



DIVISION OF
CORPORATION FINANCE

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

October 27, 2017

Kevin C. Tang
Chief Executive Officer
Odonate Therapeutics, LLC
4747 Executive Drive, Suite 510
San Diego, CA 92121

Re: Odonate Therapeutics, LLC
Draft Registration Statement on Form S-1
Submitted September 29, 2017
CIK No. 0001717452

Dear Mr. Tang:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary, page 1

1. Please disclose here and in the Business section any active INDs related to tesetaxel, the date of filing for each IND, the sponsor, the subject matter and the status of the IND. Please include similar disclosure with respect to the EMA or any other drug regulatory authorities.
2. Please explain what a "manageable side effect profile" is.

3. We note your disclosure on page 2 that tesetaxel is a new chemical entity. Please disclose your basis for such statement and whether that has been established by any regulatory authority.

CONTESSA: A Multinational, Multicenter, Randomized Phase 3 Study of Tesetaxel in MBC, page 3

4. Please revise your disclosure in the first paragraph at the top of page 4 to remove any implication that the FDA or EMA have approved or signed-off on the CONTESSA trial. Please also disclose what differs in your design of CONTESSA so that you believe it can serve as a single pivotal study sufficient for product registration.

Tesetaxel Clinical Experience, page 3

5. Please disclose the dates (or a range of dates) for the 22 clinical studies. Please also disclose the dates and sponsor for each of TOB203 and 927E-PRT005. Please also disclose all severe or serious adverse effects that occurred in these studies and the incidence of occurrence. Please make similar revisions in your Business section.

We have only limited assets and will need to raise additional capital , page 12

6. Please disclose in this risk factor how long you will be able to fund your current operations based on your current financial standing and how much additional capital you will need to fund your operations for the next 12 months.

Our product candidates may cause undesirable side effects , page 14

7. Please disclose in this risk factor when tesetaxel was placed on a clinical hold by the FDA and when the clinical hold was lifted. Please also describe the serious adverse events patients experienced that resulted in the clinical hold being put in place.

Use of Proceeds, page 36

8. We note your disclosure of the intended use of proceeds in this section. Please disclose the approximate amount intended to be used for CONTESSA and for the other purposes listed. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, state the amounts and sources of such other funds needed for each such specified purpose and the sources thereof. Refer to Item 504 of Regulation S-K and Instruction 3.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Equity Based Compensation, page 50

9. Once you have an estimated offering price or range, please explain to us how you

determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Business, page 53

10. Please identify the preclinical studies referred to on page 57 that show that the pharmaceutical agents have reduced antitumor activity in chemotherapy-resistant tumor cells.

Preclinical Overview, page 59

11. Please explain the significance of GI50 and the measurement of less than 1 NM.
12. Please disclose the sponsor, date and duration for each of the preclinical studies discussed in this section. Please disclose similar information for each of the studies discussed under "Clinical Development Program" on pages 62 - 73.

Clinical Development Program, page 62

13. We note your disclosure on page 63 that 8 clinical studies in the table have been completed, but we only see 7 marked as "final study data available" in the table. Please advise.

Study TOB203: A Phase 2 Study of Teseaxel as First-line Chemotherapy for MBC , page 63

14. Please separately disclose the complete response rate and partial response rate for both TOB203 and 927E-PRT005.
15. Please disclose why the response was not evaluable for two patients.

Study 927E-PRT005: A Phase 2 Study of Teseaxel as Mixed-line Chemotherapy for MBC , page 64

16. Please disclose why two patients were unable to complete at least one cycle of therapy.

Teseaxel Efficacy, Tolerability and Dosing Regimen as Compared to Available Chemotherapies , page 65

17. We note your disclosure on page 67 that teseaxel is associated with a low pill burden and a patient-friendly dosing schedule (2-5 pills taken once every 21 days), whereas capecitabine is associated with a high pill burden and a challenging dosing schedule (approximately 100-150 pills per 21-day cycle on a twice-daily schedule). Please

provide the basis for such statements. Please also provide us the sources for the dosing regimen table on page 67.

Percentage of MBC Patients Who Did Not Receive Additional Chemotherapy after Progressing on First-line Chemotherapy Treatment , page 69

18. Your disclosure in this section implies that the reason MBC patients do not receive second-line chemotherapy is due to increased toxicity. Please tell us how you concluded that toxicity was the reason that MBC patients did not receive second-line chemotherapy.

Clinical Studies Evaluating Lower Doses of Capecitabine Combined with a Taxane , page 72

19. We note your disclosure that the trend toward improved efficacy with lower doses of capecitabine may result from the significantly lower proportion of patients discontinuing study therapy prematurely because of toxicity, and highlights the importance of administering capecitabine using a schedule that optimizes dose intensity and tolerability according to Lortholary *et al* in *Breast Cancer Research and Treatment*. Please supplementally provide us a copy of the relevant portion of Lortholary *et al* in *Breast Cancer Research and Treatment* that supports this statement.

Studies in Patients with Other Forms of Cancer , page 73

20. Please revise this section to clearly disclose specific details and parameters of each of the referenced trials, including the sponsor, the date(s) and duration of the studies, any established endpoints, metrics used, specific measurements and observations including those relating to tumor formation, migration, metastasis and vascularization, and statistical significance.

Daiichi Sankyo License Agreement , page 74

21. Please disclose any other material terms of this license agreement such as the nature and scope of the intellectual property transferred, duration, royalty term, termination provisions, investment features and/or any share purchases and payment provisions including up-front or execution payments received or paid or aggregate amounts paid or received to date under the agreement.

Patents and Proprietary Rights , page 75

22. Please disclose the patent expiration date for the each of your issued patents. Please indicate, if not already done, the type of patent (composition of matter, use or process) for each patent.

Implications of Being an Emerging Growth Company, page 87

23. Please supplementally provide us with copies of all written communications, as defined

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in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Management, page 89

24. We note that Mr. Davis is currently the CEO of Boxer Capital. Please disclose whether Mr. Davis has been the CEO of Boxer Capital for the past five years or the other positions Mr. Davis held with Boxer Capital during such time. Please disclose Mr. Johnson's principal occupation and employment during the past five years. Please disclose when Mr. Lemkey was named Chief Operating Officer of Tang Capital Management, LLC. Refer to Item 401(e)(1) of Regulation S-K.

Executive Compensation, page 96

25. We note that Mr. Lemkey was one of two executive officers of the company in 2016. Item 402(m)(2) of Regulation S-K states that disclosure must be provided for the smaller reporting company's two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of the last completed fiscal year. Please provide the disclosure required by Item 402 of Regulation S-K for Mr. Lemkey for 2016.

General

26. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

You may contact Sasha Parikh at 202-551-3627 or Sharon Blume at 202-551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmiento at 202-551-3798 or Erin Jaskot at 202-551-3442 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Ryan A. Murr, Esq.