



DIVISION OF  
CORPORATION FINANCE

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

June 30, 2014

Via E-mail

Kenneth L. Waggoner  
Chief Executive Officer and President  
Nuvilex, Inc.  
12510 Prosperity Drive  
Suite 310  
Silver Spring, Maryland 20904

**Re: Nuvilex, Inc.**  
**Form 10-K for Fiscal Year Ended April 30, 2013**  
**Filed July 29, 2013**  
**Response Dated May 27, 2014**  
**File No. 333-68008**

Dear Mr. Waggoner:

We have reviewed your supplemental response 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 within ten business days by amending your filing, by providing the requested information, or by advising us when you will provide the requested response. 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 filing and the information you provide in response to these comments, we may have additional comments.

Item 1. Business

1. We note your response to our prior comment 1 and proposed disclosure to be included in footnote 2 to your next annual report on Form 10-K. Instead of or in addition to footnote 2, however, please ensure that the discussion of your relationship and arrangements with SG Austria, Austrianova Singapore, Bio Blue Bird and Drs. Günzburg and Salmons appears in the body of your annual report under the section entitled "Item 1 – Business."
2. We note your statement in response to our prior comment 1 that you will file certain agreements with your next annual report on Form 10-K. Please acknowledge that these agreements include:

- The licenses with Bavarian Nordic A/S and GSF Forschungszentrum für Umwelt u. Gesundheit GmbH, obtained in the acquisition of Bio Blue Bird; and
- The Manufacturing Framework Agreement with Austrianova Singapore

In addition, you should also file as exhibits:

- The Master Services Agreements with Inno Biologics and ViruSure;
- The July 2013 license form Austrianova Singapore for the use of its encapsulation technology in diabetes treatments and the Cell-in-a-Box trademark;
- If a final, definitive agreement has been signed, The Collaborative Research Agreements with the University of Veterinary Medicine, Vienna and the University of Munich

To the extent these agreements have been finalized and executed, please provide a description of the material terms of each.

3. We note your response to our prior comment 4. To the extent such information is not already disclosed, please provide all of the following information for each of your material license and/or collaboration agreements:

- The nature and scope of any intellectual property transferred;
- The duration of the agreement and of any royalties owed;
- A summary of termination provisions;
- Any investment features or share purchases; and
- A description of any other material rights and obligations of the parties, including material payment obligations, which may include:
  - Aggregate amounts paid or received to date under agreement;
  - Aggregate future potential milestone payments to be paid or received;
  - Royalty rates;
  - Profit or revenue-sharing provisions; and
  - Minimum purchase requirements, if applicable

4. Please expand your proposed disclosure to clarify the factual basis for your statement that “Austrianova Singapore is considered the world’s foremost expert in this unique and proprietary technology” or make clear that this is your opinion.

5. We note your statement on the top of page four of your response letter that “Drs. Günzburg and Salmons together are serving as if they were Nuvilex’s Chief Scientific Officer(s), and are so in all but name only.” In the following paragraph, you state that “Günzburg and Salmons have agreed to function as the ‘Chief Scientific Officers’ of Nuvilex for its preclinical studies and clinical trials in diabetes.” Please clarify your relationship with Drs. Günzburg and Salmons, as the extent of their positions and involvement with Nuvilex is not well defined. Please discuss the specifics of their duties

and responsibilities, whether they are expected to be officially appointed as the company's Chief Scientific Officers, whether and the extent to which they are compensated for their services, any contractual restrictions on their use of the company's proprietary information and assets, and the specific nature and extent of their involvement in the company's scientific endeavors. In addition, if the company's relationship with Drs. Günzburg and Salmons is governed by contract, please file all applicable contracts as exhibits and disclose their material terms.

6. We note your statement that "the success of SG Austria/Austrianova Singapore and the Company are co-dependent in almost every respect." Please discuss in detail the nature of this co-dependence. If the company's relationship with SG Austria and Austrianova Singapore is governed by one or more contracts that have not been disclosed, please file these as exhibits and disclose the material terms thereof.
7. Please expand your disclosure to explain, with specificity, the "major role" Dr. Matthias Löhr will play in the development of your pancreatic cancer treatment. If the company's relationship with Dr. Löhr is or will be governed by contract, please disclose the material terms of such contract and file it as an exhibit if a final version has been executed by the parties.

Cell Therapy Product Development , page 5

8. We note your response to our prior comment 2. Please expand your proposed disclosure to define and explain the following terms and concepts to provide a lay investor with a reasonable understanding of such terms and concepts:
  - "WHO/NCI guidelines on common toxicity criteria;"
  - "EORTC criteria;" and
  - "Karnofsky score"
9. We note your statement on page 11 that the combination of CapCell plus ifosfamide used in the Phase 1/2 clinical trial "was both safe and efficacious." Because approval of the FDA and other comparable regulatory agencies is dependent on such agencies making a determination (according to criteria specified in law and agency regulations) that a drug or biologic is both safe and effective, it is premature for you to describe or suggest that your product candidate, or any other non-approved product, is safe and/or effective. Accordingly, please delete this wording throughout your proposed disclosure, as applicable. In addition, please revise your disclosure as necessary to make clear that any observations you make about your products' potential for safety and/or efficacy are your own, are not based on the FDA's or any other comparable governmental agency's assessment and do not indicate that your products will achieve favorable results in any later stage trials or that the FDA or comparable agency will ultimately determine that your product is safe and effective for purposes of granting marketing approval.

10. We also note your statement that “no statistical parameters were used in determining either safety or efficacy.” Please explain what this means in layman’s terms and how this affects your conclusions about the Phase 1/2 trial.
11. We note your statement on page 11 describing the combination of Abraxane plus gemcitabine as the “current best available chemotherapeutic treatment for advanced, inoperable pancreatic cancer...” To the extent practicable, please discuss on page 10 under “Comparisons to Standard of Care” how clinical results observed in patients treated with Abexane plus gemcitabine compare to the combination of CapCell plus ifosfamide.

Patents, Intellectual Property and Trade Secrets, page 9

12. We note your response to our prior comment 3. However, not all of the information we requested been addressed and it is unclear which patents correspond to which license agreements. In other cases, you have not identified the licensor, the expiration date of the patent, the type of patent protection or the jurisdiction in which the patent rights are held. Please revise your proposed disclosure to clearly address all of the following information for each material patent. You may wish to provide this information in a tabular format:
  - A list of specific products, product groups and technologies to which such patents relate;
  - Whether such patents are owned or licensed from third parties and, if licensed, identification of the applicable licensors for each material patent;
  - Type of patent protection, such as composition of matter, use or process;
  - Patent expiration dates;
  - Identification of all applicable jurisdictions, including non-U.S.; and
  - Contested proceedings and/or third-party claims

Item 11. Executive Compensation, page 39

13. We note your response to our prior comment 6 and your statement in proposed footnote (5) that “Robert F. Ryan was suspended without pay in May 2014.” Please provide us with an explanation regarding the circumstances of the decision to suspend Dr. Ryan and discuss the impact on the company. In addition, please provide your analysis why this suspension and negotiation of a global settlement with Dr. Ryan has not yet, to our knowledge, been disclosed publicly. We may have further comment based on your response.

Item 13. Certain Relationships and Related Transactions, and Director Independence, page 43

14. We note your response to our prior comment 9. Please provide us with your proposed disclosure required by Item 404(a) of Regulation S-K, “Transactions with Related Persons” with respect to all qualifying transactions since the beginning of your last fiscal

year. In addition, please advise us of the 404(a) disclosure that should have been included in your 2013 10-K. We may have further comments based on your response.

Item 15. Exhibits, page 44

15. We note your response to our prior comment 7. Notwithstanding your representation that there were no employment agreements, written or oral, with any named executive officers at the time the company's 2013 10-K was filed, your proposed disclosure indicates that the company agreed to compensation terms with Messrs. Ryan and Crabtree on July 1, 2013 and May 1, 2013, respectively. The company did not file its 2013 Form 10-K until July 27, 2013, which suggests that the terms of employment were in place before the 10-K was filed. Moreover, the ongoing negotiation between the company and Mr. Ryan would not preclude the need to file his existing employment agreement as an exhibit. Finally, Ms. Gruden has been employed by the company in various capacities, including Interim Chief Financial Officer, since 2010. As such, it seems likely that at the time the 2013 10-K was filed she too was working for the company in accordance with some agreement, whether written or oral, that specified the terms of her employment. If so, such agreement should have been filed as an exhibit to the company's 10-K.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please contact Christina De Rosa at (202) 551-3577, Dan Greenspan at (202) 551-3623 or me at (202) 551-3715 with any questions.

Sincerely,

*/s/ Daniel Greenspan for*

Jeffrey P. Riedler  
Assistant Director