ARATANA THERAPEUTICS, INC.
Form 8-K
November 17, 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): November 17, 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.

In connection with an Investor Day held in New York City on November 12, 2015, Aratana Therapeutics, Inc. (the "Company") recently updated its business information as follows:

Galliprant® (formerly referred to as AT-001) (grapiprant for osteoarthritis pain in dogs)

The Company believes there is a significant market opportunity for treatment of osteoarthritis in dogs. According to market research, 14.7 million dogs are diagnosed with osteoarthritis each year. Of those dogs, 9.7 million are being treated for the condition, and 2.4 million are treated with nonsteroidal anti-inflammatory drugs ("NSAIDs") for more than 20 days, representing a $180 million market.

According to market research, the total NSAID ex-manufacturer market in the United States is $357 million per year, $177 million of which represents treatment for acute pain and $180 million of which represents treatment for chronic pain.

Entyce® (formerly referred to as AT-002) (capromorelin for inappetence in dogs)

The Company believes there is a significant market opportunity for the treatment of inappetence in dogs. According to market research, 9.8 million dogs in the United States are inappetent each year, and 4.1 million of such dogs are treated for the condition (2.3 million for acute inappetence and 1.8 million for chronic inappetence).

The Company recently completed a pivotal field effectiveness study conducted under protocol concurrence with the Center for Veterinary Medicine. The placebo-controlled, blinded, multi-site study compared Entyce to placebo for the treatment of inappetence in more than 200 client-owned dogs. Effectiveness parameters included owner assessment of appetite and body weight gain. Dogs were treated with 3 mg/kg once daily by oral liquid for four days. The primary endpoint of the study was based on an owner assessed appetite score on day four. The Entyce group showed a statistically significant higher success rate of approximately 70% compared to a success rate of the placebo group of approximately 45%. A secondary endpoint of the study was based on an appetite questionnaire, which besides food consumption evaluated behavior such as willingness to eat or seeking for food. The success rate was approximately 65% of dogs in the Entyce group compared to approximately 30% of the placebo group. In addition, approximately 75% of dogs in the Entyce group showed an increase in body weight compared to approximately 45% in the placebo group. Success rates are subject to change upon completion of review by the Food and Drug Administration.

Nocita® (formerly referred to as AT-003) (bupivacaine liposome injectable suspension in dogs)

The Company believes that there is a significant market opportunity for the treatment of post-operative pain in dogs. According to market research, approximately 20 million dogs in the United States undergo surgery per year and of such dogs, 5.8 million have very painful surgeries for which the Company believes veterinarians may consider using Nocita. The Company anticipates completing all technical sections for Nocita in 2016 and filing a New Animal Drug Application in late 2016.

Commercial Strategy

Based on industry sources, we believe national veterinary distributors cover approximately 90% of the companion animal veterinary hospitals in the U.S. It is our understanding that each of their sales teams can range up to 300 field sales representatives who call on the various practices every two-to-three weeks. The Company plans to have discussions with the national veterinary distributors in the first and second quarters of 2016 to discuss potential distribution arrangements for our product candidates.

Financial Guidance

Revenues

The Company expects that its revenues over the next five years will largely be comprised of product sales in the United States. The Company also anticipates entering into licensing or collaboration arrangements for sales of any approved products outside of the United States.

The Company estimates that revenue from the sale of Galliprant, Entyce and Nocita will represent the majority of its total revenues in the period from 2016 through 2020. The Company believes its potential products could generate peak revenues of over $200 million by 2020. The Company expects that, in 2016, revenue for the inappetence segment will be slightly higher due to the timing of the anticipated commercial launch, and that by 2020, revenue from the pain segment will constitute the majority of its total revenues.

Gross Margin

The Company expects gross margins to improve over time and once it reaches commercial scale, to be in line with industry leaders at approximately 65%.

Research and Development and Commercialization Spending

For 2015, the Company anticipates total research and development ("R&D") spending to be less than $30 million, as opposed to its prior guidance of $30 million to $40 million. The Company anticipates R&D spending for 2015 and 2016 to be approximately $60 million in the aggregate. For 2015, R&D spending consists primarily of costs related to program spending and headcount, as well as pre-launch manufacturing, milestone payments and FDA fees. For 2016, R&D spending is expected to consist primarily of costs related to pre-launch manufacturing and program spending, as well as headcount, milestone payments and FDA fees.

Milestone Payments

Pursuant to its current license and option agreements, the Company has potential milestone obligations to third parties of up to approximately $119.8 million. Of that amount, the Company currently anticipates making payments of approximately $26.5 million through 2020. The Company does not assume regulatory or development milestones where it has not yet planned or commenced a pivotal study, which total approximately $25 million. With respect to the commercial milestones, the Company does not currently anticipate paying $68.3 million of those milestones given the high threshold of sales required to trigger those milestones.

Cash Runway

The Company anticipates having cash, cash equivalents and short-term investments of approximately $85 million at December 31, 2015. Upon achievement of the net proceeds covenant in the Company's Loan and Security Agreement with Pacific Western Bank and Oxford Finance, which requires the Company to receive $45 million in cash proceeds in connection with a joint venture, license, collaboration or other partnering transaction and/or equity financing transaction by October 16, 2016, the Company believes it will be in a position to fully support its anticipated 2016 product launches.

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 include without limitation statements regarding the market opportunity for the treatment of osteoarthritis, inappetence and pain in dogs; regulatory filings and approvals; expectations regarding veterinarians' use of our product candidates; expectations regarding components

of future revenues; anticipated research and development spending; projections regarding our future financial results and liquidity, and our ability to support our anticipated 2016 product launches. Such 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; relating to the impairment of intangible assets AT-004, AT-005, AT-007 and AT-011; 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: November 17, 2015 By: /s/ Steven St. Peter

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