926 | $20,005 | $21,834 |
| *Gross Margin* | *77.4%* | *73.3%* | *72.0%* | *73.1%* | *73.4%* | *73.0%* | *75.4%* | *77.8%* | *78.3%* |
| 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 | $9,600 | $9,700 | $9,700 | $38,818 | $39,060 | $40,180 | $41,000 |
| R&D | $7,347 | $2,469 | $2,650 | $2,350 | $2,365 | $9,834 | $8,700 | $8,000 | $8,000 |
| Operating Income | ($3,479) | ($4,087) | ($3,738) | ($1,663) | ($652) | ($10,140) | ($1,310) | $7,477 | $15,189 |
| *Operating Margin* | *-5.3%* | *-25.3%* | *-22.2%* | *-8.7%* | *-3.2%* | *-13.9%* | *-1.6%* | *8.3%* | *15.1%* |
| Interest & Other Expense | $33,419 | $3,870 | $4,900 | $4,900 | $4,900 | $18,570 | $21,850 | $23,500 | $23,500 |
| Pre-Tax Income | ($36,898) | ($7,957) | ($8,638) | ($6,563) | ($5,552) | ($28,710) | ($23,160) | ($16,023) | ($8,311) |
| Taxes & Other | $52 | ($8) | $0 | $0 | $0 | ($8) | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Net Income | ($36,950) | ($7,949) | ($8,638) | ($6,563) | ($5,552) | ($28,702) | ($23,160) | ($16,023) | ($8,311) |
| **Reported EPS** | **($3.48)** | **($0.75)** | **($0.81)** | **($0.61)** | **($0.52)** | **($2.69)** | **($2.13)** | **($1.47)** | **($0.75)** |
| **Adjusted EPS** | **($2.67)** | **($0.41)** | **($0.47)** | **($0.27)** | **($0.18)** | **($1.33)** | **($0.79)** | **($0.13)** | **$0.56** |
| Shares Outstanding | 10,621.0 | 10,637.0 | 10,670.0 | 10,690.0 | 10,700.0 | 10,674.3 | 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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