
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934.

Date of Report: January 15, 2014
(Date of earliest event reported)

Oragenics, Inc.
(Exact name of registrant as specified in its charter)

FL
(State or other jurisdiction
of incorporation)

001-32188
(Commission
File Number)

59-3410522
(IRS Employer
Identification Number)

4902 Eisenhower Boulevard, Suite 125
Tampa, FL
(Address of principal executive offices)

33634
(Zip Code)

813-286-7900
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Item 7.01 Regulation FD Disclosure.

Dr. John N. Bonfiglio, President and Chief Executive Officer of Oragenics, Inc. (the “Company”) used the presentation (the “Presentation”), attached hereto as Exhibit 99.1 at the Biotech Showcase of the JP Morgan Healthcare Conference on January 15, 2014. The Company may use the Presentation, possibly with modification, to current and potential investors and others with an interest in the Company and its business.

The information set forth in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. In addition, the Presentation contains statements intended as “forward-looking statements” that are subject to the cautionary statements about forward-looking statements set forth in the Presentation.

By filing this Current Report on Form 8-K and furnishing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of the Company’s filings with the Securities and Exchange Commission (“SEC”) and other public announcements that Oragenics makes, by press release or otherwise, from time to time. Oragenics undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any information contained in the Presentation should be read in the context of and with due regard to the more detailed information provided in other documents we file with or furnish to the SEC, including, but not limited to, our annual report on Form 10-K for the year ended December 31, 2012 and our quarterly report on Form 10-Q for the quarter ended September 30, 2013 and through press releases or through other public disclosure.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

<u>No.</u>	<u>Description</u>
99.1	Slide Presentation dated January 15, 2014.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 16th day of January, 2014.

ORAGENICS, INC.
(Registrant)

BY: /s/ John N. Bonfiglio

John N. Bonfiglio
Chief Executive Officer



Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology

Investor Presentation

January 2014

Certain statements made in this presentation include forward-looking actions that Oragenics, Inc. (“Oragenics,” or the “Company”) anticipates based on certain assumptions. These statements are indicated by words such as “expect,” “anticipate,” “should” and similar words indicating uncertainty in facts, figures and outcomes. Such statements are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. While Oragenics believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such statements will prove to be correct. The risks associated with the Company are detailed in the Company’s various reports filed by the Company with the Securities and Exchange Commission.

- Expertise in bacteria – especially related to the oral cavity
 - **Lantibiotics** – Capable of killing bacteria, including antibiotic-resistant strains
 - **Next Generation Probiotics** – Designed to be therapeutically useful
 - **ProBiora3[®]** - OTC probiotic used to improve overall oral health

- NYSE MKT: OGEN (market cap ~\$83M)
- Founded in 1999
- Based in Tampa, FL
- Experienced management team

- Leverage expertise in lantibiotics and probiotics with Intrexon's leading synthetic biology platform via two exclusive channel collaborations (ECCs) to develop novel biotherapeutics:
 1. **Lantibiotics:** novel class of peptide antibacterial compounds produced by specific strains of bacteria
 1. **Next Generation Probiotics:** bacteria-based biotherapeutics for oral cavity, throat, sinus, and esophagus diseases
- Market proprietary OTC oral care probiotics (ProBiora3[®])

**Lantibiotics and the Need for New
Antibiotics**

**Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology**

Investor Presentation

January 2014

Sept. 2013 CDC report highlighted serious threats of antibiotic-resistant infections and need for new antibiotics:

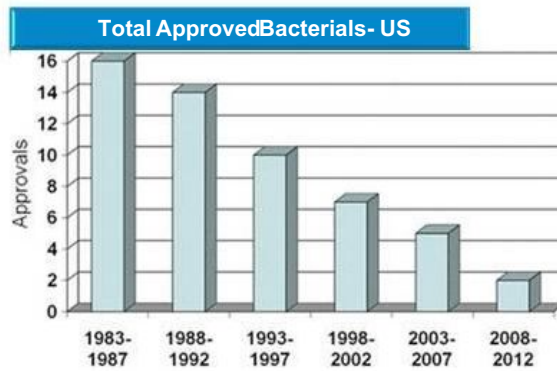
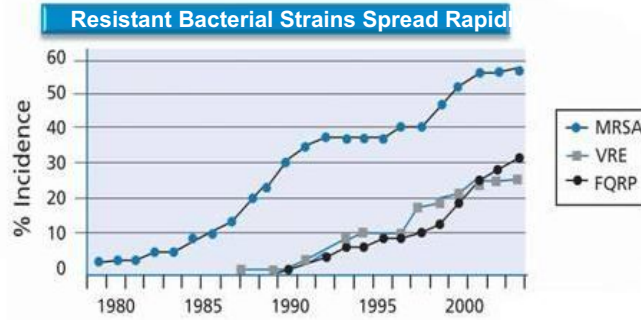
- ▣ >2 million infections and ~23,000 deaths each year in U.S. caused by resistant microbes
- ▣ >\$20 billion in direct healthcare spending from resistance infections
- ▣ >\$35 billion in additional costs due to lost productivity



"Antibiotic Resistance Threats in the United States, 2013" U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Trends Support CDC Concerns

Resistance Increases While Approvals Decrease



Lantibiotics

A Promising Solution to the Growing Health Crisis of Antibacterial Resistance

- Novel class of peptide antibacterial compounds:
 - Naturally-produced by variety of bacterial strains to attack competing gram-positive bacterial strains
 - >50 known lantibiotics and a very large number of potential analogs
 - Pipeline of new compounds to target resistant infections
 - Development as commercially-viable products previously limited by technological hurdles

Lantibiotics

A Promising Solution to the Growing Health Crisis of Antibacterial Resistance



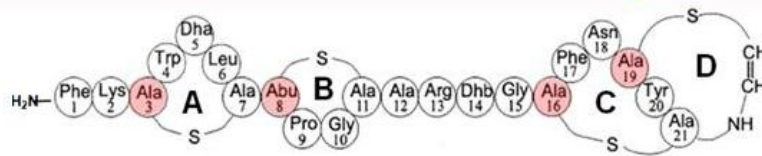
Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology

- Well-positioned to bring lantibiotics to market:
 - Intrexon collaboration expected to enable production of lantibiotics at commercial scale
 - Progress to date through Intrexon/Oragenics ECC
 - ✓ Achieved significant increase in production titer yield
 - ✓ Developing robust purification methods compared to traditional approaches
 - ✓ Completed POC that genetically modified bacteria can produce MU1140 and analogs

Lead Lantibiotic Compound MU1140

ORAGENICS

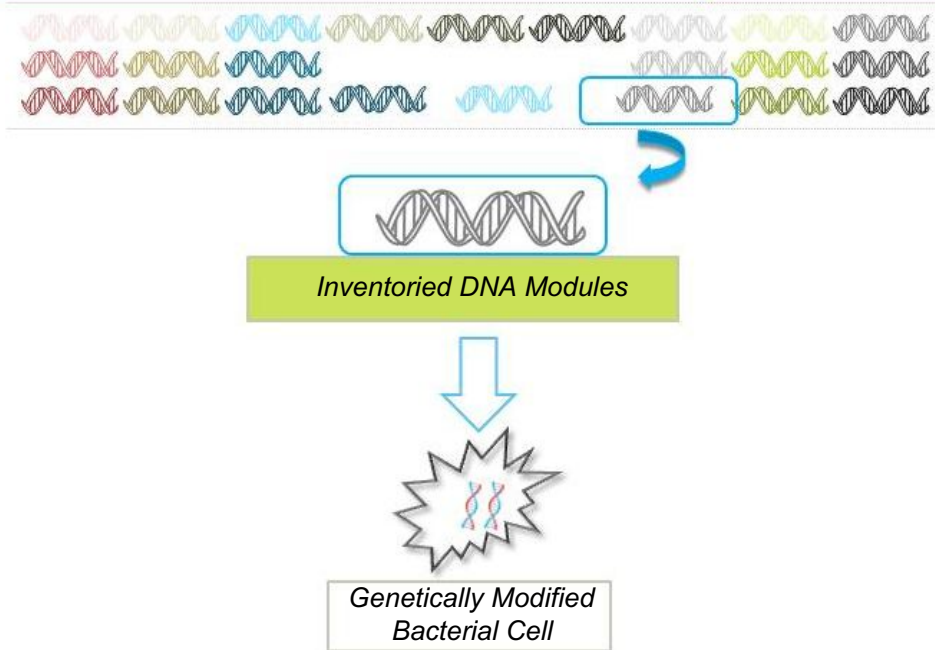
Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology



- Initial focus on MU1140, a lantibiotic shown to be effective against:
 - Methicillin-resistant *Staphylococcus aureus* (MRSA)
 - Vancomycin-resistant *Enterococcus* (VRE)
 - *Clostridium difficile* (*C. diff*)
 - Resistant Tuberculosis and others
- Preliminary preclinical data suggests:
 - Excellent therapeutic index
 - Minimal cytotoxicity *in vitro* using mouse and human cell lines; minimal immunogenicity
 - Maximum tolerated dose in mice and rats >50 mg/Kg
 - In vivo efficacy observed in a pilot rat peritonitis model using *S. aureus* (60xLD₅₀)
 - Apparent synergy with aminoglycosides

ECC with Intrexon

Platform for Engineering Bacterial Systems Through Synthetic Biology



ECC with Intrexon

Development of lantibiotics for treatment of infectious diseases in humans and animals

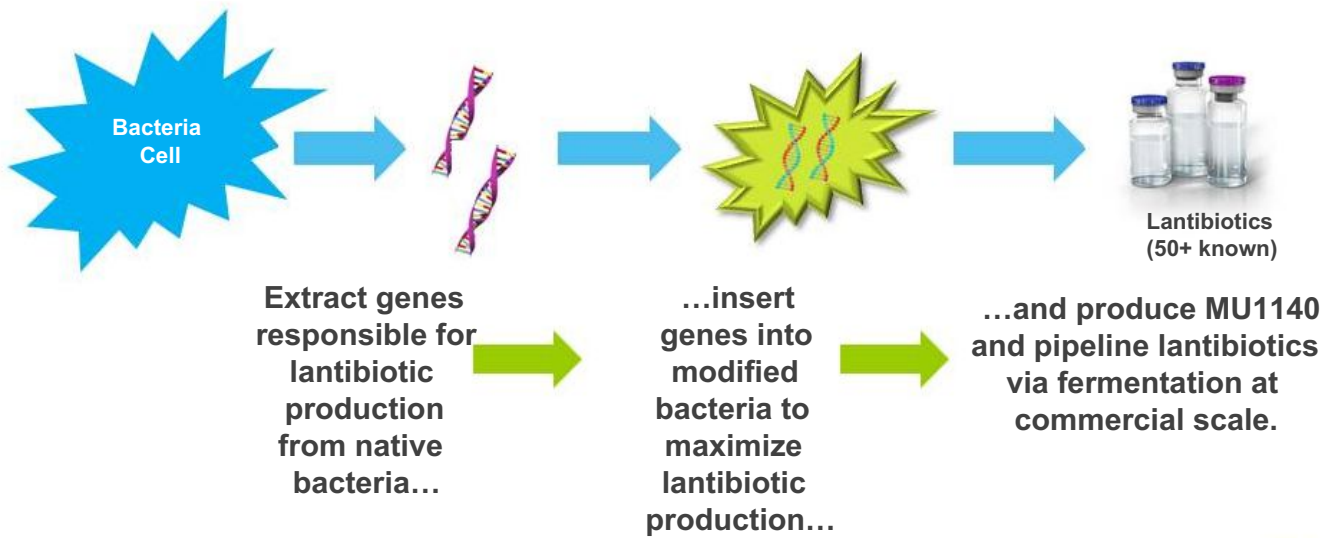
ORAGENICS

Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology

- Application of engineering principles to the design of living organisms and their constituent parts (DNA, proteins, and cells)
- Intrexon's toolset of modular molecular and cellular systems expected to enable the engineering of specific functionality into cells to allow industrial scale production of lantibiotics

ECC with Intrexon

Lantibiotics –For Resistant Bacterial Infections



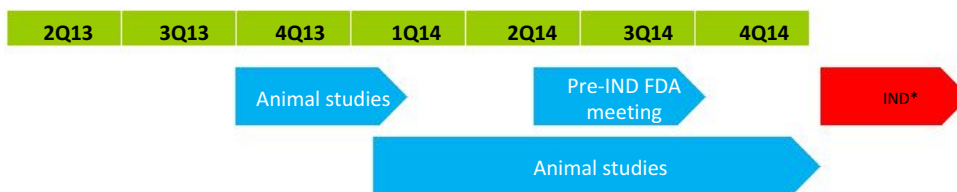
Plan for MU1140

First of 50+ Known Lantibiotics and Analogs



Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology

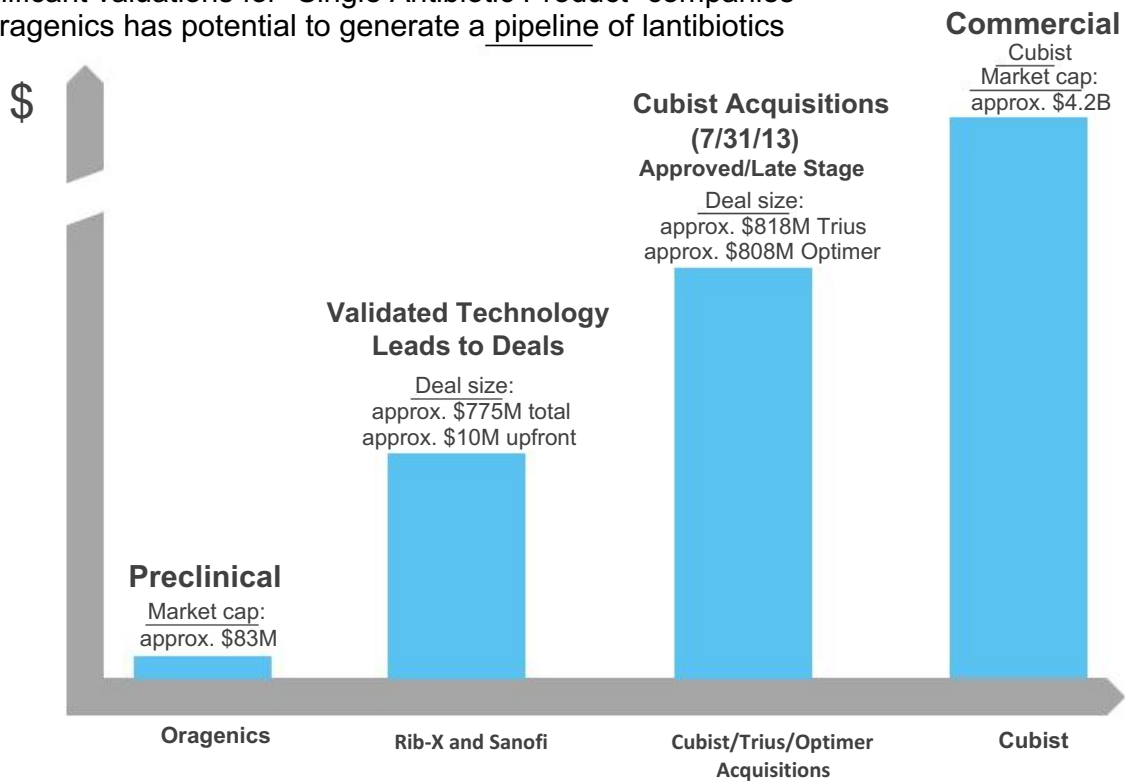
- Matrix of early experiments initiated to screen MU1140 (and several analogs/homologs) for determining primary efficacy (e.g. MICs, MTD, primary efficacy in animals, protein binding, etc.)
- Fermentation optimization/scale-up purification in progress
- IND filing expected by 2H 2015*



** Current estimate may change depending on FDA pre-IND meeting results*

Rising Market Demand for Novel Antibiotic Platforms

Significant valuations for “Single Antibiotic Product” companies –
Oragenics has potential to generate a pipeline of antibiotics



**Next Generation Probiotics For
Therapeutic Use**

**Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology**

Investor Presentation

January 2014

Next Generation Probiotics

Potential to Revolutionize Probiotics for Oral Diseases



Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology

- Developing novel probiotics focusing on treatment of patients with oral cavity, throat, sinus, and esophageal diseases through ECC with Intrexon
- Expect to genetically manipulate bacteria similar to lantibiotics program
 - Beneficial bacteria naturally part of the human oral cavity microbiome
- Genetically-engineered bacterial strains designed to deliver and release therapeutics locally at disease site to target pain management, reduce inflammation, and improve patient outcomes
- Initial indications:
 - Behçet's disease
 - Recurrent aphthous stomatitis (aka canker sores)

Behçet's disease

- Chronic relapsing multi-systemic inflammatory disorder
- Characterized by four major symptoms (oral aphthous ulcers, genital ulcers, skin lesions, and ocular lesions)
- Patients often in constant pain and have difficulty eating
- ~20,000 patients in the U.S.; similar for Europe



Recurrent Aphthous Stomatitis (aka canker sores)

- ▣ Painful ulcers; most common oral mucosal disease known
- ▣ No effective treatments
- ▣ ~200,000 patients in the U.S.
- ▣ Characterized by multiple, recurrent, small, round, or ovoid ulcers
- ▣ Usually presents first in childhood or adolescence



Fig. 1. Minor recurrent aphthous stomatitis ulcer.



Fig. 2. Major recurrent aphthous stomatitis ulcer.



Fig. 3. Herpetiform recurrent aphthous stomatitis ulcers.

Oragenics/Intrexon Solution

GM Probiotics For Oral Health



Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology



Bacteria
Cell



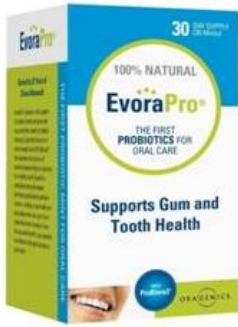
Choose the
appropriate
bacterial strain
to engineer...



...insert genes
responsible for
production of
therapeutics
agent(s)...



...deliver new
therapeutic bacteria
into oral cavity to
produce therapeutic
benefits and supplement
natural oral microbiome.



ProBiora3[®] - Only OTC Probiotic Product Specifically Designed for Oral Health

Engineering New Antibiotics and Probiotics Through Synthetic Biology



Investor Presentation

January 2014

ProBiora3[®] - OTC Product

First and Only Patented Probiotic Technology for Oral Care

ORAGENICS

Engineering New
Antibiotics and
Probiotics Through
Synthetic Biology

- Blend of 3 naturally occurring, non-pathogenic bacteria – *S.oralis*, *S.uberis*, and *S.rattus* – available without prescription and taken daily
- “Good” probiotic bacteria compete for binding sites and nutrients with “harmful” bacteria
- Release hydrogen peroxide to reduce population of pathogens in mouth
- Poor oral health linked to serious health problems, including heart disease and diabetes
- Total consumer oral care market expected to reach \$10.9 billion by 2014¹
- Also marketed for companion animals

¹*The US Market for Oral Care Products (2009)*, published by Packaged Facts

Experienced Management Team

John N. Bonfiglio, Ph.D., President, CEO & Director

- ▣ 30 years of management and pharmaceutical experience
- ▣ Prior CEO Argos Therapeutics, CEO Immune Response, CEO PeregrinePharmaceuticals, COO Cypress Bio
- ▣ Senior Management positions at Allergan Pharmaceuticals and Baxter Healthcare
- ▣ MS and PhD in Chemistry, University of California, MBA Pepperdine University

Mike Sullivan, CFO

- ▣ Prior Senior-level financial positions for both publicly and privately held businesses
- ▣ Significant experience in product licensing and IP issues
- ▣ Strong background in both domestic and international retail operations
- ▣ Florida Certified Public Accountant, ex Big 4. MBA from The Florida State University

Dr. Martin Handfield, VP of Research & Development

- ▣ Former Tenured Associate Professor, College of Dentistry at The University of Florida
- ▣ Over 14 years experience with Oragenics
- ▣ Expert in biomarkers and research surrounding antimicrobials
- ▣ Over 40 publications and 6 patents

Significant Accomplishments in 2013

Novel Antibiotics (Lantibiotics)

- ▣ Significantly increased yield of MU1140
- ▣ Identified two new potentially viable purification methods for commercially producing MU1140
- ▣ Obtained proof of concept for genetically modified bacteria capable of higher yields of MU1140 and potentially analogs

Next Generation Probiotics

- ▣ Established ECC with Intrexon -announced October 1, 2013
- ▣ Completed initial research program; commenced activity in 2014

Finance

- ▣ Raised \$3.9M in PIPE with Intrexon to support new ECC
- ▣ Raised \$11M in shelf-takedown
- ▣ Relisted on NYSE:MKT

Novel Antibiotics (Lantibiotics)

- ▣ Production of new lantibiotic analogs using genetically modified bacteria – 1H 2014
- ▣ Animal study results for MU1140/analog –1H 2014
- ▣ Pre-IND meeting with FDA -2H 2014

Next Generation Probiotics (Preliminary Timelines)

- ▣ Generation of next bacterial prototypes – 2H 2014
- ▣ GM probiotics producing cytokine therapeutics –Mid 2015
- ▣ Proof-of-concept of GM probiotic for therapeutic purposes in animals – 2H 2015