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: September 25, 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 8.01 Other Events.

On September 25, 2018 the Company posted on its website a copy of a presentation regarding the Company's lantibiotics program (the "Lantibiotics Presentation") which Lantibiotics Presentation was part of a presentation at a science symposium by Dr. Martin Handfield, the Company's Senior Vice President Discovery Research, at the Boulder Peptide Symposium held on September 24, 2018. The Lantibiotics Presentation is available under the "Presentations" tab in the "News and Media" section of the Company's website, located at www.oragenics.com.

The information contained in the Lantibiotics 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Lantibiotic 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 25th day of September, 2018.

ORAGENICS, INC.
(Registrant)

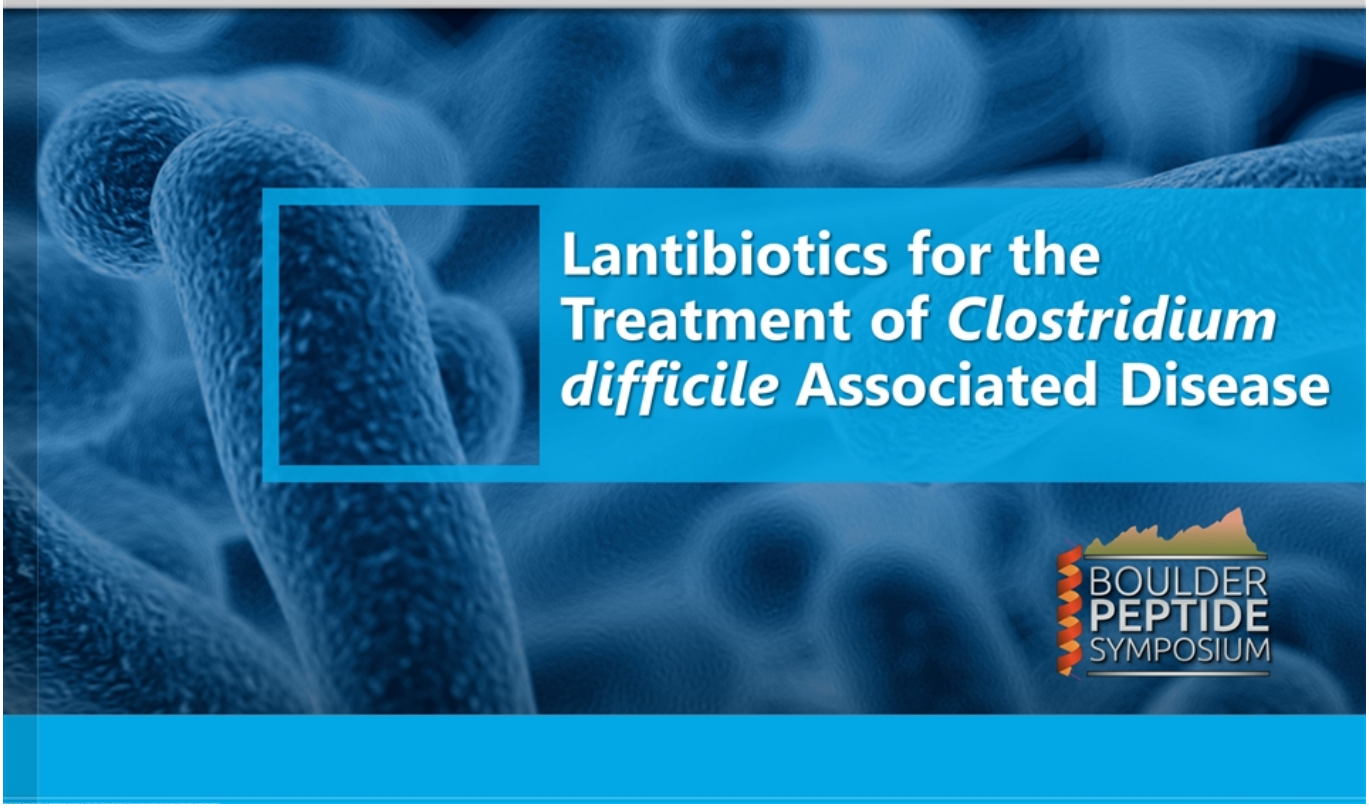
BY: /s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer

Exhibit 99.1

ORAGENICS

Martin Handfield, MS, PhD
SVP, Research
386 418 4018 ext 241
mhandfield@oragenics.com

Oragenics, Inc. (NYSE: OGEN)
13700 Progress Blvd
Alachua, FL 32615
www.oragenics.com



Lantibiotics for the Treatment of *Clostridium difficile* Associated Disease

BOULDER PEPTIDE SYMPOSIUM

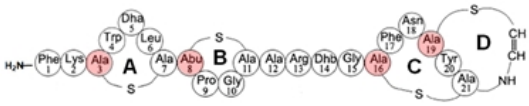
Safe Harbor Statement

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.

Development Program Overview

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

- Lantibiotics (aka lanthipeptide antibiotics) are naturally produced by variety of Gram-positive bacteria
- Prior development limited by manufacturing hurdles
- Platform: >700 lantibiotic structures created, potentially generating a pipeline of new compounds
- Platform provides potential for development in multidrug resistant infections:
  - Virulent *Clostridium difficile*
  - Methicillin Resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococci (VRE)
  - Gram(-) infections



Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

ORAGENICS

Naturally Produced Lantibiotics and Mutacin 1140

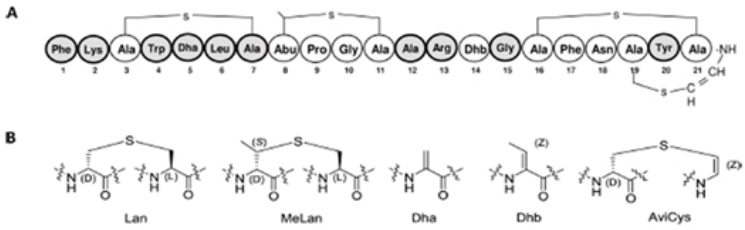
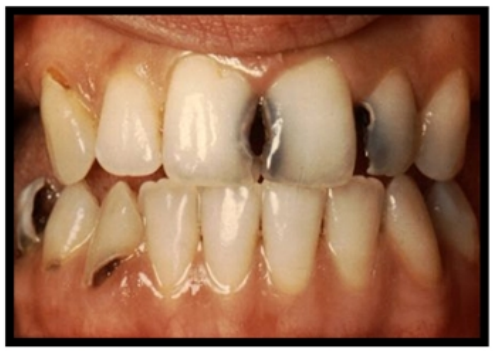
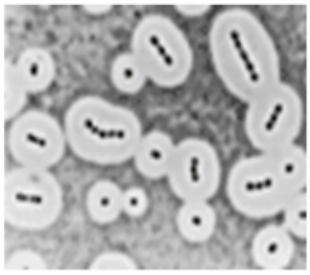


Fig 1. Structural features of MU1140 and select lead compounds. Panel (A) depicts the primary amino acid sequence of MU1140. The second generation of MU1140 variants designed in the current study focused on the residues highlighted in gray. Panel (B) depicts the structure of unusual amino acids. Panel (C) tabulates the substitutions of lead compounds carried through *in vivo* efficacy studies. Legend: amino acids, AA.

PLOS ONE | https://doi.org/10.1371/journal.pone.0197467 June 12, 2018

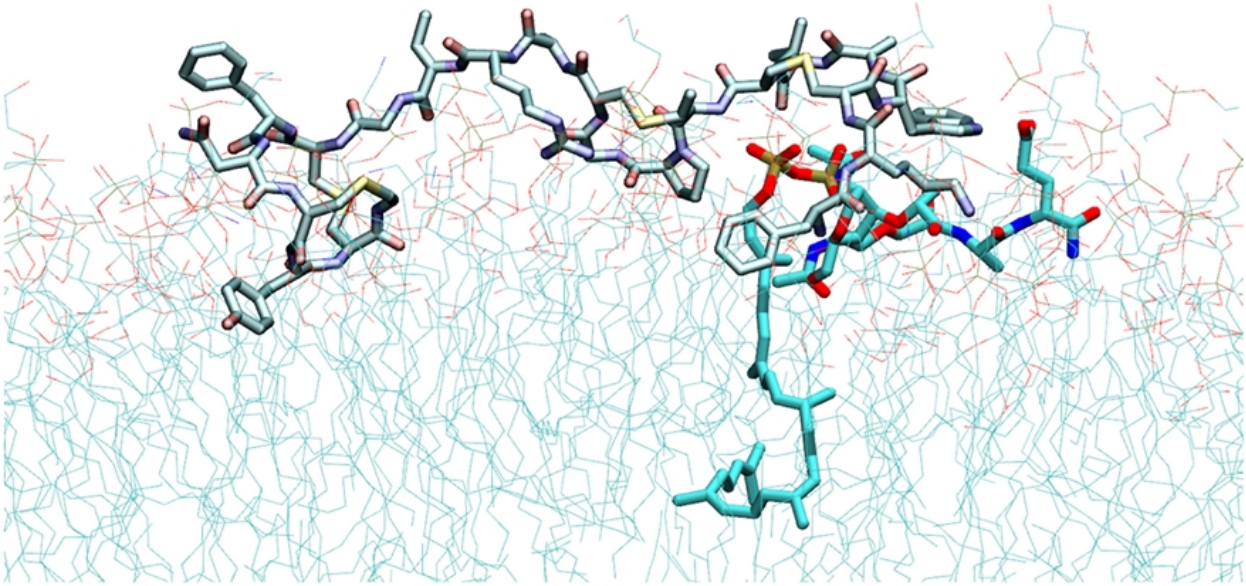


Tooth decay caused by *Streptococcus mutans*



ORAGENICS

Mutacin 1140 Binds to Lipid II



Molecular model credit: Rudramani Pokhrel and Prem Chapagain
(Florida International University)

New MOA – Lipid II Abduction

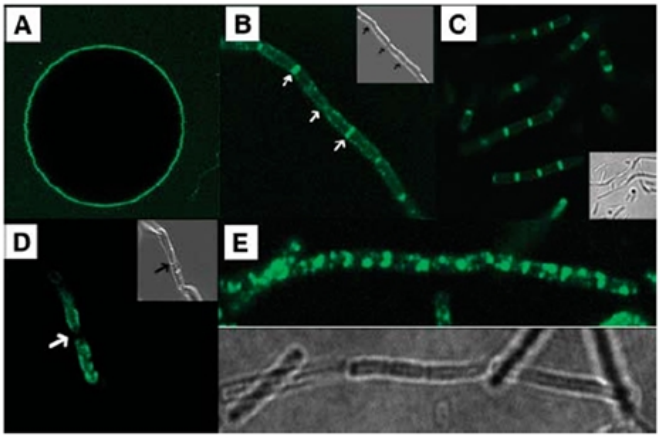


Fig. 2. Nisin segregates lipid II into nonphysiological domains in vivo. (**A**) GUV containing 0.5 mole percent wild-type lipid II 15 min after the addition of fluorescently labeled vancomycin. (**B**) *B. megaterium* cells that were incubated for 10 min with labeled vancomycin (2 μg/ml). The arrows point at newly formed division sites or older exemplars. (**C**) *B. subtilis* stained with fluorescent vancomycin (4 μg/ml). (**D**) *B. megaterium* cells after incubation for 10 min with fluorescein-labeled nisin (0.5 μg/ml). The arrow marks where the bacterium has already divided. (**E**) *B. subtilis* cells after incubation with fluorescein-labeled nisin (4 μg/ml). The bottom image in (E) and the insets in (B) to (D) show Nomarski images.

An Alternative Bactericidal Mechanism of Action for Lantibiotic Peptides That Target Lipid II

Hester E. Hasper,[1] Naomi E. Kramer,[1,2] James L. Smith,[3] J. D. Hillman,[4] Cherian Zachariah,[5] Oscar P. Kuipers,[2] Ben de Kruijff,[1] Eefjan Breukink[1]*

www.sciencemag.org SCIENCE VOL 313 15 SEPTEMBER 2006

ORAGENICS

Challenges in Developing a "Druggable" Lantibiotic

Prior development limited by:

1-Manufacturability

- Low titers at fermentation
- Technical hurdles during solid-phase synthesis
- Ability to purify pharmaceutical grade compounds
- Process scalability

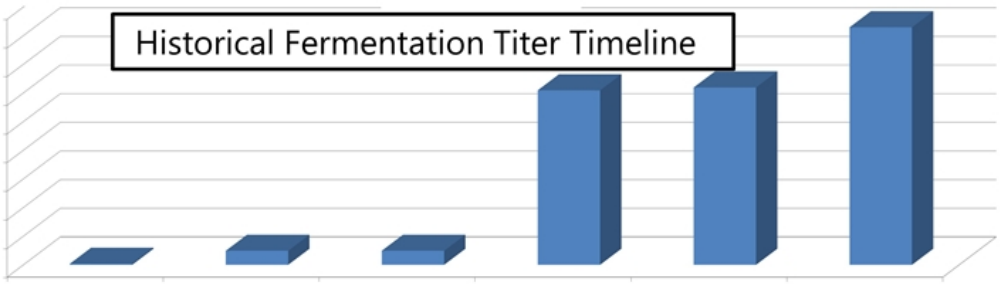
2- Physico-chemical and biological properties

- Sensitivity to proteolytic degradation

How Oragenics Addressed the Manufacturability Challenges

Combining:

- Genetic modifications of the natural host
- Fermentation optimization by DOE
- Out-of-the-box purification scheme



How Oragenics Addressed the Physico-Chemical and Biological Challenges

Platform: >700 lantibiotic structures created, generating a pipeline of new compounds:

- Gen-1: single AA substitution
- Gen-2: multiple AA substitution
- Gen-3: semi-synthetics

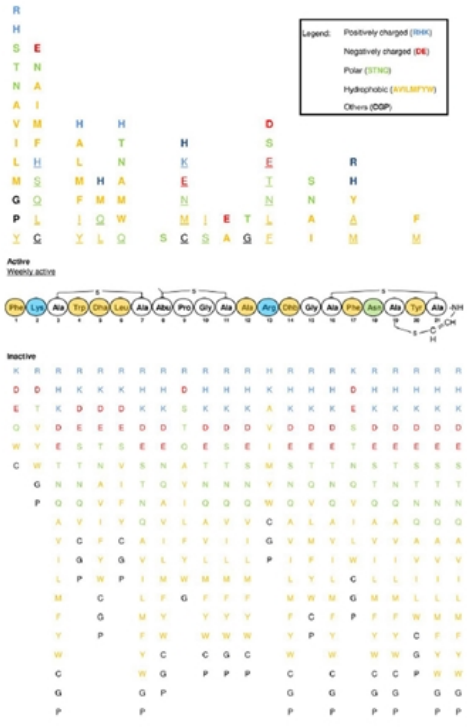


FIGURE 2 Permissive amino acid substitution map of MU1140 as derived from saturation mutagenesis and high-throughput screening. Average scores ≥2 are in bold (active), average scores between 1.5 and 2 are bold and underlined (weakly active), and inactive substitutions are presented below the structure

How to cite this article: Kers JA, Sharp RE, Muley S, et al. Blueprints for the rational design of therapeutic mutacin 1140 variants. *Chem Biol Drug Des*. 2018;00:1–14. https://doi.org/10.1111/cbdd.13365

ORAGENICS

How Oragenics Addressed the Physico-Chemical and Biological Challenges

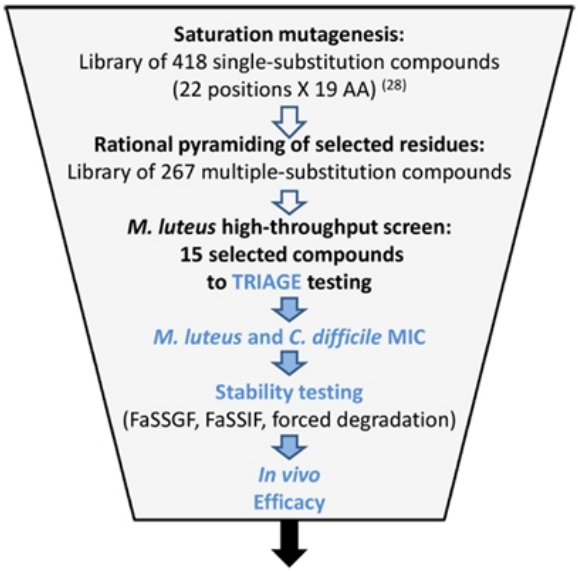


Fig 2. Triage strategy used in this study. High-throughput activity screening used robotic spotting and an optical scanner for the determination of the zones of inhibition. MIC testing provided specific activity values for the determination of the potency. Stability testing performed using biologically-relevant substrates. *In vivo* efficacy performed in the Golden Syrian hamster model of CDAD. See Materials and Methods section for details. Legend: FaSSGF, fasted-state simulated gastric fluid; FaSSIF, fasted-state simulated intestinal fluid.

https://doi.org/10.1371/journal.pone.0197467.g002

Citation:
Kers JA, Sharp RE, Defusco AW, Park JH, Xu J, Pulse ME, Weiss WJ and Handfield M (2018) Mutacin 1140 Lantibiotic Variants Are Efficacious Against Clostridium difficile Infection. Front. Microbiol. 9:415. doi: 10.3389/fmicb.2018.00415

Citation: Kers JA, DeFusco AW, Park JH, Xu J, Pulse ME, Weiss WJ, et al. (2018) OG716: Designing a fit-for-purpose lantibiotic for the treatment of *Clostridium difficile* infections. PLoS ONE 13(6): e0197467. https://doi.org/10.1371/journal.pone.0197467

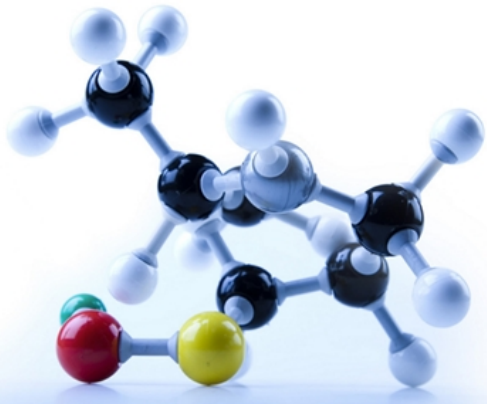
OG716 - Lantibiotic Lead against *C. difficile*

Preliminary MU1140 (parent compound) preclinical data:

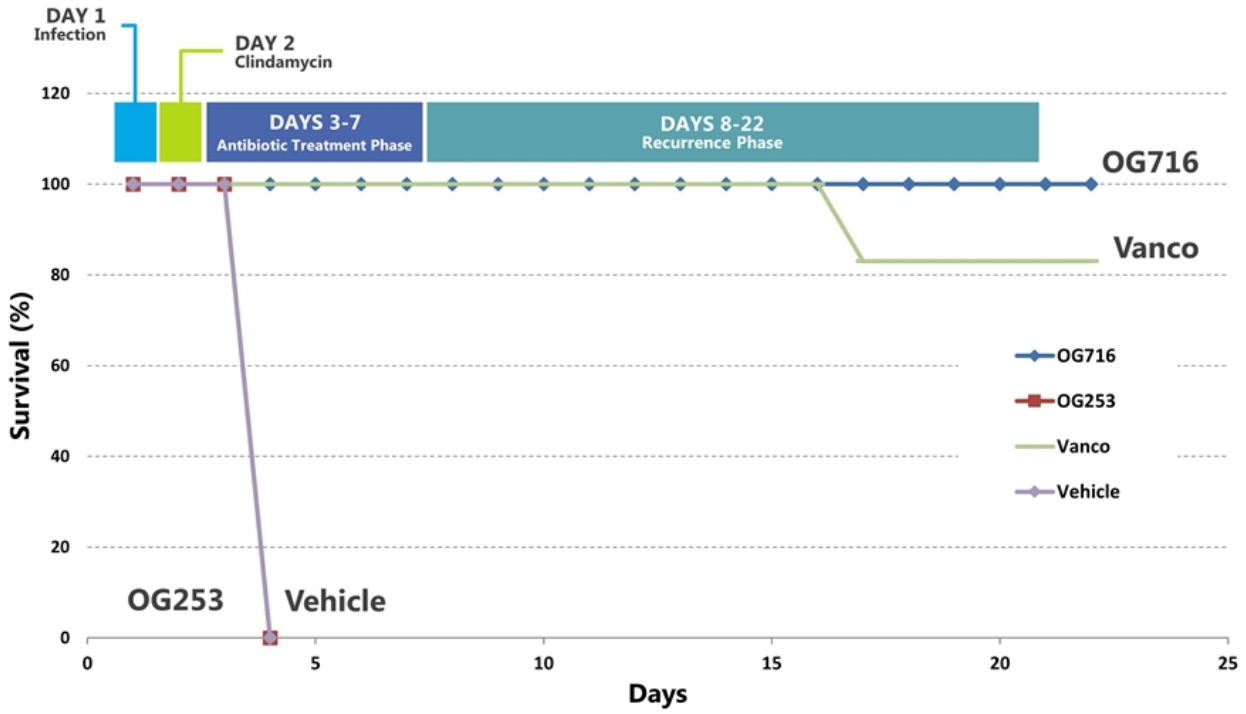
- Novel mechanism of action (unique binding to Lipid II)
- No cross-reactivity with existing classes of antibiotics
- Minimal in vitro cytotoxicity in mouse and human cell lines; minimal immunogenicity

OG716 selected as lead compound for treatment of *C. difficile* infections

- Orally active
- Microbiology profile favorably compares to previous compounds
- Potent against *Clostridium difficile* in standard animal infection model
- Intellectual property extends into late 2030s for second-generation compounds

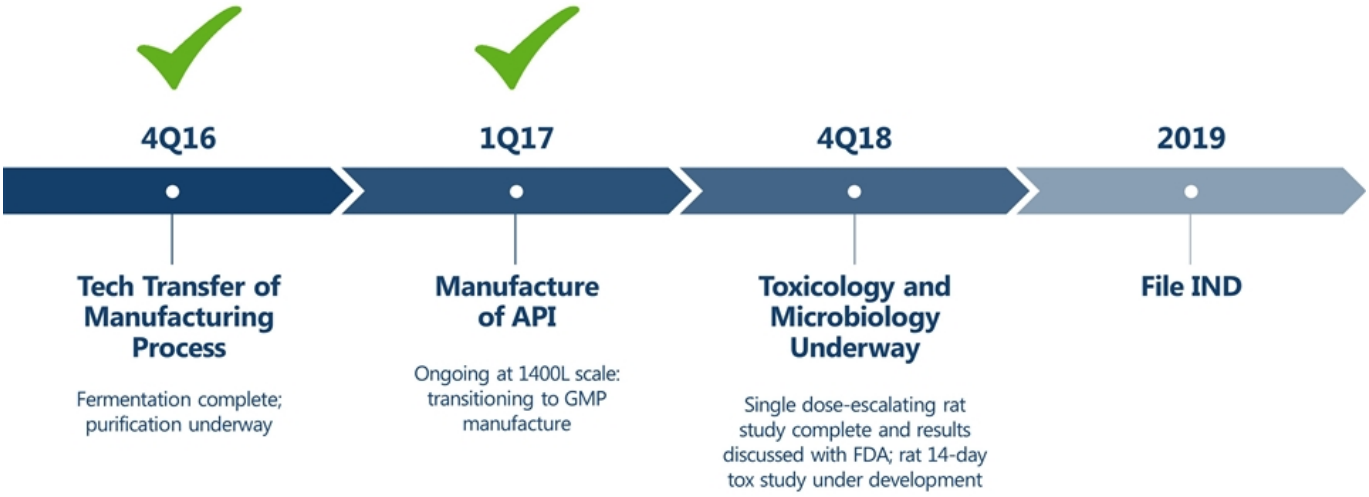


Oral OG716 Superior at Preventing *C. difficile* Deaths in Hamster Model



ORAGENICS

Lantibiotics: OG716 *C. difficile* Program Milestones



Achnowledgements

BACHEM

Christopher McGee, Ph.D. , DeAnna Long, Ph.D.,
Lara Hurant, MBA, Matteo Villain, Ph.D., Andrea Lee and the rest of the Team

UF UNIVERSITY of FLORIDA

BOULDER PEPTIDE SYMPOSIUM

intrexon better DNA

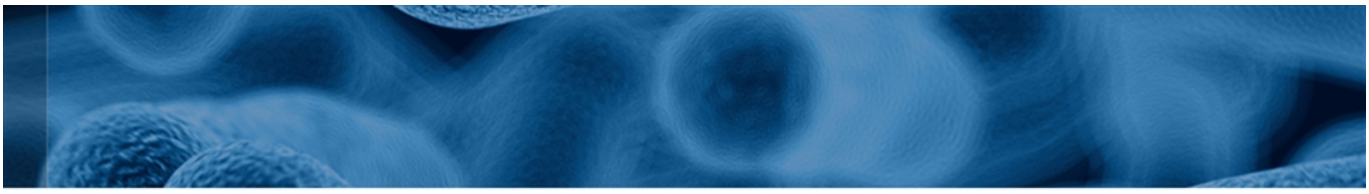
ALMAC

charles river

NSF National Science Foundation WHERE DISCOVERIES BEGIN

SEVENTHWAVE Advice. Analysis. Answers.

UMASS LOWELL

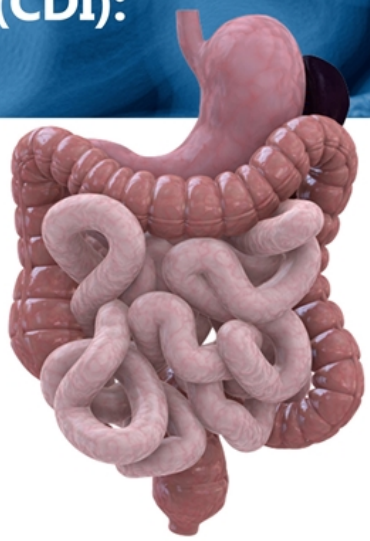


APPENDIX

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**

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

Competitive Overview

Currently Approved Therapies:

- Metronidazole
- Vancomycin
- Fidaxomicin
- Rifaximin
- Zinplava (monoclonal antibody)

Projected 2019 U.S. sales for *C. difficile:* **$426M***

Therapies under development:

Follow-on generations of existing antibiotics, enzymes and enzyme/protein synthesis inhibitors, vaccines, microbiome/fecal transplant therapies, and toxin binding polyclonal antibodies.

* Source: GlobalData