

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

June 6, 2013

Via E-mail
Randal J. Kirk
President and Chief Executive Officer
Intrexon Corporation
2875 South Ocean Boulevard, Suite 215
Palm Beach, Florida 33480

**Re:** Intrexon Corporation

 $\ \, \textbf{Draft Registration Statement on Form S-1} \\$ 

Submitted May 10, 2013 and amended May 31, 2013

CIK No. 0001356090

Dear Mr. Kirk:

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.

#### General

- 1. We note that there are a number of additional exhibits that still need to be filed. Please provide these exhibits as promptly as possible. Please note that we may have comments on these materials once they are provided.
- 2. We note that you intend to seek confidential treatment for several of your exhibits. Please note that comments on your confidential treatment request will be sent under separate cover.
- 3. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.

- 4. 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. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.
- 5. Please revise your disclosure throughout your registration statement to clarify whether you applied to obtain listing of your common stock, and if so, the status of your application. If you have not yet filed an application, please expand your disclosure to clearly state that an application has not yet been filed and disclose when you expect to file such an application.
- 6. Please update your filing with financial statements for the quarterly period ended March 31, 2013 as required by Rule 3-12 of Regulation S-X.
- 7. We note your statement, "While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data." It is not appropriate to imply that you are not liable for statements included in your registration statement. Please delete this sentence or specifically state that you are responsible for the referenced information.

# Prospectus Summary Company overview, page 1

- 8. Please provide the basis for your statement, "Intrexon is a leader in the field of synthetic biology...." Alternatively, please delete this assertion throughout your prospectus or make clear that it is your "belief" that you are a leader in the field of synthetic biology.
- 9. Please describe what you mean by the terms "gene programs" and "cellular systems" the first time you use the terms.
- 10. Please expand your disclosure to briefly describe your technology platforms.
- 11. Please expand the sentence at the bottom of page 1 to clarify that no commercial products have been enabled by your technologies to date.

# Our competitive strengths, page 2

12. Please expand your disclosure to describe your "extensive bioinformatic network."

# Risks associated with our business, page 4

13. In your last bullet point, please identify your key management personnel to which you are referring.

#### **Risk Factors**

If we lose key personnel, including key management personnel, or are unable..., page 18

- 14. To the extent that you have experienced problems attracting and retaining key management personnel in the recent past, please revise your disclosure to describe these problems.
- 15. Please quantify the amount of key man insurance that you maintain on Dr. Reed.

# We may be sued for product liability, page 20

16. To the extent that you have received notice of any material liability claims, please revise your disclosure to discuss such claims and the potential consequences. Also, please quantify the level of coverage of product liability insurance that your collaborators are required to obtain under your ECCs.

#### The markets in which our collaborators are developing products using our..., page 24

17. We note your disclosure that there are numerous companies that are developing products that may compete with, and could adversely affect the prices for, and products developed by your collaborators using your technologies. Please expand your disclosure to identify your main competitors and the products they are developing.

#### Risks related to our intellectual property, page 25

18. We note that you have patents in the U.S. and abroad that begin to expire in 2014 and 2017. Please expand your disclosure in this section to discuss your material patents, including the foreign jurisdictions in which they are granted and the specific expiration dates.

# Obtaining and maintaining our patent protection depends on compliance..., page 28

19. To the extent that you have failed to comply with any procedural, documentary, fee payment or other provisions during the patent process that could result in the abandonment or lapse of a patent or patent application, please discuss the situation and potential consequences.

#### Enforcing our intellectual property rights may be difficult and unpredictable, page 27

20. We note your statement, "Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable." It appears that you may have initiated some actions related to possible infringement of your intellectual property. If so, please discuss the situation and potential consequences in this risk factor discussion.

#### If our technologies or products using our technologies are stolen..., page 30

21. To the extent that any of your technologies, or products using your technologies, have been stolen, misappropriated or reverse engineered, please discuss the situation and potential consequences in this risk factor discussion.

#### AquaBounty will need additional capital, page 30

22. Please expand your disclosure in this section to quantify the amount of AquaBounty's cash and cash equivalents and working capital as of the most recent date practicable. Also, please disclose for how long these amounts will provide adequate funds for AquaBounty's ongoing operations. Lastly, to the extent known, please disclose the additional amount of funds that you may be required to invest in AquaBounty.

#### There is a significant uncertainty regarding regulatory approval of..., page 30

23. Please describe the significant delays that AAS has experienced in the regulatory process thus far.

#### The loss of AquaBounty broodstock would result in the loss of AquaBounty's..., page 31

24. Please define the term "broodstock" the first time it is used.

#### Use of proceeds, page 40

25. We note your intended uses of proceeds listed in the third paragraph of this section. Please expand your disclosure to specify the amount of proceeds that will be used for each of the purposes listed in this section. In regard to the proceeds that will be used to fund continued investment in your research and development platforms, please describe how far in the development process these funds will bring each of your platforms. Also, please update the section entitled, "Future capital requirements" on page 58 accordingly.

# Dilution, page 44

26. It appears that your calculations of historical net tangible book value include redeemable convertible preferred stock. The amounts attributable to preferred shareholders would

only be available to common shareholders upon the conversion of preferred stock to common stock. Please revise your calculations of historical net tangible book value to exclude redeemable convertible preferred stock or explain to us the basis for your calculation.

Management's discussion and analysis of financial condition and results of operations Results of operations

Research and development expenses, page 54

- 27. Please disclose the following information for each of your key research and development projects:
  - a. The nature, objective, and current status of the project;
  - b. The costs incurred during each period presented and to date;
  - c. The nature of efforts and steps necessary to complete the project;
  - d. The risks and uncertainties associated with completing development;
  - e. 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; and,
  - f. Whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency can be reliably determined.

#### Net operating losses, page 60

28. We note that the utilization of portions of the net operations losses may be subject to annual limitations. Please quantify the amount of losses that may be limited and the annual limitations.

# <u>Critical Accounting Policies and Estimates</u> <u>Share-based compensation, page 66</u>

29. We acknowledge your existing disclosure. Please expand your disclosure regarding the common stock valuations to discuss the method used to determine enterprise value at each valuation date. Also, prior to the effective date, please update your filing with additional disclosure that progressively bridges from your latest price per share to the mid-point of your estimated IPO price range. Reconcile and explain the differences between the values included in your analysis.

#### **Business**

Our suite of proprietary and complementary technologies
The UltraVector gene design and fabrication platform, page 80

30. We note that the UltraVector-driven build phase is performed via a proprietary modular assembly platform that incorporates a broad spectrum of DNA assembly methodologies. Please expand your disclosure to describe the "broad spectrum of DNA assembly methodologies."

- 31. Please define the terms "in vivo" and "ex vivo" the first time you use them.
- 32. We note that your Attsite recombinases mediate predictable gene exchange into host cells thereby eliminating "many of the difficulties seen with traditional gene insertions." Please describe the difficulties with traditional gene insertions and how your Attsite recombinases remedy the difficulties.

# Cell Systems Informatics, page 82

33. Please define the terms "in silico" and "de novo" the first time you use them.

#### Our ECCs

#### Ziopharm Oncology, page 88

34. Please disclose the aggregate amount of future milestones you could receive under the ECC with Ziopharm.

#### Elanco, page 89

35. Please identify the lead programs that are currently in the research phase under the ECC with Elanco and the indications that each program is designed to treat.

# Oragenics, page 90

36. Please identify the infectious diseases that lantibiotics are being developed to treat.

# Synthetic Biologics, page 90

- 37. Please identify the lead program that is currently in preclinical development under the ECC with Synthetic Biologics and the indications that this program is designed to treat.
- 38. Please disclose the aggregate amount of future milestones that you could receive from Synthetic Biologics.

#### AmpliPhi, page 91

39. We note that you are entitled to various milestone payments in the lower to mid-single-digit millions of dollars. Please quantify the aggregate amount of milestones that you are entitled to receive under the AmpliPhi ECC.

#### Genopaver, page 91

40. Please identify the lead programs under the Genopaver ECC and their specific uses.

# Soligenix, page 92

- 41. Please identify the lead program under the Soligenix ECC which is currently in the research phase.
- 42. We note that you are entitled to various milestone payments in the lower to mid-single-digit millions of dollars. Please quantify the aggregate amount of milestones that you are entitled to receive under the Soligenix ECC.

#### Competition, page 92

43. Under the first bullet point, please identify the companies which can synthesize DNA, and the companies that can develop monoclonal antibodies.

# Intellectual property, page 93

44. We note that you have also filed counterpart patents and patent applications in other countries. Please disclose the foreign jurisdictions where you have material patents or patent applications and the expiration date of your material foreign patents.

# Regulatory environment

## Regulations affecting Intrexon, page 94

45. We note that your research operations are subject to various environmental regulations. Please identify and describe these "various environmental regulations."

# Regulations affecting our ECC collaborators, page 95

46. Please describe FDA regulations, Department of Agriculture regulations, Environmental Protection Agency regulations, EMA regulations and the REACH program to which your collaborators are subject.

#### Management

# Executive officers and directors, page 99

47. We note that there are gaps in time in Mr. and Mrs. Krishnan's business experience during the past five years. Please revise your disclosure to include Mr. and Mrs. Krishnan's business experience during the past five years pursuant to Item 401(e)(1) of Regulation S-K.

#### Executive and director compensation

# Narrative to summary compensation table, page 109

48. Please disclose the annual salary that Mr. Kirk will receive as of the closing of this offering.

49. We note that you typically establish bonus targets for your named executive officers and evaluate their performance based on your achievement of corporate goals and the achievement of specified goals and objectives by each individual employee. Please expand your disclosure to describe your bonus targets. Also, please describe your corporate goals and the specified goals and objectives for each individual named executive officer, providing a quantification of the corporate or individual goal as appropriate. Lastly, please describe the level of achievement of each corporate and individual goal which led to Mr. Krishnan and Dr. Reed receiving bonuses in the amounts of \$600,000 and \$120,000, respectively, for the fiscal year ended December 31, 2012.

# <u>Certain relationships and related person transactions</u> Transactions with Third Security, LLC and affiliates

50. In the risk factor entitled, "We have engaged in transactions with companies in which Randal J. Kirk, our Chief Executive Officer, and his affiliates have an interest," you refer to your research collaboration with Biolife Cell Bank, Inc. We also note that the agreement is listed as an exhibit to be filed pursuant to Item 601(b)(10) of Regulation S-K in your initial draft registration statement. Please include a description of the agreement and its material terms, in this section and throughout your prospectus as appropriate, including the parties' rights and obligations, aggregate amounts paid/received to date under the agreement, aggregate potential milestones payments to be paid/received, royalty rates, duration and termination provisions. We note that you did not include the agreement as an exhibit in amendment no. 1 to your draft registration statement. Please file the agreement as an exhibit in your next amendment.

#### Halozyme, page 126

51. Please expand your disclosure regarding the material terms of the Halozyme collaboration and license agreement to include the duration and termination provisions of the agreement. Also, please file the agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.

#### Lock-up agreements, page 143

52. Please file the form of lock-up agreement as an exhibit.

<u>Financial Statements of Intrexon Corporation</u>
<u>Notes to Consolidated Financial Statements</u>
11. Stock Option Plans, page F-46

53. The ASC Master Glossary defines intrinsic value as "the amount by which the fair value of the underlying stock exceeds the exercise price of an option" Please revise your disclosure of intrinsic value to remove the word "deemed," when you refer to fair value.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Franklin Wyman at (202) 551-3660 or Donald Abbott at (202) 551-3608 if you have questions regarding comments on the financial statements and related matters. Please contact Johnny Gharib at (202) 551-3170, John Krug at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

Via E-mail
David I. Meyers, Esq.
Troutman Sanders LLP
1001 Haxall Point
Richmond, Virginia 23219