

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

February 28, 2011

Frank M. Reynolds Chief Executive Officer Invivo Therapeutics Holdings Corp. One Broadway, 14<sup>th</sup> Floor Cambridge, MA 02142

> Re: Invivo Therapeutics Holdings Corp Registration Statement on Form S-1

Filed February 1, 2011 File No. 333-171998

Dear Mr. Reynolds:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

#### Registration Statement Cover Page

1. Refer to footnote (1) to the fee table. Rule 416 of the Securities Act of 1933 may only be used to address changes in the number of shares issuable upon exercise of the warrants for stock splits, stock dividends and similar transactions. You may not use Rule 416 to address additional securities issuable in connection with other types of antidilution provisions, such as those based upon market fluctuations or best price provisions, like the one found in Section 3(d) of the Investor Warrant filed as Exhibit 4.3. Please revise your footnote to limit it to the types of adjustments allowed by Rule 416. Similarly revise counsel's opinion set forth as Exhibit 5.1.

# Prospectus Cover Page

- 2. Please clarify, if true, that the shares will be offered at market or privately negotiated prices. Alternatively, state the price at which selling shareholders will offer their shares.
- 3. Because your first reference to the "new bridge warrants" appears here without further explanation, please either define the term or provide other context for understandability.

## Prospectus Summary, page 1

- 4. Revise the forepart of your registration statement to disclose your assets and net loss for the most recent audited period and stub period.
- 5. Please provide a summary description of your business activities, including a discussion of your plans to develop your product through to revenue generation.
- 6. Revise the summary significantly to comply with the requirements of plain English set forth in Rule 421 of the Securities Act of 1933. In particular, avoid referring to yourself in the third person as ITHC except where it will enhance readability, clearly refer to various transactions by different names, rather than using the term "Offering" and "Closing" to refer to each, and avoid excessive use of defined, upper-cased terminology.
- 7. The first sentence on page 2 is unclear. Did the private offering occur concurrently with the merger, before the merger or on November 10 and December 3, 2010?
- 8. Refer to the third paragraph on page 2. Tell us what solicitation activities the placement agent engaged in to identify investors to participate in bridge financing.

#### Offering by Selling Security holders, page 3

9. We see on page 3 that you reference the forward-split of your common stock on a 2.02898 for 1 basis effective October 22, 2010. This transaction appears to relate solely to the legal acquirer in the merger transaction, Invivo Therapeutics Holdings Corporation. However, we note on page 1, that as part of the merger, Invivo common stock converted on a 13.7706 for 1 basis. Consistent with SAB Topic 4C, please revise the filing to give retroactive treatment to this conversion of the common stock throughout the filing. Please also revise to appropriately reconcile for us the outstanding common shares of Invivo on a pre and post merger basis, which would reflect the 13.7706 for 1 conversion.

# Risk Factors, page 5

10. Revise the third sentence under this heading to remove the suggestion that there may be other risk factors outside of this section that are not described here.

11. Please add a risk factor that addresses the risks related to the use of methylprednisolone sodium succinate.

# We will need substantial additional funding, page 5

12. Please quantify your near term funding needs as well as the amount you will need to bring your product to market.

# The results seen in our animal testing..., page 8

13. We note your disclosure on pages 30-34 regarding the testing of your products. Given such tests appear limited in nature; address the limited nature of your tests in your risk factor disclosure.

# We may require FDA approval..., page 7

14. We note that several of your risk factors appear to address the same risks related to regulatory approval including the risks of delay and that approval will ultimately not be granted. For example, this risk factor and the second and fourth risk factors on page 8 all refer to the need for regulatory approval. Please revise your risk factor disclosure for conciseness. Address each significant risk separately under its own subcaption and avoid unnecessary duplication.

# Our products could be subject to claims for patent infringement, page 12

15. Please revise this risk factor and the following risk factor for clarity and to avoid repetition. Also, given your claims regarding the creation of a "new paradigm" for the treatment of spinal cord injury clarify how you determined there is a material risk that you may infringe the patent rights of third parties.

# InVivo's Convertible Notes converted into common stock, page 15

16. Revise to indicate the remedies that note holders might seek as a result of the valuation discussed.

# Capitalization, page 20

17. Please revise to include detailed footnote disclosure quantifying and identifying each pro forma adjustment recorded along with an explanation of how each pro forma adjustment was calculated and determined for both pro-forma as adjusted columns. As part of your revised disclosure, please include all relevant assumption used in such calculations, including the conversion terms and number of warrants outstanding.

# Dilution, page 21

18. Please revise the filing to include a detailed explanation of the calculation of the dilution upon the exercise of the investor and bridge warrants. We note that it is not possible to recalculate the amounts included in the increase per share attributable to the exercising of the warrants.

# Management's Discussion and Analysis, page 22

19. Item 11(h) of the Form S-1 requires the filing of Managements' Discussion and Analysis consistent with Item 303 of Regulation S-K. For smaller reporting companies, Item 303(A) and 303(B) of Regulation S-K requires the discussion of the two most recent fiscal years and any subsequent interim periods. Please revise accordingly.

# Business, page 26

- 20. Revise significantly to explain clearly the present development stage of your product and explain clearly each step you need to take to be ready to generate revenue from your proposed product. Include in this description estimated timelines and capital needs.
- 21. Please revise your disclosure to avoid marketing style language such as the references to "groundbreaking technologies", a "new paradigm of care," a "novel approach," "world renown" and "prolific." Instead, explain clearly how your technology may improve medical care for spinal cord injuries. Also, revise your disclosure to avoid frequent reliance on defined terms such as "SCI" and "hNSC.'
- 22. Please tell us the basis for your belief that the global per unit price for your product will be \$44,000.
- We note the disclosure in the fifth risk factor on page 11 regarding applicable regulations. Please provide the disclosure required by Item 101(h)(4)(ix) of Regulation S-K.

#### Market Opportunity, page 27

24. You cite the Christopher & Dana Reeve Foundation and the NSCISC in several places in your prospectus. Please provide us with copies of reports of each of these organizations where they make these statements. Clearly mark the supporting statements in the supplemental materials. Also, clarify whether you have any relationships with these organizations.

# Our Planned First Product, page 28

25. Please expand your disclosure to describe more clearly the polymer scaffold.

# Pre-Clinical Results in Animals, page 29

- 26. Please clarify which tests were carried out by you and which tests were carried out by third parties. Also, discuss the number of subjects in the study and explain what you mean by "functional locomotive improvement" and "sustainable functional recovery."
- 27. Please explain the Basso-Beattie-Bresnahan scoring system, the 20-point observational scale used in the graph on page 32 and the neuromotor scoring system used in the graph on page 33.
- 28. Please reconcile your description of your products on pages 28 and 29 with the descriptions of the products used in the tests described in the penultimate paragraph on page 32. For example, explain the distinction between the standard PLGA scaffold and a PLGA-polylysine scaffold. Also, clarify who conducted the 2<sup>nd</sup> Primate Study.

# Clinical Regulatory Plan, page 33

29. We note your disclosure in the last risk factor on page 9 that you intend to have your products marketed outside the United States. Please describe material applicable regulations in the jurisdictions where you intend to sell your products.

# Sales and Marketing, page 35

30. In light of your early stage of development, a full page chart picturing your product delivery plans appears premature. Please revise to remove or explain how this aids an investor's understanding of your business.

# Intellectual Property, page 36

- 31. Please describe the material terms of your five year plan referenced in the fifth paragraph.
- 32. Please quantify the payments you are required to make under the licenses described.

#### Non-Executive Officers and Scientific and Business Advisory Boards, page 41

33. With a view to disclosure, please describe the structure, functions and powers of your advisory boards. Please also revise to remove promotional language that reads like a marketing document or resume.

# Executive Compensation, page 44

34. Please disclose assumptions made in determining the value of the options awarded to Frank Reynolds in 2009 as disclosed in the table on page 44. Refer to Instruction 1 to Item 402(n)(2)(vi) of Regulation S-K.

#### Board Independence, page 45

35. Please provide your analysis showing how you determined that the independence standards identified by you in this section are consistent with the requirements of Item 407(a) of Regulation S-K.

# Certain Relationships and Related Transactions, page 51

- 36. Please revise this section to clearly describe the relationships between Adam Stern, Spencer Trask Ventures and each of the "several related parties" referenced in the second paragraph.
- 37. Tell us which exhibit listed in your exhibit index represents each agreement with Spencer Trask Ventures disclosed in this section.

# Selling Securityholders, page 53

- 38. Please identify the natural person or persons who have voting or investment control of the shares held by each selling security holder that is not a natural person.
- 39. Please clarify why certain shareholders appear twice in the list such as Todd Stuart and Milen Petkov Tzvetanov. Also, it appears at least one officer or director George Nolen is included in the list. Please provide the disclosure required by Item 507 of Regulation S-K for each security holder that has had a material relationship with you within the past three years.

# <u>Unaudited Financial Statements</u>, page F-1

40. Please update the filing to comply with of Rule 8-08 of Regulation S-X. Please also provide an updated accountant's consent with any amendment to the filing.

# Note 2. Significant Accounting Policies, page F-5

#### Derivatives, page F-7

41. We note your policy that derivative financial instruments, specifically warrants to purchase common stock, "are initially recorded at fair value, or relative fair value when issued with other instruments." We note that under FASB ASC 470-20-25-2, proceeds from the sale of debt instruments with stock purchase warrants are allocated based on the relative fair value

of the debt instrument and the warrants. However, FASB ASC 815-10-30-1 requires that, "all derivative instruments shall be measured initially at fair value." Please describe for us how your policy for recording derivative financial instruments at relative fair value complies with FASB ASC 815-10-30-1.

# Note 8. Convertible Notes Payable, page F-11

42. As a result of a series of financing, the conversion features of your convertible notes payable was accelerated and certain contingent discount provisions were resolved and you recorded \$134,410 of additional interest expense related to the contingent beneficial conversion feature. Please describe for us in greater detail the contingent conversion terms of the convertible notes payable, your accounting for those contingent conversion terms in accordance with FASB ASC 470-20-25-20 and provide us with your calculation of the contingent beneficial conversion feature recorded as additional interest expense. In a related matter, please provide us with a similar analysis for the conversion of your Convertible Bridge Notes discussed on page F-16.

#### Note 15. Subsequent Events

## Reverse Merger and Private Placement of Securities, page F-15

- 43. We see that on October 26, 2010, Invivo Therapeutics Corporation completed a reverse merger with Invivo Therapeutics Holdings Corporation (formerly known as Design Source, Inc). Upon closing of this transaction, Invivo Therapeutics Holdings Corporation will transfer all of the assets and liabilities of Design Source to another subsidiary and split-off this subsidiary through the sale of its stock. Please describe for us in appropriate detail, how you accounted for and valued this reverse merger and sale of Design Source operating assets and liabilities. As part of your response, please refer to the authoritative literature, which supports your accounting for these transactions.
- 44. In this regard, historical stockholders' equity of the accounting acquirer prior to the reverse merger should be retroactively adjusted (a recapitalization) for the equivalent number of shares issued in the merger. Earnings per share for periods prior to the merger should also be adjusted to reflect the number of equivalent shares issued in this reverse merger recapitalization. Accordingly, please revise the filing to appropriately present the recapitalization of the accounting acquirer within shareholders' equity and earnings per share.
- 45. We see that you have entered into a registrant rights agreement with the investors in your private unit placement offering. We note that there are certain registrant payment arrangement penalty provisions in this agreement. Please tell us how you have accounted for these registration payment arrangements under paragraphs 30-1 to 30-5 for FASB ASC 825-20.

# <u>Pro Forma Consolidated Statement of Operations, Six Months Ended September 30, 2010, page</u> F-37

- 46. We note that Invivo Therapeutics Corporation's fiscal year ended December 31, 2010 and as of the date of this filing, the most recent balance sheet required to be filed under Rule 3-01 of Regulation S-X was September 30, 2010. We see that you have provided pro forma statements of income for the six months ended September 30, 2010. Subsequent to the reverse acquisition, the financial statements of the accounting acquirer become the financial statements of the registrant under U.S. GAAP. Accordingly, please revise the filing to include a pro forma statement of income for the period from the most recent fiscal year end of the accounting acquirer, December 31, 2009, to the most recent interim date for which a balance sheet is required, September 30, 2010, in accordance with Rule 11-02(c)(2)(i) of Regulation S-X.
- 47. Reference is made to the pro forma weighted average number of common shares outstanding, basic and diluted of 51,647,171. We note from the Merger and Related Transactions summary included on pages 1 and 2 that the weighted average pro forma common shares outstanding reflects the issuance of common shares as part of the Transactions as described on page 2. Please disclose in detail how the pro forma weighted average number of common shares outstanding, basic and diluted was calculated as of each period-end presented. Your disclosure should include in detail all relevant assumptions used in such calculation. Your disclosure should also include specific references to the common shares issuances discussed on pages 1 and 2 in the Merger Transaction and Related Transactions summary.

#### **Back Cover Page**

48. Please tell us how you determined that you need not provide the disclosure required by Item 502(b) of Regulation S-K.

#### Recent Sales of Unregistered Securities, page II-2

49. Please state the facts relied upon to make available each of the exemptions from registration you are claiming in this section.

# Exhibits and Financial Statement Schedules, page II-2

50. You should file as one exhibit your complete articles of incorporation as amended, including the October 4, 2010 amendment, without requiring investors to assemble documents from multiple filings. See Regulation S-K Item 601(b)(3).

- 51. We note that certain of your exhibits are unsigned, undated or otherwise incomplete and/or lack attachments. For example:
  - Exhibit 2.1 is unsigned and is missing exhibits;
  - Exhibits 2.2, 10.5, 10.6 are undated and unsigned; and
  - Exhibit 10.1 is unsigned, undated and appears to be missing schedules;

Please file complete agreements.

# Signatures, page II-8

52. Your registration statement must also be signed by your controller or principal accounting officer in his capacity as such. Please revise.

#### Exhibit 5.1

- 53. Counsel must opine on the legality of the securities under the laws of Nevada and may not carve out elements of Nevada law as they attempt to do in the fourth paragraph. Please revise.
- 54. We note the statement in the sixth paragraph that the opinion may not be relied upon by any other person. Investors are entitled to rely upon the opinion. Please delete the sixth paragraph.
- 55. Refer to the second sentence in the sixth paragraph. Please tell us how you will ensure that your legal opinion is current as of the date the registration statement is declared effective.

#### Form 8-K filed November 1, 2010

#### Statements of Operations, page F-4

56. We note that the column representing the statement of operations for the period from November 28, 2005 (inception) to December 31, 2009, does not agree to the statement of operations for the same period included with the Form S-1 filed February 1, 2011 on page F-21. Please reconcile for us the differences. Alternatively, please revise the affected filing to correctly present the statement of operations for the period from November 28, 2005 (inception) to December 31, 2009. Please also advise us of the accuracy of the statement of operations for the period from November 28, 2005 (inception) to June 30, 2010 included herein.

# Pro Forma Financial Statements, page F-23

57. We note that Invivo Therapeutics Corporation's fiscal year ended December 31, 2010 and as of the date of this filing, the most recent balance sheet required to be filed under Rule 3-01 of Regulation S-X was June 30, 2010. We see that you have provided pro forma statements of income for the three months ended June 30, 2010, mislabeled here as for the year-ended March 31, 2010. Subsequent to the reverse acquisition, the financial statements of the accounting acquirer become the financial statements of the registrant under U.S. GAAP. Accordingly, please revise the filing to include a pro forma statement of income for the period from the most recent fiscal year end of the accounting acquirer, December 31, 2009, to the most recent interim date for which a balance sheet is required, June 30, 2010, in accordance with Rule 11-02(c)(2)(i) of Regulation S-X.

As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Kevin Kuhar, Staff Accountant, at (202) 551-3662 or Jeffrey Jaramillo, Accounting Branch Chief, at (202) 551-3212 if you have questions regarding comments on the financial statements and related matters. Please contact Ruairi Regan at (202) 551-3269 or me at (202) 551-3528 with any other questions.

Sincerely,

Amanda Ravitz Assistant Director

cc (by facsimile): Thomas B. Rosedale, Esq.