



DIVISION OF  
CORPORATION FINANCE

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

July 17, 2012

Via E-mail

Dr. Mark Pruzanski, M.D.  
President and Chief Executive Officer  
Intercept Pharmaceuticals, Inc.  
18 Desbrosses Street  
New York, NY 10013

**Re: Intercept Pharmaceuticals, Inc.  
Confidential Draft Registration Statement on Form S-1  
Submitted June 20, 2012  
CIK No. 0001270073**

Dear Dr. Pruzanski:

We have reviewed your confidential 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 confidential draft registration statement or 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 confidential draft registration statement or filed registration statement, we may have additional comments.

Confidential Draft Registration Statement on Form S-1

1. Please supplementally provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.
2. Please note that our comments on your request for confidential treatment of exhibits to your draft registration statement will be provided under separate cover.

3. Please provide us supplemental copies of proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use.
4. Some of your disclosure includes scientific or statistical jargon or terms of art that may be unfamiliar to lay readers. Where appropriate, please expand your disclosure to include explanations of terminology so that it may be understood by average investors, in the first instance you use this terminology. Language in your filing that you should explain are:
  - The term “analog”;
  - The term “agonist”;
  - The phrase “second line treatment” when referring to your product candidates;
  - The phrase “upper limit normal” when referring to the design of your Phase 3 POISE trial;
  - The phrase “bilirubin level” when referring to the design of your Phase 3 POISE trial; and
  - The abbreviation “SEM” within the chart illustrating the results of the open label long-term safety and efficacy extension study.

Prospectus Summary, page 1

5. You state that you developed your product candidates using your expertise in bile acid chemistry. Please revise your disclosure to indicate whether the expertise and technology that serve as the basis for your product candidates was developed in-house or by parties affiliated with the Company. To the extent the technology underlying your product candidates was developed by affiliates of the Company, you should identify the affiliated party, any intellectual property transferred, and the terms of its transfer to the company. To the extent that you provide further disclosure in the Prospectus Summary, please expand your Business Section to include this information if it is not already disclosed.
6. We note your statement on page 2 that “[a]lthough ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond adequately to treatment.” Please explain what it means to “respond adequately” to treatment.

In addition, please revise your disclosure to describe the specific data that led you to conclude that ursodiol has “limited efficacy” and identify the “potential patient compliance concerns” in relation to the use of ursodiol. To the extent, that there is existing controversy remains in the scientific community as to the efficacy of ursodiol for PBC, you should amend your disclosure to note this and to discuss any potential ramifications, particularly how these uncertainties cast doubt upon the viability of OCA as an alternative to ursodiol. As appropriate, you should amend your disclosure in the Prospectus Summary, Risk Factor section, and wherever else you discuss the efficacy of ursodiol.

Risk Factors, page 10

“We will require substantial additional funding, which may not be available . . .,” page 10

7. Please expand this risk factor to quantify your current working capital and your existing cash and cash equivalents.

“Delays in the commencement, enrollment and completion of clinical trials . . .,” page 15

8. To the extent that you have encountered any material delays with your clinical trials, or have been forced to suspend or terminate one or more trials, please revise to describe such events.

“Even if approve, our product candidates may not achieve broad market acceptance. . .,” page 21

9. Please expand your risk factor to explain why OCA will have a much higher planned cost than ursodiol.

“We depend on third-party contractors for a substantial portion . . .,” page 26

10. To the extent that you have experienced any problems with your contractors such as those described in this risk factor, please revise to describe those problems.

“We may not be able to manage our business effectively if we are unable . . .,” page 27

11. If you have previously experienced difficulty attracting and retaining qualified scientific and technical personnel, please so disclose.
12. Please expand this risk factor to identify the other key employees and consultants upon which you are dependent.

“We may be subject to claims that our employees have wrongfully used . . .,” page 33

13. To the extent that you have experienced any problems with your employees such as those described in this risk factor, please revise to describe those problems.

“We have a significant stockholder, which will limit your ability to influence . . .,” page 35

14. Please expand this risk factor to identify Dr. Tallarigo and Mr. Fundaro as the two directors that are nominated by Genextra and disclose the current positions they hold as officers of Genextra.

“We have broad discretion in the use of net proceeds from this offering . . .,” page 36

15. We note your cross-reference to the Use of Proceeds section. Please expand this risk factor to describe the manner in which you intend to use the net proceeds from this offering. The Risk Factors section should contain all material information related to the risks of your offering and business; accordingly, cross-references to other sections of your prospectus are not appropriate.

“We are an ‘emerging growth company’ and will be able to avail ourselves . . .,” page 37

16. We note your statement that you qualify as an “emerging growth company” as defined in the Jumpstart Our Businesses Act. In this risk factor, you indicate that you could cease to be an “emerging growth company” if the market value of your common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before the end of the prescribed 5-year period. Please revise and expand this risk factor to disclose that you could remain an emerging growth company until the earliest of:

- The last day of the fiscal year in which you have total annual gross revenues of \$1 billion or more;
- The last day of your fiscal year following the fifth anniversary of the date of the first sale of common equity securities pursuant to an effective registration statement;
- The date on which you have issued more than \$1 billion in nonconvertible debt during the previous three years; or
- The date on which you are deemed to be a large accelerated filer.

Dilution, page 46

17. Please revise your dilution computation and disclosure to include the impact of the reclassification of warrants with registration rights to liabilities in your pro forma net tangible book value (deficit) per share to be consistent with your capitalization presentation.

Management’s Discussion and Analysis of Financial Condition and Results of Operations, page 50

Critical Accounting Policies and Estimates, page 54

Valuation of Stock-Based Compensation and Warrant Liability, page 55

18. In order for us to better understand your fair value estimates of your common stock reflected in your financial statements, please provide the following information for June, 30, 2011, October 13, 2011, December 15, 2011, December 31, 2011, March 31, 2011 (recent warrant liability remeasurement dates and share-based payment issuance dates):

- Description of the method used to estimate fair value;
- Description and quantification of the significant assumptions; and
- Factors contributing to the change, or lack thereof, from the prior valuation.

Please update your response to include any subsequent issuance of share-based payments through the effectiveness of your registration statement.

19. Please revise your disclosure surrounding the second table on page 56 to clarify the date when the intrinsic value that will be presented is determined and how it is determined. To the extent that you intend to disclose that there is no intrinsic value for each grant identified because the exercise price equals the fair value on that date, please ensure that your table reflects zero value. In addition, please disclose the aggregate intrinsic value for your vested and unvested options outstanding at the most recent balance sheet date as well as for your currently outstanding options based on the mid-point of your offering price range.
20. Once you have determined the proposed price range, please expand your disclosure to include each significant factor contributing to the difference between the fair value as of the date of your most recent equity award and the estimated mid-point of your offering range.
21. Please note that we are deferring the evaluation of common stock related compensation expenses until you specify the estimated offering price.

Valuation of Stock-Based Compensation and Warrant Liability, page 55  
Stock Option Grants on October 13, 2011 and December 15, 2011, page 58

22. Please elaborate on the causes for the lack of change in your common stock fair value during this period. In this regard, please describe how the following factors you list here changed from your previous fair value estimates and how they offset:
  - The regulatory status of your programs;
  - The general market conditions for private company financings for development stage companies;
  - The impact of your collaboration agreements; and,
  - The regulatory uncertainty around your development program for OCA.
23. Your statement that “no significant event or other circumstances... occurred that would indicate a change... in the fair value of [y]our common stock” appears to contradict the countervailing factors listed in the first paragraph of this section. Please revise your discussion to remove this apparent inconsistency.

Liquidity and Capital Resources, page 62  
Contractual Obligations and Commitments, page 65

24. Please revise your contractual obligation table or accompanying disclosures to include the following:

- Your milestone obligations, including those for NIDDK, that have not been achieved as of December 31, 2011. If you are not able to estimate the timing of the payments, disclose that fact and the types of events that would trigger the payment obligations;
- Development obligations with respect to DSP and Servier license and collaborations. In addition, provide a discussion of these obligations;
- All financial obligations you may have as a result of the significant agreements described under Note 3 to the Financial Statements on page F-13; and
- Estimated operating expenses of facility leases, such as tax and building costs.

Business, page 68

Our Lead Candidate: Obeticholic Acid, or OCA, for PBC, page 71

25. If Investigational New Drug applications have been submitted to the FDA for any indication of OCA, please so disclose, identify the individual or entity that filed each of the INDs, and indicate when each application was filed.

Potential Use of OCA to Treat Bile Acid Diarrhea, page 79

26. You disclose that the Imperial College of London is acting as the sponsor of the OBADIAH trial. Please disclose whether you have any agreement with the Imperial College of London concerning the development of OCA for this indication. If you do, please expand your disclosure to discuss the material terms of this agreement, including the obligations of each party, the payment provisions, and the term and termination provisions. In addition, please file this agreement as an exhibit to your Form S-1 pursuant to Item 601(b)(10) of Regulation S-K.

Strategic Collaborations and Research Arrangements, page 80  
Dainippon Sumitomo Pharma, page 80

27. Please revise your disclosure to disclose the specific tiered double digit percentage royalties that you will have to pay to DSP based on net sales of OCA products.

Intellectual Property, page 86

28. If you have material patents granted in any foreign jurisdictions, please expand your disclosure to name these jurisdictions.

Limitation of Directors' and Officers' Liability and Indemnification

29. Please add a risk factor that addresses the risk to your business and financial condition of the provisions in your restated certificate of incorporation and restated by-laws that limit the liability of your directors, and require you to indemnify your directors and officers to the fullest extent permitted under Delaware law.

Executive and Director Compensation, page 104

Narrative to Summary Compensation Table, page 104

30. You indicate that Drs. Pruzanski, Shapiro, and Ms. Duncan are eligible to receive certain payments if the officer is terminated "without cause" or resigns for "good reason." Please briefly describe what constitutes "without cause" and "good reason" for purposes of payment.

Principal Stockholders, page 115

31. Please disclose the identity of the individual(s) with voting and dispositive power over the shares held by beneficial owner Visium Balanced Offshore Fund, Ltd.

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm, page F-2

32. Please obtain an auditor's report that covers the period from inception through December 31, 2011. Otherwise, please tell us why you cannot have your period from inception through December 31, 2007 audited and formally request a waiver from audit from the Division of Corporation Finance's Office of the Chief Accountant. Please see instructions for requesting such a waiver at [www.sec.gov/divisions/corpfin/cfconcise.shtml](http://www.sec.gov/divisions/corpfin/cfconcise.shtml).

Notes to Consolidated Financial Statements

2. Summary of Significant Accounting Policies

C. Unaudited Pro Forma Information, page F-8

33. You indicate that you anticipate that all of your preferred stock outstanding will convert into shares of common stock upon the completion of your offering. Please explain to us why it is appropriate to reflect the conversion of these preferred shares throughout your filing absent automatic conversion or an agreement by the holders to convert.

E. Principles of Consolidation, page F-8

34. Please expand your disclosure to describe how you plan to liquidate Intercept Italia S.R.L. Clarify whether it qualifies as a discontinued operation under ASC 205-20 or held-for-sale classification under ASC 360-10-45-9.

3. Significant Agreements

Dainippon Sumitomo Pharma Co, Ltd. (DSP), page F-11

35. Please provide the following disclosures as required under ASC 605-28-50-2:
- A description of each milestone and related contingent consideration;
  - A determination of whether each milestone is considered substantive;
  - The factors that you considered in determining whether the milestone or milestones are substantive; and,
  - The amount of consideration recognized during the period for the milestone or milestones.

Les Laboratories Servier and Institut de Recherches Servier (Servier), page F-12

36. Please revise your disclosure to disclose the following information:
- Duration of the agreement;
  - The information required under ASC 605-28-50-2 consistent with the preceding comment;
  - The percentage of the development costs incurred by Servier you will reimburse when you enter into a partnership agreement or commence development or commercialization activities in the U. S.;
  - Development costs incurred by Servier as of the reporting dates that are subject to reimbursement;
  - Whether 100% of the costs incurred for the Pellicciari and TES agreements are reimbursable by Servier; and
  - If the Pellicciari and TES agreements extend beyond the duration of this agreement, whether the costs incurred beyond the duration of this agreement are reimbursable.

Consulting Agreements with Professor Pellicciari, page F-13

37. Please revise your disclosure to disclose the following information:
- Your 2012 payment obligations for the OCA, INT-767 and INT-777 product candidates agreement extended through 2012; and
  - A description of the results of the research collaboration that will trigger the performance bonus.

TES Pharma SRL (TES), page F-13

38. Please describe your obligations under this agreement, including the fee structure.



National Institute of Diabetes and Digestive and Kidney Disease Institute (NIDDK), page F-13

39. Please tell us whether you have any obligation beyond the milestone payments disclosed here for this contract.

WIL Research Laboratories, LLC (WIL), page F-14

40. Please revise your disclosure to disclose the following information:

- Duration of the agreement;
- Separate quantification of \$4.0 million between periodic installments and milestones;
- Description of events that would trigger the milestone obligations; and
- The amount of additional costs incurred to date, if any.

7. Warrants to Purchase Common Stock, page F-15

41. Please describe how the warrant exercise price will be adjusted if additional shares of common stock were issued at a price less than the warrants' exercise price.
42. Please explain to us why you used the Black-Scholes option-pricing model, instead of a binomial or lattice pricing model or a simulation model, to value your warrants with down-round protection provisions. It appears that the Black-Scholes model does not take into account the potential changes to the exercise price while binomial, lattice or simulation models are better suited to handle such potential changes.

Registration Rights page F-16

43. Please revise your disclosure, here or in Note 2C, to clarify why the registration rights associated with the warrants issued in 2003 and 2004 trigger liability accounting reclassification upon the completion of your offering. In this regard, it appears from your warrant agreements submitted as exhibits that your obligation to maintain the effectiveness of the registration of the underlying common stock and to maintain a listing on a national securities exchange or quotation system are outside your control thereby requiring liability classification because you may be forced to settle the warrants in cash if you are unable to maintain effectiveness and/or listing.

General

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in text searchable PDF files using the secure e-mail system we describe on our website at <http://www.sec.gov/divisions/corpfin/cfannouncements/cfsecureemailinstructions.pdf>.

Please use your Central Index Key, or CIK number, in your correspondence to us about your submission. If you did not have one when you submitted your confidential draft registration statement, we assigned one to you. You will need your CIK number to make your initial filing on EDGAR and you must take a number of steps to prepare for that filing. Following the procedures set forth in Section 3.3.1.1 of the EDGAR Filer Manual – Volume I at <http://www.sec.gov/info/edgar/edgarfm-vol1-v12.pdf>, you must:

- Submit a request to us to convert your EDGAR status to an electronic filer if we generated the CIK number for you.
- Request access codes and passwords to file your registration statement on the EDGAR system. If you already had a CIK number when you submitted your confidential draft, we used that number and you should confirm that you have your access codes available for filing.

If you need new or replacement EDGAR access codes and passwords, we suggest that you complete the process to obtain them well in advance of your targeted filing date. Please call the Division's Filer Support team at 202-551-8900 (choose option number four) if you have questions about this process. If you do call, please make sure to tell us that we have already assigned a CIK number to your company and have that number available.

- Make any necessary changes to your contact information and business and mailing addresses in EDGAR prior to making your initial filing so we can contact you about your filing.

When you publicly file your confidential draft registration statement and amendments on EDGAR in accordance with Section 106(a) of the JOBS Act, please:

- Attach each submission, including exhibits, to your initial registration statement as a separate Exhibit 99 document and clearly identify each confidential submission attached as an Exhibit 99 document (e.g., "Confidential Draft # 1"). Do not attach submissions marked to show changes from earlier submissions.
- Submit each item of correspondence you sent to us in connection with your confidential draft submissions, including your responses to our comments, as a separate "CORRESP" submission on EDGAR.

As you prepare correspondence to us in connection with your confidential draft registration statement, please keep in mind that we will expect you to submit that same correspondence on EDGAR so that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (SEC Staff to Release Filing Review Correspondence Earlier). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR,

Dr. Mark Pruzanski, M.D.  
Intercept Pharmaceuticals, Inc.  
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please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Kei Nakada at (202) 551-3659 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Rose Zukin at (202) 551-3239 or Bryan Pitko at (202) 551-3203 with any other questions. In this regard, please feel free to contact me at (202) 551-3710.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler  
Assistant Director

cc: Scott A. Samuels, Esq.  
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111