

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

August 1, 2013

Via E-mail
Michael G. Hanna, Jr., Ph.D.
Chief Executive Officer
Vaccinogen, Inc.
5300 Westview Drive, Suite 406
Frederick, MD 21703

Re: Vaccinogen, Inc.

Registration Statement on Form 10-12(g)

Filed July 5, 2013 File No. 000-54997

Dear Dr. Hanna:

We have reviewed your filing and have the following comments. In our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter within 10 business days 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, please tell us why in your response.

After reviewing the information you provide in response to these comments, we may have additional comments.

General

- 1. Please note that your registration statement will become effective by operation of law 60 days from the date you filed it and that you will then be responsible for filing reports required by Section 13 of the Securities Exchange Act of 1934, even if we have not completed the review process of your filing. If you do not wish to incur those obligations until all of the following issues are resolved, you should withdraw your registration statement and resubmit a new registration statement when you have revised your document.
- 2. 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, please make the appropriate changes in accordance with our comments.

Cover Page, page 1

3. Please include the registrant's I.R.S. Employer Identification Number on the cover page as required by Form 10.

Item 1. Business

Agreements with Intracel Holdings Corporation, pages 2-3

4. Please disclose all material obligations under the Organon agreement between OrganonTeknika and Intracel that you have now assumed. Be sure to discuss all material terms of this agreement to the extent that they now apply to you.

Vaccines in Immunotherapy of Cancer, pages 4-5

- 5. We note the following statement in this section: "They point out that ideally the target should be tumor-specific and that 'it is important...." To the extent that you use direct quotations here and elsewhere from outside sources, please be sure to clearly indicate the source of the quote.
- 6. Please define the term "antigen" the first time it is used and explain the significance of antigen discovery in cancer research.
- 7. We note the following statement: "In addition, by using the patients' primary tumor resected at surgery as the source of the antigens, embraces the heterogeneity of cancer cells." Please revise this sentence to clarify its meaning.
- 8. Please define the terms "heterogeneous" and "homogenous" as they apply to cancer. Please additionally expand on the significance of your conclusion that cancer is a heterogeneous as opposed to homogenous disease.
- 9. Please define the term "surgical resection" at its first use in this section.
- 10. We note your statement that "Consequently, with polyvalent cancer vaccines, a robust and therapeutic immune response cannot be provided by allogeneic cells or even a relatively minor component of 'off the shelf' common antigens." Please separately define the terms polyvalent and allogeneic and clarify the significance of this statement. Please also define the term "autologous" the first time it is used in this section.
- 11. Please revise your statement regarding the widely recognized heterogeneity of cancer, in light of the uncertainty with respect to the homogeneity versus heterogeneity considerations described at page 4 of the registration statement.

OncoVAX Overview, page 5

12. Please expand on the discussion of OncoVAX to explain how it is administered to patients. For example, by what route is the vaccine administered, and how soon is it available to patients after surgical removal of the tumors?

OncoVAX Clinical Trials in Colon Cancer Patients, page 6

- 13. Please define the terms "adjuvant therapy" and "immunogenicity" at their first use in this section.
- 14. Please explain what the acronym BCG refers to.

Phase IIIa Trial 8701, page 8

- 15. Please eliminate your reference to the "proceeds from this offering" on this page, as this registration statement does not relate to an offering.
- 16. Please revise your disclosure to indicate what a p-value of 0.0015 on a log rank and 0.008 on a five year event free analysis indicate about the statistical significance of the Phase IIIa Trial for OncoVAX.

<u>Planned Trials – Stage II Colon Cancer, Phase IIIb Trial, page 13</u>

- 17. Please define your use of the phrase "best of breed" team and explain how you seek to organize such a team to conduct the Phase IIIb trial.
- 18. Please disclose whether you or a third party has filed an investigational new drug (IND) application for OncoVAX or a related compound. If an IND has been filed, please disclose the identity of the filer and the date the application was filed. Alternately, if no IND has been filed, please explain why.
- 19. Please clarify that the primary endpoint of the planned Phase IIIb trials is a statistically significant improvement in recurrence-free survival.

Planned Trial – Phase I/II Trial in Stage III Colon Cancer, page 14

20. Please provide a heading for your table at page 14 which identifies the information presented in the table. Please also consider using a larger font for the other headings of the table as they are difficult to read.

Human Monoclonal Antibodies ("HuMabs") Program, page 15

21. Please define the term monoclonal antibody the first time it is used in this section.

22. Please explain what "attractive IP benefits" are associated with monoclonal antibody technologies as compared to small molecule treatments.

Competitive Advantage, page 16

23. Please define the phrase "high avidity binding potential" and explain how this factor represents a competitive advantage.

Fully Human Monoclonal Antibodies, page 17

24. Please revise your disclosure to discuss the difference between fully human and humanized HuMabs.

<u>Immune Libraries</u>, pages 17-19

- 25. In light of the considerable uncertainty surrounding your HuMab research and development program, the fact that your product candidate is still in clinical trials, and your lack of prior experience with commercialization, please remove the table at page 19 with respect to forecasted licensing for HuMabs. In the alternative, please provide a reasonable basis for the forecasts provided.
- 26. We note your statement on page 19 that the European Medicines Agency has declared fully HuMabs safe. Please revise you disclosure to explain how and when the EMA's statement was made. In addition, please explain the significance of the EMA's statement that "treatments could not be given sooner than once a month."

Colon Cancer Commercial Market Opportunity, page 21

27. Please indicate the source of the data included in the chart on page 21 or delete it from the registration statement.

OncoVAX Market Penetration Assumptions, pages 24-25

28. Given the uncertainty surrounding your future ability to commercialize your product candidate, please remove the chart on page 25 showing market penetration and eliminate the discussion of your product's market penetration assumptions on page 24. Alternatively, please provide a reasonable basis for your assumptions in this section. For example, if your data in this section are supported by your own marketing study, please disclose that fact in this section and the specific findings of the study.

OncoVAX Pricing, page 25

29. We note your disclosure regarding the anticipated pricing for OncoVAX. Please revise your disclosure to explain how you reached this estimate. In this regard, please explain

how you used Provenge as a benchmark and why the use of Provenge provides a reasonable basis to determine the anticipated pricing for OncoVAX.

Stage III Colon Cancer Opportunity, page 26

30. Please delete the reference in this section to "use of proceeds from this offering," as this registration statement does not relate to an offering.

2015-2016: Costs to Commercialize

Revenues, page 28

31. We note that your revenue projections make significant assumptions as to the likely commercialization of OncoVAX, your ability to market and sell OncoVAX, and the likelihood of entering related manufacturing and distribution partnerships. These assumptions diminish the value of the forecasts provided. As such, please remove these forecasts from your disclosure in light of the significant uncertainties and risks involved in the development OncoVAX and, in particular, in consideration of the fact that OncoVAX may never obtain regulatory or marketing approval.

Supplies, page 28

32. We note that OrganonTeknika supplies you with a key product used in processing OncoVAX. Please describe all material terms of the supply agreement between you and OrganonTeknika and file the agreement as an exhibit to the Form 10.

Manufacturing Costs, page 28

33. We note disclosure on page 27 stating that you own a manufacturing facility in the Netherlands that "will process all tumors for the planned clinical trials." Please disclose in your discussion of manufacturing how your product candidate, the OncoVAX vaccine, is manufactured. If a third party manufactures or will manufacture your product candidate, please disclose that fact here, describe all material terms of any related agreement, and file the agreement as an exhibit to the Form 10.

Intellectual Property, page 29

- 34. We note your statement that "sterility will be required for any product to reach the US market . . . [t]his could result in a regulatory barrier to entry to competitors." Please clarify the meaning of this statement and explain its significance to your intellectual property.
- 35. We note you hold two U.S. patents relating to OncoVAX and that one of them relates to sterility. Please revise your disclosure to clarify what exactly these patents cover and the type of protection they offer. For example, do they offer composition-of-matter or method-of-use protection, and do they cover the entirety of the product candidate or part

- of it? We also note that the patent relating to sterility expires in 2025. Please disclose the expiration date for the other U.S. patent.
- 36. Please disclose in this section all material terms of the Patent Security Agreement between you and the Abell Foundation. Please include a complete discussion of the provisions under which you may default and lose ownership of your intellectual property.
- 37. Similarly, we note your risk factor disclosure on page 39 stating that Organon has a security interest in your intellectual property and that you have not made certain required payments to Organon. Please explain how your failure to make these payments does not amount to a default, and identify the conditions under which you could default and trigger forfeiture of your intellectual property to Organon.

Competition, page 30

38. Please describe in this section any competing therapies of which you are aware, either existing or in development, for treatment of Stage II and Stage III colon cancer.

FDA Approval Process, page 31

39. Please expand the discussion of the FDA regulatory scheme. Specifically, please include definitions and explanations of Investigational New Drug (IND) applications, Special Protocol Assessments (SPAs), and Biologics License Applications (BLAs).

Taxes, page 36

40. We note you have not filed any U.S. tax returns since 2007. Please disclose your current total U.S. tax liability outstanding in this section, including any related penalties.

Item 1A. Risk Factors

"We have a history of significant losses from continuing operations...," page 37

41. Please revise this risk factor to quantify the amount of cash on hand, the amount of expenses incurred in the last fiscal year, your total outstanding debt, and how much you expect your annual expenses to increase as a result of your reporting obligations once this registration statement is effective.

"If an event of default is declared under agreements with Organon...," page 39

42. Please revise your risk factor to provide a brief description of your obligations under your agreement with OrganonTeknika and the circumstances that would constitute an event of default under your agreement.

"If an event of default is declared under our security agreements with the Abell Foundation...," page 40

43. Please revise your risk factor to provide a brief description of your obligations under your agreement with the Abell Foundation and the circumstances that would constitute an event of default under your agreement.

"We depend on key personnel for our continued operations...," page 39

44. You reference that fact the loss of one or more certain key personnel would be significantly detrimental to you. Please expand the discussion to disclose instances in which you have actually experienced this risk and the circumstances involved. For example, it appears that you lost a Chief Executive Officer in June 2012.

"You may not be able to liquidate your investment...," page 51

45. Please disclose under this risk factor the tier of the OTC Markets on which your common stock is currently listed.

"The requirements of being a public company may strain our resources...," page 55

46. Please include a separate risk factor indicating any risks to your business posed by tax laws and regulations, whether U.S. or foreign, and specifically disclose the fact that you are currently delinquent on taxes owed to the U.S., including the total amount.

<u>Item 2. Financial Information</u>
<u>Management's Discussion and Analysis</u>
<u>Overview, page 56</u>

47. We note your statement on this page that you are a biotechnology company with more than three decades of research into combating cancer. Please revise this statement to clarify that Vaccinogen was founded in 2007 and relies on such prior research to further develop its product candidates.

<u>Critical Accounting Policies</u> <u>Intangible Assets, page 60</u>

- 48. Please expand your disclosure regarding your review of impairment of the cost of acquired patents associated with OncoVax® to be used in research and development and the commercialization cancer related vaccines, to disclose:
 - The carrying value at December 31, 2012;
 - Whether your review is done by individual patent or in the aggregate, and your rationale therefore;
 - The last date at which events or changes in circumstances indicated that the carrying value may not be recoverable, the sum of the undiscounted cash flows expected to

- result from the use and eventual disposition of the patents at that date and the significant assumptions in determining those cash flows; and
- If the date in the preceding bullet was other than the latest date for which a balance sheet is presented in the filing, disclose why you believe the circumstances discussed in ASC 360-10-35-21.e. were not present at the latest balance sheet date presented.

Future Liquidity & Needs, page 69

- 49. Please briefly describe the terms of the "Unit offering" referenced here, including how and when these funds may be available to the company.
- 50. Please provide management's estimate as to how long the company can continue operations with current cash on hand. Please additionally provide the company's rate of negative cash flow per month in this section.

Contractual Obligations, page 69

51. We note your inclusion of lease obligations for 2013 in this table. Please include all of the company's relevant contractual obligations, including current debt obligations, in the tabular format required under Item 303(a)(5) of Regulation S-K.

<u>Item 5. Directors and Executive Officers, page 73</u>

- 52. We note that some of your directors and executive officers appear to have relationships with your current affiliates. For example, we note that Dr. Hanna was Chairman and Chief Scientific Officer of Intracel and Chief Operating Officer of Organon Teknika, while Mr. Kane is currently on the board of Intracel. For each instance in which a director or executive officer has or has had such a relationship, please clearly identify the relevant company as an affiliate as required by Item 401(e) of Regulation S-K. In addition, please ensure disclosure is clear regarding whether the relationship with such affiliates has ended or is ongoing.
- 53. Please expand Mr. Cohen's biography to include the name and principal business of the organizations for which he has worked over the last five years as required by Item 401(e) of Regulation S-K.

Involvement in Certain Legal Proceedings, page 75

54. Please confirm in this section whether any director or executive officer has experienced any of the applicable events under Item 401(f) of Regulation S-K in the past ten years.

<u>Item 9. Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters</u> Market Information, page 82-83

55. We note your disclosure that your stock trades on the OTC Markets and that you plan to upgrade your tier to OTC.QB once this Form 10 becomes effective. Please disclose the current tier of the OTC Markets on which your common stock is listed.

<u>Item 10. Recent Sales of Unregistered Securities, pages 85-91</u>

56. For each sale of securities listed in this section, please briefly state the facts relied upon to make the relevant exemption available as required under Item 701(d) of Regulation S-K.

Audited Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm, page F-3

57. As required by Rule 2-02(a) of Regulation S-X, please revise the auditor's report to include a signature. Please refer to Rule 232.302 of Regulation S-T, which discusses signatures in electronic filings.

Notes to Consolidated Financial Statements 3. Summary of Significant Accounting Policies Inventory, page F-12

58. Based on your disclosure that inventory primarily consists of a product used in creating vaccines using the OncoVAX® technology platform, you appear to capitalize products in inventory prior to regulatory approval. Please explain to us how this accounting policy complies with GAAP. Include specific references to any applicable authoritative literature that supports this treatment.

Financial Instruments

Derivative Financial Instruments, page F-15

59. Please revise your disclosure to discuss your rationale for classifying the Bridge Loan as a derivative financial instrument. Include a discussion of the specific assumptions used in determining the fair value of this liability.

4. Agreements with Intracel, page F-16

60. Please revise your disclosure to include a discussion of your accounting treatment of the series of events starting with your October 2007 License Agreement, the Asset Transfer and Stock Exchange Agreement in June 2010, and the issuance of additional Series B preferred stock in December 2010. Include in your disclosure the significant factors,

assumptions, and methodologies used in determining the value of each transaction. Tell us your basis under GAAP to support the accounting of each transaction.

Notes to Unaudited Condensed Consolidated Financial Statements

9. Fair Value Measurements

Abell Option, page F-60

61. Please expand your disclosure to include a discussion of the significant assumptions and the methodology used in determining the fair value of the option. Disclose why the fair value of the option is greater than the \$5 million of common stock to be acquired under the agreement.

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 all 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.

You may contact Don Abbott at (202) 551-3608 or Jim Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, Bryan Pitko at (202) 551-3203, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler Assistant Director

cc: Via E-mail
Gregory R. Carney, Esq.
Indeglia & Carney