



DIVISION OF  
CORPORATION FINANCE

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

April 20, 2018

James Sagemark  
Chief Executive Officer  
InSitu Biologics, Inc  
38730 Woodlane Drive  
Suite 102  
Woodbury, MN 55125

**Re: InSitu Biologics, Inc**  
**Draft Offering Statement on Form 1-A**  
**Submitted on March 23, 2018**  
**CIK No. 0001723443**

Dear Mr. Sagemark:

We have reviewed your draft offering 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 offering statement or publicly filing your offering statement on EDGAR. Please refer to Rule 252(d) regarding the public filing requirements for non-public submissions, amendments and correspondence. 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 your amended draft offering statement or filed offering statement and the information you provide in response to these comments, we may have additional comments.

Draft Offering Statement on Form 1-A Filed March 23, 2018

Use of Proceeds to the Company, page 35

1. We note your expected use of proceeds varies based on the number of shares you may sell. However, it is not clear how you will be able to scale back your development plans if you sell significantly less than 100% of the shares you intend to offer. For example, if you are only able to sell 50% of the shares you are offering how will you be able to reduce the amounts you intend to allocate to laboratory supplies and support, facility and regulatory fees and consultants? Please disclose how long you expect the proceeds to last

if you sell 75%, 50%, 25% or 10% of the total amount of shares offered.

Plan of Distribution, page 38

2. We note your offering statement indicates that Bitcoin is an acceptable subscription form. Please provide the following additional information with a view toward disclosure:
  - Tell us how you will be able to meet the requirements to offer the shares at the same price given Bitcoin's volatile price. How will you calculate the Bitcoin price per share.
  - Tell us whether you intend to hold Bitcoin or monetize it at the time of the subscription.
  - Tell us what consideration you gave to including a risk factor discussing the impact of holding such assets and/or accepting this a form of subscription.
  - Tell us what consideration you gave to including a risk factor discussing the volatility of the Bitcoin, liquidity issues and the impact holding such assets may have on your balance sheet, statement of operations and statement of cash flows.
  - Tell us whether you intend to use a specific exchange to convert your Bitcoin into US dollars or other fiat currency.
  - Tell us what about any security concerns or other limitations associated with any particular exchange you intend to use.

Description of the Business, page 41

3. We note your disclosure on F-8 and F-10 that you entered into a license agreement with Lifecore Biomedical, LLC related to Matrix. In your business section, please include a description of the material terms of the agreement and file this agreement as an exhibit. Please refer to Item 10(a)(2) of Part II and Item 17(6) of Part III of Form 1-A.
4. The description of your business is limited to AnestaGel. However, the discussion on page 12 indicates that you have additional product candidates in your Drug Delivery Programs in which you are developing improvements to pharmaceutical ingredients that have already been determined to be safe and effective.
5. Please revise the description of your business to clearly state the current stage of development of AnestaGel and describe the regulatory process, including all the processes you must complete before your product candidate will be considered for FDA approval. For example, describe the various phases of clinical trials and clarify whether you have filed an IND.

Summary , page 41

6. Throughout your document you indicate that AnestaGel is safe and effective. For example:
  - On page 42 "AnestaGel is a unique, novel product for pain control that is safe, efficacious ..." and "InSitu's preclinical GLP and feasibility studies suggest that

AnestaGel may deliver faster and longer lasting pain relief than EXPAREL."

- On page 47 "AnestaGel can provide immediate and longer lasting pain control."
- On page 53 "AnestaGel was proven to last longer and provide a greater analgesic effect than EXPAREL"; "bupivacaine was proven to be released from AnestaGel into the blood as long as 96-120 hours after injection..." and "clearly demonstrated pain relief without toxic effect."

Safety and efficacy are assessed throughout all stages of clinical trials and the determinations are within the sole authority of the FDA or comparable foreign regulatory entity. If accurate, you may indicate that the product candidate was well tolerated and there were no serious adverse effects. Additionally, you can describe the data you collected during the preclinical trials and any observations that you used to determine that the product candidate was successful in alleviating pain.

7. Please identify your manufacturing partner, describe the terms of your agreement and explain the meaning of the phrase "unique manufacturing capability."
8. Please delete the statements that "AnestaGel represents the chance for the Company to quickly take a leading position in the pain market...", "that the significant investment and development history...substantially mitigates the risk of final development and commercialization," and it "provides the unique product materials to potentially dominate the non-opioid perioperative pain management market and compete very effectively with EXPAREL." Since your product candidate is in the very early stages of development, FDA approval and market success are currently speculative. With respect to the head to head comparisons with EXPAREL, please limit your statements to the data collection and observations from your preclinical trial and clearly state that EXPAREL is an FDA approved and commercially available drug.

#### History , page 43

9. Please clarify whether you have a license to the CCF technology, identify the licensing party, describe the material terms and file the agreement as an exhibit.

#### Intellectual Property & Patent Portfolio, page 50

10. As to your material patents, clarify whether you directly own or license the patents and patent applications and describe the duration and effect of the patents. If licensed from a third party, please identify the third party. Additionally, for each material patent, please describe the type of patent protection such as composition of matter, use or process; patent expiration dates and expected expiration dates for pending patent applications; and the

identification of all applicable jurisdictions where patents are granted or patent applications are pending.

11. Reference is made to the images on pages 51 and 52. Please revise the tables to ensure that the text provided in these images can be easily read by investors.

Overview of Clinical Data & Process, page 53

12. Please provide the details and parameters of your preclinical trials, including clinical endpoints, duration of treatment, metrics utilized, statistical significance, etc.

Directors, Executive Officers and Significant Employees, page 59

13. Please disclose when Messrs. Segermark, Knapp, Taylor, Hutchins, and Sipple began serving as officers. Please also disclose the dates of his principal occupations and employment during the past five years, and the name and principal business of any corporation or other organization in which such occupations and employment were carried on. Please see Item 10(c) of Part II of Form 1-A.
14. Please identify the members of your Scientific Advisory Board and provide the disclosure required by Item 10 of Form 1-A.

You may contact Ibolya Ignat at 202-551-3636 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Suzanne Hayes at 202-551-3675 with any other questions.

Division of Corporation Finance  
Office of Healthcare & Insurance