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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 6, 2019 (February 5, 2019)

VANDA PHARMACEUTICALS INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-34186	**03-0491827**
(Commission File No.)	**(IRS Employer Identification No.)**

2200 Pennsylvania Avenue NW
Suite 300E
Washington, DC 20037
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (202) 734-3400

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On February 5, 2019, Vanda Pharmaceuticals Inc. (Vanda) issued a press release announcing the filing of a lawsuit against the U.S. Food and Drug Administration (the FDA). A copy of the press release is filed as Exhibit 99.1 hereto and incorporated by reference herein. On February 5, 2019, Vanda also released an open letter to the FDA. A copy of the open letter is filed as Exhibit 99.2 hereto and incorporated by reference herein.

The information in Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated February 5, 2019.
99.2	Open Letter to the U.S. Food and Drug Administration by Vanda Pharmaceuticals Inc. released February 5, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 6, 2019

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams
Name: Timothy Williams
Title: Senior Vice President, General Counsel and Secretary

Exhibit 99.1

Vanda Pharmaceuticals Takes a Stand Against Unnecessary Animal Research

Company pursuing legal action against the FDA for requiring unnecessary studies that would result in the death of dozens of dogs without legal authority.

Washington, DC – February 5, 2019 — Vanda Pharmaceuticals Inc. has filed a complaint against the U.S. Food and Drug Administration (FDA) requesting that the court lift a partial clinical hold the agency illegally imposed prohibiting Vanda from studying a promising new drug in humans for more than 12 weeks without conducting unnecessary and unethical animal studies.

Vanda has taken this legal action as it works through the FDA development process for tradipitant, a potential treatment for several human conditions including gastroparesis.

During the course of drug development, animal studies are routinely conducted to identify potential toxicities in humans. FDA guidance documents outline the types of animal studies, including the appropriate species and duration, that are recommended to provide sufficient evidence of safety before a drug is studied in humans. However, the recommendations in FDA guidance documents are not legally binding on either the FDA or drug developers. If a company submits information to the FDA to show that further study in humans would be safe based on different information, the FDA is supposed to evaluate the company's proposal and make a case-specific, science-based determination as to whether it agrees.

In Vanda's case, the FDA did not do so. It has instead treated a non-binding recommendation that nine-month non-rodent toxicity studies should be conducted before a drug is studied in humans for longer than three months as a non-negotiable requirement. Solely because Vanda has refused to conduct this study, which usually involves young beagles as the test subjects, each of which must be "sacrificed" to permit evaluation of the animal's tissues, the FDA has placed a partial clinical hold on Vanda's studies of tradipitant. Tradipitant studies can proceed up to 12 weeks duration. The FDA has imposed this partial hold without providing any specific scientific justification. As a matter of law, the FDA is not permitted to do that. As a result, Vanda has sued in federal court for judicial relief.

Numerous preclinical animal studies have already been conducted with tradipitant, including a three-month rat study, a six-month rat study and a three-month dog study, at doses up to 300 times the intended human equivalent dose. These studies have not identified any clinically relevant safety signals for humans. Clinical studies of tradipitant in humans have also suggested that tradipitant is well-tolerated, as have clinical and preclinical studies of drugs in the same class as tradipitant. In addition, scientific literature has shown that nine-month studies in dogs are unlikely to identify clinically relevant safety signals that are not already identified in three-month studies.

“We believe that there is no scientific justification for the requirement that tradipitant be tested in a nine-month dog study, given its currently understood safety profile in both animals and humans, and further, that these studies should not be a routine requirement for all sponsors,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO. “The FDA is ignoring a large body of published scientific evidence which concludes that these chronic dog studies do not offer any additional useful information. That policy is based on old, outdated science and requires the killing of too many dogs without any scientifically justified purpose. Yet, companies have been reticent to stand up to the FDA and demand that it change its policy. Vanda is unwilling to accept the status quo.”

Vanda proposes that the FDA has violated the law by making nine-month dog toxicity studies a de facto requirement, with the threat of severe consequences, such as a clinical hold and the threat of civil injunction or criminal prosecution, if disregarded, without promulgating this “requirement” as a regulation under the required notice-and-comment rulemaking procedures. Federal government agencies must propose regulations and solicit comments from the public before they are finalized and treated as binding, but the FDA failed to follow that procedure here.

“We believe that we have an ethical responsibility to reduce, refine and replace animal experimentation to the maximum extent possible,” said Dr. Polymeropoulos. “While the FDA purports to aspire to the same goals, its refusal to entertain alternatives to a nine-month dog study based on tradipitant’s efficacy results to date, clean safety record, and the unmet medical need for gastroparesis treatments, suggests otherwise.”

Along with filing the lawsuit, Vanda has released an open letter (here) urging others to join the company in demanding that the FDA review and revise its outdated policy.

ABOUT VANDA PHARMACEUTICALS INC.:

Vanda is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

MEDIA CONTACTS:

AJ Jones II
Burson Cohn & Wolfe (BCW)
1110 Vermont Avenue, NW, Suite 1200
Washington, D.C. 20005
202-530-0400
pr@vandapharma.com

Elizabeth Van Every
Burson Cohn & Wolfe (BCW)
230 Park Avenue South
New York, NY 10003
212-614-3881
pr@vandapharma.com

Exhibit 99.2

Open Letter to the Food and Drug Administration

Vanda Pharmaceuticals Takes a Stand Against Unnecessary Animal Research

Everyone can agree that it is critical to confirm the safety of drug products before they come to market. As part of the drug development process, the U.S. Food and Drug Administration (the FDA) asks companies to perform multiple animal studies of different lengths and in different species to identify potential toxicities that could pose risks to humans. One type of study the FDA routinely mandates is a non-rodent toxicity study of nine months' duration, and it is typically conducted in young beagle dogs, though it can also be conducted in non-human primates (e.g., monkeys) or minipigs. For this type of study, all of the animals must be euthanized (or "sacrificed," in the scientific jargon) at the conclusion of their study participation so that their tissues can be analyzed.

In many, if not most, cases these longer-term, non-rodent toxicity studies are unnecessary. Killing animals without a scientifically justified purpose is unethical and inhumane. Such studies should not be conducted routinely, but instead should be the exception rather than the rule: they should be conducted only in specific circumstances when there is a strong, science-based rationale for conducting them.

In mandating nine-month, non-rodent toxicity studies, the FDA is ignoring a large body of published scientific evidence which concludes that nine-month dog studies rarely, if ever, identify toxicities that were not already identified in three-month studies, and do not yield new information that is important for the purpose of understanding how the drug will impact humans. Based on this literature, as well as an extensive assessment of toxicity study results, the U.S. Environmental Protection Agency (the EPA) concluded that longer-term toxicity studies in dogs do not provide essential toxicity information. As a result, in 2007 the EPA abolished its blanket requirement to conduct 12-month dog toxicity studies as part of pesticide registration, and now requires longer-term toxicity studies in dogs only on an exceptional, case-by-case basis.

It is striking that over the past two decades, advances in technology have revolutionized drug development, but the FDA has not revisited its approach to animal toxicity studies. The toxicity studies required by the FDA are the same in 2019 as they were in 1997, and the FDA's stated basis for its policy is an analysis published in 1999, which did not reach any conclusion as to the potential human significance of any toxicological findings identified in longer-term studies.

The FDA has in its files all of the animal research from every new human drug that has been approved for use in the U.S. In the name of ethical animal research and good science, Vanda calls on the FDA to review its own records and to identify those animal studies that are routinely scientifically useful, and under what circumstances. Those animal studies that generally add little value and result in the killing of animals without good reason should be identified and required only on an exceptional, case-by-case basis where scientifically justified. Vanda is confident, based on its own review of existing data in the public domain, that such an analysis would provide further proof that nine-month non-rodent toxicity studies fall into the latter category, and would shed light on the need for other types of animal testing as well. Such an analysis of the FDA's rich trove of data is long past overdue.

Vanda asks the boards of directors, executives and employees of drug companies, animal advocacy organizations, the scientific community, and the public at large to join it in asking the FDA to pay attention to recent scientific developments, conduct a comprehensive and up-to-date analysis of the value of animal studies, and abolish its one-size-fits-all approach to animal research. This approach, including routinely requiring nine-month non-rodent toxicity studies, results in the unnecessary sacrifice of too many dogs and other animals.

Vanda's Tradipitant – A Case in Point

Vanda is developing tradipitant, a neurokinin 1 receptor (NK1R) antagonist, for the treatment of several human diseases including gastroparesis. Gastroparesis is a serious chronic digestive disorder that causes symptoms including nausea, vomiting, early satiety, abnormal fullness after meals, and abdominal pain. It affects up to 6 million Americans, mostly women, and is associated with significant morbidity as well as significant disruption of social and occupational functioning. The only currently approved gastroparesis treatment in the U.S. is metoclopramide, which has a black-box warning limiting treatment duration to twelve-weeks due to risk of developing tardive dyskinesia with longer-term use. Tardive dyskinesia is a serious and potentially irreversible movement disorder. There are no approved long-term treatments for gastroparesis.

Tradipitant has been studied in numerous animal studies to date, including three-month and six-month rat and three-month dog toxicity studies at doses up to 300 times the intended human equivalent dose, without clinically significant safety signals. The lack of clinically relevant safety findings in animal studies is consistent with findings for FDA-approved NK1R antagonists that share tradipitant's mechanism of action, and which have been studied in longer-duration, non-rodent toxicity studies. Tradipitant has also been studied in 15 clinical studies to date, where the drug appeared to be well-tolerated and presented no clinically relevant safety signals. Based on these studies and promising safety and efficacy results in a Phase II clinical study, tradipitant has the potential to become the first new treatment for gastroparesis in the last 40 years.

Given this context, and the substantial body of scientific literature indicating that nine-month dog studies are highly unlikely to uncover additional clinically relevant safety information, Vanda does not believe it should have to euthanize dozens of dogs in an unnecessary, unethical nine-month toxicity study before moving on to studying tradipitant in humans for longer than 12 weeks' duration. The FDA disagrees. Despite multiple communications between Vanda and the FDA, including teleconferences, a request for formal dispute resolution, communications with the Director of the FDA's Center for Drug Evaluation and Research (CDER) and the Director of CDER's Office of New Drugs, the FDA insists that Vanda must conduct an additional 9-month non-rodent toxicity study, not because the FDA has any tradipitant-specific safety concerns that need to be further explored in the additional study, but rather because it has adopted a non-binding guidance document that it now says "requires" that Vanda conduct the study.

It is clear after months of discussions with the FDA that the agency's opinion is immutable and that it views the guidance document's recommendation of nine-month non-rodent toxicity study as a binding requirement. For this reason, and because Vanda refused to do a nine-month dog

study in the absence of any scientific basis for conducting such a study with tradipitant, the FDA issued a partial clinical hold order to prevent Vanda continuing to study tradipitant in humans for longer than 12-weeks' duration, even though a longer-term treatment for gastroparesis patients is urgently needed. Vanda is now taking a stand for these patients and against the needless sacrifice of animals, challenging the FDA's imposition of the clinical hold in court.

Why Vanda is Taking a Stand

The animal studies the FDA demands, including the nine-month, non-rodent toxicity study, have been considered routine in the pharmaceutical industry for decades, despite the growing body of evidence discrediting such studies' scientific value. For this reason, drug companies typically conduct the studies reflexively, without challenging the FDA.

The FDA has relied on industry complacency for too long. Vanda refuses to sacrifice young beagles or other animals in a study that serves no scientific purpose. Vanda believes that we all have an ethical responsibility to reduce, refine and replace animal experimentation to the maximum extent possible. While the FDA purports to aspire to the same goals, its actions with respect to tradipitant and its inflexible demand that companies conduct toxicity studies that have been shown to serve little scientific purpose suggest otherwise. Vanda is therefore standing up to the FDA and hopes that other scientists, drug companies, animal advocates, and the public will do the same.

Call to Action

Vanda asks the boards of directors, executives and employees of drug companies, animal advocacy organizations, scientists, and the public at large to join it in asking the FDA to conduct a comprehensive and up-to-date analysis of the value of animal studies, and abolish its one-size-fits-all approach to animal research, including nine-month, non-rodent toxicity studies, which results in the unnecessary sacrifice of too many dogs and other animals.