

ARATANA THERAPEUTICS, INC.

Form 8-K

December 20, 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): December 20, 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

(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))  
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 8.01. Other Events.

The Company recently updated its business information as follows:

On December 20, 2017, the Company announced the United States Department of Agriculture (the “USDA”) Center for Veterinary Biologics granted the Company conditional licensure for Canine Osteosarcoma Vaccine, Live Listeria Vector (AT-014) for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Canine Osteosarcoma Vaccine is a novel immunotherapy developed by the Company using a listeria-based antigen delivery system licensed from Advaxis, Inc. Canine Osteosarcoma Vaccine is a lyophilized formulation of a modified live, attenuated strain of listeria that activates cytotoxic T-cells. Because the therapeutic expresses a tumor-associated antigen, it directs the T-cells to fight cancer cells, even after the bacteria are cleared. Thus, the therapeutic capitalizes on the dog’s immune system and its ability to attack bacterial infections, redirecting it to fight cancer cells.

Data from a clinical study in 18 client-owned dogs with osteosarcoma suggests that the immunotherapy may be able to delay or prevent metastatic disease and may prolong overall survival in dogs with osteosarcoma. The single-arm study evaluated dogs that had primary tumor removal and four doses of carboplatin chemotherapy, followed by the therapeutic vaccine every three weeks for three doses. Median survival time was 956 days compared to 423 days for a historical control group ( $p < 0.05$ ). A separate field safety study submitted to USDA for conditional licensure demonstrated that the most common adverse events included lethargy, diarrhea and fever. Four serious adverse events were observed.

As required by USDA to progress from conditional licensure to full licensure, we plan to conduct an extended field study in a clinical setting and anticipate initiating the study in early 2018. Initially, the therapeutic will be made available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study.

Forward-Looking Statements



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 therapeutics; effects of system failures or security breaches; failure to perform under our agreements with Elanco Animal Health, or termination thereof; failure to obtain ownership of issued patents covering our therapeutic 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 therapeutic 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the Securities and Exchange Commission, or SEC, on March 14, 2017, 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.

---

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: December 20, 2017

By:

/s/ Steven St. Peter  
Steven St. Peter

President and Chief Executive Officer

---