ARATANA THERAPEUTICS, INC.
Form 8-K
September 25, 2015

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): September 24, 2015

ARATANA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-35952	38-3826477
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1901 Olathe Blvd., Kansas City, KS 66103

(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))

Item 8.01. Other Events.

Aratana Therapeutics, Inc. (the "Company") recently updated its business information as follows:

The Company continues to advance its pipeline of novel therapeutics, including four products at pivotal stage (AT-001, AT-002, AT-003 and AT-014), while concluding from post-licensure marketing studies that the canine lymphoma products, AT-004 and AT-005, will not fully capture the market opportunity. The Company is pursuing second generation monoclonal antibodies and other solutions to canine lymphoma.

AT-001 (grapiprant for osteoarthritis pain in dogs)

On September 8, 2015, the Company received from the FDA's Center for Veterinary Medicine ("CVM") the technical section complete letter for effectiveness, which in addition to safety and CMC, constitutes the third and final major technical section complete letter.

The Company expects to finalize label negotiations, complete the other minor sections, and intends to submit an administrative New Animal Drug Application ("NADA") in the first quarter of 2016. Approval is anticipated in the second quarter of 2016, which if approved, is expected to enable the Company to commence commercialization of the product in the fall of 2016.

AT-002 (capromorelin for inappetence in dogs)

On August 26, 2015, the Company submitted the technical section for effectiveness, which included the results of the positive pivotal field effectiveness study conducted under protocol concurrence with the CVM. The Company anticipates a response from the CVM by February 22, 2016.

The Company anticipates receiving its technical section complete for CMC in late-2015 or shortly thereafter. Accordingly, the Company anticipates submitting an NADA in early 2016, which if approved, is expected to enable the Company to commence commercialization of the product in mid-2016 or shortly thereafter.

AT-003 (bupivacaine liposome injectable suspension in dogs)

On August 23, 2015, the Company submitted the technical section for effectiveness, which included the results of the positive pivotal field effectiveness study for post-operative pain management in dogs undergoing knee surgery conducted under protocol concurrence. The Company anticipates a response from the CVM by February 20, 2016.

The Company has received a response to its first CMC technical section submission, and the Company anticipates re-submitting the CMC section in late-2015. Accordingly, the Company anticipates submitting an NADA, which if approved, is expected to enable the Company to commence commercialization in late-2016.

AT-004 and AT-005 (monoclonal antibodies for canine lymphoma)

The Company has enrolled approximately 50 dogs in its Mini B-CHOMP study, investigating the use of AT-004 in combination with abbreviated chemotherapy in canine B-cell lymphoma. The results are anticipated in mid-2016. Previously, the Company had received the encouraging results of three independent studies looking at using AT-004 in combination with chemotherapy.

The Company has been conducting two randomized, placebo-controlled studies (T-CHOMP and T-LAB) looking at the potential benefit of AT-005 in combination with two specific chemotherapy protocols and conducting a clinical experience program, or T-CEP, where oncologists use the product at their discretion and share the data with the

Company. Although dogs are still being followed in those studies and final results are expected by mid-2016, the Company completed an analysis of the results thus far, and AT-005 does not seem to be adding significant progression free survival in canine T-cell lymphoma. Recent scientific studies suggest that AT-004 and AT-005 are not as specific to the targets as expected.

Given the mixed clinical and scientific results, the Company does not believe that AT-004 or AT-005 in their current, first-generation forms will capture the desired lymphoma market opportunity. Therefore, the Company is

pursuing second generation monoclonal antibodies and other efforts in lymphoma which are intended to deliver break-through benefits.

The first generation products, AT-004 and AT-005, are expected to continue to be available to oncologists as they are USDA licensed and the Company is manufacturing these products today. The Company believes the revenue and gross margin opportunity for the first generation monoclonal antibodies will be modest, but given that there are not alternative monoclonal antibodies available to veterinarians, the Company intends to maintain product availability.

Forward-Looking Statements

Some of the information contained in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. In this report, the words "anticipates," "believes," "expects," "intends," "future," "could," "estimates," "plans," "would," "should," "potential," "contin words or expressions (as well as other words or expressions referencing future events, conditions or circumstances) identify forward-looking statements. These forward-looking statements involve 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: our history of operating losses and expectations of losses for the foreseeable future; failure to obtain sufficient capital to fund our operations; our substantial dependence on the success of certain of our product candidates; our dependence on novel technologies and compliance with complex regulatory requirements; our inability to obtain regulatory approval for our existing or future product candidates; the lack of commercial success of our current or future product candidates; our inability to realize all of the anticipated benefits of our acquisitions and difficulty integrating acquired businesses; the uncertainty of outcomes of the development of pet therapeutics, which is a lengthy and expensive process; effects of competition; our inability to identify, license, develop and commercialize additional product candidates; our failure to attract and keep senior management and key scientific personnel; our reliance on third-party manufacturers, suppliers, and partners; regulatory restrictions on the marketing of our product candidates; unanticipated difficulties or challenges in the relatively new field of biologics development and manufacturing; our small commercial organization; difficulties managing the growth of our organization; our significant costs of operating as a public company; risks related to the restatement of our financial statements for the year ended December 31, 2013 and the identification of a material weakness in our internal control over financial reporting; changes in distribution channels for pet therapeutics; consolidation of our customers; limitations on our ability to use our net operating carryforwards; impact of generic products; unanticipated safety or efficacy concerns; our limited patents and patent rights; our failure to comply with our intellectual property license obligations; our infringement of third party patents and challenges to our patents or rights; litigation resulting from the misuse of our confidential information; the uncertainty of the regulatory approval process; our failure to comply with regulatory requirements or obtain foreign regulatory approvals; our failure to report adverse medical events related to our products; legislative or regulatory changes; the volatility of our stock price; our status as an "emerging growth company," as defined in the JOBS Act; the potential for dilution if we sell shares of our common stock in future financings; the influence of significant stockholders over our business; and effects of anti-takeover provisions in our charter documents and under Delaware law. 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 16, 2015, 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: September 24, 2015 By: /s/ Steven St. Peter

Name: Steven St. Peter, M.D.
Title: President and Chief Executive Officer