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: December 3, 2018
(Date of earliest event reported)

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

FL	**001-32188**	**59-3410522**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

4902 Eisenhower Boulevard, Suite 125
Tampa, FL **33634**
(Address of principal executive offices) **(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Beginning on December 4, 2018, Oragenics, Inc. (the "Company") plans to make a series of investor presentations (the "Investor Presentation") a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company also expects to use the Investor Presentation at the LD Micro Cap Conference beginning on December 4, 2018 and from time to time thereafter in connection with presentations to potential investors, industry analysts and others. The Investor Presentation is available under the "Presentations" tab in the "News and Media" section of the Company's website, located at www.oragenics.com.

By filing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company 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 warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

The information presented in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed to be "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, unless the Company specifically states that the information is to be considered "filed" under the Exchange Act or specifically incorporates it by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation

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 3rd day of December, 2018.

ORAGENICS, INC.
(Registrant)

BY: /s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer

Exhibit 99.1

ORAGENICS

Alan F. Joslyn, PhD
President & CEO
813 286 7900 ext 232
ajoslyn@oragenics.com

Oragenics, Inc.
4902 Eisenhower Blvd., Suite 125
Tampa, FL 33634
www.oragenics.com

DEVELOPING NOVEL ANTIBIOTICS AND BIOTHERAPEUTICS THROUGH SYNTHETIC BIOLOGY

Investor Presentation

NYSE American: OGEN

Safe Harbor Statement

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.

Investment Highlights

1

Phase 2 ongoing clinical program in a ~$25MM market cap company with near-term catalysts; recent positive interim safety results

2

AG013 for Oral Mucositis: Large unmet clinical need - no drug is approved to prevent OM in the broad cancer population; Affects >770,000 cancer patients annually

3

Lantibiotics Platform: A novel class of peptide antibacterial compounds, with activity against a variety of MDR infections

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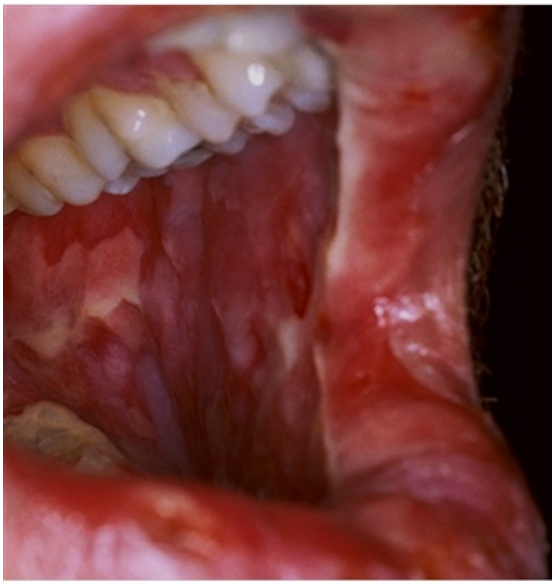
AG013: First-in-Class Therapy for Oral Mucositis

Oral Mucositis



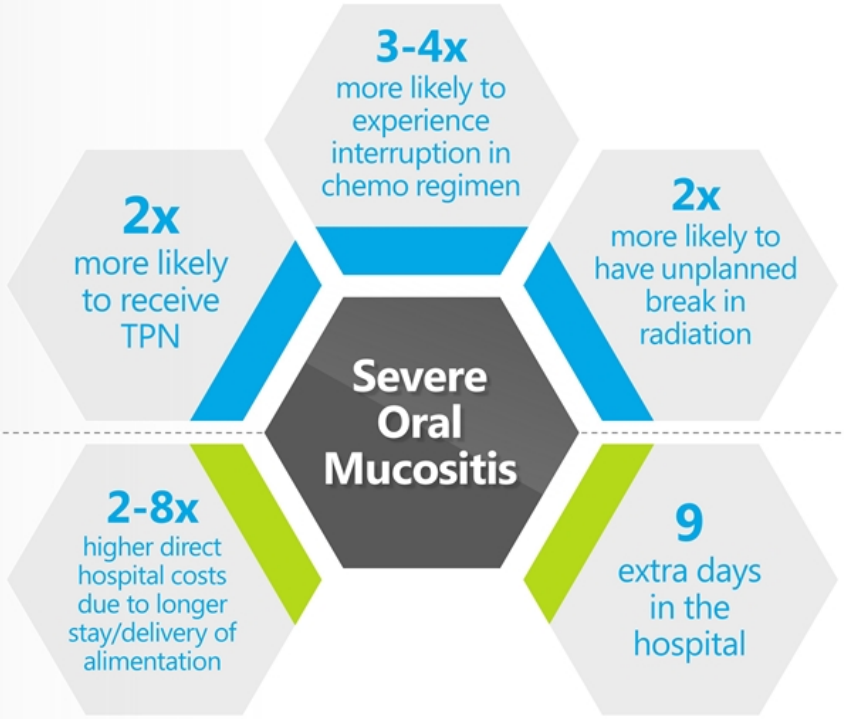
- Most common and debilitating complication of cancer chemo and radiation therapy.
- Caused by breakdown of mucosal lining resulting in formation of oral ulcers.
- Inability to eat/drink (WHO grades 3 & 4) resulting in nutritional deficits and potential alterations of cancer treatment regimens.
- **Large Addressable Market**: > 770,000 U.S. newly diagnosed cancer patients receiving conventional chemotherapy and radiation are at increased risk of developing OM*

*Center Disease Control, 2017

Economic and Clinical Impact of Severe OM

Clinical Impact:

Economic Impact:



Nonzee et al Cancer 2008; 113: 1446-52
Vera_Llonch et al Cancer 2006: 106: 329-36
Carlotto et al Pharmacoeconomics 2013: 2013: 753-66

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AG013: Target Product Profile

- Convenient, flavored oral rinsing solution composed of genetically modified *Lactococcus lactis* (non-pathologic food grade bacterium) engineered to deliver mucosal protectant human Trefoil Factor 1 (hTFF1) to mucosal tissues
  - Trefoil Factors (TFF's) are a class of peptides involved in protecting mucosal tissues against damage and in subsequent repair
- Cost effective (low COGs) rinse provides daily continuous oropharyngeal coverage with *L. lactis* producing hTFF1 during entire cancer treatment regimen

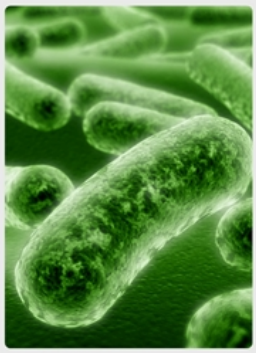
Efficacy endpoints include:

Prevention: No severe OM (WHO grade 3 or 4) during chemoradiation course

Treatment: Reduced number of days of severe OM versus comparator (standard of care)

AG013 in Action

1



AG013 is delivered via lactococcus

2

The combination is freeze-dried into vials

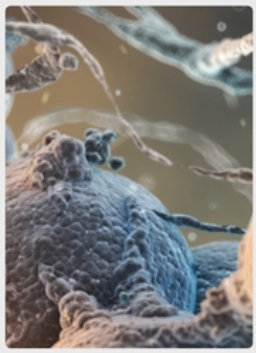
3

Patient mixes powder with a raspberry-flavored solution

4

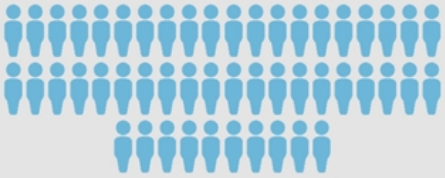
Patient swishes for 30 seconds after every meal

5



This activity promotes a protein called trefoil factor, which regrows the oral lining

AG013 Superior to Available Treatments

	AG013	Kepivance
Sales	TBD	$14,000,000
Patients	 >500,000	 20,000 (indicated only for bone marrow transplant induction chemo patients)
Method	 Oral rinse, outpatient	 Intravenous, inpatient

$600MM palliative care products provide temporary symptomatic relief

* All figures approximate;

AG013 Has Large Addressable Market With Potential W.W. Sales >$1.0Bn for Oral Mucositis

REVENUE-BASED FORECAST ASSUMPTIONS

Potential Global Market:

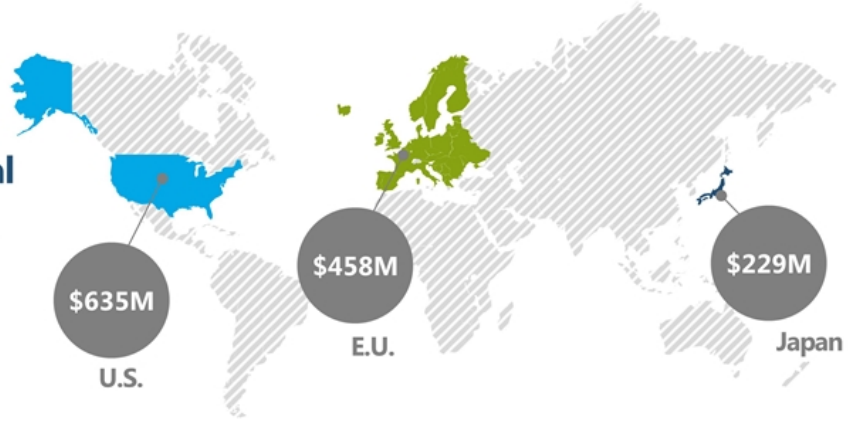
6.2 MILLION+
new patients ww/yr
(1.2MM develop OM)

Peak Share:

20-25%

Cost:

$100
per day



Gross Margin:

90%

Intellectual property relating to AG013 extends into 2030s

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AG013: Phase 2 Study Design Agreed with FDA

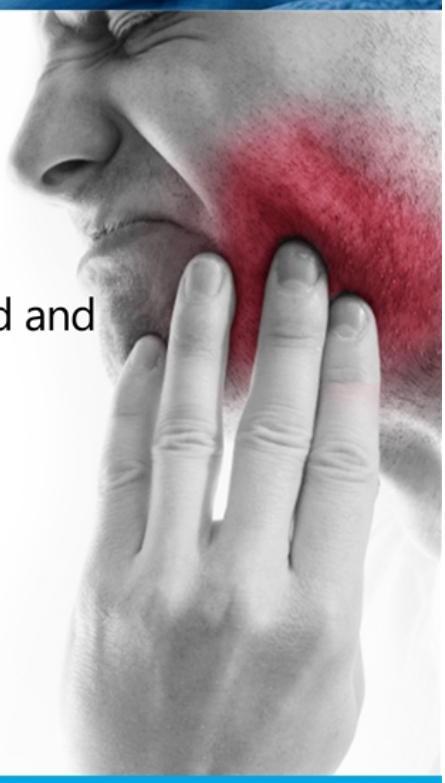
- Double-blind, placebo – controlled evaluation of daily AG013 ($2x10^{11}$ CFU) TID oral rinse for duration of cancer treatment regimen
- 160-180 evaluable patients with head and neck cancer receiving chemoradiation therapy over 7-9 weeks and standard of care for prevention of OM
- ~45 clinical centers in United States and Europe

AG013 Received **FDA Fast Track** Designation

- **Primary efficacy endpoint:** Duration (in days) of severe OM (WHO grades 3 (unable to eat) & 4 (unable to drink))
- **Sample size consideration:** 160 evaluable patients (80/group) provides 80% power to detect 5-day difference between groups with respect to severe OM
- **OM secondary endpoints:** number of OM free (WHO grades 1 & 2) days, time to onset, use of pain medication, alteration in cancer regimens

AG013 Clears FDA Safety Hurdle: Positive Interim Safety Results

- 24 Patients randomized with 19 patients completing therapy.
- Adverse event profiles similar between AG013 and Placebo.
- Serious Adverse Events consistent with Head and Neck Cancer Patients: fever, neutropenia, infections, nausea & vomiting.
- No reports of bacteremia or sepsis
- Discontinuations:
  - **Severe Oral Mucositis: 3 patients**
  - **Nausea & Vomiting: 3 patients**
  - **Non-compliance: 2 patients**



AG013: Timeline of Key Events

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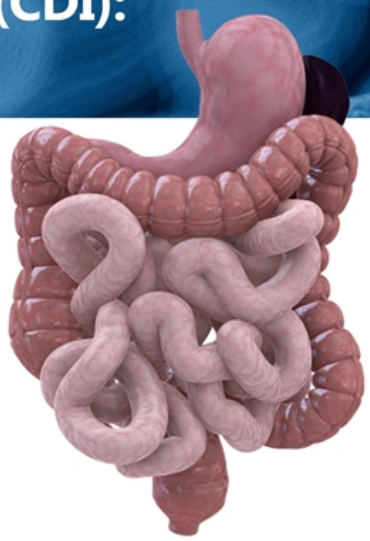
Novel Lantibiotic Platform for
Multidrug Resistant Bacterial Infections

CDC Antibiotic-Resistant Threats, 2017 (cases/yr, US)

Drug-resistant pathogen	blue = gram (+) grey= gram (-)	Infections/year
Clostridium difficile		**500,000**
Carbapenem-Resistant Enterobacteriaceae (CRE)		9,000
Neisseria gonorrhoeae		246,000
MDR Acinetobacter		7,300
Drug-Resistant Campylobacter		310,000
Extended Spectrum ß-lactamase Enterobacteriaceae		26,000
Vancomycin-Resistant Enterococcus (VRE)		**20,000**
MDR *Pseudomonas aeruginosa*		6,700
Drug-Resistant Non-Typhoid Salmonella		100,000
Drug-Resistant Typhoid Salmonella		3,800
Drug-Resistant Shigella		27,000
Methicillin-Resistant *Staphylococcus aureus* (MRSA)		**80,000**
Drug-Resistant *Streptococcus pneumoniae*		**1,200,000**

Center Disease Control; U.S. MDR pathogen update, 2017

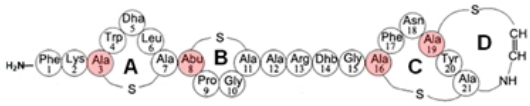
C. difficile and *C. difficile* Infection (CDI): Epidemiology



- *C. difficile* is an infection of the colon causing colitis by producing toxins that damage lining of the colon
- 500,000 infections annually resulting in 29,000 deaths
- 83,000 will experience at least one recurrence
- Deaths have increased 400% since 2000
- Healthcare-associated infections occur: 37% hospital onset, 36% nursing home onset, 27% community onset
- *C. difficile* associated diarrhea is associated with a 1-2 week hospital stay
- **Emerging problem**: 8% of CDI associated with onset of concomitant Vancomycin Resistant Enterococci (VRE) infection

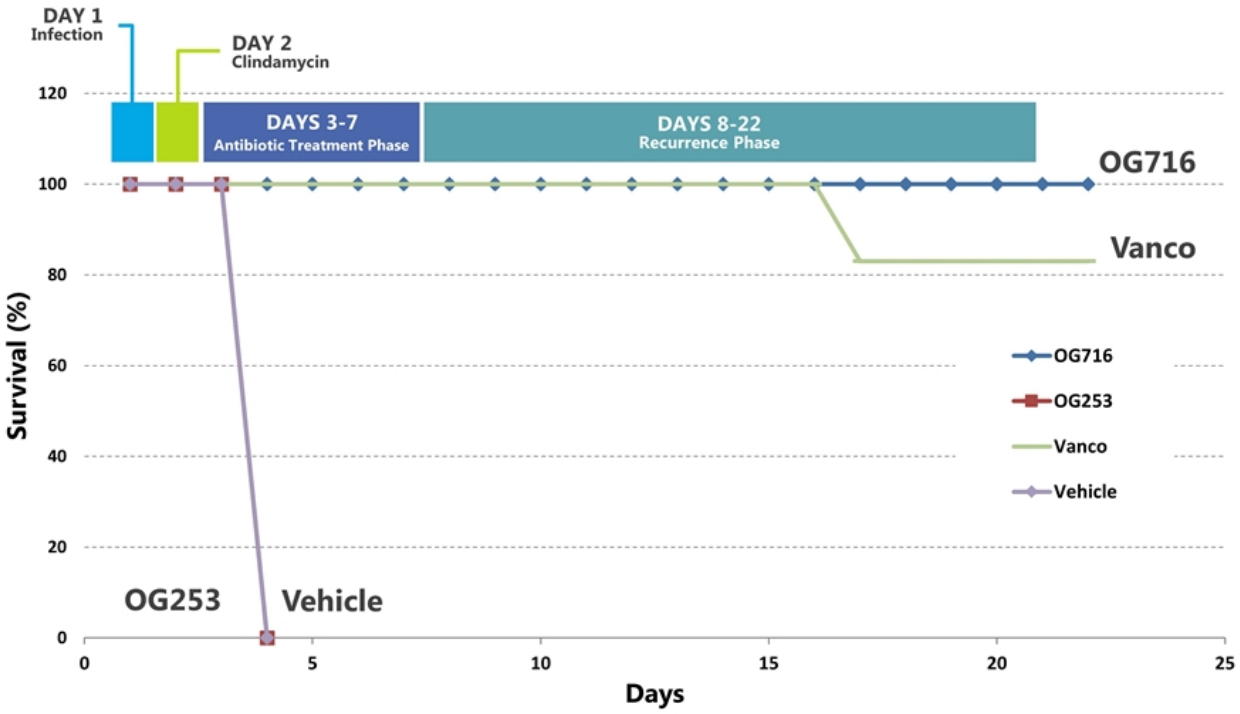
Lantibiotics: Novel Platform of Antibiotics to Treat Serious Life-Threatening Infections

- Lantibiotics are novel class of peptide antibacterial compounds naturally produced by variety of Gram-positive bacterial strains to attack competing bacterial strains
- Platform: >700 lantibiotic structures created, potentially generating a pipeline of new compounds
- Prior development limited by manufacturing technical hurdles
- Platform provides potential for development in multidrug resistant infections:
  - Methicillin Resistant *Staphlococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococci (VRE)
  - Virulent *Clostridium difficile*
  - Gram(-) infections



Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

Oral OG716 Superior at Preventing *C. difficile* Deaths in Hamster Model



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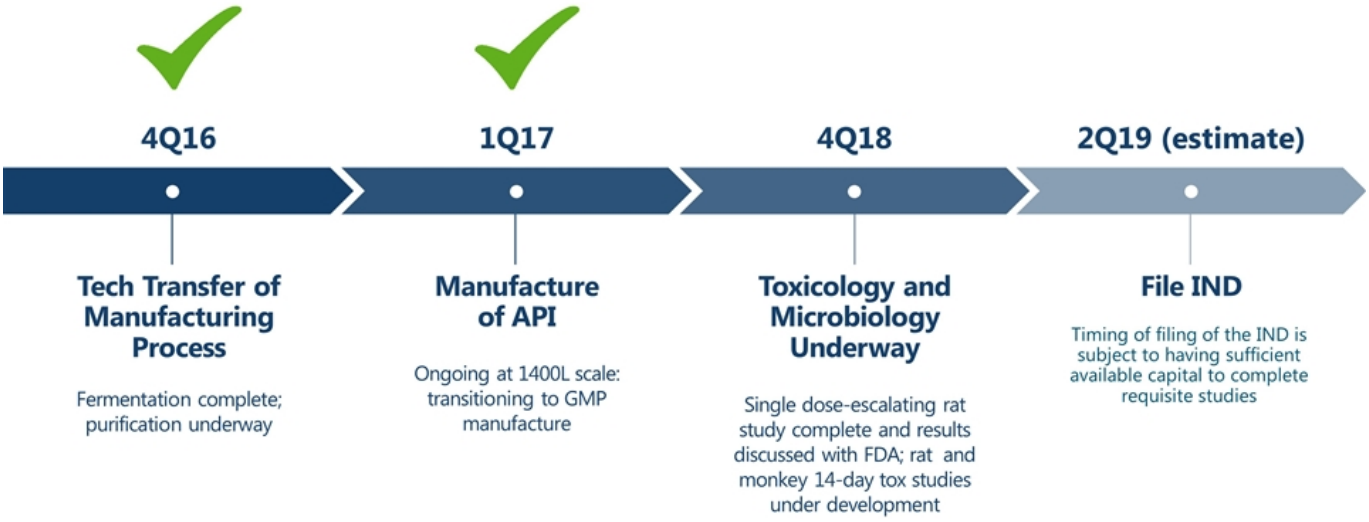
Lantibiotics: OG716 *C. difficile* Program Milestones



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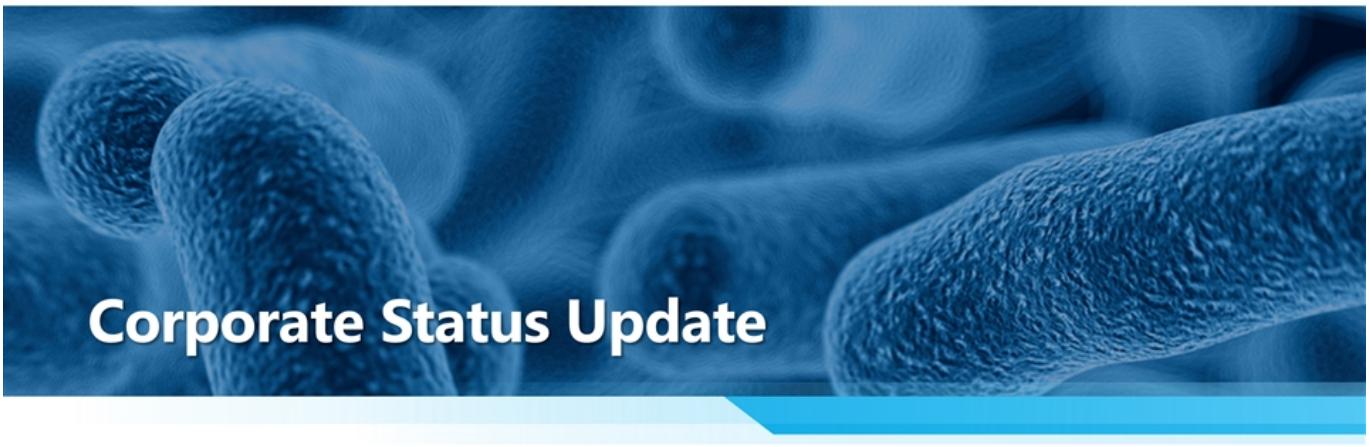

Corporate Status Update

Capitalization

	Common Stock Equivalents
Common Stock Outstanding *	29,433,135
Series A Convertible Preferred*	941,701
Series B Convertible Preferred*	1,320,002
Series C Non-Convertible Perpetual Preferred*** (101.733 shares outstanding)	-
Warrants (WAEP $1.74)*	7,371,925
Reserved for issuance under stock incentive plan*	2,009,250
Total	41,076,013

Major Shareholders	Common Stock	Common Stock Equivalents
Koski Family	6.4%	6.3%
Intrexon Corporation (NYSE:XON)	5.3%	3.8%

Other Institutional Investors

- MSD Credit Opportunity Master Fund LP
- Harvest Intrexon Enterprise Fund I, LP
- Harvest Intrexon Enterprise Fund I (AI), LP
- Altium Capital Management LP
- Empery Asset Management, LP

Pro-Forma Cash** $22.3M

* Information is as of November 13, 2018.

** Information is as of November 13, 2018 and includes $9.5 million in cash proceeds as a result of the exercise of 9.5 million warrants.

*** As of November 8, 2017, the Non-Voting, Non-Convertible Series C Preferred Shares have a stated value of $33,847 per share and have an accruing dividend of 12% per year. The Series C Preferred Shares resulted from the conversion of approximately $3.3 million in debt obligations previously owed to Intrexon.

The Series A, B, and C Preferred stock have no price based downround protection for the conversion price.

Experienced Management Team

Dr. Alan F. Joslyn
Director, President and Chief Executive Officer

- Assumed CEO position at Oragenics in June 2016
- Held CEO positions at several private biotechnology companies including Sentinella Pharmaceuticals, Edusa Pharmaceuticals and Mt. Cook Pharma
- Presently sits on the board of Synergy Pharmaceuticals (NASDAQ: SGYP)
- Over 25 years of drug development experience at Glaxo, Johnson & Johnson and Penwest

Mike Sullivan
Chief Financial Officer

- Held senior-level financial positions for both publicly and privately held businesses
- Significant experience in product licensing and IP issues with strong background in both domestic and international retail operations

Dr. Martin Handfield
Senior Vice President, Discovery Research

- Molecular Microbiologist and former Tenured Associate Professor, College of Dentistry at The University of Florida
- Prolific researcher focusing on infectious diseases, host-pathogen interactions and non-invasive diagnostics