



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

DIVISION OF  
CORPORATION FINANCE

Mail Stop 4720

March 31, 2016

Ron Bentsur  
Chief Executive Officer  
UroGen Pharma Ltd.  
9 Ha'Ta'asiya Street  
Ra'anana 4365007, Israel

**Re: UroGen Pharma Ltd.  
Draft Registration Statement on Form F-1  
Submitted March 4, 2016  
CIK No. 0001668243**

Dear Mr. Bentsur:

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.

Overview, page 1

1. Please revise the initial paragraph to disclose whether Mitomycin C is a generic or a branded drug. Provide similar disclosure on page 2 with respect to Imiquimod and botulinum toxin. With reference to your disclosure on page 93, also disclose, if true, that Mitomycin C currently is used "off-label" for the indications you target. Briefly explain what "off-label" means and revise here or elsewhere, as applicable, to explain whether off-label status impacts the pathway for regulatory approval. Also, briefly explain the term "adjuvant therapy" here at first use.
2. Please revise here to explain briefly what a "Compassionate Use" program is and, as applicable, why it is significant. Also revise your Government Regulation discussion in

the business section to provide additional disclosure concerning the requirements for achieving this designation and its impact on your clinical development.

Our Competitive Strengths, page 5

3. The first two headings in this section and your disclosure at the bottom of page 5 concerning “existing” and “approved” drugs suggest that you have brought drugs to market in the past. We note, however, that your disclosure on page 18 indicates that you have limited experience conducting clinical trials and that you have never progressed a product candidate through to regulatory approval. Accordingly, please revise these headings and disclosures to clarify and balance your statements concerning your abilities and expertise.

Risks Associated with Our Business, page 7

4. Please revise the final bullet point on page 7 to highlight briefly the adverse tax consequences that you reference, such as the three identified in the final full paragraph on page 48. Also, highlight the annual IRS filing requirements that you reference on page 144. Please also revise the final sentence of the bullet point to clarify your present intention to not provide the information necessary for holders to make the QEF election. In this regard, we refer to your disclosures on pages 49 and 144.

Implications of Being an “Emerging Growth Company”..., page 8

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

Capitalization, page 57

6. Please tell us why it is appropriate to include the exercise of warrants to purchase Series A-1 preferred shares in your pro forma presentation. In your response tell us how these exercises are factually supportable and directly attributable to your planned offering. Reference for us the authoritative literature you rely upon to support its inclusion. This comment also applies elsewhere, as applicable, such as in your summary financial data on page 11.

Components of Results of Operations, page 62

7. We note your disclosure concerning the \$1.9 million in grants from OCS for research and development funding. Please revise to indicate whether all of your product candidates are subject to the royalty obligations or identify the specific ones that are.

Research and development expenses, net, page 62

8. Please revise your disclosure, either here or in your results of operations discussion, to disclose the costs you incurred during each period presented by project. If you do not maintain any research and development costs by project, disclose that fact and explain why you do not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project.

Critical Accounting Policies and Estimates  
Stock-Based Compensation, page 68

9. Please revise your table of stock option grants on page 69 to include all option grants through the date of your filing.
10. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

Business, page 73

11. Please revise the Business section to discuss when each clinical trial and/or compassionate use program commenced and, as applicable, the primary endpoints for each on-going and completed trial or program.
12. Please revise the narrative disclosures about each product candidate to discuss observed adverse events, including the number of adverse events and the applicable grade levels. In this regard, we note your risk disclosure on page 17 indicating that you have observed several adverse events and serious adverse events in your clinical trials.
13. Please describe the meaning and significance of the following terms at your first reference:
  - Black Box Warning
  - Statistically Significant
  - Noncovalent Derivatives
  - Complex, Chelate or Clathrate of a Molecule

Initial Clinical Results for MitoGel, page 83

14. Please file as an exhibit Dr. Wirth's consent to use the pre-treatment and post-treatment images.

Vesimune, page 89

15. Please revise to disclose who conducted the Phase 1 study. In this regard, we note your disclosure on page 61 indicating that you acquired Vesimune during the fourth quarter of 2015.

Next Steps..., page 91

16. Please revise to identify the large pharmaceutical partner. Describe the material terms of your arrangements with the partner. Also, file the agreement or agreements as material contracts or explain to us why each one does not require filing pursuant to Regulation S-K, Item 601(b)(10).

Competition, page 93

17. Please revise to discuss the competitive conditions in the markets for treating overactive bladder and interstitial cystitis.

Certain Relationships..., page 128

18. Please revise to discuss the material terms of the Investors' Rights Agreement, dated September 18, 2014, which is referenced in your Exhibit Index.
19. Please revise to discuss the material terms of the Telormedix SA asset purchase agreement, which is referenced in your Exhibit Index, as well as any other material arrangements with this related party.

Notes to the Financial Statements

Note 7 – Share Capital:

c. Terms of the Company's convertible preferred shares, page F-14

20. Please explain to us why your warrants to purchase Series A-1 preferred stock are classified as liabilities yet your preferred stock is classified in equity. Reference for us the authoritative literature you rely upon to support your accounting. In your response specifically tell us why you characterize in Note 6b the "Deemed Liquidation" events disclosed in Note 7c3 as being redemption events yet in the latter note you do not do so. In addition, explain why each of these events is solely in your control.

Exhibits

21. Please file all employment agreements you have with your executive officers. In this regard, we reference your disclosures on page 123 and at the bottom of page F-19. Refer to Item 601(b)(10)(ii) of Regulation S-K. Also, file as an exhibit Dr. Beldegrun's management services agreement which is referenced on page 128.

You may contact Mark Brunhofer at (202) 551-3638 or James Rosenberg, Senior Assistant Chief Accountant, at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Michael Gershon at (202) 551-6598 or Joseph McCann at (202) 551-6262 with any other questions.

Sincerely,

/s/ Joseph McCann for

Suzanne Hayes  
Assistant Director  
Office of Healthcare and Insurance

cc: Joshua A. Kaufman, Esq.  
Cooley LLP