

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

DIVISION OF CORPORATION FINANCE

September 30, 2010

Roger L. Hawley Chief Executive Officer Zogenix, Inc. 12671 High Bluff Drive, Suite 200 San Diego, CA 92130

> Re: Zogenix, Inc. Registration Statement on Form S-1 Filed September 3, 2010 File No. 333-169210

Dear Mr. Hawley:

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.

# FORM S-1

#### General

- 1. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus.
- 2. Please note that when you file a pre-effective amendment that includes your price range, it must be bone fide. We interpret this to mean that your range may not exceed \$2 if you price below \$20 and 10% if you price above \$20.
- 3. Please provide us proofs of all graphic, 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.

4. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not exhaustive lists. If our comments are applicable to portions of the filing that we have not cited as examples, make the appropriate changes in accordance with our comments.

## Prospectus Summary Overview, page 1

5. Please disclose on the bottom of page 2 that you acquired the DosePro technology and patents from Aradigm.

## **Risk Factors**

"The development of a REMS for ZX002 could cause significant delays in the approval process for ZX002..." page 23

6. Since this risk factor relates to the risks surrounding the requirement of the development of a REMS, please explain the term REMS in this risk factor.

"If we are unable to attract and retain key personnel, we may not be able to manage our business effectively..." page 27

7. To the extent that you have experienced problems attracting or retaining key personnel, please expand your disclosure to describe these problems.

# "Sumavel DosePro, ZX002 and our other product candidates may cause undesirable side effects..." page 39

8. Please expand your disclosure in this risk factor to discuss the currently known side effects and adverse effects associated with Sumavel DosePro and ZX002. Please also disclose the frequency of each of the side effects and adverse effects.

# Special Note Regarding Forward-Looking Statements and Market Data, page 59

9. Please delete the statements "we have not independently verified market and industry data from third-party sources" and "neither our internal research nor these definitions have been verified by any independent source." These statements appear to imply that you are not taking liability for the statistical and other industry and market data included in your registration statement. It is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Alternatively, please expand your disclosure to include a statement specifically accepting liability for this information.

#### Use of Proceeds, page 61

- 10. You disclose that you intend to use approximately \$ million of the net proceeds from this offering to fund Phase 3 clinical trials and related development activities for ZX002. Please expand your disclosure to disclose the stage of development for ZX002 that you expect this portion of the offering proceeds will enable you to complete.
- 11. You disclose that the remainder of the proceeds will be used to fund the ongoing commercialization of Sumavel DosePro and for working capital and other general corporate purposes. Please separately state the amount of proceeds that will be used to fund the ongoing commercialization of Sumavel DosePro and the amount of proceeds that will be used for working capital and other general corporate purposes.

## Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expenses, page 71

12. With respect to the agreement with Elan, please expand your disclosure to clarify the nature of the development and commercial events that trigger future milestone payments including an estimate of the anticipated timing of such payments.

<u>Critical Accounting Policies and Estimates</u> <u>Revenue Recognition</u> <u>Product Sales Allowances, page 76</u>

- 13. To the extent applicable, please revise your disclosure to enhance your discussion of the estimates of items that reduce gross revenue such as wholesaler and retail pharmacy discounts, prompt pay discounts, chargebacks and rebates, patient discount programs, stocking allowances, returns, and other allowances and discounts to include the following:
  - Disclose the amount of each accrual at the balance sheet date and the effect that could result from using other reasonably likely assumptions than what you used to arrive at each accrual such as a range of reasonably likely amounts or other type of sensitivity analysis.
  - If applicable, discuss any shipments made as a result of incentives and/or in excess of your customer's ordinary course of business inventory level. Discuss your revenue recognition policy for such shipments.
  - In your discussion of results of operations for the period to period revenue comparisons, discuss the amount of and reason for fluctuations for each type of reduction of gross revenue (i.e. product returns, chargebacks, customer rebates and other discounts and allowances) including the effect that changes in your estimates of these items had on your revenues and operations.

#### <u>Stock Based Compensation</u> Common Stock Valuation, page 79

- 14. We have reviewed your disclosure with respect to the valuation of your common stock and have the following comments:
  - You disclose that your board of directors considered a number of subjective and objective factors that include contemporaneous valuations performed by an independent valuation specialist. Please revise your disclosure to clarify the nature and extent of the independent valuation specialist's involvement in estimating the fair value of your common stock and management's reliance on the work of this specialist. Please refer to Question 141.02 of the Compliance and Disclosure Interpretations on Securities Act Sections, which can be found at: <a href="http://www.sec.gov/divisions/corpfin/guidance/sasinterp.htm">http://www.sec.gov/divisions/corpfin/guidance/sasinterp.htm</a>.
  - Qualitatively and quantitatively discuss the significant factors, assumptions and methodologies used to determine enterprise value at each assessment date.
  - Disclose how each of the three valuation methods discussed on page 80 were weighted at each valuation date in 2009 and 2010, including each reassessment. Disclose, and explain to us, why a valuation that used the cost approach as factor to determine enterprise value was still appropriate after receiving FDA approval in 2009 and product revenue in 2010.
  - Qualitatively and quantitatively explain how each valuation considered the anticipated timing of a potential liquidity event, namely the probability of completing an initial public offering under the probability weighted expected return method.
  - Quantify the amount of the discount for lack of liquidity as a private company at each valuation assessment date. Explain why this discount is acceptable in terms of providing a reasonable and supportable determination of fair value.
  - Qualitatively and quantitatively disclose how you estimated the revenue and revenue growth dates used in preparing your discounted cash flows analysis.
  - Please explain to us if the "best economic outcome" model is similar to one the three methods commonly used in practice described in Chapter 10 of the AICPA Practice Aid. If it not similar to the three methods, tell us why this model is appropriate.
  - When you have determined the IPO price, please disclose the intrinsic value of your stock options granted, as of the most recent balance sheet date presented. Discuss each significant factor contributing to the difference between the fair value as of the date of each grant and the estimated IPO price or if a contemporaneous valuation by an unrelated valuation specialist was obtained subsequent to the grants but prior to the IPO, the fair value as determined by that valuation. After reviewing this disclosure, we may raise additional comments.

• Please continue to update your disclosures for any grants or equity issuances up until the time of effectiveness of your registration statement and include grants to non-employees as appropriate.

#### Business Our Product and Product Candidates

Sumavel DosePro Pivotal Clinical Program, page 105

15. You disclose that adverse events seen in your clinical studies for Sumavel DosePro were consistent with previously reported adverse events for injectable sumatriptan and included flushing, tightness in chest, and injection site reactions, among others. Please revise to disclose all adverse events.

# Sumavel DosePro Post-Approval Clinical Program, page 106

16. You disclose that you recently completed a Phase 4 open-label, multicenter study in the United States to evaluate treatment satisfaction, treatment confidence, and subject preference for Sumavel DosePro in adult subjects diagnosed with migraine and currently treated with triptans. Although the analysis of study results was recently completed, you state that you intend to disclose these results at relevant clinical symposia and via peerreview publications in 2011. Please provide us with a detailed analysis that supports your conclusion that the results of this study are not material information that is required to be disclosed in this registration statement.

#### ZX002 Phase 3 Clinical Development Program, page 109

17. On page 21, you disclose that you had discussions and responses with the FDA at your End of Phase 2 meeting. On page 109, you disclose that based upon feedback from the FDA at your End of Phase 2 meeting, and assuming positive outcomes from the studies described above, you do not believe that additional Phase 3 safety and efficacy trials will be required to support your proposed label. On page 122, you disclose information regarding a Special Protocol Assessment from the FDA. Please expand your disclosure on pages 21 and 109 to explain the nature of your discussions with the FDA and clarify whether you have a Special Protocol Assessment from the FDA for ZX002. If you have a Special Protocol Assessment, please disclose the material terms thereof and whether you believe your trials are compliant with those terms.

#### Prior Clinical Development of ZX002, page 109

18. You disclose that efficacy of the 40 mg dose of ZX002 did not significantly differ from the hydrocodone bitartrate/acetaminophen active comparator in any of the efficacy outcome measures. Please expand your disclosure where appropriate to disclose the extent to which this result was discussed with the FDA and whether the FDA provided you with any input as to what type of study and/or results might be required for a

successful NDA. Please also disclose the context or source of the FDA input (e.g. a Special Protocol Assessment, in discussions during the End of Phase 2 meeting, etc.).

## Our DosePro Technology and Pre-clinical Pipeline, page 110

19. Please expand your disclosure to identify the clinical trials and market research studies in which DosePro has been shown to be preferred by patients and physicians over conventional needle-based systems.

#### <u>Manufacturing</u> Patheon UK Limited, page 116

20. Please expand your disclosure regarding the terms of this agreement to disclose whether this manufacturer is the exclusive supplier of these components.

## Collaborations, Commercial and License Agreements, page 117

21. Please expand your disclosure for each of the agreements in this section to disclose the payments made and/or received to date and a range of royalty payments (e.g. low singledigit or a range not to exceed ten percent) as we believe these are material terms of these agreements. For your agreement with Astellas, you should disclose a range of the percentage of net sales that represents the service fees.

#### Compensation Discussion and Analysis Performance Bonuses, page 148

22. You disclose that in lieu of performance bonuses, your board of directors instituted a companywide retention bonus program, which paid one to three months of base salary to each full-time employee upon the FDA's approval of Sumavel DosePro and the closing of your Series B preferred stock financing. You disclose that this bonus was based on the achievement of two performance objectives. Please provide us with a detailed analysis that supports your characterization of these bonuses as a retention bonus rather than a performance bonus. We also note that you suspended your executive performance bonus program. Please disclose the date that you suspended this plan. In addition, if when you suspended the plan, you believed that a number of performance objectives would not be met under the plan, please disclose the objectives and the fact that you did not believe they would be met under the plan.

#### Long-Term Equity Incentives, page 149

23. You disclose that in September 2009, the board of directors awarded the various options to your named executive officers that vest in monthly installments over two years. Please expand your disclosure to disclose why you did not use your typical vesting schedule for these options. In addition, please provide disclosure of why you choose to award the specific number of options to each named executive officer. Although you provide various general factors that you may take into account, it does not appear that you include

disclosure of what was considered for each named executive officer and how the amount was determined. Please revise to provide this additional disclosure.

## Employment Agreements and Release Agreements, page 154

24. Please file a copy of your consulting agreement with Mr. Nassif as an exhibit to your registration statement.

## Principal Stockholders, page 174

25. It appears that information regarding Thomas, McNerney & Partners, L.P. is disclosed in footnote 5 and information regarding Chicago Growth Partners II, L.P. is disclosed in footnote 4. Please revise accordingly.

<u>Consolidated Financial Statements</u> <u>Consolidated Statement of Cash Flows, page F-7</u>

26. Here you show net proceeds received from the issuance of convertible preferred stock of \$54.9 million. This appears to contradict your disclosure on page 90, which states "In 2009 we received net proceeds of \$69.7 million from our Series B preferred stock financing". Please revise your disclosure to clarify this apparent discrepancy.

## <u>Revenue Recognition</u> Product Revenue, page F-12

27. You state "units dispensed are generally not subject to return". Please tell us, and disclose the circumstances under which such units would be subject to return.

# 7. Convertible Preferred Stock and Stockholders' Equity Conversion Rights, page F-28

28. Please clarify for us, and in your disclosure, the nature of the anti-dilution adjustments. Also explain to us how you determined that the conversion feature was not an embedded derivative under ASC 815-15-25 which would require fair value accounting under ASC 470-20-25.

# <u>9. Stock Option Plan</u> Stock Based Compensation, page F-31

29. Please tell us why the volatility range decreased between December 31, 2009 and June 30, 2010.

#### 12. Subsequent Events, page F-35

30. Please disclose the accounting treatment of the warrants issued to Oxford and Silicon Valley Bank.

#### Exhibit Index

31. We note that the exhibits in the below each refer to one or more exhibits, annexes or schedules which are attached to these agreements and which do not appear to have been provided.

Exhibit Number	Missing exhibit, annex or schedule
10.14	Office Lease by and between R.B. Income
	Properties and Verus Pharmaceuticals, Inc.
10.24	Exhibits A, B and C
10.27	Exhibits A, B and C

Please be aware that when you file an agreement pursuant to Item 601(b)(10) of Regulation S-K, you are required to file the entire agreement, including all exhibits, schedules, appendices and any document which is incorporated in the agreement. Please provide a copy of the above exhibits with the full and complete agreement, including any exhibits, schedules and appendices which are included in such agreement. Please note that if these agreements are otherwise filed as an exhibit to this registration statement you may insert a note in brackets on the page which the annex or schedule is to be located as to the exhibit number of the filed document.

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 Tabatha Akins at (202) 551-3658 or Don Abbott at (202) 551-3608 if you have questions regarding comments on the financial statements and related matters. Please contact Jennifer Riegel at (202) 551-3575 or me at (202) 551-3715 with any other questions.

Sincerely,

Jeffrey Riedler Assistant Director

cc: Scott N. Wolfe, Esq. Cheston J. Larson, Esq. Matthew T. Bush, Esq. Latham & Watkins LLP 12636 High Bluff Drive, Suite 400 San Diego, CA 92130