

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

April 24, 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 Filed July 29, 2013

File No. 333-68008

Dear Mr. Waggoner:

We have reviewed your filing 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 disclosure that you, SG Austria and Austrianova Singapore Private Limited "are now partners working together on multiple fronts." Please expand your disclosure to more specifically describe your partnership activities and arrangements, including the terms of any material contracts. If any such contracts exist, please also file them as exhibits.

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## Cell Therapy Product Development, page 5

- 2. We note your reference to the "successfully" completed Phase 1/2 studies of your live-cell encapsulation technology in the treatment of pancreatic cancer. Please expand your description of these trials to provide specific details, parameters and results of the studies, including:
  - Date(s) of trials and location;
  - Identity of trial sponsor(s);
  - Trial design (e.g., single-arm, open label);
  - Patient information (e.g., number of patients enrolled and treated and the criteria for participation in the study);
  - Duration of treatment and dosage information (both amount and frequency);
  - Specific clinical endpoints established by the trial protocol;
  - Observational metrics utilized and the actual results observed;
  - Comparisons to standard of care; and
  - Conclusions drawn and the extent to which the data suggested safety and/or efficacy, including whether statistical significance was demonstrated. Please include a brief discussion of the importance and use of statistical significance in clinical trial analytics, including a discussion of "p-values"

### Patents, Intellectual Property and Trade Secrets, page 9

- 3. We note your statement that "Nuvilex and its subsidiaries...own, co-own or have exclusive worldwide licensing rights to numerous patents in multiple countries over four technical areas: live cell encapsulation, pigment modification, microencapsulation and disinfectant/germicidal compositions." For each of these technical areas, please expand your disclosure to provide your material patents and any pending patent applications to the extent you have not already done so, including the following:
  - A list of specific products, product groups and technologies to which such patents relate:
  - Whether such patents are owned or licensed from third parties;
  - 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
- 4. We note your discussion of your rights to the material patents owned by Bavarian Nordic and GSF. Please file any agreements governing these rights between Bio Blue Bird or other related entities and Bavarian Nordic and GSF, as well as any other material license agreements, as exhibits pursuant to Item 601(b)(10) of Regulation S-K. In addition,

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please provide a detailed discussion of any such agreement(s) that sets forth the material terms of the agreement(s). These include the following, as applicable:

- Nature and scope of the intellectual property transferred;
- Duration of agreement and of any royalties owed;
- Termination provisions;
- 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:
  - o Aggregate amounts paid or received to date under agreement;
  - o Aggregate future potential milestone payments to be paid or received;
  - o Royalty rates;
  - o Profit or revenue-sharing provisions; and
  - o Minimum purchase requirements, if applicable

# <u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>

Recent Issuance of Unregistered Securities, page 16

5. In compliance with Item 701 of Regulation S-K, for each issuance of unregistered securities within the past three years, please name the persons or identify the class of persons to whom the securities were sold and indicate the section of the Securities Act or the rule of the Commission under which exemption from registration was claimed and state briefly the facts relied upon to make the exemption available.

#### Item 11. Executive Compensation, page 39

6. Please provide all of the disclosure required by Item 402(p) of Regulation S-K, "Outstanding Equity Awards at Fiscal Year-End."

### Item 15. Exhibits, page 44

- 7. Please file the employment agreements of all of your named executive officers, including Patricia Gruden, Dr. Robert F. Ryan and Dr. Gerald W. Crabtree as exhibits to your Form 10-K and include such in your list of exhibits.
- 8. We note that the Third Addendum to Asset Purchase Agreement by and between Nuvilex and SG Austria, dated June 25, 2013 and listed as Exhibit 2.6 to your Form 10-K (incorporated by reference to Form 8-K filed July 17, 2013) omits well over one hundred pages of the agreement. Please refile this agreement in its entirety. If you wish to request confidential treatment under Exchange Act Rule 24b-2, you may do so by following the procedures set forth in the Division of Corporation Finance's Staff Legal Bulletin 1A, available at http://www.sec.gov/interps/legal/slbcf1r.htm.

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

9. Please provide all of the disclosure required by Item 404 of Regulation S-K, "Transactions with Related Persons." Specifically, you must disclose the information required by Item 404(a) with respect to all qualifying transactions since the beginning of your last fiscal year and provided information concerning your policy and procedures for reviewing and approving related party transactions required by Item 404(b).

## Signatures, page 46

10. Please amend your 10-K to provide the signature of your Principal Accounting Officer.

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 Exchange Act of 1934 and all applicable Exchange 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.

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