

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

Mail Stop 4546

January 13, 2017

Johnson Y.N. Lau Chief Executive Officer Athenex, Inc. 1001 Main Street, Suite 600 Buffalo, NY 14203

Re: Athenex, Inc.

Draft Registration Statement on Form S-1

Submitted December 16, 2016

CIK No. 0001300699

Dear Dr. Lau:

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.

About This Prospectus

Market and Industry Data and Forecasts, page ii

1. Please revise the cautionary language in this section to clarify that you are liable for the information you include in the registration statement.

Prospectus Summary

2. Based on your disclosure elsewhere in the prospectus, it appears that your Global Supply Chain Platform is material to your current operations as it is currently your sole source of revenue. Please briefly discuss the nature of operations for both your Global Supply Chain and Commercial Platforms in the Summary.

- 3. You may indicate the number or percentage of clinical trial participants who met the clinical trial end points and that the product candidates were well tolerated. However, statements regarding efficacy and safety are determinations that only the FDA and foreign government equivalent regulations have the authority to make. Please delete your statements indicating that your product candidates are safe and effective throughout your document, including comparisons to the current standard of care.
- 4. Please revise the discussion of Oraxol to clarify that you are conducting your clinical trial of your product candidate with ramucirumab with Eli Lilly.

Our Mission and Strategy

Rapidly and concurrently advance our clinical product candidates, page 6

5. To the extent known, please indicate when you intend to commence your partnered clinical program in China for KX-02 and explain how this will accelerate the development timeframe. Please provide corresponding disclosure in your Business discussion on page 115.

Risks related to our Business, page 7

6. Please identify all serious adverse effects that have occurred in clinical trials for each of your product candidates.

Implications of Being an Emerging Growth Company, page 7

- 7. 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.
- 8. We note your disclosure on page 101 of the prospectus that you have irrevocably elected not to avail yourselves to the extended transition period available under Section 7(a)(2)(B) of the Securities Act and, as such, you will adopt new or revised accounting standards on the relevant dates on which such standards are required for other public companies. This statement on page 8 indicating that you are in the process of evaluating this benefit seems to imply that you may rely on this benefit. Please revise to clearly indicate your intentions with respect to Section 7(a)(2)(B).

Risk Factors, page 13

9. Please include a risk factor indicating the risk that the FDA may not accept the results from clinical trials that are conducted outside the US. Alternatively, tell us why you do not believe this presents a risk.

Regulatory approval may be substantially delayed..., page 24

10. We note that the Category 1 application process has a fast track review and approval mechanism. Please clarify how the process is fast tracked. For example, does this pathway involve fewer trials, a priority review schedule or other mechanism to process the application more quickly?

Our drug candidates have caused and may cause undesirable adverse events..., page 26

11. Please identify the serious adverse effects for each of your product candidates.

We depend on our agreements with Hanmi Pharmaceutical..., page 46

12. Please describe the circumstances under which you would be required to negotiate the sale of your rights to Hanmi.

Our total revenue is highly dependent on the limited number of API customers..., page 47

13. Please identify the two customers that generated 46% and 64% of your revenues.

Our future success depends on our ability to retain our Chief Executive Officers..., page 52

14. If Avalon Global Holdings or RSJ currently present any potential conflicts of interest, please revise the discussion to describe them.

If product liability lawsuits are brought against us . . . , page 59

15. We note your disclosure that you currently carry clinical trial insurance. Please indicate the extent to which you believe this insurance is adequate.

Management's Discussion and Analysis of Financial Condition and Results of Operations Key Components of Results of Operations Research and Development Expenses, page 86

- 16. You state that research and development activities are central to your business model. On page 4 you name key research and development projects that are underway. Please disclose the following information for each of your major research and development projects:
 - The costs incurred during each period presented and to date;
 - The nature of efforts and steps necessary to complete the project; and
 - The extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the 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 your resources being used on the project.

Critical Accounting Policies and Significant Judgments and Estimates Stock-Based Compensation and Fair Value of our Common Stock Valuation Approaches, page 89

- 17. Please tell us specifically how you determined the \$11.00 fair value of your common stock since July 2016. In your response tell us:
 - What valuation technique(s), if any, that you employed and how they were used;
 - How the issuance of convertible notes that have an underlying variable conversion price between 75% and 80% of a future unknown IPO price provides any indication of the then current value of common stock; and
 - Whether and how you used the assistance of any third-party valuation specialist.
- 18. 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 Acquisitions, Intangible Assets, Goodwill, and Contingent Consideration, page 92

- 19. Given your historical losses and the significant amount of goodwill recorded on your balance sheet, please tell us whether any of your reporting units are at risk of failing step-one of your impairment test. If so, please revise to your disclose this fact as well as:
 - The percentage by which fair value exceeded carrying value as of the date of the most recent test;
 - The amount of goodwill allocated to the reporting unit;
 - A description of the methods and key assumptions used and how the key assumptions were determined;
 - A discussion of the degree of uncertainty associated with the key assumptions; and
 - A description of potential events and/or changes in circumstances that could reasonably be expected to negatively affect the key assumptions.

<u>Liquidity and Capital Resources</u> <u>Indebtedness, page 98</u>

- 20. Please disclose the principal amount outstanding under the Polymed promissory notes.
- 21. Please disclose the number of common shares underlying the convertible loan agreements as of a recently practicable date.

Industry Background

U.S. market share of spending by formulation and oncology segment, page 105

22. Please briefly describe what types of therapy comprise each of the segments depicted in the graphic. For example, what types of therapies are included in "hormonals"? Moreover, please denote by footnote or otherwise the category or categories under which your product candidates will fall.

Actinic Keratosis, page 107

23. Please include the years over which the National Ambulatory Medical Care Survey was conducted.

Changes in the U.S. oncology reimbursement landscape may benefit our patients, page 108

24. Please briefly describe the ways in which adoption of the OCM model might impact your business.

Business, page 110

- 25. Please clarify the meaning of any significant scientific or technical terms the first time they are used in the prospectus in order to ensure that lay readers will understand the disclosure. For example, and without limitation, please define each of the following at their first use in this section or where appropriate in the prospectus:
 - novel kinase binding selection
 - tubular polymerization
 - ingonal, imiquimod, fluorouracil
 - MTD
 - 503B products

Overview, page 110

- 26. Please tell us the country where each of your clinical trials were conducted or are currently being conducted.
- 27. Please explain the relevance of the statement that that the Oraxol clinical trial was designed similarly to the Phase 3 pivotal study for Abraxane.

Our Orascovery Product Candidates, page 121

28. We note your disclosure regarding the adverse events observed during the Oratecan clinical studies. To the extent you have experienced any serious adverse events pertaining to the

clinical trials of your other product candidates to date, please include these in your disclosure and consider including a risk factor discussion specific to such serious adverse events.

Commercial Platform

Our Commercial Operations, page 139

29. Please disclose the nine approved FDA products you have the rights to market and sell as well as the fourteen products pending FDA approval.

Intellectual Property, page 141

30. Please disclose any specific patents you own that are material to your operations, including the year in which they expire.

<u>License and Collaboration Agreements</u> Hanmi Licensing Agreements, page 142

- 31. Please disclose the upfront payment you received under the Hanmi out-license agreement. Additionally, please disclose the aggregate milestones receivable under each the out-license agreement.
- 32. We note your disclosure that the tiered royalty payments under each of the agreements are in the low double digits. Please revise to narrow the ranges to within ten percentage points for each tier. Alternatively you may provide one range if you indicate the number of tiers and the aggregate is no wider than ten percentage points for each tier. For example, 3 tiers with a range from the low double digits to the low forties. Similarly, revise the description of royalties under your agreements with PharmaEssentia, Guangzhou Xiangxue.

Management

Executive Officers and Directors, page 172

33. We note that the biographical information for each of Drs. Pedder and Wu, Ms. Campbell and Messrs. Leung and Zhang does not cover respective the individual's business experience for the full past five years, as required by Item 401(e) of Regulation S-K. Please expand your biographical description for each individual to cover this period.

Executive and Director Compensation Named Executive Officer Employment Agreements, page 181

34. We note that you have entered into employment agreements with certain of your named executive officers. Please describe the material terms of these agreements in the prospectus and file the agreements as exhibits to your next amendment.

<u>Certain Relationships</u> and <u>Related Party Transactions</u> <u>Voting Agreements, page 189</u>

35. We note that the Mandra Health Limited and Manson Fok voting agreements are subject to 10% and 5% ownership thresholds, respectively. Please indicate the expected percentage ownership for each of Mandra Health Limited and Manson Fok following the offering.

Notes to Consolidated Financial Statements

Note 2: Summary of Significant Accounting Policies

Revenue Recognition, page F-11

36. In your Key Components of Results of Operations disclosure on page 85 you disclose the existence of licensing and collaboration projects that involve upfront payments, milestone payments and payments for providing research and development services. Please revise your policy note to indicate how you account for multiple-element arrangements including, but not limited to, how you determine whether you have separate units of accounting, how you allocate arrangement consideration among these units and how you account for milestone receipts. To the extent you have any significant collaboration agreements, please provide the disclosures required by ASC 605-25-50-2 and ASC 605-28-50-2.

Patent Costs, page F-12

37. Please tell us the nature of the patent related costs you charge to research and development expenses and how these costs meet the definition of either research or development under the glossary at ASC 730-10-20. In your response, specifically tell us the amounts of patent related costs incurred in each period presented in your registration statement and explain why these costs are not excluded from research and development expenses under ASC 730-10-55-2i. This comment also applies to the combined financial statements of Polymed Therapeutics, Inc. and Chongqing Taihao Pharmaceuticals Co., Ltd. as they have a similar policy as disclosed on page F-48.

Note 19: Business Segment, Geographic, and Concentration Risk Information, page F-36

38. Please provide your revenue by product and service or group of similar products and services as required by ASC 280-10-50-40. In this regard, it appears from disclosure here and elsewhere that, at a minimum, you manufacture and sell clinical and commercial products, active pharmaceutical ingredients and medical devices.

You may contact Christine Torney at (202) 551-3652 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Josh Samples at (202) 551-3199 or me at (202) 551-3675 with any other questions.

Sincerely,

/s/ Suzanne Hayes

Suzanne Hayes Assistant Director Office of Healthcare and Insurance

cc: Michael J. Rosenthall, Esq. Sidley Austin LLP