Table of Contents

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Registration No. 333-183685

PROSPECTUS

ORAGENICS, INC.

9,437,834 Shares of Common Stock

This prospectus relates to the resale by the investors listed in the section titled "Selling Shareholders", and we refer to the investors as the Selling Shareholders (the "Selling Shareholders") of up to 9,437,834 shares of our Common Stock, par value $0.001 per share (the "Common Stock"). The Common Stock was acquired by the Selling Shareholders in connection with a private placement offering we completed in July 2012 (the "July 2012 Private Placement"). We are registering the resale of the Common Stock as required by the Registration Rights Agreement we entered into with the Selling Shareholders in connection with the July 2012 Private Placement (the "Registration Rights Agreement").

The Selling Shareholders may offer and sell or otherwise dispose of the shares described in this prospectus from time to time through public or private transaction at prevailing market prices, at prices related to such prevailing market prices, at varying prices determined at the time of sale, at negotiated prices, or at fixed prices. See "Plan of Distribution" beginning on page 30 for more information.

We will not receive any of the proceeds from the Common Stock sold by the Selling Shareholders.

We have agreed to pay certain expenses in connection with this registration statement and to indemnify the Selling Shareholders against certain liabilities. The Selling Shareholders will pay all underwriting discounts and selling commissions, if any, in connection with the sale of the shares of Common Stock.

Our Common Stock is listed on the NYSE MKT under the symbol "OGEN." On April 11, 2013, the last reported sale price of our Common Stock was $2.65 per share.

Investing in the Securities involves a high degree of risk. See the section entitled " Risk Factors" beginning on page 6 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is May 2, 2013.

Table of Contents

Table of Contents

Prospectus

ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. Neither we nor the Selling Shareholders have authorized anyone to provide you with information that is different from such information. If anyone provides you with different or inconsistent information, you should not rely on it. The Selling Shareholders are offering to sell Common Stock only in jurisdictions where offers and sales are permitted. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date.

The Selling Shareholders are offering the Common Stock only in jurisdictions where such issuances are permitted. The distribution of this prospectus and the issuance of the Common Stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the issuance of the Common Stock and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, the Common Stock offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

It is important for you to read and consider all of the information contained in this prospectus in making your investment decision. To understand the offering fully and for a more complete description of the offering you should read this entire document carefully, including particularly the “Risk Factors” section beginning on page 6. You also should read and consider the information in the documents to which we have referred you in the sections entitled “Where You Can Find Additional Information” and “Incorporation of Certain Information by Reference”.

As used in this prospectus, unless the context requires otherwise, the terms “we”, “us”, “our”, or “the Company” refer to Oragenics, Inc. and its subsidiaries on a consolidated basis. References to “Selling Shareholders” refers to those shareholders listed herein under “Selling Shareholders” and their successors, assignees and permitted transferees.

ABOUT FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), about the Company and its subsidiaries. These forward-looking statements are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, and can be identified by the use of forward-looking terminology such as “believes”, “expects”, “may”, “will”, “could”, “should”, “projects”, “plans”, “goal”, “targets”, “potential”, “estimates”, “pro forma”, “seeks”, “intends”, or “anticipates” or the negative thereof or comparable terminology. Forward-looking statements include discussions of strategy, financial projections, guidance and estimates (including their underlying assumptions), statements regarding plans, objectives, expectations or consequences of various transactions, and statements about the future performance, operations, products and services of the Company and its subsidiaries. We caution our shareholders and other readers not to place undue reliance on such statements.

Our businesses and operations are and will be subject to a variety of risks, uncertainties and other factors. Consequently, actual results and experience may materially differ from those contained in any forward-looking statements. Such risks, uncertainties and other factors that could cause actual results and experience to differ from those projected include, but are not limited to, the risk factors set forth in the section entitled “Risk Factors” beginning on page 6 of this prospectus and elsewhere in the documents incorporated by reference in this prospectus, including our Annual Report on Form 10-K for the year ended December 31, 2012.

All written or oral forward-looking statements attributable to us or any person acting on our behalf made after the date of this prospectus are expressly qualified in their entirety by the risk factors and cautionary statements contained in and incorporated by reference into this prospectus. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and in the documents incorporated by reference in this prospectus and does not contain all the information you will need in making your investment decision. You should read carefully this entire prospectus and the documents incorporated by reference in this prospectus before making an investment decision, especially the information presented under the heading "Risk Factors."

Overview

We are a healthcare company focused primarily on developing novel antibiotics and oral health products. Within oral health we are marketing our oral health probiotics blend, ProBiora3 to consumers and to dental professionals. We also maintain a suite of other patented technologies stemming from several years of our research efforts in the oral health space.

Our Antibiotics

Members of our scientific team discovered that a certain bacterial strain produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. Lantibiotics, such as MU1140, are highly modified peptide antibiotics made by a small group of Gram positive bacterial species. Approximately 60 lantibiotics have been discovered since 1927 when the first lantibiotic, nisin, was discovered. Lantibiotics are generally recognized to be potent antibiotic agents.

We have performed preclinical testing on MU1140, which has demonstrated the molecule's novel mechanism of action. MU1140 has proven active preclinically against all Gram positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections or HAIs. The most common HAIs are caused by drug-resistant bacteria, including methicillin-resistant *Staphylococcus aureus*, or MRSA, vancomycin-resistant *Enterococcus faecalis*, or VRE; and *Clostridium difficile,* or *C. diff*. We believe the need for novel antibiotics is increasing as a result of the growing resistance of target pathogens to existing FDA approved antibiotics on the market.

The challenge presented by lantibiotics is that they have been difficult to investigate for their clinical usefulness as a therapeutic agent in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of any of these molecules. Standard fermentation methods are used to make a variety of currently marketed antibiotics. When such fermentation methods are used to make lantibiotics the result is the production of only minute amounts of the lantibiotic.

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately our commercialization efforts, we are currently pursuing the following paths:

- In June 2012, we entered into a worldwide exclusive collaboration agreement (ECC) with Intrexon Corporation (Intrexon) for the development and commercialization of the native strain of MU1140 using Intrexon's advanced transgene and cell engineering platforms. We expect to pursue our research and development efforts with Intrexon in accordance with the terms of the ECC on the development of the MU1140 molecule and potential derivatives of the molecule.
- We also produced a synthetic version of MU1140 known as MU1140-S. We created MU1140-S using our patented, novel organic chemistry synthesis platform known as DPOLT (Differentially Protected Orthogonal Lanthionine Technology). We engaged Bachem Americas, Inc. ("Bachem"), a peptide synthesis manufacturing company to assist us with research on producing greater amounts of MU1140-S. While the work performed by Bachem generated improvements in the yield of components necessary to synthesize MU1140-S, further research was determined to be needed, which was beyond the scope of our initial agreement with Bachem. We continue to pursue this research internally through the use of existing grant funds.

We have previously performed preclinical testing on native MU1140 and such testing has demonstrated the molecule's novel mechanism of action. We expect to begin preclinical activities on either native MU1140, or an analog developed under the ECC with Intrexon, in the second half of 2013. These preclinical activities are expected to include toxicity results, pharmacokinetic studies, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. Pursuit of clinical trials toward the goal of ultimately obtaining regulatory approval will depend upon further successful advancements in our research collaboration efforts with Intrexon and our efforts to have additional product manufactured. Developments from these efforts will dictate our regulatory path. If our preclinical work is successful, we would expect to file an Investigational New Drug application with the FDA by the first quarter of 2015.

Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. We believe these developments represent progress toward our goal of commercial production of sufficient quantities of MU1140 and delivers a step in validating the lantibiotics platform targeting infectious diseases. Previously, the ability to manufacture MU1140 by fermentation was originally thought not to be commercially feasible due to low titers and difficulties in purification. In addition to the optimization of fermentation and purification strategies, we are working to leverage Intrexon's genetic and cell engineering expertise to produce analogs of MU1140 toward the goal of establishing a pipeline of new lantibiotics.

Manufacturing requirements and methods for producing MU1140, or an analog, will primarily be dependent upon the end results of our efforts under the ECC with Intrexon. We are actively seeking a third party manufacturer to produce additional quantities of MU1140, or a designated analog, based upon the developments achieved from our work with Intrexon. The additional quantities of MU1140, or a designated analog, are needed for the consummation and pursuit of our preclinical testing activities.

Our Probiotic Products

We are marketing a variety of probiotic products that we developed. Our probiotic products contain the active ingredient ProBiora3, a patented blend of oral care probiotics that promote fresher breath, whiter teeth and support overall oral health. We have conducted scientific studies on ProBiora3 in order to market our products under self-affirmed Generally Recognized As Safe status, or GRAS. We sell our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics business and consistent with these efforts:

- We are refocusing our efforts on our direct-to-consumer channel, including internet, as well as on our Dental channel, which entails distribution to Dentists throughout the United States.
- We initiated two, double blinded randomized, placebo controlled clinical studies one at the University of Washington and the other at Loma Linda University in California that we believe could allow us to enhance the claims we can make about our ProBiora3 products and assist us in registering the product for commercial sale in the European Union. While we have received preliminary data from the University of Washington study the results are inconclusive and we continue to analyze the data and study parameters. We are also supporting a two-year study in children in Scandinavia.
- To better serve our customers, we continue to evaluate new delivery systems which we believe will enable us to deliver ProBiora3 to new markets and end-users;
- *ProBiora3 Distribution Agreement.* On January 22, 2013, we announced that we entered into a three year distribution agreement with Organic Wave, Inc. Under the terms of the agreement, Organic Wave will be the exclusive distributor of our oral care probiotics for pets in Japan under the Evora Pet name as well as a private label brand. The pet product will contain ProBiora3; our patented proprietary blend of three probiotics specifically designed for improved oral health.
- *European Patent.* On March 12, 2013, we announced we had received our first patent approval in Europe for our ProBiora3. The approval provided additional protection for ProBiora3's proprietary blend of three probiotic bacteria, specifically designed to enhance oral health, whiten teeth and freshen breath. European Patent No. 1659885, entitled "Compositions and Methods for the Maintenance of Oral Health," affords protection for ProBiora3 for use in a broad spectrum of potential applications, including the prevention of tooth decay and periodontal diseases, halitosis, and other therapeutic and cosmetic applications. The claims further protect ProBiora3 in several delivery forms, such as food supplements, tablets, and mouth rinses.

Other Product Candidates and Technologies.

We also possess and have developed other product candidates and technologies that originated from the discoveries of our scientific team. These other product candidates and technologies include our SMaRT Replacement Therapy, our weight loss agent, LPT3-04, DPOLT which was specifically designed as a methodology for synthesizing lantibiotics using traditional organic chemistry techniques. We continue to consider and evaluate opportunities that could promote the advancement of our other product candidates and technologies. We believe our other product candidates and technologies could provide potential partnership opportunities for us. For our product candidates and technologies we expect to devote limited financial resources toward continued research and development while exploring the possibilities for outlicensing such product candidates or entering into partnerships or collaborative arrangements for the further development of such product candidates.

Our SMaRT Replacement Therapy. Our SMaRT Replacement Therapy is based on the creation of a genetically modified strain of bacteria that colonizes in the oral cavity and replaces native bacteria that cause tooth decay. Our SMaRT Replacement Therapy product candidate is designed to be a painless, one-time, five-minute topical treatment applied to the teeth that has the potential to offer lifelong protection against dental caries, or tooth decay. While we commenced a Phase 1b clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, the very restrictive study enrollment criteria required by the FDA made the enrollment of candidates meeting the restrictive criteria difficult. Due to the enrollment difficulty we encountered with our initial our Phase 1a clinical trial and now with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial and instead focus our efforts on possible partnering opportunities that may exist for our SMaRT Replacement Therapy.

Our Weight Loss Agent-LPT3-04. LPT3-04 is a naturally occurring compound which is normally consumed in the human diet in small amounts, in the course of our SMaRT Replacement Therapy research, our scientific team also discovered that consumption of a significant amount of LPT3-04, resulted in dose-dependent weight loss in experimental animal models. We have filed a patent application for use of LPT3-04 for weight regulation with the United States Patent Office. We believe this product candidate is positioned for collaboration, particularly or outlicensing opportunities, which we expect to pursue.

The July 2012 Private Placement Financing and Secured Debt Conversion

On July 30, 2012 (the "July 2012 Private Placement"), we entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain accredited investors which we collectively refer to as the Selling Shareholders. Pursuant to the Purchase Agreement the Selling Shareholders purchased an aggregate of 8,666,665 shares of our common stock at a price per share of $1.50 (the "Common Shares") for aggregate gross proceeds of $13.0 million. In addition, we issued warrants to purchase up to 771,169 shares of our common stock to our placement agent Griffin Securities, Inc. (the "Agent Warrants"). We intend to use the net proceeds from this July 2012 Private Placement to accelerate development of several of our key initiatives including the Exclusive Channel Collaboration Agreement with Intrexon Corporation ("Intrexon") relating to the our lantibiotics program, sales and marketing of our probiotic product lines and general corporate purposes.

Because the July 2012 Private Placement constituted a "qualified financing" under the terms of our existing Loan Agreement with the Koski Family Limited Partnership, or KFLP, our largest shareholder, our secured debt in the principal amount of $2.5 million, together with accrued but unpaid interest thereon, due to the KFLP was automatically converted contemporaneously with the closing of the July 2012 Private Placement into 1,692,123 shares of common stock issued to the KFLP at the same price of $1.50 per share paid by the Purchasers in the July 2012 Private Placement. The KFLP waived receiving comparable registration rights as the Purchasers in the July 2012 Private Placement as well as its piggyback registration rights applicable to the July 2012 Private Placement.

Intrexon also waived its piggyback registration rights applicable to the July 2012 Private Placement and waived its participation rights. As a result of the conversion of the secured indebtedness, the Loan Agreement together with the related Security Agreement and related agreements have been terminated which eliminated all of our long-term debt.

In connection with the Purchase Agreement, we also entered into a Registration Rights Agreement, with the Selling Shareholders. Under the Registration Rights Agreement we were required to: file a registration statement with the Securities and Exchange Commission ("SEC"); have it declared effective; and maintain its effectiveness (subject to certain exceptions) for one year; to register for resale the Common Shares and shares issuable pursuant to the Agent Warrants.

Corporate and Other Information

We were incorporated in Florida in 1996 and commenced operations in 1999. We amended our articles of incorporation in 2002 in order to change our name from Oragen, Inc. to Oragenics, Inc., and consummated our initial public offering in June 2003. We have devoted substantially all of our available resources to the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through December 31, 2012, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008 our revenues were derived solely from research grants. Since 2008, our revenues have also included sales of our ProBiora3 products, which we initiated in late 2008. For the years ended December 31, 2012 and 2011, our net revenues were $1,331,764 and $1,444,447, respectively.

As of December 31, 2012, we had an accumulated deficit of $54,086,362 and we have yet to achieve profitability. We incurred net losses of $13,090,446 and $7,678,868 for the years ended December 31, 2012 and 2011, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our product candidates through preclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization. We are continuing our efforts to raise additional capital. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

Our executive office is located at, 4902 Eisenhower Boulevard, Suite 125 Tampa, Florida, 33634 and our research facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. Our telephone number is (813) 286-7900 and our website is http://www.oragenics.com. Information on, or that can be accessed through, our website is not part of this prospectus and should not be relied on in connection with this offering.

For a complete description of our business, financial condition, results of operations and other important information, we refer you to our filings with the Securities and Exchange Commission (the "SEC") that are incorporated by reference in this prospectus, including our Annual Report on Form 10-K for the year ended December 31, 2012. For instructions on how to find copies of these documents, see "Where You Can Find Additional Information."

The Offering

The following is a brief summary of the offering. You should read the entire prospectus carefully, including "Risk Factors" and the information, including financial information relating to us included in our filings with the Securities and Exchange Commission and incorporated in this document by reference.

Common stock offered by the Selling Shareholders	9,437,834 shares of common stock.
Selling Shareholders	See "*Selling Shareholders*" beginning on page 25.
Common stock outstanding (1)	27,489,080.
Use of proceeds	We will not receive any proceeds from the sale or other disposition of the shares of common stock covered by this prospectus. See "*Use of Proceeds*" on page 24.
NYSE MKT Symbol	Our Common Stock is quoted on the NYSE MKT under the ticker symbol "OGEN".
Risk Factors	You should consider the matters set forth under "*Risk Factors*" beginning on page 6, as well as other cautionary statements throughout or incorporated by reference in this prospectus, before deciding to invest in shares of our common stock.

(1) The number of shares of our common stock outstanding is based upon the number of shares outstanding as of April 11, 2013. This number does not include:

- 669,373 shares of our common stock issuable upon exercise of options outstanding, at a weighted average exercise price of $4.63 per share;
- 3,035,982 shares of our common stock issuable upon exercise of currently outstanding warrants, at a weighted average exercise price of $3.62 per share; and
- 2,659,711 shares reserved for issuance under our 2012 Equity Incentive Plan.

RISK FACTORS

Readers and prospective investors in our common stock should carefully consider the following risk factors as well as the other information contained or incorporated by reference in this prospectus.

If any of the following risks actually occurs, our financial condition, results of operations and liquidity could be materially adversely affected. If this were to happen, the value of our common stock could decline, and if you invest in our common stock, you could lose all or part of your investment.

The discussion below highlights some important risks we have identified related to our business and operations and an investment in shares of our common stock, but these should not be assumed to be the only factors that could affect our future performance and condition, financial and otherwise. We do not have a policy of updating or revising forward-looking statements except as otherwise required by law, and silence by management over time should not be construed to mean that actual events are occurring as estimated in such forward-looking statements.

Risks Related to Our Business

We have incurred significant losses since our inception and expect to continue to experience losses for the foreseeable future.

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $13.1 million and $7.7 million for the years ended December 31, 2012, and 2011, respectively. As of December 31, 2012 our accumulated deficit was approximately $54.1 million. We have devoted a significant amount of our financial resources to research and development, including our preclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date has not generated significant revenue. We expect that the costs associated with our exclusive channel partnership with Intrexon Corporation and the development and commercialization of our MU1140 product candidates and lantibiotics using Intrexon's advanced transgene and cell engineering platforms, as well as our expected increased marketing and sales efforts for our ProBiora3 products will increase the level of our overall expenses significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth of our revenues. If we are unable to develop and commercialize our other product candidates or if sales revenue from ProBiora3 products is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business.

Developing and commercializing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As a result of the approximately $12.0 million in net proceeds from our private placement of common stock in July 2012, we anticipate that our cash resources as of December 31, 2012 will be sufficient to fund our operations for at least the next 15 months. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. Because we currently expect to devote a significant portion of our resources to develop and commercialize our antibiotic product candidates and for ProBiora3 sales and marketing efforts, further progress with the development of our other product candidates including our SMaRT Replacement Therapy, and LPT3-04 product candidates may be significantly delayed and may depend on the success of our development efforts involving our antibiotic product candidates. Our actual costs, as well as the actual revenues from sales of our ProBiora3 products, may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. If our current cash, cash equivalents and short-term investments are not

sufficient to fully implement our business strategy and sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

Our success will also depend on our ability to significantly increase sales of our ProBiora3 products which is currently our only source of product revenue and has not generated substantial revenues to date.

Currently our sole source of product revenues is from sales of our ProBiora3 products, which began in late 2008 and have generated only modest revenues to date. Sales of our ProBiora3 products were $1,194,878, $1,229,510 and $1,128,895 for the years ended December 31, 2012, 2011 and 2010, respectively. While we plan to significantly increase the amount we spend on sales and marketing efforts for our ProBiora3 products, there can be no assurance that it will result in a significant increase in sales. If we are unable to generate significant revenues from our ProBiora3 products our business, financial condition and results of operations will be materially adversely affected.

Our success will depend on our ability to obtain regulatory approval of our antibiotic product candidates and their successful commercialization.

Our antibiotic product candidates have not received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. We have incurred and will continue to incur significant costs relating to the preclinical and clinical development of our antibiotic product candidates including MU1140 or any analogs thereof we may develop. We have performed extensive preclinical testing using native MU1140 and have since entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation. We expect to begin preclinical activities on either MU1140 or an analog in the second half of 2013. Those activities are expected to include toxicity results, pharmacokinetic studies, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. If our preclinical work is successful, we would expect to file an Investigational New Drug application with the FDA by the first quarter of 2015. Even if we are able to conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our product candidates. If our MU1140 or other antibiotic product candidates are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

The channel partnering arrangement with Intrexon is based on an early stage technology in the field of lantibiotics.

Our exclusive channel collaboration arrangement with Intrexon contemplates the use of Intrexon's advanced transgene and cell engineering platforms for the development and production of lantibiotics**.** Such technologies have a limited history of use in the design and development of active pharmaceutical ingredients and drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease and may therefore involve unanticipated risks or delays.

We will incur additional expenses in connection with our exclusive channel collaboration arrangement with Intrexon.

Pursuant to our exclusive channel collaboration with Intrexon, we are responsible for future research and development expenses of product candidates developed under such collaboration, the effect of which we expect will increase the level of our overall research and development expenses going forward. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We expect to add additional personnel to support our exclusive channel collaboration with Intrexon.

Because our collaboration with Intrexon is relatively new, we have yet to assume development responsibility and costs associated with such program. In addition, because development activities are determined pursuant to a joint steering committee comprised of Intrexon and ourselves and we have not yet identified a specific product candidate from the Intrexon collaboration, future development costs associated with this program may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaboration due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development.

We may not be able to retain the exclusive rights licensed to us by Intrexon to develop and commercialize lantibiotic products.

Under our exclusive channel collaboration agreement with Intrexon (the "ECC"), we are responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting preclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). During the first 18 months, neither we nor Intrexon may terminate the ECC, except under limited circumstances. Following the first 18 months, Intrexon may terminate such agreement if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECC and if the ECC is terminated it would prevent us from achieving our business objectives.

Our success will depend on our ability to partner or sub-license our MU1140 or other antibiotic product candidates and Replacement Therapy product candidate and their subsequent successful commercialization.

Our MU1140 and other antibiotic product candidates, Replacement Therapy and other product candidates are in early stage development and will require partners with substantial financial resources to continue the development of each of these products to commercialization. In addition, none of these product candidates have received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. We recently determined to cease pursuit of our second Phase 1 clinical trial to examine the safety and genetic stability of an attenuated version of the SMaRT strain in humans. There can be no assurance that a new clinical trial for our SMaRT Replacement Therapy product candidate will be commenced, by us in the future or that we will be able to establish a partner relationship or sublicense our Replacement Therapy technology for future development. In addition, we do not know whether any of our clinical trials will be successful or can be completed within our current expected budget. For our MU1140 and other antibiotic product candidates, we have performed extensive preclinical testing using native MU1140 and expect to continue to pursue the preclinical testing of our MU1140 and other antibiotic product candidates during 2013. Even if we are able to partner and conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our MU1140 or other antibiotic product candidates or other product candidates. If our MU1140 product candidate, other antibiotic product candidates or other product candidates are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

Our financial results could vary significantly from quarter to quarter and are difficult to predict.

Our revenues and operating results could vary significantly from quarter to quarter due to a variety of factors, many of which are outside of our control. As a result, comparing our operating results on a period-to-period basis may not be meaningful. In addition, we may not be able to predict our future revenues or results of operations. We base our current and future expense levels on our internal operating plans and sales forecasts, and our operating costs are to a large extent fixed. As a result, we may not be able to reduce our costs sufficiently to compensate for an unexpected shortfall in revenues, and even a modest shortfall in revenues could disproportionately and adversely affect financial results for that quarter. Individual products represent meaningful portions of our revenues in any quarter. We may

incur significant or unanticipated expenses associated with our research and development efforts of our product candidates under development. In addition to other risk factors discussed in this section, factors that may contribute to the variability of our quarterly results include:

- the timing of release of new products and services by us and our competitors, particularly those that may represent a significant portion of revenues in any given period;
- the popularity of new products, and products released in prior periods;
- changes in pricing policies by us or our competitors;
- fluctuations in the size and rate of growth of overall consumer and retailer demand for our ProBiora3 products;
- our success in entering new geographic markets;
- decisions by us to incur additional expenses, such as increases in marketing or research and development;
- the level of expenses associated with our clinical trials;
- accounting rules governing recognition of revenues;
- the amount we reserve against returns and allowances; and
- the timing of compensation expense associated with equity compensation grants.

As a result of these and other factors, our quarterly and annual operating results could be materially adversely affected. Moreover, our operating results may not meet announced guidance or the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

Current and future economic and market conditions could materially adversely affect our revenues, expense levels and profitability.

The U.S. economy and the global economy are recovering from a severe recession. Factors such as uncertainties in consumer spending, a sustained regional and/or global economic downturn or slow recovery may reduce the demand for our ProBiora3 products. Furthermore, challenging economic conditions also may impair the ability of our customers to pay for our commercial products. Because consumer spending for our ProBiora3 products can generally be considered a discretionary purchase, we may experience a more negative impact on our business due to these conditions than other companies that do not depend on discretionary spending. If demand for our ProBiora3 products declines or our customers are otherwise unable to pay for our products, we may be required to offer extensive discounts or spend more on marketing than budgeted and our revenues, expense levels, and liquidity position will be materially adversely affected.

We are subject to government regulation of the processing, formulation, packaging, labeling and advertising of our consumer products.

Under the Federal Food, Drug, and Cosmetic Act, or FDCA, companies that manufacture and distribute foods, such as our ProBiora3 products, are limited in the claims that they are permitted to make about nutritional support on the product label without FDA approval. Any failure by us to adhere to the labeling requirements could lead to the FDA's requiring that our products be repackaged and relabeled, which would have a material adverse effect on our business. In addition, companies are responsible for the accuracy and truthfulness of, and must have substantiation for, any such statements. These claims must be truthful and not misleading. Statements must not claim to diagnose, mitigate, treat, cure or prevent a specific disease or class of disease. We are able to market our ProBiora3 products in reliance on the self-affirmed Generally Recognized As Safe, or self-affirmed GRAS, status of our active ingredient, ProBiora3. No governmental agency or other third party has made a determination as to whether or not ProBiora3 has achieved GRAS status. We make this determination based on independent scientific opinions that ProBiora3 is not harmful under its intended conditions of use. If the FDA, another regulatory authority or other third party denied our self-affirmed GRAS status for ProBiora3, we could face significant penalties or be required to undergo the regulatory approval process in order to market our probiotic products, and our business, financial condition and results of operations will be adversely affected. We cannot guarantee that in such a situation ProBiora3 would be approved.

The FDA's Good Manufacturing Practices, or GMPs, describe the methods, equipment, facilities, and controls for producing processed food and set the minimum sanitary and processing requirements for producing safe and wholesome food. Those who manufacture, package, or hold human food must comply with the GMPs. If we or our suppliers fail to comply with the GMPs, the FDA may take enforcement action against us or our suppliers.

The processing, formulation, packaging, labeling and advertising of our probiotic products are subject to regulation by one or more federal agencies including the FDA, the Federal Trade Commission and the Environmental Protection Agency. Our activities are also subject to regulation by various agencies of the states and localities in which our probiotic products are sold. Any changes in the current regulatory environment could impose requirements that would limit our ability to market our probiotic products and make bringing new products to market more expensive. In addition, the adoption of new regulations or changes in the interpretation of existing regulations may result in significant compliance costs or discontinuation of product sales and may adversely affect our business, financial condition and results of operations. While our ProBiora3 products are categorized as foods, it is possible that the FDA or a state regulatory agency could classify these products as a cosmetic or a drug. If the products are classified as cosmetics rather than a food, we would be limited to making claims that the products cleanse and beautify, but we could not make structure or function claims. If our probiotic products are classified as drugs, we would not be able to market the ProBiora3 products without going through the drug approval process. Either of these events would limit our ability to effectively market our products and would adversely affect our financial condition and results of operations. If the FDA or a state regulatory agency viewed the products as cosmetics or drugs, they could claim that the products are misbranded and require that we repackage and relabel the products and impose civil and/or criminal penalties. Either or both of these situations could adversely affect our business and operations.

If we undertake product recalls or incur liability claims with respect to our ProBiora3 products, such recalls or claims could increase our costs and adversely affect our reputation, revenues and operating income.

Our ProBiora3 products are designed for human and animal consumption and we may face product recalls or liability claims if the use of our products is alleged to have resulted in injury or death. ProBiora3 is classified as a food ingredient and is not subject to pre-market regulatory approval in the United States. Our ProBiora3 products contain ingredients that do not have long histories of human or animal consumption. Previously unknown adverse reactions resulting from consumption of these ingredients could occur. We may have to undertake various product recalls or be subject to liability claims, including, among others, that our ProBiora3 products include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. A product recall or liability claim against us could result in increased costs and could adversely affect our reputation with our customers, which, in turn, could have a material adverse effect on our business, financial condition and results of operations.

Product liability insurance is expensive, is subject to deductibles and coverage limitations, and may not be available in the future. While we currently maintain product liability insurance coverage, we cannot be sure that such coverage will be adequate to cover any incident or all incidents. In addition, we cannot be sure that we will be able to obtain or maintain insurance coverage at acceptable costs or in a sufficient amount, that our insurer will not disclaim coverage as to a future claim or that a product liability claim would not otherwise adversely affect our business, financial condition and results of operations. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also require significant management attention.

If we fail to comply with our obligations in the agreements with the University of Florida Research Foundation, Inc., under which we license our rights to MU1140 and to SMaRT Replacement Therapy, our license to these product candidates may be terminated and we will be unable to commercialize these product candidates.

We hold our MU1140 and SMaRT Replacement Therapy product candidates under licenses from the University of Florida Research Foundation, Inc., or UFRF. Under the terms of the licenses, we must spend at least $1,000,000 per year on development of those product candidates until the first commercial sale of products derived from those product candidates has occurred. In addition, we must pay $25,000 per quarter as minimum royalties to the UFRF under our license agreements. The UFRF may terminate our licenses to MU1140 and to SMaRT Replacement Therapy if we breach our obligations to timely pay these amounts, to submit development reports as required under the license agreements or commit any other breach of any other covenants contained in the license agreements. There is no assurance that we will be able to comply with these conditions in a timely manner or at all. If our license agreements are terminated, we will be unable to commercialize these product candidates.

Until commercial sale of any products developed from these licensed product candidates takes place, we will not earn any revenues from these product candidates and will, therefore, need additional financing to fund our required royalty payments and development expenses, such as through the commercialization and sale of our ProBiora3 products, the sale of our debt or equity securities, or otherwise. There can be no assurance that we will achieve sufficient sales of our ProBiora3 products or be able to raise the capital necessary to meet our obligations under our licenses. If we are unable to meet our obligations under these licenses, we may lose the licenses to these product candidates and our business, financial condition and results of operations will be materially adversely affected.

We depend on third-party manufacturers for our ProBiora3 products. The loss of any manufacturer or any interruptions in the supply of our ProBiora3 products, would have a negative impact on our revenues and profitability.

We currently have no manufacturing facilities and are dependent upon establishing relationships with independent manufacturers to supply our product needs. We currently have a one supplier that is able to produce two of the three strains of bacteria needed to produce ProBiora3 and one supplier that is able to produce one of the strains of bacteria needed to produce ProBiora3. These suppliers use proprietary methodologies to produce these three strains of bacteria. We believe our arrangements with our contract manufacturers have the capacity to meet our current and expected future manufacturing needs. Although we have qualified and used at least two contract manufacturers for each step in our manufacturing process, we do not have a long-term supply agreement or commitment with any of our manufacturers. If our manufacturers are unable or unwilling to produce our ProBiora products in sufficient quantities, or at all, at acceptable pricing in accordance with specifications we establish from time to time we would need to find alternative manufacturers that are qualified. If, in such instances, we are unsuccessful in obtaining alternative manufacturers, it could impair our ability to sell our ProBiora3 products and would have a negative impact on our revenues and profitability. In addition, competitors who own their manufacturing facilities may have an advantage over us with respect to pricing, availability of product and in other areas through their control of the manufacturing process.

The risks associated with the numerous factors that could cause interruptions in the supply of our products, including manufacturing capacity limitations, regulatory inspections, changes in our sources for manufacturing, disputes with a manufacturer, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials, are magnified when the suppliers are limited in number. Any interruption in the supply of finished products could hinder our ability to timely distribute our products and satisfy customer demand. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose those orders, our customers may cancel other orders, and they may choose instead to stock and purchase competing products. This could result in a loss of our market share and negatively affect our revenues and operations.

If our manufacturers in general fail to meet our requirements and the requirements of regulatory authorities, our revenues may be materially adversely affected.

We do not have the internal capability to manufacture our ProBiora3 products or our LPT3-04 Weight Loss, SMaRT Replacement Therapy, MU1140, or other antibiotic product candidates under GMPs, as required by the FDA and other regulatory agencies. In order to continue to develop our product candidates, apply for regulatory approvals for our MU1140 and other antibiotic product candidates, and commercialize our ProBiora3 products and other product candidates, we will need to contract with third parties that have, or otherwise develop, the necessary manufacturing capabilities.

There are a limited number of manufacturers that operate under GMPs that are capable of manufacturing our ProBiora3 products. Furthermore, manufacturing MU1140 or our other potential antibiotic product candidates derived from lantibiotics on a commercial scale have not yet been undertaken, so there are additional technical skills needed for the manufacture of MU1140 that will further limit the number of potential manufacturers. As such, if we are unable to enter into supply and processing contracts with any of these manufacturers or processors for our MU1140 and other antibiotic product candidates, or ProBiora3 products we may incur additional costs and delays in development and commercialization.

Problems with these manufacturing processes such as equipment malfunctions, facility contamination, labor problems, raw material shortages or contamination, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers and even minor deviations from normal procedures, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and insufficient inventory.

If we are required to find an additional or alternative source of supply, there may be additional costs and delays in the development or commercialization of our product candidates. Additionally, the FDA and other regulatory agencies routinely inspect manufacturing facilities before approving a New Drug Application, or NDA, or Biologic License Application, or BLA, for a drug or biologic manufactured at those sites. If any of our manufacturers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our commercial products and product candidates may be delayed.

All of our contract manufacturers must comply with the applicable GMPs, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. If our contract manufacturers do not comply with the applicable GMPs and other FDA regulatory requirements, we may be subject to product liability claims, the availability of marketed products for sale could be reduced, our product commercialization could be delayed or subject to restrictions, we may be unable to meet demand for our products and may lose potential revenues and we could suffer delays in the progress of preclinical testing and clinical trials for products under development. We do not have control over our third-party manufacturers' compliance with these regulations and standards. Moreover, while we may choose to manufacture our products ourselves in the future, we have no experience in the manufacture of pharmaceutical or biological products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical or biological products. Regardless of the manufacturer of our products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

We may be unable to find a method to produce MU1140 in large-scale commercial quantities. If we cannot, we will be unable to generate revenues from sales of our MU1140 product candidate.

Our antibiotic product candidate, MU1140, is produced by our strain of *S. mutans*. To date, it has been produced only in laboratory cultures. In March 2005 we successfully developed a methodology for producing MU1140 in quantities sufficient to undertake its preclinical testing. In addition, we developed the DPOLT synthetic chemistry methodology to allow large-scale commercial production of, a synthetic version of MU1140, known as MU1140-S. However, this methodology may not be feasible for cost effective, large scale manufacture. We also recently entered into an exclusive collaboration agreement with Intrexon Corporation to use its advanced transgene and cell engineering platforms to achieve sufficient production quantities of MU1140. While preliminary results from these efforts have demonstrated progress in the increase in production of MU1140 we need to contract with a third party manufacturer to produce additional quantities in order to be able to pursue further preclinical testing. If we are not able to utilize either of these methodologies for large-scale manufacture, we will be unable to partner and generate revenues from this product candidate and our business, financial condition and results of operations will be materially adversely affected. The manufacturing of MU1140 or any other possible antibiotic product candidates based on lantibiotics, is a highly exacting and complex process. Manufacturing MU1140 or any other antibiotic candidates derived from lantibiotics on a commercial scale has not yet been achieved so there are additional risks that such efforts will not be successful. The Intrexon technology may not be feasible to efficiently develop methodologies to enable large scale manufacturing of MU1140 or other antibiotic product candidates. Third-party manufacturers must have additional technical skills and must take multiple steps to attempt to control the manufacturing processes.

Our ProBiora3 products and our antibiotic product candidates and other product candidates face various forms of competition from other products in the marketplace.

The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Most of the competition that our ProBiora3 products and our antibiotic product candidates and other product candidates face comes from companies that are large, well established and

have greater financial, marketing, sales and technological resources than we have. Our ProBiora3 products compete with a range of consumer and nutraceutical products. Our commercial success with MU1140 and other possible antibiotic product candidates will depend on our ability and the ability of any sub-licensees to compete effectively in marketing and product development areas including, but not limited to, sales and branding, drug safety, efficacy, ease of use, patient or customer compliance, price, marketing and distribution. There can be no assurance that competitors will not succeed in developing and marketing products that are more desirable or effective than our ProBiora3 products or the products developed from our product candidates or that would render our products obsolete and non-competitive. We anticipate that our SMaRT Replacement Therapy technology would compete with other companies attempting to develop technologies in the oral health care market, including vaccines.

We rely on the significant experience and specialized expertise of our senior management and scientific team and we have incurred significant turnover in key positions over the last several years.

Our performance is substantially dependent on the continued services and on the performance of our senior management and scientific team, who have extensive experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees. In May 2011, we hired Dr. John Bonfiglio as Chief Executive Officer and in February 2012, we hired Mr. Michael Sullivan, CPA as our Chief Financial Officer. The loss of the services of these key employees could harm our ability to develop and commercialize our product candidates. We have no key man life insurance policies. We have employment agreements with Dr. Bonfiglio and Mr. Sullivan. The term of each of these employment agreements is for an indefinite period and will end when the employment relationship is terminated by either party for any or no reason.

We need to hire and retain additional qualified scientists and other highly skilled personnel to maintain and grow our business.

Our future success depends on our ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial and research personnel in all areas within our organization. We plan to continue to grow our business and will need to hire additional personnel to support this growth. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other biotechnology and nutraceutical companies, as well as universities and research institutions. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or be unable to fill new positions requiring key persons with appropriate experience. If we fail to attract, integrate and retain the necessary personnel, our ability to maintain and grow our business could suffer significantly.

If our MU1140 or other antibiotic product candidates are shown to be ineffective or harmful in humans, we will be unable to generate revenues from these product candidates.

Before obtaining regulatory approvals for the commercial sale of our MU1140 product candidate or other antibiotic product candidates, we must demonstrate through preclinical testing and clinical trials that our products are safe and effective for use in humans. To date the testing of the antibiotic substance MU1140 has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies with any MU1140 or any analog thereof. It is possible that when these studies are conducted, they will show that our antibiotic candidates are ineffective or harmful in humans. If MU1140 or any analogs thereof are shown to be ineffective or harmful in humans, we will be unable to commercialize and generate revenues from sales of this compound. If we are unable to generate revenues from MU1140 or any other antibiotic product candidates, our business, financial condition and results of operations will be materially adversely affected.

We intend to rely on third parties to pay the majority of the costs associated with obtaining regulatory approval for, and manufacturing and marketing of, our MU1140 and SMaRT Replacement Therapy product candidates. If we are unable to obtain agreements with third parties to fund these costs, we will have to fund such costs ourselves or we may be unable to extract any value from these technologies.

As we continue our development of MU1140 and other potential antibiotic product candidates as well as our efforts with our SMaRT Replacement Therapy product candidate, we intend to either license these product candidates to, or partner with, one or more major pharmaceutical companies at the earliest possible time in their product development. If we do so, we intend for these licensees or partners to pay the costs associated with any remaining

development work, regulatory submissions, clinical trials and the manufacturing and marketing of our product candidates. If we are unable to license our product candidates or otherwise partner with third parties, we will have to fund the costs of our clinical trials ourselves or we will be unable to extract any value from these technologies. We will also have to establish our own manufacturing facilities and find our own distribution channels. This would greatly increase our future capital requirements and we cannot assure you that we would be able to obtain the necessary financing to pay these costs or that we will be generating significant revenues from any of our products, such as ProBiora3, sufficient to cover the associated costs. If we do not generate sufficient revenues to cover the associated costs or we cannot obtain financing on acceptable terms or at all, our business, financial condition and results of operations will be materially adversely affected.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborative partners typically allow partners significant discretion in electing whether or not to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborative partners may devote to products based on the collaboration, and our partners may choose to pursue alternative products. Our partners may not perform their obligations as expected. Business combinations or significant changes in a collaborative partner's business strategy may adversely affect a partner's willingness or ability to complete its obligations under the arrangement. Moreover, we could become involved in disputes with our partners, which could lead to delays or termination of the collaborations and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our partner may be able to terminate the agreement under certain circumstances. If any collaborative partner were to terminate or breach our agreement with it, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing our product candidates would be materially and adversely affected.

We are subject to risks of doing business internationally as we attempt to expand our sales through international distributor relationships.

We have entered into a number of international distributor agreements for our ProBiora3 products. As a result, we expect to increase our revenues from international sales. A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, and we may encounter certain risks of doing business internationally including the following:

- reduced protection and enforcement for our intellectual property rights;
- unexpected changes in, or impositions of, legislative or regulatory requirements that may limit our ability to sell our products and repatriate funds to the United States;
- political and economic instability;
- fluctuations in foreign currency exchange rates;
- difficulties in developing and maintaining distributor relationships in foreign countries;
- difficulties in negotiating acceptable contractual terms and enforcing contractual obligations;
- exposure to liabilities under the U.S. Foreign Corrupt Practices Act;
- potential trade restrictions and exchange controls;
- creditworthiness of foreign distributors, customer uncertainty and difficulty in foreign accounts receivable collection; and
- the burden of complying with foreign laws and
- Potential for fines for claimed violations of foreign laws and regulations.

As we attempt to expand our sales internationally, our exposure to these risks could result in our inability to attain the anticipated benefits and our business could be adversely impacted. Our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. However, any of these factors could adversely affect our international operations and, consequently, our operating results.

If our intellectual property rights do not adequately protect our products or product candidates, or if third parties claim we are infringing their intellectual property rights, others could compete against us more directly or we could be subject to significant litigation. Such results could prevent us from marketing our products or product candidates and hurt our profitability.

Our product and product candidates are protected by patents and patent applications, including patents exclusively licensed from the University of Florida Research Foundation, Inc., or the UFRF. We are the exclusive worldwide licensee to the patents for SMaRT Replacement Therapy and MU1140, which are owned by the UFRF. Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks and licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide adequate protection against competitors. In addition, any future patent applications may fail to result in patents being issued. Also, those patents that are issued may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Moreover, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

In addition to patents and trademarks, we rely on trade secrets and proprietary know-how. We seek protection of these rights, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our proprietary rights could seriously impair our competitive position.

In the event of an infringement or violation, we may face litigation and may be prevented from pursuing product development or commercialization. We may receive in the future, notice of claims of infringement of other parties' proprietary rights. We may not have the financial resources to defend against claims of infringement by other parties. Infringement or other claims could be asserted or prosecuted against us in the future and it is possible that past or future assertions or prosecutions could harm our business.

The FDA instituted numerous clinical holds with respect to our Phase 1 clinical trial program for our SMaRT Replacement Therapy product candidate. Although the clinical holds were lifted with respect to the attenuated version of the SMaRT strain, a clinical hold remains in effect for our IND for the non-attenuated SMaRT strain. If the FDA does not lift the clinical hold on this IND, we will be unable to conduct the clinical trials necessary to obtain marketing approval of our product candidate. The FDA's concerns that resulted in these clinical holds may lead to the imposition of a new clinical hold or holds or the failure of our product candidates to obtain marketing approval.

In December 1998, the FDA imposed a clinical hold on the IND for our SMaRT strain. The FDA expressed concerns about the potential for DNA transfer into or from the SMaRT strain; the possible creation of an organism with increased ability to colonize and produce dental caries; and the potential for the transfer of the strain between humans. We met with the FDA to discuss proposed trials of an attenuated SMaRT strain to address the FDA's concerns, and the FDA informed us that such trials required a separate IND. We submitted an IND for the attenuated strain in March 2003.

The FDA then imposed multiple clinical holds with respect to the Phase 1 clinical trials of the attenuated strain. Specifically, we received clinical hold letters in May 2003, February 2004, June 2007 and August 2007. In connection with the clinical hold letter in May 2003, the FDA requested that we provide preclinical data on eradication of the attenuated version of the SMaRT strain once it had been implanted and a plan for the eradication of the attenuated strain in the trial subjects and their spouse or partners. In an April 2004 meeting, the FDA suggested that we conduct two eradication trials: one in subjects without teeth, and, if successful, another trial in subjects with teeth. We submitted revised protocols in accordance with FDA's suggestions, and in November 2004 the FDA lifted the clinical hold for the attenuated strain.

We initiated our first Phase 1 clinical trial in April 2005, but we found it difficult to find subjects who fit the FDA's highly cautious inclusion and exclusion criteria, particularly with respect to the subjects' lack of dentition. We

concluded this trial early after enrolling only two of the 15 planned subjects. The FDA then recommended that we revise the protocol for the evaluation of ten healthy male subjects, ranging from 18 to 30 years old and with normal dentition, in an institutionalized setting. After we submitted additional information, the FDA issued another clinical hold letter in June 2007 for the proposed trial with the attenuated strain, citing the need for a plan with respect to serious adverse effects; a plan for the eradication of the attenuated strain in trial subjects' offspring; and a required pregnancy test for female partners of subjects. We submitted additional protocols in response to the FDA's concerns. In August 2007, the FDA issued another clinical hold letter with required revisions to the protocol for offspring of subjects. We submitted a response to the clinical hold letter in September 2007, and the FDA removed the clinical hold for our Phase 1 trial in the attenuated strain in October 2007.

While we commenced a Phase 1b clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, the very restrictive study enrollment criteria required by the FDA made the enrollment of candidates meeting the restrictive criteria difficult. Due to the enrollment difficulty we encountered with our initial our Phase 1a clinical trial and now with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial and instead focus our efforts on possible partnering opportunities that may exist for our SMaRT Replacement Therapy.

There can be no assurance that future clinical trials for the attenuated strain will be successful, or that the FDA will ever lift the clinical hold on the non-attenuated SMaRT strain. In addition, there can be no assurances that we will be able to locate a partner willing to pursue further development of our SMaRT Replacement Therapy technology. If the FDA does not lift the clinical hold on the non-attenuated SMaRT strain, we or a partner would not be able to conduct the clinical trials necessary to pursue marketing approval of the SMaRT strain.

The FDA may impose additional requirements that may significantly increase the time and expense of obtaining FDA approval. Although the FDA has removed the clinical holds with respect to our Phase 1 trials for the attenuated strain, if the FDA has further concerns regarding the safety or risks associated with our trials, the FDA could implement another clinical hold on our ongoing trial or future trials or raise concerns as a part of a future NDA review process for our SMaRT Replacement Therapy product candidate, which could delay or prevent marketing.

Our antibiotic product candidates and SMaRT Replacement Therapy product candidate are subject to substantial government regulation, including the regulation of preclinical testing and clinical trials. If we are unable to obtain regulatory approval for our product candidates we will be unable to generate revenues.

The production and marketing of products which may be developed from our MU1140, and other antibiotic product candidates based on lantibiotics and our SMaRT Replacement Therapy product candidate and our research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. Most of the product candidates we are developing must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process before they can be marketed in the United States or internationally.

If we fail to obtain regulatory approval for our MU1140 product candidate or other antibiotic product candidates based on lantibiotics, or if the FDA fails to lift the clinical hold on our IND for non-attenuated version of SMaRT, we may have to cease further development. Clinical trials on our MU1140 other possible antibiotic product candidates and our SMaRT Replacement Therapy product candidate are expected to take several years to fully complete. The commencement or completion of preclinical studies or clinical trials can be delayed or prevented for a number of reasons, including:

- our belief that SMaRT Replacement Therapy is one of the first genetically modified bacterial strains for use in humans, which may cause the FDA to proceed with additional caution;
- difficulties in finding a partner with the resources to support large and expensive clinical development and commercialization costs;
- findings in preclinical studies;
- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size and nature of patient population, proximity of patients to clinical sites, eligibility criteria for the trial, nature of the trial protocol, the availability of approved effective treatments for the relevant condition and competition from other clinical trial programs for similar indications;
- severe or unexpected drug or biologic-related side effects experienced by patients in a clinical trial; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the trial, lack of efficacy, side effects, or personal issues, or who are lost to further follow up.

Clinical trials also may be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

We cannot assure you that clinical trials will demonstrate the safety or effectiveness of our MU1140 antibiotic product candidate or any other antibiotic product candidates we may pursue or as to our SMaRT Replacement Therapy product candidate, or will otherwise satisfy regulatory requirements. Our preclinical studies or clinical trials may produce negative or inconclusive results, there may be inconsistencies between early clinical trial results and results obtained in later clinical trials, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products. If we are unable to resolve the FDA's concerns, we will not be able to obtain regulatory approval for these product candidates.

The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA or other governmental regulatory approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals or ongoing clinical trials, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

We may encounter such delays and rejection of our product candidates by the FDA or other regulatory authority may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, or changes in regulatory policy during the period of product development. More stringent regulatory approval processes in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk, and higher expenses. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our licensed, patented product candidates for different indications or to market updated products that represent extensions of our basic product candidates. In addition, we may not receive FDA approval to export our products based on our licensed, patented product candidates in the future, and countries to which products are to be exported may not approve them for import.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our product candidates. It is possible that the applicable regulatory authority will issue additional regulations further restricting the sale of our product candidates. Any change in legislation or regulations that govern

the review and approval process relating to our future product candidates could make it more difficult and costly to obtain approval for new products based on our product candidates, or to produce, market, and distribute such products if approved.

We cannot assure you that the market and consumers will accept our product candidates. If they do not, we will be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

The commercial success of our ProBiora3, MU1140 antibiotic product candidate, other possible antibiotic product candidates and our other product candidates and technologies will depend in part on market acceptance by consumers. Biopharmaceutical companies have received substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and internationally. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of product candidates developed by biopharmaceutical companies could be delayed or impaired in certain geographical areas as a result. Products based on our product candidates may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and biotechnology companies. Market acceptance of products based on our product candidates will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our product candidates. If they do not, we may be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

If our products do not receive favorable third-party reimbursement, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not generate significant revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as Health Maintenance Organizations, or HMOs. Reimbursement from third parties depends greatly on our ability to present data which demonstrate positive outcomes and reduced utilization of other products or services as well as cost data which show that treatment costs using the new product are equal to or less than what is currently covered for other products. If our products do not receive favorable third-party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenues and harm our business.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Federal and state legislatures will likely continue to focus on health care reform, controlling the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

Risks Related to Our Common Stock

KFLP, together with members of the Koski family, have a substantial interest in our outstanding shares of common stock.

As of March 1, 2013, the KFLP, together with members of the Koski family, beneficially own approximately 45% (which reflects the July 31, 2012 conversion of the outstanding indebtedness of the Company to the KFLP into shares of common stock) of our outstanding shares of common stock, and includes outstanding warrants to acquire 2,170,925 shares of our common stock that were issued in connection with our Debt Exchange Agreement and Loan Agreement.

Christine L. Koski and Robert C. Koski, serve on our Board of Directors and they each share voting and investment powers with two other Koski family members as general partners of the KFLP. As a result, subject to compliance with applicable NYSE MKT requirements, the Koski family will be able to affect the outcome of, or exert significant influence over, all matters requiring shareholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our shareholders from realizing a premium over the market price for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other shareholders, and, accordingly, the Koski family could cause us to enter into transactions or agreements that we would not otherwise consider.

Certain provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may prevent a change of control of our company that a shareholder may consider favorable.

Provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may discourage, delay or prevent a change of control of our company that a shareholder may consider favorable. These provisions include:

- authorization of the issuance of “blank check” preferred stock that could be issued by our Board of Directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquirer;
- the ability of our Board of Directors to amend the bylaws without shareholder approval;
- vacancies on our Board may only be filled by the remaining directors and not our shareholders;
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders;
- obligations to make certain payments under executive employment agreements in the event of a change of control and termination of employment; and
- immediate vesting of all stock options.

As a result, these provisions could discourage bids for our common stock at a premium and limit the price that investors are willing to pay in the future for shares of our common stock. However, in our articles of incorporation we expressly elected not to be governed by Sections 607.0901 and 607.0902 of the Florida Business Corporation Act, which are statutory anti-takeover provisions relating to affiliated transactions and control share acquisitions,

respectively. As such, we do not have the protection of these statutes in connection with any unwanted takeover attempts which could have the effect of encouraging an attempted change of control without first negotiating with our Board of Directors.

Our stock price has historically been volatile and the trading volume of our stock has been low.

Since our initial public offering in June 2003 and through March 1, 2013 our stock price has fluctuated from $90.00 to $0.75 per share. The trading price of our common stock has been, and may be, subject to wide fluctuations in response to a number of factors, many of which are beyond our control. These factors include:

- quarter-to-quarter variations in our operating results;
- our perceived funding needs;
- the results of testing, technological innovations, or new commercial products by us or our competitors;
- governmental regulations, rules, and orders;
- our level of, and expected future use of, working capital;
- general conditions in the healthcare, dentistry, or biopharmaceutical industries;
- comments, research reports and/or earnings estimates by securities analysts;
- developments concerning patents or other intellectual property rights;
- litigation or public concern about the safety of our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of directors, officers and key personnel;
- release of transfer restrictions on our outstanding shares of common stock or sales of additional shares of common stock;
- potential litigation initiated against us; and
- the additional sale of common stock by us in capital raising transactions.

Historically, the daily trading volume of our common stock has been relatively low and on some days our stock does not trade at all. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will increase. In addition, the stock market in general has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. To the extent our stock price fluctuates or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

We cannot assure you that our new listing on the NYSE MKT will increase the liquidity of our common stock or that it will continue to be listed on the NYSE MKT.

Our common stock commenced trading on the NYSE MKT (formerly the NYSE Amex and the American Stock Exchange) on April 10, 2013, and we are subject to certain NYSE MKT continued listing requirements and standards. Historically the daily trading volume of our shares is relatively low which has made our common stock significantly less liquid and there can be no assurance that liquidity will increase as a result of being listed on the NYSE MKT. We may also incur costs that we have not previously incurred for expenses for compliance with the rules and requirements of the NYSE MKT. We cannot provide any assurance that we will be able to continue to satisfy the requirements of the NYSE's continued listing standards. A delisting of our common stock could negatively affect the price and liquidity of our common stock and could impair our ability to raise capital in the future.

The issuance of additional equity securities by us in the future could result in dilution to our existing shareholders.

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law or NYSE MKT requirements. Any issuance of additional equity securities by us in the future could result in dilution to our existing shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing shareholders. These issuances would dilute your percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. For example, we have recently issued a significant number of shares of our common stock in connection with financings and establishing strategic relationships and as a result our outstanding shares have increased from 5,894,176 shares as of December 31, 2011 to 27,382,830 as of December 31, 2012.

We will also be required to issue additional shares of our common stock of up to 4.5% of our then outstanding common stock to Intrexon as follows: (i) 1% upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration; (ii) 1.5% upon the dosing of the first patient in the first Phase 2 clinical study; and (iii) 2% upon the dosing of the first patient in the first Phase 3 clinical study, which issuances will result in additional dilution. You may also incur additional dilution if performance awards are made pursuant to our long term incentive programs for executives and non-employee directors or holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock.

Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. We have recently issued a significant number of shares of common stock and the number of outstanding shares has increased from 5,894,176 shares as of December 31, 2011 to 27,382,830 as of December 31, 2012. In June of 2012 we issued to Intrexon 4,392,425 shares of our common stock which are subject to piggy – back registration rights. On July 31, 2012, we issued 8,666,665 shares of Common Stock to investors and Warrants to purchase an additional 771,169 shares of Common Stock to the placement agent and pursuant to a Registration Rights Agreement we are required to register these shares and warrant shares for resale. On August 31, we filed a Registration Statement on Form S-1 to register the resale of these shares by the purchasers. The Registration Statement as amended was declared effective by the SEC on September 26, 2012. Accordingly, these shares may be resold in the open market.

As of December 31, 2012, there were 27,382,830 shares of our common stock outstanding, with another 3,235,982 shares of common stock issuable upon exercise of warrants to investors, 660,423 shares issuable upon exercise of options outstanding and an additional 2,668,661 shares available for option grants under our 2012 Equity Incentive Plan. The issuance of shares of our common stock under our 2012 Equity Incentive Plan is covered by Form S-8 registration statements we filed with the Securities and Exchange Commission, or SEC, and upon exercise of the options, such shares may be resold into the market. We have also issued shares of common stock and warrants in connection with previous private placements. Such shares are available for resale as well as certain of the shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction, which are deemed to be “restricted securities,” as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. The resale of shares acquired from us in private transactions could cause our stock price to decline significantly.

In addition, from time to time, certain of our shareholders may be eligible to sell all or some of their restricted shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six-month holding period: (i) affiliated shareholders, or shareholders whose shares are aggregated, may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then-outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated shareholders may sell without such limitations, in each case provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one-year holding period without any limitation or restriction.

We are unable to estimate the number of shares that may be sold because this will depend on the market price for our common stock, the personal or business circumstances of sellers and other factors.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members for our Board of Directors.

As a public company, we are already subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act. Additionally, as an NYSE MKT listed company, we are subject to NYSE MKT listing rules and requirements. The requirements of these rules and regulations may increase our legal, accounting and financial compliance costs; may make some activities more difficult, time-consuming and costly; and may also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors and Board committees or as executive officers.

As a public company we are also required to assess our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act and file periodic reports with the SEC. If we are unable to comply with these requirements in a timely manner, or if material weaknesses or significant deficiencies persist, the market price of our stock could decline and we could be subject to sanctions or regulatory investigations, which could harm our business. We must perform an assessment of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. If we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act or the SEC reporting requirements in a timely manner, or if we continue to note or identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. As a smaller reporting company, we do not have to have our independent registered public accounting firm report on the effectiveness of our internal control over financial reporting. If in the future we no longer meet the requirements of a smaller reporting company, our independent registered public accounting firm will have to report on our internal controls over financial reporting. There can be no assurance that our independent registered public accounting firm will not identify material weaknesses which could have an adverse effect on our stock price.

FORWARD-LOOKING STATEMENTS

Statements included in this prospectus, including information incorporated herein by reference, which are not historical in nature are intended to be, and are hereby identified as, forward-looking statements for purposes of the safe harbor provided by Section 21E of the Securities and Exchange Act of 1934 (the "Exchange Act"). The words "may," "will," "anticipate," "should," "would," "believe," "contemplate," "expect," "estimate," "continue," "may," and "intend," as well as other similar words and expressions of the future, are intended to identify forward-looking statements. We caution readers that forward-looking statements are estimates reflecting our judgment based on current information, and are subject to certain risks and uncertainties that could cause actual results to differ materially from anticipated results. Such risks and uncertainties include, among others, the matters described in the "Risk Factors" of this prospectus and the following:

- We have incurred significant operating losses since our inception and cannot assure you that we will increase revenues or achieve profitability.
- We will need to raise additional capital to fully implement our business strategy.
- The success, timing and expenses of our collaboration efforts with Intrexon and expected clinical trials
- We are subject to extensive and costly regulation by the FDA, which must approve our product candidates in development and could restrict or delay the future commercialization of certain of our product candidates.
- We may be unable to achieve commercial viability and acceptance of our ProBiora3 products and proposed product candidates or increase sales of our ProBiora3 products.
- Orders we receive for our consumer and professional products may be subject to terms and conditions that could result in their cancellation or the return of products to us.
- We may be unable to successfully operate internationally.
- We may be unable to improve upon, protect and/or enforce our intellectual property.
- We may be unable to enter into strategic collaborations or partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or maintain strategic collaborations or partnerships.
- We may be adversely impacted by a continuing or worsening worldwide financial crises and its impact on consumers, retailers and equity and debt markets as well as our ability to obtain required additional funding to conduct our business.
- We are subject to significant competition.
- As a public company, we must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization to satisfy reporting requirements, which add to our costs and require additional management time and resources.
- Our license for our MU-1140 product candidate and SMaRT™ Replacement Therapy with the University of Florida Research Foundation is subject to termination under certain circumstances.

Further information on other factors that could materially affect our Company is included in the SEC filings incorporated by reference in this prospectus. See also "*Risk Factors*" contained herein and therein.

USE OF PROCEEDS

All of the shares of common stock covered by this prospectus are being sold by the Selling Shareholders. See “Selling Shareholders” on page 25. We will not receive any proceeds from these sales of shares of our common stock. A portion of the shares covered by this prospectus are issuable upon exercise of the Agent Warrants to purchase our common stock. Upon any exercise of the Agent Warrants for cash, such Selling Shareholders would pay us the exercise price of the warrants. Cash received from exercise of Agent Warrants will be used for general corporate purposes. Additionally, the Warrants are exercisable on a cashless basis. If any Agent Warrants are exercised on a cashless basis, we would not receive any cash payment from such Selling Shareholders upon any exercise of such Agent Warrants.

The Selling Shareholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Shareholders for brokerage, accounting, tax, or legal services or any other expenses incurred by the Selling Shareholders in disposing of the shares. We will bear all other costs, fees, and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, and fees and expenses of our counsel and our accountants.

DETERMINATION OF OFFERING PRICE

The Selling Shareholders will determine at what price they may sell the offered shares, and such sales may be made at prevailing market prices, or at privately negotiated prices.

SELLING SHAREHOLDERS

We have prepared this prospectus to allow the Selling Shareholders or their successors, assignees or other permitted transferees to sell or otherwise dispose of, from time to time, up to 9,437,834 shares of our Common Stock. This prospectus covers the offer and sale by the Selling Shareholders of up to an aggregate of 9,437,834 shares of common stock. Of the shares of common stock being offered under this prospectus 8,666,665 were acquired by the purchasers in our July 2012 Private Placement and 771,169 shares were able to be acquired pursuant to the Agent Warrants we issued in connection with our July 2012 Private Placement which Agent Warrants are currently exercisable.

The shares of common stock sold to the Selling Shareholders in the July 2012 Private Placement were sold pursuant to an exemption from registration provided by Rule 506 of Regulation D under the Securities Act. In connection therewith, the investors made to us certain representations, warranties, covenants, and conditions customary for private placement investments.

The table below presents information regarding the Selling Shareholders and the shares of our Common Stock that they may sell or otherwise dispose of from time to time under this prospectus. The table is based on information supplied to us by the Selling Shareholders and reflects holdings as of August 27, 2012. Percentages of beneficial ownership are based upon 27,204,721 shares of Common Stock issued and outstanding as of August 27, 2012. Beneficial ownership is determined under Section 13(d) of the Exchange Act and generally includes voting or investment power with respect to securities and including any securities that grant the Selling Shareholders the right to acquire Common Stock within 60 days of August 27, 2012. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the shares, subject to community property laws where applicable.

We do not know when or in what amounts the Selling Shareholders may sell or otherwise dispose of the shares covered hereby. We currently have no agreements, arrangements or understandings with the Selling Shareholders regarding the sale of any of the shares by them other than the registration rights agreements described below. The Selling Shareholders might not sell any or all of the shares covered by this prospectus or may sell or dispose of some or all of the shares other than pursuant to this prospectus. Because the Selling Shareholders may not sell or otherwise dispose of some or all of the shares covered by this prospectus and because there are currently no agreements, arrangements or understandings with respect to the sale or other disposition of any of the shares, we cannot estimate the number of the shares that will be held by the Selling Shareholders after completion of the offering.

Each Selling Shareholder has indicated to us that neither it nor any of its affiliates has held any position or office or had any other material relationship with us in the past three years except as described in the footnotes to the table.

The shares of common stock being offered under this prospectus may be offered for sale from time to time during the period the registration statement of which this prospectus is a part remains effective, by or for the accounts of the Selling Shareholders named below.

	Shares of Common Stock			
Name of Selling Shareholder	Beneficially Owned Prior to the Sale of all Shares covered by this Prospectus	Covered by this Prospectus	Beneficially Owned After the Sale of all Shares covered by this Prospectus	As a Percent of Total Outstanding After the Sale of Shares covered by this Prospectus
Fidelity Select Portfolios: Biotechnology Portfolio (1)	1,558,058	1,558,058	0	0%
Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund (1)	108,608	108,608	0	0%
MSD Credit Opportunity Master Fund, L.P. (2)	1,325,000	1,325,000	0	0%
White Rock Capital Partners, L.P. (3)	1,120,000	1,100,000	20,000	*
NRM VII Holdings I, LLC (4)	5,249,980	857,555	4,392,425	16.1%
Allen Adler	300,000	300,000	0	0%
Smokeshire Partners LLC (5)	250,000	250,000	0	0%
Oppenheim Asset Management S.a.r.l. on behalf of FCPOP Medical BioHealth-Trends (6)	226,667	226,667	0	0%
Roger J. LaGratta IRA Custodian	200,000	200,000	0	0%
Neil P. McCauley	200,000	200,000	0	0%
Eugene Mark Landry	170,000	170,000	0	0%
Selig Zises	150,000	150,000	0	0%
Michael H. Wehrle	125,000	125,000	0	0%
John F. LaGratta	100,000	100,000	0	0%
Edward Feigeles & Kathryn Green JTWROS	100,000	100,000	0	0%
Sean McCance	100,000	100,000	0	0%
Anthony Marinelli IRA	100,000	100,000	0	0%
Neil P. McCauley IRA	100,000	100,000	0	0%
Laurence Zalk	100,000	100,000	0	0%
William P. Saunders	100,000	100,000	0	0%
Mintz and Co. (7)	100,000	100,000	0	0%
JDH Investment Management, LLC (8)	100,000	100,000	0	0%
Dr. Frederick Telling (9)	212,592	98,111	114,481	*
Nancy Zises IRA	75,000	75,000	0	0%
The Weaver Family 2004 Dynasty Trust (10)	66,667	66,667	0	0%
Christina W. Vest	66,667	66,667	0	0%
Steve H. Kanzer	68,367	66,667	1,700	*
IPConcept Fund Management SA, an administration company according to Luxembourg Law, acting in its own name but on behalf of Apo Medical Opportunities – Medical Strategy ("ICP") (11)	63,333	63,333	0	0%
Medical Strategy GmbH for Pharma/Whealth Management Company S.A. on behalf of PHARMA/wHEALTH (12)	53,333	53,333	0	0%
Howard Klion, IRA	50,000	50,000	0	0%
John A. MacPhee and Donna H. MacPhee	50,000	50,000	0	0%
Jay Zises IRA	50,000	50,000	0	0%
Estelle Nisson	50,000	50,000	0	0%
Raymond Scott	50,000	50,000	0	0%
John G. Bickerman	50,000	50,000	0	0%
Daniel T. and Helen M. Hartnett JTWROS	34,000	34,000	0	0%
Kidco Management L-2, LLC (13)	33,333	33,333	0	0%
Harry D. Schulman	33,333	33,333	0	0%
Marcus Pelham-Webb Rollover IRA	33,000	33,000	0	0%
Louis Vigden	30,000	30,000	0	0%
Hauck & Aufhaeuser Banquiers S.A. (14)	29,000	29,000	0	0%

Name of Selling Shareholder	Beneficially Owned Prior to the Sale of all Shares covered by this Prospectus	Covered by this Prospectus	Beneficially Owned After the Sale of all Shares covered by this Prospectus	As a Percent of Total Outstanding After the Sale of Shares covered by this Prospectus
Janina Casey	25,000	25,000	0	0%
Stephen S. Lipton	25,000	25,000	0	0%
Dorothy C. Weaver	23,333	23,333	0	0%
William J. Dalton	23,000	23,000	0	0%
Richard Molinsky	20,000	20,000	0	0%
Lis C. Waterman	17,000	17,000	0	0%
David Andres Weaver	17,000	17,000	0	0%
Margus Ehatamm	16,000	16,000	0	0%
MS SB C/F Mai N Pogue IRA	16,000	16,000	0	0%
Meredith Bowen Waterman	15,000	15,000	0	0%
Joseph A. Condo /Christine P. Condo JTWROS	10,000	10,000	0	0%
Susan K. Rho	6,000	6,000	0	0%
Griffin Securities, Inc. (15)	385,585	385,585	0	0%
Adrian Stecyk (15)	385,584	385,584	0	0%

(1) Fidelity Management & Research Company ("Fidelity"), 82 Devonshire Street, Boston, Massachusetts 02109, a wholly-owned subsidiary of FMR LLC and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of 1,666,666 shares of the Company as a result of acting as investment adviser to various investment companies registered under Section 8 of the Investment Company Act of 1940. Edward C. Johnson 3d and FMR LLC, through its control of Fidelity, and the funds each has sole power to dispose of the 1,666,666 shares owned by the Funds. Members of the family of Edward C. Johnson 3d, Chairman of FMR LLC, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d, Chairman of FMR LLC, has the sole power to vote or direct the voting of the shares owned directly by the Fidelity funds, which power resides with the Funds' Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established by the Funds' Boards of Trustees. Fidelity has indicated that it may be deemed to be an affiliate of a registered broker-dealer. Fidelity has represented that it acquired the shares in the ordinary course of business and, at the time of the acquisition of the shares, had no agreements or understandings, directly or indirectly, with any person to distribute the shares.

(2) MSD Credit Opportunity Master Fund, L.P. is the record and direct beneficial owner of the securities. MSDC Management, L.P. is the investment manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, MSD Credit Opportunity Master Fund. MSDC Management (GP), LLC is the general partner of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, MSDC Management, L.P. Each of Glenn R. Fuhrman, John C. Phelan and Marc R. Lisker is a manager of MSDC Management (GP) and may be deemed to have or share voting and/or dispositive power over, and beneficially own, the common shares beneficially owned by MSDC Management. Each of Mr. Fuhrman, Mr. Phelan and Mr. Lisker disclaim beneficial ownership of such common shares, except to the extent of the pecuniary interest of such person in such shares.

(3) In accordance with Rule 13d-3 under the Exchange Act, Thomas U. Barton and Joseph U. Barton may be deemed control persons of the shares owned by White Rock Capital Partners, LP, with final voting power and investment control over such shares.

(4) NRM VII Holdings I, LLC ("NRM Holdings"), a Delaware limited liability company that is controlled by Randal J. Kirk, is the record and direct beneficial owner of the 857,555 shares of common stock covered by this Prospectus. An additional 4,392,425 shares of common stock are owned by Intrexon Corporation, a Virginia corporation of which Mr. Kirk is the Chairman and Chief Executive Officer and over which Mr. Kirk, directly and through certain affiliates, has voting and dispositive power of a majority of the outstanding capital stock.

Mr. Kirk may therefore be deemed to have voting and dispositive power over the 857,555 shares of common stock covered by this Prospectus and the 4,392,425 shares of common stock owned by Intrexon Corporation. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein.

(5) Smokeshire Partners, LLC is the record and direct beneficial owner of the shares of common stock. Mintz and Co. is the manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Smokeshire Partners, LLC. Lowell A. Mintz is the senior partner of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Mintz and Co.

(6) Oppenheim Asset Management Services S.a.r.l. ("Oppenheim") is record and direct beneficial owner of the shares of common stock on behalf of FCPOP Medical BioHealth-Trends.

(7) Mintz and Co. is the record and direct beneficial owner of the shares of common stock. Lowell A. Mintz is the senior partner of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Mintz and Co.

(8) JDH Investment Management, LLC is the record and direct beneficial owner of the shares of common stock. John D. Harkey Jr. is the manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, JDH Investment Management, LLC.

(9) Dr. Frederick Telling is a director of the Company and our Chairman. The shares included as covered by this prospectus represent the shares Dr. Telling acquired in our July 2012 Private Placement. The shares beneficially owned by Dr. Telling also include (i) 55,000 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director compensation program, (ii) 49,481 shares awarded pursuant to the long term incentive program component of our director compensation program with 13,081 shares thereof entitled to be issued upon the approval of an amendment to our option plan by our shareholders, and (iii) 10,000 previously shares acquired directly by Dr. Telling in open market transactions.

(10) David Andres Weaver is the trustee of the Weaver 2004 Dynasty Trust and as such has voting and investment power over the shares listed.

(11) This selling shareholder has indicated that it may be deemed to be an affiliate of a registered broker-dealer and has represented to us that it purchased the shares in the ordinary course of its business and, at the time of purchase, with no arrangement or understanding, directly or indirectly, with any persons to distribute such shares.

(12) This selling shareholder has indicated that it may be deemed to be an affiliate of a registered broker-dealer and has represented to us that it purchased the shares in the ordinary course of its business and, at the time of purchase, with no arrangement or understanding, directly or indirectly, with any persons to distribute such shares.

(13) Kidco Management L-2, LLC is the record and direct beneficial owner of the shares of common stock. Mr. Jeffery Scott Fraser is the manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Kidco Management L-2, LLC.

(14) Hauck & Aufhaeuser Banquiers S.A. ("H&A") is the record and direct beneficial owner of the shares of common stock. Hauck & Aufhaeuser Investment Gesellshaft S.A. ("H&A Investment"), is the investment manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, H&A. Achim Welschoff is the individual who may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, H&A Investment.

(15) Consists of warrants received as our placement agent in our July 2012 Private Placement. Griffin Securities, Inc. is a registered broker-dealer that served as the placement agent in connection with our July 2012 Private Placement. Adrian Stecyk is the Chief Executive Officer of Griffin Securities, Inc. and an affiliate of a registered-broker-dealer. Mr. Stecyk has voting and dispositive power with respect to the warrants. On January 31, 2013, Griffin exercised a portion of its warrant through its right to do so on a cashless exercise basis. As a result of the exercise 200,000 shares of the warrant were utilized and 106,250 shares were issued to Griffin and able to be sold under this registration statement.

The Selling Shareholders, or their partners, pledgees, donees, transferees or other successors that receive the shares and their corresponding registration in accordance with the registration rights agreement to which the Selling Shareholder is party (each also a selling shareholder for purposes of this prospectus), may sell up to all of the shares of our common stock shown in the table above under the heading "Covered by this Prospectus" pursuant to this Prospectus in one or more transactions from time to time as described below under "Plan of Distribution." However, the Selling Shareholders are not obligated to sell any of the shares of our common stock offered by this prospectus.

Information about the Selling Shareholders may change from time to time. Any changed information with respect to which we are given notice will be included in prospectus supplements.

PLAN OF DISTRIBUTION

We are registering the shares of Common Stock to permit the resale of these shares of Common Stock by the Selling Shareholders and any of their transferees, pledgees, assignees, donees, and successors-in-interest from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the Selling Shareholders of the shares of Common Stock. Upon any exercise of the Agent Warrants by payment of cash, however, we will receive the exercise price of the Agent Warrants. We will bear all fees and expenses incident to our obligation to register the shares of Common Stock.

The Selling Shareholders, or their pledges, donees, transferees, or any of their successors in interest selling shares received from a Selling Shareholder as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus, may sell all or a portion of the shares of Common Stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the Selling Shareholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of Common Stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. The Selling Shareholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. These sales may be affected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the distribution of the Common Stock by any Selling Shareholders to its partners, members or Shareholders;
- through one or more underwritten offerings on a firm commitment or best efforts basis;
- sales pursuant to Rule 144;
- broker-dealers may agree with the Selling Shareholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Shareholders may also transfer the shares of Common Stock by gift. We do not know of any arrangements by the Selling Shareholders for the sale of any of the shares of Common Stock.

The Selling Shareholders may engage brokers and dealers, and any brokers or dealers may arrange for other brokers or dealers to participate in effecting sales of the shares of Common Stock. These brokers, dealers or underwriters may act as principals, or as an agent of a Selling Shareholder. Broker-dealers may agree with a Selling Shareholder to sell a specified number of the shares of Common Stock at a stipulated price per security. If the broker-dealer is unable to sell the shares of Common Stock acting as agent for a Selling Shareholder, it may purchase as principal any unsold shares of Common Stock at the stipulated price. Broker-dealers who acquire shares of Common Stock as principals may thereafter resell the shares of Common Stock from time to time in transactions in any stock exchange or automated interdealer quotation system on which the shares of Common Stock are then listed, at prices and on terms then prevailing at the time of sale, at prices related to the then-current market price or in negotiated transactions. Broker-dealers may use block transactions and sales to and through broker-dealers, including transactions of the nature described above.

The Selling Shareholders may also sell the shares of Common Stock in accordance with Rule 144 under the Securities Act of 1933, as amended, rather than pursuant to this prospectus, regardless of whether the shares of Common Stock are covered by this prospectus.

If the Selling Shareholders effect such transactions by selling shares of Common Stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions, commissions or fees from the Selling Shareholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions, commissions or fees as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the Selling Shareholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The Selling Shareholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Shareholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The Selling Shareholders may pledge, hypothecate or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees, secured parties or persons to whom the securities have been hypothecated may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of Selling Shareholders to include the pledgee, transferee or other successors in interest as Selling Shareholders under this prospectus. The Selling Shareholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In addition, a Selling Shareholder may, from time to time, sell the shares of Common Stock short, and, in those instances, this prospectus may be delivered in connection with the short sales and the shares of Common Stock offered under this prospectus may be used to cover short sales.

The Selling Shareholders and any underwriters, broker-dealer or agents participating in the distribution of the shares of Common Stock may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any underwriters, broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the Selling Shareholders and any discounts, commissions or concessions allowed or reallowed or paid to broker- dealers. The Selling Shareholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares of Common Stock against certain liabilities, including liabilities arising under the Securities Act.

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any Selling Shareholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

The Selling Shareholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of Common Stock by the Selling Shareholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of Common Stock to engage in market-making activities with respect to the shares of Common Stock. All of the foregoing may affect the marketability of the shares of Common Stock and the ability of any person or entity to engage in market-making activities with respect to the shares of Common Stock.

The shares of Common Stock offered hereby were originally issued to the Selling Shareholders pursuant to an exemption from the registration requirements of the Securities Act. We agreed to register the shares of Common Stock under the Securities Act, and to keep the registration statement of which this prospectus is a part effective until the earlier of the date on which the Selling Shareholders have sold all of the securities or one year after the shares were acquired by the Selling Shareholder. We will pay all expenses of the registration of the shares of Common Stock pursuant to the Registration Rights Agreement, estimated to be $60,000 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or "Blue Sky" laws; *provided*, *however*, that a Selling Shareholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the Selling Shareholders against liabilities, including some liabilities under the Securities Act, in accordance with the Registration Rights Agreement, or the Selling Shareholders will be entitled to contribution. We may be indemnified by the Selling Shareholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the Selling Shareholder specifically for use in this prospectus, in accordance with Registration Rights Agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms that are included in our amended and restated articles of incorporation (as amended) and our bylaws (as amended) as well as the specific agreements such descriptions relate to. This summary is qualified in its entirety by the specific terms and provisions contained in our restated articles of incorporation, bylaws and the specific agreements described herein, copies of which we have filed as exhibits to the registration statement of which this prospectus is a part, and by the provisions of applicable law.

Overview

Authorized Capital Stock

Our authorized capital stock consists of 50,000,000 shares of common stock, par value $0.001, and 20,000,000 shares of preferred stock, without par value. As of the date of this prospectus there were [27,489,080] shares of our common stock issued and outstanding and no shares of our preferred stock issued and outstanding.

Authorized but Unissued Capital Stock

Florida law does not require shareholder approval for any issuance of authorized shares other than in connection with certain mergers to which we may be a party. These additional shares may be used for a variety of corporate purposes, including future public offerings to raise additional capital or to facilitate corporate acquisitions.

Common Stock

Voting

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the shareholders. Approval of an amendment of our articles of incorporation, a merger, a share exchange, a sale of all our property or a dissolution must be approved by a majority of all votes entitled to be cast. Such votes may be cast in person or by proxy as provided in Article I Section 8 of our bylaws.

Distributions

Our Board of Directors, subject to any restrictions contained in (i) the Florida Business Corporation Act, or FBCA; or (ii) our amended and restated articles of incorporation, as amended, or Articles of Incorporation, may make distributions upon our securities. Distributions may be paid in cash, in property, or in our securities.

We have not declared or paid any distributions on our common stock. We presently intend to retain our future earnings, if any, to fund the development and growth of our business and, therefore, do not have plans to pay any dividends in the foreseeable future.

Other Rights

Upon our liquidation, dissolution or winding-up, after payment in full of our liabilities and the amounts required to be paid to holders of any outstanding shares of preferred stock, if any, all holders of our common stock will be entitled to receive a pro rata distribution of all of our assets and funds legally available for distribution.

No shares of our common stock are subject to redemption or have preemptive rights to purchase additional shares of our common stock or any of our other securities.

Preferred Stock

Our Board of Directors has the authority, without action by our shareholders, to designate and issue up to 20,000,000 shares of preferred stock in one or more series or classes and to designate the rights, preferences and privileges of each series or class, which may be greater than the rights of our common stock. We do not have any shares of preferred stock either designated or outstanding. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of our common stock until our Board of Directors determines the specific rights of the holders of the preferred stock. However, the effects might include:

- restricting dividends on our common stock;

- diluting the voting power of our common stock;
- impairing liquidation rights of our common stock; or
- delaying or preventing a change in control of us without further action by our shareholders.

The Board of Directors' authority to issue preferred stock without shareholder approval could make it more difficult for a third-party to acquire control of our company, and could discourage such attempt. We have no present plans to issue any shares of preferred stock.

Options and Warrants

As of the date of this prospectus there were 669,373 options to acquire shares of our common stock outstanding at exercises prices between $1.20 and $17.00 under our 2012 Equity Incentive Plan and 2,659,711 shares were available for future grants under our 2012 Equity Incentive Plan. As of such date, we also have warrants outstanding to acquire an aggregate of 3,035,982 shares of our common stock at an exercise price of between $1.50 to $26.00. Holders of options and warrants do not have any of the rights or privileges of our shareholders, including voting rights, prior to exercise of the options and warrants. The number of shares of common stock for which these options and warrants are exercisable and the exercise price of these options and warrants are subject to proportional adjustment for stock splits and similar changes affecting our common stock. We have reserved sufficient shares of authorized common stock to cover the issuance of common stock subject to the options and warrants. Included in the number of our outstanding warrants are (i) warrants to acquire 571,169 shares of our common stock at an exercise price of $1.50 (constituting the warrants remaining after a portion of such warrants were exercised through a cashless exercise in January 2013) we issued to the placement agent in connection with the closing of our private placement on July 31, 2012 and (ii) warrants to acquire 2,170,925 shares of our common stock at an exercise price of $2.00 that were issued to the Koski Family Limited Partnership, pursuant to the terms of a Debt Exchange Agreement and a new Loan Agreement with the KFLP (which Loan Agreement was subsequently terminated in connection with our July 2012 Private Placement).

Contingent Share Issuance-Intrexon

On June 5, 2012, pursuant to the Stock Issuance Agreement between the Company and Intrexon Corporation ("Intrexon"), we issued to Intrexon 4,392,425 shares of our common stock as a technology access fee, in consideration for the execution and delivery of the Exclusive Channel Collaboration Agreement we simultaneously entered into with Intrexon.

Under the Stock Issuance Agreement, we also agreed to make certain payments to Intrexon upon our achievement of designated milestones in the form of shares of our Common Stock or at our option make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issues). The milestone events and amounts payable are as follows: (i) filing of the first Investigational New Drug application with the U.S. Food and Drug Administration that number of shares of common stock equal to the number of shares of common stock comprising 1.0% of the Base Shares ; (ii) upon the dosing of the first patient in the first Phase 2 clinical study, that number of shares equal to the number of shares of common stock comprising 1.5% of the Base Shares; (iii) upon the dosing of the first patient in the first Phase 3 clinical study, that number of shares of common stock equal to the number of shares of common stock comprising 2% of the Base Shares; (iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for a Company Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares of common stock equal to the number of shares of common stock comprising 2.5% of the Base Shares; and (v) upon the granting of the first regulatory approval of an Oragenics Product, that number of shares of common stock (equal to the number of shares of common stock comprising 3% of the Base Shares.

Base Shares is defined in the Stock Issuance Agreement to mean (i) the number of shares of our common stock together with any securities or instruments convertible or exercisable for shares of common stock issued and outstanding at the time of the relevant Milestone Event, (ii) minus any shares issuable upon conversion of capital

inducement securities. Capital Inducement Securities is defined in the Stock Issuance Agreement to mean warrants or other convertible securities of the Company issued to investors in connection with a debt or equity investment in the Company that are issued in addition to the primary investment securities and in an amount not to exceed 10% of the overall number of shares issued in the investment (on an as-converted to common stock basis).

Equity Participation Right-Intrexon

Pursuant to the Stock issuance Agreement, Intrexon was also entitled, at its election, to participate in future securities offerings by us that constitute "qualified financings" and purchase securities equal to 30% of the number of shares of common stock or other securities sold in such offering (exclusive of Intrexon's purchase). For this purpose, a "qualified financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least $1,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended, at the time of issuance or we agree to register the resale of such shares. Intrexon waived its right to participate in the July 2012 Private Placement.

Registration Rights

Koski Family Limited Partnership ("KFLP"). Pursuant to the June 2009 Private Placement with the KFLP, we also agreed to provide the KFLP with certain registration rights in connection with any underwritten or other offering by us within five years of such agreement. We are required under the June 2009 Private Placement to register on behalf of KFLP 15% of the total number of shares being offered, except that in an underwritten public offering the inclusion of shares is subject to the discretion of the managing underwriter. The KFLP waived its registration rights in connection with the Company's July 2012 Private Placement.

Intrexon Corporation. Pursuant to the Stock Issuance Agreement, we granted certain registration rights to Intrexon. The registration rights consisted of "piggyback registration" rights which permit Intrexon to participate in any firm commitment underwritten offering of securities by us, subject to underwriter cutbacks and lockups. In addition, we are precluded from granting registration rights in connection with a private placement unless (i) all shares held by Intrexon are, at the time of such private placement, included on a registration statement, or (ii) we agree, in connection with such private placement, to grant Intrexon the right to include on the registration statement a number of Intrexon's Company shares equal to one half of the number of shares to be registered on behalf of the other holders or prospective holders. Intrexon waived its registration rights in connection with the Company's July 2012 Private Placement.

Purchasers in July 2012 Private Placement. In connection with the Offering, the Company also entered into a registration rights agreement with the Purchasers (the "Registration Rights Agreement"). The Registration Rights Agreement required that the Company file a registration statement (the "Initial Registration Statement") with the Securities and Exchange Commission (the "SEC") within forty-five (45) days of the closing date of the Offering (the "Filing Date") for the resale by the Purchasers of all of the Common Shares and all shares of Common Stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto (the "Registrable Securities"). On August 31, 2012, the Company filed Form S-1 Registration Statement with the SEC. On September 21, 2012 the Company filed Amendment No. 1 to Form S-1 Registration Statement with the SEC. On September 26, 2012 the Registration Statement was declared effective by the SEC. Upon the occurrence of certain events (each an "Event"), including, but not limited to, that the Initial Registration Statement is not filed prior to the Filing Date, the Company will be required to pay liquidated damages to each of the Purchasers equal to 1.5% of the aggregate purchase price paid by such Purchaser for the Registrable Securities upon the date of the Event and then monthly thereafter until the earlier of: (i) the Event is cured, or (ii) the registrable shares are eligible for resale under Rule 144 without manner of sale or volume limitations. In no event shall the aggregate amount of liquidated damages payable to each of the Purchasers exceed in the aggregate 10% of the aggregate purchase price paid by such Purchaser for the Registrable Securities.

We also agreed to use our commercially reasonable efforts to keep the Registration Statement effective for resales until the earlier of (1) one year from the closing date (2) the date that all of the shares of our common stock included in the Registration Statement have been resold thereunder or under Rule 144 promulgated under the Securities Act, or (3) the date that all of the shares of our common stock covered by such registration statement may be sold without volume or manner of sale restrictions under Rule 144. The registration rights agreement contains cross-indemnification provisions between us and the Selling Shareholders.

This description of the Registration Rights Agreement is intended to be a summary of the terms of the agreement that are material to a purchaser of our common stock. It does not purport to be complete and is subject to, and qualified in its entirety by reference to, the complete text of the registration rights agreement, which was filed as an exhibit to the Form 8-K we filed on August 2, 2012, is an exhibit to the registration statement of which this prospectus is a part by incorporation by reference.

Certain Anti-Takeover Provisions

Florida Law

We are not subject to the statutory anti-takeover provisions under Florida law because in our articles of incorporation we have specifically elected to opt out of both the "control-share acquisitions" (F.S. 607.0902) and the "affiliated transactions" (F.S. 607.0901) statutes. Since these anti-takeover statutes do not apply to a corporation that has specifically elected to opt out of such provisions we would not be able to invoke the protection of such statutes in the event of a hostile takeover attempt.

Articles of Incorporation and Bylaw Provisions

Our articles of incorporation and bylaws contain provisions that could have an anti-takeover effect. These provisions include

- authorization of the issuance of "blank check" preferred stock that could be issued by our Board of Directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquiror;
- the ability of the Board of Directors to amend the bylaws without shareholder approval;
- vacancies on our board may only be filled by the remaining Directors and not our shareholders; and
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders.

These provisions in our articles of incorporation and bylaws could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which shareholders might otherwise receive a premium for their shares over their current prices. Such provisions could also limit the ability of shareholders to approve transactions that shareholders may deem to be in their best interests and could adversely affect the price of our common stock.

On September 24, 2010 the shareholders approved an amendment to our articles of incorporation to effect a 1-for-20 reverse stock split with an aggregate of 35,000,000 shares of capital stock consisting of 15,000,000 shares of common stock and 20,000,000 shares of preferred stock. On August 30, 2010 the shareholders approved an amendment to our articles of incorporation to increase the capital stock to an aggregate of 70,000,000 shares consisting of 50,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Listing of Common Stock

Our common stock is currently listed on the NYSE MKT under the trading symbol "OGEN."

Transfer Agent and Registrar

The transfer agent and registrar of our common stock is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004, telephone: (212) 509-4000.

LEGAL MATTERS

The validity of the Common Stock offered by this prospectus will be passed upon by Shumaker, Loop & Kendrick, LLP, Tampa, Florida.

EXPERTS

The audited financial statements of Oragenics, Inc. as of December 31, 2012 and 2011, and for the two-year period ended December 31, 2012, included in our Annual Report on Form 10-K for the year ended December 31, 2012, incorporated by reference in this prospectus have been audited by Mayer Hoffman McCann P.C., an independent registered public accounting firm, as stated in their report dated March 22, 2013, which is incorporated by reference herein, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other documents with the Securities and Exchange Commission ("SEC"). These filings contain important information which does not appear in this prospectus. You may read and copy, at prescribed rates, any documents we have filed with the SEC at its Public Reference Room located at 100 F Street, N.E., Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We also file these documents with the SEC electronically. You can access the electronic versions of these filings on the SEC's website found at http://www.sec.gov.

We have filed with the SEC a registration statement for the securities under the Securities Act. This prospectus, which forms part of the registration statement, does not contain all the information contained in the registration statement. Whenever a reference is made in this prospectus to any of our contracts or other documents, the reference may not be complete and, for a copy of the contract or document, you should refer to the exhibits that are part of the registration statement.

You may inspect and copy the registration statement at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549 upon payment of certain prescribed fees. You may obtain information on the operation of the SEC's public reference facilities by calling the SEC at 1-800-SEC-0330. You may also access the registration statement electronically through the SEC's Electronic Data Gathering, Analysis and Retrieval, or EDGAR, system at the SEC's website located at http://www.sec.gov.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. Information incorporated by reference is considered to be part of this prospectus, except for any information that is superseded by information included directly in this prospectus. Any statement contained in this prospectus or a document incorporated by reference in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document that is incorporated by reference in this prospectus modifies or superseded the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below (excluding any portions of such documents that have been "furnished" but not "filed" for purposes of the Exchange Act).

- Our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 26, 2013;
- Our Definitive Proxy Statement on Schedule 14A, filed with the SEC on September 17, 2012;
- Our Current Reports on Form 8-K, filed February 15, 2013, April 8, 2013 and April 23, 2013.
- Our Current Reports on Form 8-A, filed April 8, 2013.

We also incorporate by reference into this prospectus all documents filed pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and our prior termination of the offering by the Selling Shareholders; *provided, however*, that we are not incorporating any information furnished under Item 2.02 of Item 7.01 of any current reports on Form 8-K we may subsequently file.

We will provide a copy of any and all of the information that is incorporated by reference in this prospectus to any person, including a beneficial owner, to whom a prospectus is delivered, without charge, upon written or oral request. Written requests for copies should be directed to Attn: Chief Financial Officer, Oragenics, Inc., 4902 Eisenhower Blvd., Suite 125, Tampa, Florida 33634. Telephone requests for copies should be directed to the Chief Financial Officer at (813) 286-7900.

We maintain an Internet website at www.oragenics.com where the incorporated reports listed above can be accessed. Neither this website nor the information on this website is included or incorporated in, or is a part of, this prospectus or any supplement to the prospectus.

Table of Contents

9,437,834 SHARES OF COMMON STOCK

ORAGENICS, INC.

PROSPECTUS

May 2, 2013

Neither we nor the Selling Shareholders have authorized any dealer, salesperson or other person to give any information or to make any representations not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information. This prospectus is not an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. The information in this prospectus is current as of the date of this prospectus. You should not assume that this prospectus is accurate as of any other date.