VIVUS INC
Form DEFA14A
May 14, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant x

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Check the appropriate box:

o Preliminary Proxy Statement
o **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
o Definitive Proxy Statement
o Definitive Additional Materials
x Soliciting Material under §240.14a-12

VIVUS, INC.
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

x No fee required.
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(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

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(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

On May 13, 2013, VIVUS, Inc., or the Company or VIVUS, released a letter to the Company s stockholders updating the stockholders on recent developments in the Company s business. A copy of the letter is attached as Exhibit 1.

Important Additional Information

VIVUS, its directors and certain of its executive officers may be deemed to be participants in the solicitation of proxies from VIVUS stockholders in connection with the matters to be considered at VIVUS s 2013 Annual Meeting of Stockholders. VIVUS has filed a preliminary proxy statement with the U.S. Securities and Exchange Commission (the SEC) in connection with any such solicitation of proxies from VIVUS stockholders. INVESTORS AND STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND ACCOMPANYING PROXY CARD AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION. Information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, is set forth in the preliminary proxy statement and other materials to be filed with the SEC in connection with VIVUS s 2013 Annual Meeting of Stockholders. Information regarding the direct and indirect beneficial ownership of VIVUS s directors and executive officers in VIVUS securities is included in their SEC filings on Forms 3, 4 and 5, and additional information can also be found in VIVUS s Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on February 26, 2013, Amendment No. 1 to VIVUS s Annual Report on Form 10-K/A, filed with the SEC on April 30, 2013, and in VIVUS s preliminary proxy statement on Schedule 14A in connection with VIVUS s 2013 Annual Meeting of Stockholders, filed with the SEC on May 13, 2013. Stockholders can obtain any proxy statement, any amendments or supplements to the proxy statement and other documents filed by VIVUS with the SEC for no charge at the SEC s website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of VIVUS s corporate website at www.vivus.com.

Exhibit 1

May 13, 2013

Dear Fellow Stockholder:

I am writing to update you regarding our recent accomplishments. Since Qsymia® (phentermine and topiramate extended-release) capsules CIV was approved last year, our strategic objectives have been to raise awareness of its benefits among healthcare providers specializing in metabolic disease and to remove barriers to patient access while maintaining full control of this highly valuable asset. We believe that our recent progress has greatly improved our options for maximizing stockholder value and we remain open to considering a broad range of opportunities to achieve this important goal. To this end, we have begun discussions with large pharmaceutical companies to explore how we can work together to increase reach to prescribing physicians and the public. We believe this is critical to maximizing the value of Qsymia.

Over the past seven months since the launch of Qsymia, VIVUS has successfully built the commercial foundation for the medical obesity treatment category and the Qsymia brand. Prior to the Qsymia launch, obesity was not recognized by providers as a medical condition that warranted treatment. Just this month, the American Association of Clinical Endocrinologists (AACE) published treatment algorithms which include the use of pharmacotherapy as a first-line management for overweight and obese patients with prediabetes, diabetes, and other obesity-related co-morbidities. Before we entered the market, reimbursement for branded medication in this category was nonexistent. Because of our extensive effort with payors, we have attained access to Qsymia for 34% of commercial lives in the U.S., and the Veterans Administration (VA) has recently added Qsymia to its national formulary. This is the fundamental work that needed to be accomplished in order to build a new medical treatment category, and we have made great progress through these efforts.

In mid-April, VIVUS successfully achieved another major milestone in our ongoing commercialization efforts with FDA approval of our Risk Evaluation and Mitigation Strategy (REMS) modification for Qsymia. This approval will allow patients to access Qsymia at certified retail pharmacies nationwide. Since the approval, we have been busy executing the implementation plan to ensure certified retail pharmacy availability of Qsymia by mid-July 2013.

VIVUS has built sustainable momentum with cardiometabolic specialists and accomplished several key milestones that set the foundation for the medical obesity treatment category. One of our most important goals for 2013 is the expansion of both access and reimbursement for Qsymia, the only FDA-approved oral medication shown to achieve more than 10% average weight loss in obese patients.

VIVUS HAS ACHIEVED IMPORTANT MILESTONES FOR QSYMIA AND STENDRA

In 2012, despite a difficult FDA environment, we successfully developed and achieved FDA approvals for Qsymia and STENDRA (avanafil).

In the case of Qsymia, the approval came with a REMS and Elements To Assure Safe Use including allowing distribution only by certified mail order pharmacies. The recent FDA approval of our amendment and modification to the REMS for Qsymia is an important accomplishment in our ongoing commercialization strategy. This critical milestone indicates broader and improved patient access to Qsymia through thousands of certified retail pharmacies, and significantly simplifies the prescribing and dispensing process for healthcare providers.

Both Qsymia and STENDRA were internally developed and VIVUS has maintained full ownership of these assets, providing us with the flexibility to pursue a full range of options to maximize stockholder value.

VIVUS HAS SUCCESSFULLY EXECUTED
THE INITIAL PHASE OF ITS COMMERCIAL STRATEGY

Since the approval of Qsymia, our team has hit the ground running. Under the oversight of our Board, VIVUS management has implemented a clear, consistent and ongoing strategy to build a successful Qsymia franchise. We have proactively educated healthcare providers (specifically, cardiometabolic specialists and other key opinion leaders) about obesity as a chronic medical condition requiring treatment and educated these thought leaders about Qsymia s favorable efficacy and safety profile. As of March 31, 2013, we have made nearly 90,000 calls on 25,000 targeted healthcare providers, and since launch we have trained more than 300 physician speakers who have conducted approximately 800 peer-to-peer programs for more than 9,300 participating attendee physicians. We also have conducted continuing medical education programs for over 13,000 healthcare providers. Additionally, as of March 31, 2013, more than 39,500 unique patients have been dispensed a prescription for Qsymia since launch.

WITH EXPANDED ACCESS AND REIMBURSEMENT,
WE BELIEVE THAT QSYMIA CAN BECOME A TOP-SELLING DRUG

Providing retail access to Qsymia through certified pharmacies, the next step in our commercialization strategy, is well underway and is expected to be introduced by mid-July 2013. This phase of our strategy includes the certification of thousands of retail pharmacies, stocking of Qsymia in the distribution system and the continued notification of the product s availability to prescribers and patients. Once completed, healthcare providers will be able to send patients directly to certified pharmacies to fill their Qsymia prescriptions, which will significantly reduce time between provider-patient discussions and initiation of therapy. **We believe that the proven clinical efficacy and broader access for patients through certified retail pharmacies will result in significant prescription growth, and will help Qsymia realize its potential to become a top-selling drug.**

We have made significant progress in our reimbursement efforts. Qsymia is currently available on the Express Scripts national formulary, and in April 2013, we successfully entered into an agreement with Medco Health Solutions (Medco) whereby Qsymia has been added to the Medco national formulary. Under the agreement, patients covered by Medco will have a co-payment of approximately $50.00 to $60.00 for a monthly prescription of Qsymia. **These formulary agreements with the largest Pharmacy Benefit Managers (PBM) in the U.S. should significantly reduce out-of-pocket costs for many patients who are prescribed Qsymia and should support continued patient and clinician adoption.** The Veterans Administration National PBM recently published a Criteria for Use for Qsymia. Now veterans whose body mass index (BMI) and other health criteria fall within the Qsymia label can access Qsymia for a co-pay of $9.00. Clearly, decision makers at Medco, Express Scripts and the VA have taken significant steps to address medical obesity within their membership.

We also were pleased to see published in *Health Economics Review* (Feb-2013) a study demonstrating that effective medical treatment providing 10% to 15% weight loss can lead to significant reductions in Medicare spending by reversing or mitigating health consequences such as type 2 diabetes, hypertension and dyslipidemia in obese or overweight patients. These types of data are critical to potential payors and public policy makers as they demonstrate the positive impact that an effective weight loss therapeutic drug can have on healthcare costs. **We believe that the medical obesity category is emerging and the drug treatment rate for this indication will increase.** For example, the American Association of Clinical Endocrinologists has incorporated obesity management and FDA-approved anti-obesity medications - along with lifestyle modifications - into a new comprehensive treatment algorithm for individuals with prediabetes, diabetes, dyslipidemia and hypertension.

WE REMAIN COMMITTED TO QSIVA APPROVAL IN EUROPE AND INTEND TO FILE IN OTHER TERRITORIES AROUND THE WORLD

As evidenced by the recent withdrawal of a competitive product s marketing authorization application (MAA) from the centralized procedure in Europe, the regulatory environment in Europe remains challenging for new obesity therapies. For us, Europe remains an important opportunity. We are currently working with our European team of clinical, legal, and regulatory advisors to evaluate and confirm our regulatory strategy in Europe, which may include a near-term filing of an MAA under the decentralized procedure in selected countries. Longer-term, we may utilize interim data from our Cardiovascular Outcomes Trial (CVOT) to file in the remainder of the countries.

VIVUS RECENTLY RECEIVED A POSITIVE RECOMMENDATION SUPPORTING APPROVAL OF THE EUROPEAN VERSION OF STENDRA

VIVUS recently announced that the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorization in the European Union for SPEDRA (avanafil), for the treatment of erectile dysfunction. This positive opinion is another important milestone in the VIVUS regulatory track record and positions us to participate in a large opportunity in the European market. We remain focused on monetizing the value of the STENDRA asset for stockholders, and we are engaged in partnership talks with several companies for commercialization in the U.S. and international markets.

THE VIVUS BOARD OF DIRECTORS IS ACTIVELY ENGAGED IN OUR COMPANY S FUTURE. THE VIVUS BOARD CONSISTS OF NINE HIGHLY-QUALIFIED DIRECTORS, SEVEN OF WHOM ARE INDEPENDENT AND FOUR OF WHOM WERE APPOINTED WITHIN THE LAST THIRTEEN MONTHS

The VIVUS Board of Directors has played a critical role in our recent progress and in positioning VIVUS with the flexibility to maintain a full range of options to opportunistically maximize value for all of our stockholders. The Board is comprised of proven business leaders who possess a broad range of management, financial, clinical and operational experience, as well as expertise in the biopharmaceutical industry and other areas important to VIVUS. To further accelerate execution of the VIVUS strategy, the Board recently appointed three new highly-qualified independent directors: Robert N. Wilson, chairman of Mevion Medical Systems and former vice chairman of the Board of Directors of Johnson & Johnson; J. Martin Carroll, former senior executive at Boehringer Ingelheim; and Jorge Plutzky, M.D., a leading clinician, researcher and scientist. The VIVUS Board consists of nine highly-qualified directors, seven of whom are independent and four of whom were appointed within the last thirteen months.

Mr. Wilson served in several key roles at Johnson & Johnson, including the Executive Committee from 1983 through 2003 and Vice Chairman of the Board of Directors from 1988 through 2003. Mr. Wilson played a key role in the rapid growth of the pharmaceutical, device and diagnostic businesses within Johnson & Johnson. He is a highly qualified and experienced professional with proven leadership in the healthcare industry and invaluable expertise in pharmaceutical development, brand building and operations.

Mr. Carroll served in a number of top roles at Boehringer Ingelheim including Head, Global Strategy and Development and Managing Director, President and Chief Executive Officer, U.S. from 2003 through 2011. During his tenure, Mr. Carroll was instrumental in guiding the launch of Spiriva® and Pradaxa® in the U.S. In addition, he was involved in the diabetes market through BI s partnership with Eli Lilly and the launch of Tradjenta®, a novel option for treating type 2 diabetes. Mr. Carroll played a major role in working with the BI board of managing directors to develop strategic approaches for a number of BI businesses, focusing mainly on pharmaceuticals.

Dr. Plutzky is Director of the Vascular Disease Prevention Program, which includes the Lipid/Prevention Clinic, in the Cardiovascular Medicine Division at Brigham and Women s Hospital, a role he has held since 1996. He is internationally recognized as an expert in both the basic science and clinical issues related to lipid disorders and cardiometabolic disease. Dr. Plutzky is known particularly for his broad interdisciplinary background that spans endocrinology and cardiology, and for his extensive experience with biotechnology and pharmaceutical concerns, as well as regulatory affairs. He is a member of the scientific advisory boards of the Sarnoff Cardiovascular Research Foundation and Ember Therapeutics, and he has also been elected to the American Society for Clinical Investigation.

We look forward to their contributions as we continue to execute critical steps in our commercialization strategy.

We also recently announced that Richard Fante, former president U.S., CEO North America and regional vice president Americas at AstraZeneca, has agreed to provide advisory services to the Company. Mr. Fante s vast experience and unique perspectives building several primary care products into market-leading brands will be extremely valuable as we seek to expand Qsymia s primary care presence.

You should also be aware that a dissident stockholder, First Manhattan Co., has nominated six of its own hand-picked representatives to replace existing members of your Company s Board of Directors and effectively seize control of your Company. We strongly believe that a near-complete turnover of the Board at this time would significantly jeopardize the progress we are making toward our strategic objectives and is not in the best interest of stockholders. We intend to vigorously oppose First Manhattan s hostile solicitation and urge you to DISREGARD ALL WHITE PROXY CARDS SENT TO YOU BY FIRST MANHATTAN. We expect to communicate more fully about this in the near future.

VIVUS HAS SIGNIFICANT OPPORTUNITIES AHEAD

VIVUS is at a critical juncture in its development. We believe in the value of our franchises and our ability to successfully commercialize Qsymia.

In connection with the upcoming VIVUS 2013 Annual Meeting of Stockholders, you can expect to hear more from the VIVUS team about the progress we are making in commercializing and developing innovative, next-

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generation therapies to address unmet needs around the world and how we are driving value for all of our stockholders.

On behalf of the VIVUS Board of Directors and management team, I appreciate the continued interest and support of all of our stockholders.

/s/
Leland F. Wilson
Chief Executive Officer

About Qsymia

Qsymia is approved in the U.S. and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes, or high cholesterol.

The effect of Qsymia on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established.

Important Safety Information

Qsymia® (phentermine and topiramate extended-release) capsules CIV is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors (MAOIs); or in patients with hypersensitivity to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Females of reproductive potential should have a negative pregnancy test before treatment and monthly thereafter and use effective contraception consistently during Qsymia therapy. If a patient becomes pregnant while taking Qsymia, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

About Avanafil

STENDRA (avanafil) is approved by the FDA for the treatment of erectile dysfunction, or ED, in the U.S. VIVUS, through collaboration arrangements with third parties, intends to market and sell STENDRA in the U.S., and if approved, under the trade name SPEDRA in the EU and other territories outside the U.S. Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian Pacific Rim countries.

VIVUS is currently in discussions with potential partners to commercialize STENDRA in the United States and other territories throughout the world.

It is recommended that STENDRA should be taken approximately 30 minutes before sexual activity. STENDRA should not be taken more than once per day. For more information about STENDRA, please visit www.Stendra.com.

Important Safety Information

STENDRA (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.

STENDRA may affect the way other medicines work. Tell your healthcare provider if you take any of the following; medicines called HIV protease inhibitors, such as ritonavir (Norvir), indinavir (Crixivan), saquinavir (Fortavase or Invirase) or atazanir (Reyataz); some types of oral antifungal medicines, such as ketoconazole (Nizoral), and itraconozale (Sporonox); or some types of antibiotics, such as clarithromycin (Biaxin), telithromycin (Ketek), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including STENDRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of STENDRA.

Drinking too much alcohol when taking STENDRA may lead to headache, dizziness, and lower blood pressure.

STENDRA in combination with other treatments for ED is not recommended.

STENDRA does not protect against sexually transmitted diseases, including HIV.

The most common side effects of STENDRA are headache, flushing, runny nose and congestion.

Please see full patient prescribing information for STENDRA (50 mg, 100 mg, 200 mg) tablets.

About VIVUS

VIVUS is a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity and sexual health. For more information about the company, please visit www.vivus.com.

Forward Looking Statements

This letter contains forward looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward looking words or phrases such as may, believe, expect, forecast, intend, anticipate, predict, should, planned, likely, estimated, and potential, the negative use of these words or other similar words. All forward looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our limited commercial experience with Qsymia® in the United States, or U.S.; (2) the timing of initiation and

completion of the clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA; (3) the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; (4) the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements; (5) the impact of distribution of Qsymia through a certified home delivery pharmacy network; (6) our ability to implement the recently FDA approved amendment to the REMS for Qsymia, which, allows dispensing through certified retail pharmacies; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) the negative opinion of the European Medicines Agency s, or EMA, Committee for Medicinal Products for Human Use, or CHMP, for the Marketing Authorization Application, or MAA, for Qsymia; (9) our ability to successfully commercialize Qsymia or establish a marketing partnership for avanafil; (10) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (11) our history of losses and variable quarterly results; (12) substantial competition; (13) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (14) uncertainties of government or third party payor reimbursement; (15) our reliance on sole source suppliers; (16) our reliance on third parties and our collaborative partners; (17) our failure to continue to develop innovative investigational drug candidates and drugs; (18) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (19) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (20) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (21) the results of post-marketing studies are not favorable; (22) compliance with post-marketing regulatory standards is not maintained; (23) the volatility and liquidity of the financial markets; (24) our liquidity and capital resources; (25) our expected future revenues, operations and expenditures and (26) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, including the Form 10-K for the year ended December 31, 2012, filed with the SEC on February 26, 2013, as amended by the Form 10-K/A filed on April 30, 2013.

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