VIVUS INC
Form DEFA14A
June 05, 2013

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

SCHEDULE 14A

(RULE 14A-101)

INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION

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

Filed by the Registrant x

Filed by a Party other than the Registrant o

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
x Definitive Additional Materials
o 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.
o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(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):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

o Fee paid previously with preliminary materials.
o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

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

(3) Filing Party:

(4) Date Filed:

On June 5, 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 and urging them to vote for the Company s director nominees at the Company s 2013 Annual Meeting of Stockholders. The letter is being mailed to the Company s stockholders. A copy of the letter is attached as Exhibit 1.

Important Additional Information

On June 3, 2013, VIVUS filed a definitive proxy statement and GOLD proxy card with the Securities and Exchange Commission, or the SEC, in connection with the solicitation of proxies for its 2013 Annual Meeting of Stockholders. Stockholders are strongly advised to read VIVUS s 2013 proxy statement because it contains important information. Stockholders may obtain a free copy of the 2013 proxy statement and other documents that the Company files with the SEC from the SEC s website at www.sec.gov or VIVUS s website at www.vivus.com.

Exhibit 1

June 5, 2013

Dear Fellow Stockholder:

At VIVUS s Annual Meeting of Stockholders, scheduled for July 15, 2013, you will make an important decision regarding the future of your investment in the Company. First Manhattan Co. (FMC) is seeking to replace the entire VIVUS Board of Directors with its own slate of nine director nominees in order to advance, in our view, its own interests. We believe the replacement of all of the incumbent directors at the present time is not in the best interest of VIVUS s stockholders.

Under the guidance of the Board of Directors, VIVUS s management team successfully developed and won FDA approval for Qsymia, acknowledged by FMC to be the most effective obesity drug ever developed. Since winning FDA approval in July 2012, VIVUS s Board and management have made valuable progress on our retail commercialization plan for Qsymia and have begun discussions with large pharmaceutical companies to expand our presence with primary care doctors. The campaign by FMC to replace VIVUS s entire Board of Directors, and presumably its management, jeopardizes our progress and puts your investment in VIVUS at risk. **Other than replacing the entire Board and management team, which would likely throw the Company into turmoil at a critical juncture, FMC has failed to articulate a plan as to what they would do differently if they were to take control of VIVUS.** Our independent Board has the relevant expertise, the in-depth understanding of our business, and will provide the continuity necessary to maximize value for all of VIVUS s stockholders.

Your vote is important in this election and we urge you to continue to support the VIVUS Board. To elect VIVUS s Board nominees, we encourage you to vote today by Internet, by telephone or by signing and dating the enclosed GOLD proxy card and returning it in the postage-paid envelope. Please vote each and every GOLD proxy card or GOLD voting instruction form you receive since you may hold shares in multiple accounts.

Consider the following in deciding how to vote at the upcoming Annual Meeting:

VIVUS HAS A CLEAR AND CONSISTENT PLAN TO BUILD A SUCCESSFUL QSYMIA BRAND AND TO INCREASE STOCKHOLDER VALUE

VIVUS s Board of Directors and management team have been consistent in their strategy to ensure commercial success for Qsymia. We are making significant progress in laying the foundation for Qsymia by expanding patient access, gaining payor reimbursement and creating awareness with physicians. **Recent important milestone events have already increased stockholder value and we believe will increase sales in the near future**:

- FDA approval of the Risk Evaluation and Mitigation Strategy (REMS) modification to allow for retail distribution;

- increasing insurance coverage;
- recognition of obesity as a drug treatment category by the American Association of Clinical Endocrinologists (AACE); and
- a recent publication in Health Economics Review that highlights Qsymia s positive impact on Medicare spending and overall patient quality of life.

Increasing Patient Access. The VIVUS management team has recently gained FDA approval allowing retail pharmacy distribution. Following the launch of Qsymia in September 2012, one of our priorities was to obtain approval of our REMS modification to allow access outside of the restrictive mail-order only channel. This important milestone was achieved in April 2013. Retail distribution will allow us to broaden the distribution of Qsymia to thousands of certified retail pharmacies, improve patient access to Qsymia, and significantly simplify the prescribing and dispensing process for healthcare providers.

With the REMS modification approval from the FDA, we have begun developing our initial direct-to-consumer (DTC) campaign. The DTC efforts are focused on encouraging patients to ask their doctor about Qsymia a critical step in increasing consumer awareness and building Qsymia into a top-selling brand. Over the next several months, our team will be diligently focused on the retail roll-out. The retail implementation includes: finalizing wholesaler agreements; building our distribution network; building and validating REMS-compliant databases; enrolling, training and certifying each pharmacy location; shipping product to wholesale and chain distribution centers; stocking certified retail pharmacies; and promoting the availability of Qsymia to prescribing doctors and patients. We expect to announce retail availability by mid-July 2013, at which time we anticipate that Qsymia will be stocked in thousands of certified retail pharmacies.

Broadening Payor Reimbursement. At launch there was minimal insurance coverage for branded obesity medications. Through our efforts, we have obtained coverage for Qsymia patients with insurance plans managed by Express Scripts and Medco Health Solutions. Qsymia is also available to patients treated through the Veterans Administration. Our goal for 2013 is to gain coverage for 50% of the 160 million people with private insurance, at tier 3 or better. With approximately 34% of the 160 million now covered for Qsymia, we are well on our way to achieving this goal.

Creating Physician Awareness. In May 2013, the American Association of Clinical Endocrinologists (AACE) published treatment algorithms that, for the first time, include the use of weight loss drugs as a first-line management for overweight and obese patients. We were encouraged to see AACE address the critical role of effective weight loss drugs and we are confident that other physicians, payors and public policy makers will recognize the significance of these new guidelines. This is a critical step in the formation of a large, chronic, drug treatment category.

We have positioned Qsymia to be a cost-saver for the healthcare system, which we believe will help drive coverage and further adoption. We were encouraged by the recent study published in *Health Economics Review*, which demonstrated that 10% to 15% weight loss can lead to significant reductions in Medicare spending by reversing or reducing health consequences in obese or overweight patients. This study, which included data from our phase 3 clinical trials of Qsymia, highlighted that collectively, among the estimated 11.2 million eligible Medicare patients, the lifetime savings could total in the billions of dollars. This study and the new AACE treatment algorithms mentioned above are important as they demonstrate the positive impact that an effective weight loss therapeutic medication can have on healthcare costs and patient lives. We expect this new information to be instrumental in supporting our efforts to obtain additional coverage from both private and government payors.

Throughout 2013 we expect to continue to expand both access and reimbursement for Qsymia. We have a clear strategy and plan for increasing patient and physician adoption. The Board and management team are critical to continued progress in the future. A wholesale turnover in the Board or management will put at risk the continued successful implementation of this plan.

We are building upon these achievements and others as we enter into the Primary Care Physician expansion phase of our commercial strategy. With these successes, we have also begun discussions with large pharmaceutical companies to explore how we can collaborate to increase our reach to primary care physicians. We remain open to pursuing whichever options maximize stockholder value. **Members of our current Board and our management team are deeply involved in the discussions with large pharmaceutical companies and a complete change of the Board and management during this critical time will likely delay or potentially derail a transaction.**

FMC HAS FAILED TO SHARE ITS PLAN FOR VIVUS AND WHAT IT WOULD DO DIFFERENTLY FROM WHAT IS ALREADY BEING DONE

In contrast to the strategy that your Board and management team are executing, FMC has failed to communicate any detailed strategic or tactical plan for VIVUS. **Other than replacing the entire Board and presumably our management team, which would likely throw the Company into turmoil at a critical juncture, FMC has failed to articulate what they would do differently if they were to take control of VIVUS.** Replacing the Board and management at this stage when discussions are already underway with pharmaceutical companies risks delays and may jeopardize a deal. Relationships with large pharmaceutical companies often take time to develop and Board or management turnover during this crucial time will risk execution on the plans and tactics already being implemented. Your management team has successfully navigated VIVUS through a tough regulatory and early commercial launch environment and has achieved key milestones that have positioned the Company for success and growth in the near future.

PROTECT YOUR INVESTMENT: FMC IS SEEKING DISPROPORTIONATE REPRESENTATION ON YOUR BOARD

Although if elected, FMC s director nominees will have fiduciary obligations to the Company s stockholders, we believe that FMC is seeking Board representation disproportionate to its stake in VIVUS by waging a proxy contest for full control of your Board. **We strongly believe that it is not in the best interests of our stockholders for the entire slate of director nominees to be selected by a single stockholder who owns less than 10% of the Company s stock.** Furthermore, FMC has announced that it may seek to have the Company, and therefore you, the stockholder, reimburse FMC and its advisors for this expensive proxy contest (initiated by FMC) an amount that FMC estimates will be as much as $1.3 million. **Protect your investment. Protect the value of Qsymia and the future of VIVUS.**

Your Board and management team are committed to strong corporate governance, and we recognize the importance of bringing fresh and diverse perspectives to the boardroom. That is precisely why **the Board has added four highly experienced, independent directors in the last 14 months after completing a diligent search process for directors** who would act in accordance with the best interest of **ALL** VIVUS stockholders. **As proven leaders in the healthcare industry, these directors have enhanced the Board with unique operational, commercial and clinical expertise and valuable relationships to advance the Company s strategy**.

FMC S NOMINEES LACK CRITICAL EXPERIENCE TO

DRIVE LONG-TERM STOCKHOLDER VALUE

Replacing your current Board with FMC s director nominees some with little to no operational experience in pharmaceutical commercialization and development at this important stage would be disruptive and could potentially jeopardize the progress your existing Board is making toward achieving the Company s strategic objectives.

Your current Board has a track record for enhancing stockholder returns and has completed a significant number of partnership and M&A transactions that have created value. Since 2000, VIVUS Board members have completed approximately $75 billion in healthcare M&A transactions. This track record is significantly more extensive than FMC s nominees, who have completed transactions for a total consideration of less than $25 billion.

Four out of FMC s nine director nominees have no current public company board experience; **seven out of nine** have no executive experience with pharmaceutical commercialization. **We believe that our nominees have more relevant experience and are better equipped to guide VIVUS into the future.**

In April 2013, the Company requested that the Nominating and Governance Committee of your Board be given the opportunity to evaluate and interview each of FMC s director nominees. FMC informed the Company that it would not have its director nominees participate in the Nominating and Governance Committee s interview process. We were disappointed that FMC elected not to cooperate with our Nominating and Governance Committee but instead continued its unfortunate and ongoing attempt to seek Board representation disproportionate to its stake in VIVUS.

OUR INDEPENDENT BOARD HAS EXPERTISE SPECIFICALLY

RELEVANT TO OUR STRATEGY AND REPRESENTS THE INTERESTS OF ALL STOCKHOLDERS

The current VIVUS Board is comprised of proven leaders who possess a broad range of commercial, management, clinical and operational experience, as well as expertise in the pharmaceutical industry and other areas important to VIVUS. The VIVUS Board, which includes seven independent directors, is committed to maximizing value for all stockholders and to considering a broad range of opportunities to achieve this objective. Your directors have a combined total of 220 years of pharmaceutical experience and 45 years of related clinical experience.

Furthermore, the highly independent VIVUS Board has a stockholder-friendly corporate governance structure that provides rigorous oversight of VIVUS s strategic direction. Your Board is elected annually and all three of the standing committees of the Board are comprised entirely of independent directors to ensure effective and independent oversight of management.

YOUR BOARD UNANIMOUSLY RECOMMENDS STOCKHOLDERS VOTE

FOR VIVUS S NOMINEES ON THE GOLD PROXY CARD TODAY

VIVUS is at a critical juncture in the commercialization of Qsymia. We believe in the value of Qsymia and our ability to successfully execute on our strategy. VIVUS seeks your support in electing the Company s nine highly qualified nominees and your Board unanimously recommends that stockholders vote **FOR** the Company s experienced and extremely capable director nominees: Leland F. Wilson; Peter Y. Tam; Mark B. Logan; J. Martin Carroll; Charles J. Casamento; Ernest Mario, Ph.D.; Jorge Plutzky, M.D.; Linda M. Dairiki Shortliffe, M.D.; and Robert N. Wilson.

Your vote is extremely important, no matter how many or how few shares you own. Whether or not you plan to attend the Annual Meeting, you have an opportunity to protect your investment in VIVUS by voting the **GOLD** proxy card. We urge you to vote today by Internet, by telephone or by signing and dating the enclosed **GOLD** proxy card and returning it in the postage-paid envelope provided. **Please do not return or otherwise vote any proxy card sent to you by FMC.** If you have already voted a white proxy card sent to you by FMC, you have every right to change that vote by simply voting a later-dated **GOLD** proxy card. If you have any questions please contact Morrow & Co., which is assisting us in connection with this year s Annual Meeting, at (800) 662-5200 or (203) 658-9400.

On behalf of your Board, we appreciate your continued support of VIVUS.

Sincerely,

/s/ Leland F. Wilson
Leland F. Wilson
Chief Executive Officer

About Qsymia

Qsymia® (phentermine and topiramate extended-release) capsules CIV 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/m(2) or greater (obese) or 27 kg/m(2) 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 VIVUS

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

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to the implementation of our REMS amendment and expansion to retail distribution, the broadening payor reimbursement, the expansion of Qsymia s primary care presence, the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS s Form 10-K for the year ending December 31, 2012, as amended by the Form 10-K/A filed on April 30, 2013, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

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