



Oragenics, Inc.

Initiating Coverage with BUY and \$2.50 Target

Strong product potential for drugs to treat large markets aimed at: 1) cancer patients undergoing chemotherapy and; 2) antibiotic resistant patients. We believe positive milestones and clinical data over the next two years will provide a catalyst for company shares.

United States EN: Oragenics, Inc.
Healthcare

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COVERAGE INITIATION

Rating: BUY

Ticker: OGEN

Price: \$0.86

Target: \$2.50

Initiating with BUY: We are initiating coverage of Oragenics, Inc. with a BUY rating and \$2.50 price target

Cancer patients undergoing chemo: Chemotherapy causes mouth and throat ulcers in 7% of patients. Oragenics has a product to prevent ulcers, can be taken at home and is used as a mouthwash. It isn't obvious which patients will get mouth ulcers making use by all the preferred option. We estimate the market potential is greater than \$1 billion.

Antibiotic resistant patients: The CDC says there are approximately 500,000 cases of clostridium difficile in the US each year. It is an infection of the colon causing colitis by producing toxins that damage the lining of the colon resulting in the death of 29,000 among those for whom all other antibiotics fail. The company is commercializing an antibiotic to treat serious life-threatening infections from multidrug resistant bacterial infections. We estimate the market potential is greater than \$1 billion

Oragenics business model allows it to focus on commercialization and clinical trials: Oragenics business mainly relies on contractual relationships with Intrexon Corporation (NASDAQ: XON, NR). Intrexon is a synthetic biology company focused on the early development of pharmaceutical products. Rather than developing these products further, it seeks partners with specific product development expertise. As its partner, OGEN focuses on regulatory approval, commercial development, sales and marketing. We believe this is a more capital efficient way to get products to market. If Oragenics is successful, there can be significant upside that comes along with an exclusive license. It compensates Intrexon along the way through some combination of technology access fees, royalties, milestones and reimbursements of certain costs. If it is unsuccessful, Oragenics owes nothing further.

Current valuation attractive: We calculate a 12-month price target for shares of OGEN to be \$2.50 based on a synthetic dividend discount model, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities.

Company Description

Based in Tampa, FL, Oragenics, Inc. is developing novel antibiotics and biotherapeutics through synthetic biology.

Stock Data

Exchange:	NYSE American
52-week Range:	\$0.38 - \$4.00
Shares Outstanding (million):	29.4
Market cap (\$million):	\$25
EV (\$million):	\$11
Debt (\$million):	\$0
Cash (\$million):	\$13.8
Avg. Daily Trading Vol. (\$million):	~\$1
Float (million shares):	27.4
Short Interest:	5.6%
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2018A</u> <u>(Cur.)</u>	<u>2019E</u> <u>(Cur.)</u>	<u>2020E</u> <u>(Cur.)</u>
Q1 Mar	0.0A	0.0E	0.0E
Q2 Jun	0.0A	0.0E	0.0E
Q3 Sep	0.0A	0.0E	0.0E
Q4 Dec	<u>0.0E</u>	<u>0.0E</u>	<u>0.0E</u>
Total	0.0E	0.0E	0.0E
EV/Revs	NMF	NMF	NMF

Earnings per Share (pro forma)

	<u>2018A</u> <u>(Cur.)</u>	<u>2019E</u> <u>(Cur.)</u>	<u>2020E</u> <u>(Cur.)</u>
Q1 Mar	(0.42)A	(0.08)A	(0.06)E
Q2 Jun	(0.38)A	(0.08)A	(0.06)E
Q3 Sep	(0.35)A	(0.08)E	(0.07)E
Q4 Dec	<u>(0.10)E</u>	<u>(0.08)E</u>	<u>(0.07)E</u>
Total	(0.29)E	(0.31)E	(0.25)E
P/E	N/A	N/A	N/A

Important Disclosures

Ascendant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making an investment decision.

For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 13.

Figure 1: Orogenics, Inc.'s Stock Price (5-years)



Source: Nasdaq.com

INVESTMENT THESIS

Orogenics is in the commercial, regulatory and business development stage of bringing to market two potentially novel drugs:

- AG013. When patients undergo chemotherapy approximately 7% worldwide (1.2 million new patients) will develop oral mucositis (OM), which is a painful and sometimes debilitating breakdown of the lining of the mouth and throat that leads to painful ulcers. In the extreme form, the pain becomes so severe, the patient can no longer eat or drink and the treatment must be stopped. At the moment there is no way to know who will get OM. As envisioned, the Orogenics product would be prescribed for all chemotherapy patients to ensure none of them get ulcers. It can be taken at home and comes in the form of a powder that is mixed with water and used as a mouthwash. The current competing treatment is an expensive inpatient infusion. AG013 would cost approximately \$100/day (treatment lasts 24± days) and has similar profit margins to most bio-tech companies. The company is in Phase 2 which we expect will complete enrollment in 2Q19. The addressable market is greater than \$1 billion. It has the added benefit that by preventing oral ulcers, it reduces demand for Opioid pain killers, which is a societal plus.
- OG716. This compound is a novel platform of antibiotics to treat serious life-threatening infections from multidrug resistant bacterial infections. CDC says there are approximately 500,000 cases of clostridium difficile in the US each year. It is an infection of the colon causing colitis by producing toxins that damage the lining of the colon resulting in the death of 29,000 among those for whom all other antibiotics fail. This product is in toxicology studies right now and progressing favorably. The company will file an investigational new drug (IND) application with the FDA when it has sufficient capital to complete requisite studies. We estimate this would have an addressable market over \$1 billion.

VALUATION

We are initiating coverage of Orogenics with a BUY rating and a 12-month price target of \$2.50, which is based on a synthetic-dividend discount model. As the company is still in clinical trials, it generates minimal, if any revenues and significant losses so traditional valuation metrics are not useful.

Our assumptions are that the company continues to raise capital both this year and the next three. In year five it reaches breakeven and in 10 years' time it has captured 7% share of its addressable market, which we feel is conservative. Our valuation model is shown in Figure 2 below. The model sums up all earnings per share, discounted at 10% to arrive at a per share value and terminal value growth is assumed to be GDP. Note, this model understates future novel product developments, probably understates the tax benefits, but offsetting that, the earnings never have a down year.

Figure 2 – Oragenics, Inc. – Valuation Model

Target Price: \$2.50					
Year	EPS	Discounted EPS	Share Count (Millions)	Net Income (\$Millions)	Sales (\$Millions)
2019	(0.31)	(0.31)	41	(12.4)	0
2020	(0.25)	(0.23)	54	(13.6)	0
2021	(0.31)	(0.26)	65	(20.2)	0
2022	(0.31)	(0.23)	85	(26.4)	0
2023	0.01	0.01	90	1.0	\$10
2024	0.20	0.12	92	20.0	\$67
2025	0.28	0.16	94	28.0	\$93
2026	0.42	0.22	96	42.0	\$140
2027	0.43	0.20	98	43.3	\$144
2028	0.44	0.19	100	43.7	\$146
Terminal Value:		2.63			

Source: Ascendant Capital Markets

Although Oragenics share price YTD has been weak (+0.6%), we believe that there are near term catalysts that can drive the stock. As the company is likely to make significant progress (and milestones) in its drug development and product commercialization over the next several years, we believe this will result in much improved visibility into future cash flows.

COMPANY

Business Model

Oragenics business mainly relies on contractual relationships with Intrexon Corporation (NASDAQ: XON, NR). Intrexon is a synthetic biology company focused on the early development of pharmaceutical products. Rather than developing these products further, it seeks partners with specific product development expertise. These arrangements; one company providing early stage product development and the other focused on regulatory approval, commercial development, sales and marketing are called exclusive channel collaborations, or ECCs. These ECCs are exclusive and aren't easily terminated. So long as the collaboration continues, the two agree that each will not alone or with another party, develop and commercialize products within the field of the ECC. Generally, Intrexon does not have the right to terminate an ECC except in limited circumstances such as the collaborator's failure to exercise diligent efforts in performing its obligations under the ECC, including its development of products enabled by its technologies, or its breach of a term of the ECC that remains uncured for a specified period of time. If successful, Oragenics receives an exclusive license to use all of the technologies in a designated field, potentially in perpetuity.

We believe this is a more capital efficient way to get products to market. If Oragenics is successful, there can be significant upside that comes along with an exclusive license. It compensates Intrexon along the way through some combination of technology access fees, royalties, milestones and reimbursements of certain costs. If it is unsuccessful, Oragenics owes nothing further.

Product Overview

Oragenics is focused on becoming a leader in developing novel antibiotics against infectious disease and on developing effective treatments for oral mucositis.

OGEN's Oral Mucositis Product Candidate-Clinical

In June of 2015, Orogenics entered into a worldwide Exclusive Channel Collaboration Agreement (“Oral Mucositis ECC”) with Intrexon Corporation (“Intrexon”) and Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon, pursuant to which it obtained certain exclusive rights to AG013 as a potential treatment of oral mucositis, or OM for cancer patients, which Orogenics intend to continue to develop. AG013, is an oral rinsing solution designed to deliver human Trefoil Factor 1 (hTFF1) to protect and regenerate damaged mucosal lining of the oral cavity.

The Oral Mucositis ECC grants Orogenics an exclusive worldwide license to utilize Intrexon’s and Actobiotics’ intellectual property to develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans through the administration of an effector via genetically modified bacteria, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (the “Field”). It also grants OGEN an exclusive license in the Field under all Information Controlled by Actobiotics (or otherwise by Intrexon) and existing as of the Effective Date relating to the regulatory approval of AG013, including regulatory filings, data, clinical trial reports, and rights thereunder.

In November of 2017 the Oral Mucositis ECC was amended to: (i) consolidate the development milestone payments into one payment of \$27,500,000 being due six months after receiving FDA approval of a New Drug Application; (ii) reduce the sublicense revenue percentage OGEN would have had to pay from 50% to 25% of sublicensing revenue; and (iii) revise the field in which it has exclusive rights to the Oral Mucositis product candidate for the treatment of Oral Mucositis to clarify that OGEN has an exclusive right for the treatment of Oral Mucositis in humans regardless of etiology. The November amendment superseded an amendment to the Oral Mucositis ECC in May 2017. As of the date of this report, none of the Oral Mucositis ECC milestones had been achieved. Effective January 1, 2018, Intrexon assigned its interest in the Oral Mucositis ECC and related SIA (excluding Intrexon’s standstill obligation) to its wholly owned subsidiary, ActoBio Therapeutics, Inc. We show the market opportunity in Figure 3.

Clinical Data

OM results in a painful inflammation and mucosal ulceration in the lining of the oral cavity, throat and esophagus and is one of the most commonly reported adverse events associated with cancer chemotherapy. Approximately 770,000 patients annually in the US are at an increased risk of developing OM according to cancer statistics provided by the Center for Disease Control (CDC) in 2017. OM has a negative effect on patient well-being and if severe, negatively affects adherence to a patient’s cancer treatment regimen. At present, Orogenics is not aware of any drug that is approved to prevent the condition broadly and current therapies are primarily palliative in nature, only addressing symptom relief but not treating the underlying causes of the condition.

In a Phase 1b clinical trial in 25 cancer patients with OM, AG013 was safe and well tolerated. Data published in the journal *Cancer* showed a 35% reduction of the duration of ulcerative OM in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of the patients treated with AG013 were full responders while all placebo-treated patients developed ulcerative OM. Additionally, in a Phase 1 pharmacokinetic (PK) study in 10 healthy volunteers, AG013 bacteria adhered to the buccal mucosa and actively secrete protein locally, resulting in homogeneous exposure of the entire mucosal surface up to 24 hours after administration of the rinse. During the first quarter of 2016, Orogenics conducted a confirmatory animal study on AG013. AG013 has been granted Orphan Drug status in the European Union. In November of 2016, the United States Food and Drug Administration (the “FDA”) granted Fast Track designation for AG013, and Orogenics believe it may be eligible for Biologic License Application exclusivity as well.

OGEN has have developed a Phase 2 protocol for AG013 with the FDA under the fast track designation. The study is a double blind, placebo controlled, evaluation of daily AG013, administered three times a day, oral rinse for the duration of the cancer treatment. The study is expected to enroll between 160-180 evaluable patients receiving chemoradiation for treatment of head and neck cancer for 7 to 9 weeks. The primary endpoint is a reduction, compared to the placebo, in the number of days of severe oral mucositis. In addition, a number of secondary endpoints are being evaluated. In August of 2016, Orogenics received feedback from the FDA in response to OGEN’s Type C meeting and the pursuit of a Phase 2 trial on AG013 for the treatment of oral mucositis in head and neck cancer patients. Orogenics filed an Investigational New Drug (“IND”) update in March 2017 and Orogenics initiated the Phase 2 study with AG013 in the United States in 2017 with the expectation that Orogenics will expand the trial into Europe in 2018. The Phase 2 trial is a double-blind, placebo-controlled, 2-arm, multi-center trial in which approximately 200 patients will be randomized in a 1:1 ratio to receive either a placebo or AG013. The clinical trial will be conducted at approximately 45 clinical sites across the United States and Europe. The purpose of the Phase 2 study (NCT03234465) is to evaluate the efficacy, safety and tolerability of topically administered AG013 compared to placebo for reducing the incidence and severity of OM in patients undergoing traditional chemoradiation for the treatment of head and neck cancer. Key efficacy measures include collection of data

regarding the duration, time to development, and overall incidence of OM (World Health Organization scale used) during the active treatment phase, beginning from the start of chemoradiation therapy until 2 weeks following its completion.

OGEN has completed enrollment of the interim analysis cohort, which included 24 randomized patients in OGEN’s Phase 2 clinical trial of AG013 for the treatment OM. Nineteen of those patients were included in the unblended safety evaluation, of which 10 received AG013. Orogenics recently announced positive results from OGEN’s interim safety analysis, which was requested by the FDA on patients from OGEN’s Phase 2 clinical trial of AG013 for the treatment of OM. The study provided information that, Orogenics believes, likely indicates that the overall incidence of severe OM is less than would be anticipated in the general population.

Safety was evaluated on the basis of treatment-emergent adverse events, vital signs, weight, physical examinations, clinical laboratory assessments and the presence of AG013 in whole blood. Tolerability measures (taste, consistency and smell) were collected from the patient diaries. In addition, the reasons for study treatment discontinuation were also summarized. Following review of the data by an independent Data Safety Monitoring Board (DSMB), it was concluded that the clinical trial can proceed with no changes to the study. The data analysis indicated that the distribution of adverse events was similar between AG013 and placebo. The serious adverse events reported were consistent with those commonly reported in a head and neck cancer population receiving traditional chemoradiation therapy treatments and included fevers, neutropenia, anemia, nausea and vomiting, infections and oral (mouth and throat) pain. There were no reports of bacteremia or sepsis. Of patients that discontinued participation in the clinical study, 4 patients experienced adverse events, including 3 patients who developed nausea and vomiting, 2 patients that were non-compliant with the study procedures and 3 patients developed severe OM.

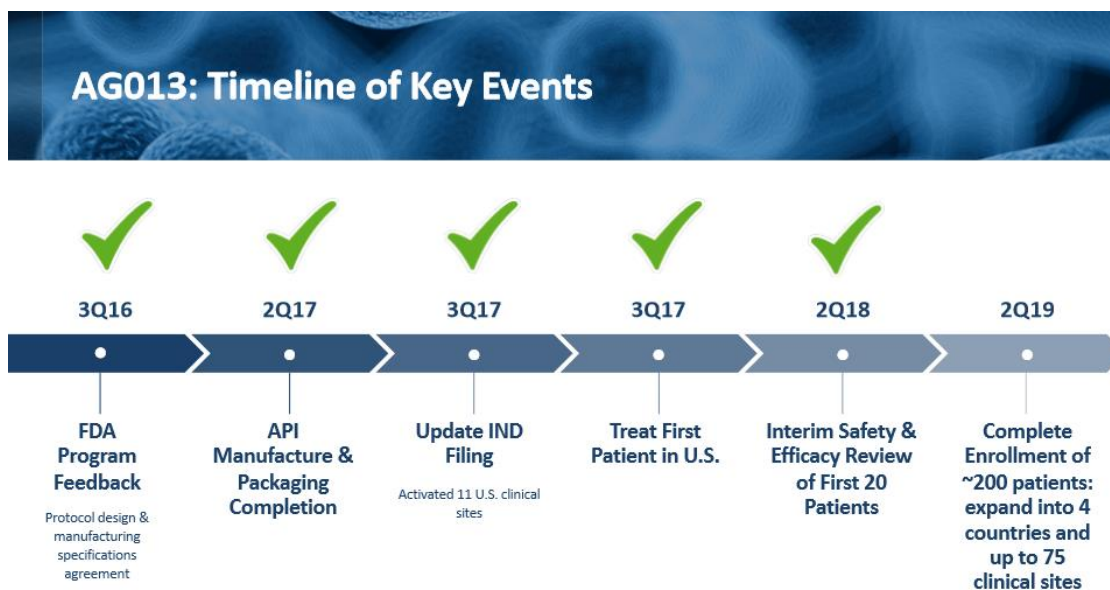
Given the clearance by the DSMB, Orogenics expect to proceed with patient enrollment for OGEN’s AG013 clinical trial, which it hopes to accelerate by the addition of clinical sites in the U.S. and Europe. Orogenics expects to report top-line results of the completed phase 2 trial in late 2019. We show AG013 milestones in Figure 4.

Figure 3 – Orogenics, Inc. – AG013 Market Opportunity



Source: Company presentation. All figures approximate.

Figure 4 – Orogenics, Inc. – AG013 Milestones



Source: Company presentation.

OGEN’s Antibiotic Product Candidate-Preclinical

Members of OGEN’s 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, to date. Orogenics believes lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

The Lantibiotic ECC grants Orogenics an exclusive worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, exporting, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease (“Orogenics Products”). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Orogenics Products, and otherwise is non-exclusive. Subject to limited exceptions, OGEN may not sublicense the rights described without Intrexon’s written consent.

In November of 2017, Orogenics amended the Lantibiotic ECC to: (i) consolidate the development milestone payments into one payment of \$25,000,000, being due six months after receiving FDA approval of a New Drug Application, (ii) reduce the sublicense revenue percentage it would have had to pay from 50% to 25% of sublicensing revenue, (iii) reduce the royalty rate from 25% of Product Profit to 10% of Net Sales, (iv) revise the form of milestone payments from being share based or cash at the Company's election to only cash, and (v) commit that Diligent Efforts (as defined in the Lantibiotic ECC) in pursuing the Lantibiotic Program would be deemed satisfied in 2018 provided that at least \$1,200,000 was expended for the advancement of the Lantibiotic Program. As of the date of this report none of the Lantibiotic ECC milestones had been achieved. This doesn’t mean that no progress has been made as we show in Figure 5.

Clinical Data

In nonclinical testing, MU1140 has shown activity against all Gram-positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections, or HAIs. A high percentage of hospital-acquired infections are

caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) or multidrug-resistant Gram-negative bacteria. Oragenics believes 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.

Lantibiotics have been difficult to investigate for their clinical usefulness as therapeutic agents in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of these molecules. Traditional fermentation methods can only produce minute amounts of the lantibiotic.

In June 2012, Oragenics entered into the Lantibiotic Exclusive Channel Collaboration agreement (“Lantibiotic ECC”) with Intrexon for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon’s advanced transgene and cell engineering platforms. Through OGEN’s work with Intrexon, Oragenics has been able to produce a significant increase in the fermentation titer of MU1140 compared to standard fermentation methods and have discovered a new purification process for MU1140. OGEN’s work with Intrexon generated a substantial number of homologs of MU1140, and Oragenics is continuing its research and development and collaboration efforts with Intrexon to develop potential derivatives of the MU1140 molecule using genetically modified bacteria.

In OGEN’s pre-clinical studies to support a potential IND filing with the FDA, Oragenics tested a total of six homologs of MU1140 for certain compound characteristics, including but not limited to: drug activity (based on minimum inhibitory concentration or “MIC”) equal or better than “standard of care” drugs against certain drug-resistant bacteria, safety, toxicity, stability, and manufacturability. An animal study specifically evaluated homolog efficacy in relation to survival, measurable amounts of *Clostridium difficile* (“*C. diff*”) colony forming units, and toxin levels. Three homologs demonstrated promising results with one homolog, OG253 achieving a 100% survival rate throughout the entire study in contrast to an approximately 30% survival rate for the vancomycin positive control.

Based on these early results, Oragenics selected a lead candidate, OG253, for which Oragenics had a pre-IND meeting with the FDA in November of 2015 regarding the pursuit of an IND for OG253. Following additional research and development on second generation lantibiotics, in August of 2016, Oragenics opted to select a second generation lantibiotic, OG716, for treatment of *C. diff* as its new lead candidate. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from OGEN’s MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of toxins A & B and *C. diff* spores when compared to a vancomycin positive control.

The timing of the filing of an IND regarding OG716 is subject to OGEN’s having sufficient available capital given all of OGEN’s anticipated needs and expected requirements in connection with its ongoing research and development initiatives. While Oragenics was able to raise additional capital during the year ended December 31, 2017, Oragenics currently expect the IND for a first-in-human clinical study of OG716 to be filed with the FDA based on OGEN’s ability to complete the requisite studies, contingent on sufficient funding, part of which was obtained in 2018.

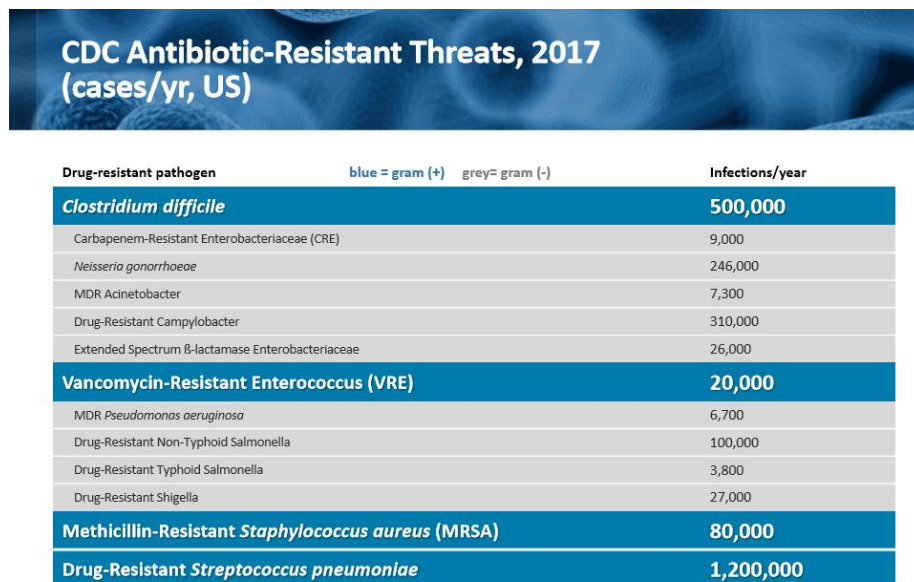
On January 28, 2019 the company announced the results of a preclinical trial of OG716 that was published in the peer reviewed journal, *Antimicrobial Agents and Chemotherapy*. The preclinical study demonstrated that following oral administration of the maximum feasible dose of OG716 in hamster models, there were no observable toxicities nor observable side effects, nor was there any effect on intestinal motility. Treatment of animals infected with *C. difficile* resulted in a dose-dependent survival, and no recurrence at the upper dose tested. Further, researchers observed that the compound remained constrained only in the gastrointestinal tract. Lantibiotics, including OG716, are a novel class of peptide antibacterial compounds naturally produced by a variety of Gram-positive bacteria. Oragenics’ lantibiotic library offers a large pipeline for the development of novel antibiotics in several indications. The scale of the treatment opportunity is shown in Figure 6.

Figure 5 – Orogenics, Inc. – OG716 Progress



Source: Company presentation. All figures approximate.

Figure 6 – Orogenics, Inc. – OG716 Treatment Opportunity



Source: Company presentation.

Other Product Candidates and Technologies.

In addition to OGEN's lantibiotics and oral mucositis product candidates, Oragenics also has other candidates and technologies in the oral care and weight loss areas. Oragenics does not intend to continue to develop these potential product candidates and technologies without partnering with a third party.

MANAGEMENT TEAM

Alan Joslyn, Ph.D.

President and Chief Executive Officer

Dr. Joslyn was a partner in Lazarus Pharmaceuticals. Prior to that he served as the Chief Executive Officer and Director of several privately held companies including Edusa Pharmaceuticals and Sentinella Pharmaceuticals and prior to that he was the Senior Vice-President Research and Development of Penwest Pharmaceuticals and also held senior drug development positions with Johnson & Johnson.

Michael Sullivan

Chief Financial Officer

Mr. Sullivan has served as interim principal executive officer from October 30, 2014 until Dr. Joslyn was appointed and served as Chief Financial Officer, Secretary and Treasurer since February 6, 2012. Mr. Sullivan has held senior level financial positions for several publicly and privately held businesses including Utek Corporation, eANGLER, and HSN Direct International Limited. Most recently, he was the Group Financial Officer for the Investigative Services and Litigation Consulting Services segment of First Advantage Corporation. Mr. Sullivan is a Florida Certified Public Accountant. He graduated from the Florida State University with a Bachelor of Science in Accounting and a Master of Business Administration.

Dr. Martin Handfield

Senior Vice President of Discovery Research

Dr. Handfield is, the Company's Senior Vice President of Discovery Research and previously has served as Director of Research and Development. Prior to joining Oragenics, Dr. Handfield held a position as Tenured Associate Professor at the Center for Molecular Microbiology and the Department of Oral Biology at the University of Florida College of Dentistry, where he co-invented IVIAT and co-founded ivi Gene Corp. and Epicure Corp. to commercialize this and related technologies. Dr. Handfield holds a B.S. degree in Biochemistry, and a MS degree and PhD in Microbiology and Immunology from the Université Laval College of Medicine in Canada, and did postdoctoral training at the University of Florida.

INVESTMENT RISKS

The Company is subject to a number of risks, including risks that may prevent it from achieving its business objectives or may adversely affect the business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in its common stock. These risks include, but are not limited to, the following:

Preclinical, clinical and regulatory risk. Oragenics has limited experience in the conduct of clinical trials, and may be unable to obtain, regulatory approval for early-stage product candidates. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates, any of which would adversely impact commercialization, its potential to generate revenue, its business and its operating results. It may also be subject to healthcare laws, regulation and enforcement and failure to comply with those laws could adversely affect its business, operations and financial condition.

Development risk. At present, Oragenics business is dependent on the successful development and commercialization of its product candidates, in particular AG013, and OG716. It may never successfully commercialize any of its product candidates. Accordingly, it may not generate revenue through the sale of its product candidates or any future product candidates sufficient to continue operations. Under its ECCs with Intrexon and its wholly owned subsidiary ActoBio Therapeutics™, Inc. Oragenics is responsible for, among other things, funding the further anticipated development of lantibiotics and AG013 toward the goal of commercialization, including conducting nonclinical and clinical development of product candidates. Intrexon may terminate such

agreement if Orogenics does not perform certain specified requirements, including developing therapies identified to it and considered superior by Intrexon.

Commercial risk. At present, Orogenics business is dependent on the successful development and commercialization of its product candidates, in particular AGO13, and OG716. It may never successfully commercialize any of its product candidates. Accordingly, it may not generate revenue through the sale of its product candidates or any future product candidates sufficient to continue operations.

Balance sheet risk. Orogenics will require substantial additional financing and capital. To raise additional capital, it may in the future issue debt and equity securities or securities convertible into equity securities, any of which may be senior to its common stock as to distributions or in liquidation and may have other rights superior to existing stockholders.

Income risk. Operating results may fluctuate significantly, are difficult to predict and could vary from expectations due to a variety of other factors, including: its financial condition, delays in the commencement, enrollment and the timing of clinical testing for its product candidates; the timing and success or failure of clinical trials for its product candidates or competing product candidates; delays in regulatory review and approval of product candidates; the timing and level of investment in research and development activities; the cost of manufacturing; and its ability to obtain additional funding.

FINANCIALS

Orogenics fiscal year ends on December 31. We expect its next earnings report (for Q4 2018) to be in mid-to-late March. As the company is still in clinical trials, it generates minimal if any revenue.

FINANCIAL MODEL

Figure 7 - Oragenics, Inc. - Income Statement

(\$ in thousands except per share)

December ending year	2017	2018E				2018E	2019E				2019E	2020E				2020E
	Year	Q1	Q2	Q3	Q4E	Year	Q1E	Q2E	Q3E	Q4E	Year	Q1E	Q2E	Q3E	Q4E	Year
Total revenue	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Cost of Goods	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Profit	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R&D	3.54	1.33	1.27	1.58	1.60	5.78	1.80	1.80	1.80	1.80	7.20	1.90	2.00	2.00	2.00	7.90
SG&A	3.18	0.80	1.01	1.18	1.20	4.19	1.30	1.30	1.30	1.30	5.20	1.30	1.30	1.40	1.40	5.40
Total Operating Expenses	6.72	2.12	2.28	2.76	2.80	9.97	3.10	3.10	3.10	3.10	12.40	3.20	3.30	3.40	3.40	13.30
Operating Income	(6.72)	(2.12)	(2.28)	(2.76)	(2.80)	(9.97)	(3.10)	(3.10)	(3.10)	(3.10)	(12.40)	(3.20)	(3.30)	(3.40)	(3.40)	(13.30)
Total Other Items	(0.01)	0.00	0.00	(1.41)	0.00	(1.40)	0.00	0.00	0.00	0.00	0.00	0.15	0.15	0.15	0.15	0.60
Pre-Tax Income	(\$6.73)	(\$2.12)	(\$2.28)	(\$4.17)	(\$2.80)	(\$11.37)	(\$3.10)	(\$3.10)	(\$3.10)	(\$3.10)	(\$12.40)	(\$3.05)	(\$3.15)	(\$3.25)	(\$3.25)	(\$12.70)
Taxes (benefit)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income (loss)	(\$6.73)	(\$2.12)	(\$2.28)	(\$4.17)	(\$2.80)	(\$11.37)	(\$3.10)	(\$3.10)	(\$3.10)	(\$3.10)	(\$12.40)	(\$3.05)	(\$3.15)	(\$3.25)	(\$3.25)	(\$12.70)
EPS, as reported	(1.37)	(0.42)	(0.38)	(0.35)	(0.10)	(0.39)	(0.08)	(0.08)	(0.08)	(0.08)	(0.31)	(0.06)	(0.06)	(0.07)	(0.07)	(0.25)
Diluted Shares Outstanding	5	5	6	12	29	29	39	40	40	40	40	50	50	50	50	50

Sources: Company reports and Ascendant Capital Markets, LLC

Figure 8 - Oragenics, Inc. - Balance Sheet

(\$ in millions except per share)

December ending year	FY2020E	FY2019E	FY2018E	FY2017	FY2016
Balance sheet					
Current Assets					
Cash and S.T.I.	\$7.83	\$8.53	\$10.01	\$6.17	\$4.08
Accounts receivable	0.00	0.00	0.00	0.00	0.00
Inventories	0.00	0.00	0.00	0.00	0.00
Other assets	1.00	1.00	1.00	1.03	0.14
Total Current Assets	8.83	9.53	11.01	7.19	4.22
Net PP&E	0.10	0.10	0.02	0.02	0.09
Other non-current assets	0.00	0.00	0.00	0.00	0.00
Total Assets	\$8.93	\$9.63	\$11.03	\$7.21	\$4.31
Current Liabilities					
Accounts payable and accrued exp.	\$2.00	\$2.00	\$1.00	\$0.82	\$1.28
Short-term notes payable	0.00	0.00	0.00	0.08	0.07
Other current liabilities	0.00	0.00	0.00	0.00	0.00
Total current liabilities	2.00	2.00	1.00	0.90	1.34
Conv. and Long Term Debt	0.00	0.00	0.00	0.00	0.00
Other non-current	0.00	0.00	0.00	0.00	0.00
Total Liabilities	2.00	2.00	1.00	0.90	1.34
Stockholders' Equity					
Preferred stock	6.80	6.80	6.80	6.31	0.00
Common stock	0.00	0.00	0.00	0.00	0.00
Additional paid-in-capital	138.00	126.00	116.00	101.40	97.66
Retained earnings	(137.87)	(125.17)	(112.77)	(101.40)	(94.67)
Cum. trans. adj. and treasury stock	0.00	0.00	0.00	0.00	(0.03)
Total stockholders' equity	6.93	7.63	10.03	6.32	2.97
Total Liabilities and equity	\$8.93	\$9.63	\$11.03	\$7.21	\$4.31

Sources: Company reports and Ascendant Capital Markets, LLC

Figure 9 - Oragenics, Inc. - Cash Flow

Cash Flow	2020E	2019E	2018E	2017
Net Income	(\$12.70)	(\$12.40)	(\$11.37)	(\$6.73)
Accounts receivable	0.00	0.00	0.00	0.00
Inventories	0.00	0.00	0.00	0.00
Other assets	0.00	0.00	0.03	(0.89)
PP&E	0.00	(0.08)	0.00	0.07
Other non-current	0.00	0.00	0.00	0.00
Accounts payable and accrued exp.	0.00	1.00	0.18	(0.46)
Short-term notes payable	0.00	0.00	(0.08)	0.01
Other current liabilities	0.00	0.00	0.00	0.00
Conv. and Long Term Debt	0.00	0.00	0.00	0.00
Other non-current	0.00	0.00	0.00	0.00
Preferred stock	0.00	0.00	0.49	6.31
Common stock	0.00	0.00	(0.00)	0.00
Additional paid-in-capital	12.00	10.00	14.60	3.74
Stock subscription receivable	0.00	0.00	0.00	0.03
Other			0.00	0.00
Total Cash Flow	(\$0.70)	(\$1.48)	\$3.84	\$2.09

Source: Ascendant Capital Markets, LLC

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Oragenics, Inc.

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Ascendant Capital Markets, LLC Rating System

BUY: We expect the stock to provide a total return of 15% or more within a 12-month period.

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SELL: We expect the stock to have a negative total return of more than 15% within a 12-month period.

Total return is defined as price appreciation plus dividend yield.

Ascendant Capital Markets, LLC Rating System

Prior to January 31, 2014, ASCM used the following rating system:

Strong Buy: We expect the stock to provide a total return of 30% or more within a 12-month period.

- Buy:** We expect the stock to provide a total return of between 10% and 30% within a 12-month period.
- Neutral:** We expect the stock to provide a total return of between minus 10% and plus 10% within a 12-month period.
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- Speculative Buy:** This rating is reserved for companies we believe have tremendous potential, but whose stocks are illiquid or whose equity market capitalizations are very small, often in the definition of a nano cap (below \$50 million in market cap). In general, for stocks ranked in this category, we expect the stock to provide a total return of 50% or more within a 12-month period. However, because of the illiquid nature of the stock's trading and/or the nano cap nature of the investment, we caution that these investments may not be suitable for all parties.

Total return is defined as price appreciation plus dividend yield.

Ascendant Capital Markets, LLC Distribution of Investment Ratings (as of January 15, 2019)

Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
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Hold	2	5%	1	50%
Sell	0	0%	0	0%
Total	39	100%	6	15%

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