

ARATANA THERAPEUTICS, INC.
Form 8-K
February 06, 2017

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, 2017

ARATANA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-35952	38-3826477
(State or other jurisdiction of	(Commission	(I.R.S. Employer

incorporation or organization)	File Number)	Identification No.)
11400 Tomahawk Creek Parkway, Suite 340, Leawood, KS 66211		

(Address of principal executive offices) (Zip Code)

(913) 353-1000

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(Registrant's telephone number, include area code)

N/A

(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))

Item 8.01 Other Events.

In connection with the 2017 North American Veterinary Conference in Orlando, Florida, on February 6, 2017, Aratana Therapeutics, Inc. (the “Company”) provided certain business updates.

- The Company now anticipates that ENTYCE® (capromorelin oral solution) will be commercially available by late-2017. On February 2, 2017, the Company received a response from the U.S. Food and Drug Administration’s Center for Veterinary Medicine (“CVM”) in connection with the Company’s post-approval supplement request to transfer the manufacturing of ENTYCE® to a new vendor in order to produce ENTYCE® at commercial scale. The CVM has requested additional information regarding the proposed transfer in order to complete the supplemental application, and the Company intends to work with the CVM to address its request.
- With the expected later commercial launch of ENTYCE®, the Company intends to continue to focus its commercial resources on NOCITA® (bupivacaine liposome injectable suspension), a local post-operative analgesia for cranial cruciate ligament surgery in dogs, which became commercially available in the late fall of 2016. The Company is focusing on gaining access to the several hundred surgeons who frequently perform these procedures. This effort has required, and the Company expects it will continue to require, significant effort by its sales force given the longer sales cycle than what the Company would expect with a general practice product. The Company is also conducting additional clinical work in other surgical procedures to potentially expand the label for NOCITA® in dogs.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements with respect to expectations regarding when ENTYCE will be commercially available; expectations regarding our ability to resolve the CVM’s request for additional information, including in the timeframe that we expect; plans to focus commercial resources on NOCITA®; expectations regarding the sales cycle for NOCITA®; expectations regarding the sales cycle for general practice products; additional clinical work to potentially expand the NOCITA® label in dogs; and statements regarding the Company’s plans and opportunities.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our history of operating losses and our expectation that we will continue to incur losses for the foreseeable future; failure to obtain sufficient capital to fund our operations; risks relating to the impairment of intangible assets AT-004, AT-005, AT-007 and AT-011; unstable market and economic conditions; restrictions on our financial flexibility due to the terms of our credit facility; our substantial dependence upon the success of our product candidates; development of our biologic product candidates is dependent upon relatively novel technologies and uncertain regulatory pathways, and biologics may not be commercially viable; denial or delay of regulatory approval for our existing or future product candidates; failure of our product candidates that receive regulatory approval to obtain market approval or achieve commercial success; failure to realize anticipated benefits of our acquisitions and difficulties associated with integrating the acquired businesses; development of pet therapeutics is a lengthy and expensive process with an uncertain outcome; competition in the pet therapeutics market, including from generic alternatives to our product candidates, and failure to compete effectively; failure to identify, license or acquire, develop and commercialize additional product candidates; failure to attract and retain senior management and key scientific personnel; our reliance on third-party manufacturers, suppliers and partners; regulatory restrictions on the marketing of our product candidates; our small commercial sales organization, and any failure to create a sales force or collaborate with third-parties to commercialize our product candidates; difficulties in managing the growth of our company; significant costs of being a public company; changes in distribution channels for pet therapeutics; consolidation of our veterinarian customers; limitations on our ability to use our net operating loss carryforwards; impacts of generic products; safety or efficacy concerns with respect to our product candidates;

effects of system failures or security breaches; failure to obtain ownership of issued patents covering our product candidates or failure to prosecute or enforce licensed patents; failure to comply with our obligations under our license agreements; effects of patent or other intellectual property lawsuits; failure to protect our intellectual property; changing patent laws and regulations; non-compliance with any legal or regulatory requirements; litigation resulting from the misuse of our confidential information; the uncertainty of the regulatory approval process and the costs associated with government regulation of our product candidates; failure to obtain regulatory approvals in foreign jurisdictions; effects of legislative or regulatory reform with respect to pet therapeutics; the volatility of the price of our common stock; our status as an emerging growth company, which could make our common stock less attractive to investors; dilution of our common stock as a result of future financings; the influence of certain significant stockholders over our business; and provisions in our charter documents and under Delaware law could delay or prevent a change in control. These and other important factors discussed under the caption “Risk Factors” in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 15, 2016, along with our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this report. Any such forward-looking statements represent management's estimates as of the date of this report. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this report.

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.

ARATANA THERAPEUTICS, INC.

Date: February 6, 2017

By:

/s/ Steven St. Peter

Steven St. Peter

President and Chief Executive Officer
