Initiation Report

ORAGENICS INC.

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Initiation of Coverage

Oragenics Inc.

Leveraging Probiotic and Antibiotic Research to Serve a Large Global Market

Biotechnology

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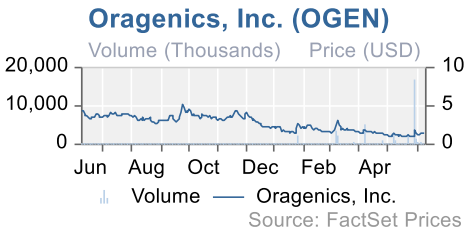
Investment Highlights:

- Oragenics has positioned **AG013 to treat over 2.2 million patients worldwide annually, enough to generate over $1.5 billion in sales and secure 20-25% market share if approved**. AG013 is a peptide oral rinse developed to treat oral mucositis (OM), one of the most common and debilitating complications that arises during cancer therapy, which still lacks approved preventive treatments. The absence of effective drugs has resulted in a large potential market for any new treatments for OM. On May 30, 2018, Oragenics' announced **positive results of an interim safety analysis of AG013 in its ongoing study of an initial group of 20 patients** enrolled in its 200-patient phase 2 clinical trial
- Oragenics is also developing OG716, a second-generation variant of MU1140, **identified for its potential effectiveness in treating clostridium difficile infections (CDI)**, which affect 500,000 people a year in the U.S. alone; associated deaths have increased 400% in the past two decades. The CDI treatment market is growing rapidly, with U.S. sales projected at $426 million in 2019. Amid limited approved therapies, OG716 appears to be a means of preventing this life-threatening infection. Oragenics plans to file for an Investigational New Drug (IND) by the end of this year for OG716, assuming sufficient financing is available
- **Oragenics' strategic partnership with Intrexon provides exclusive access to major proprietary technologies** to accelerate research and development (R&D) and reduce funding costs. Additionally, the company recently completed a **$1.8 million direct common stock offering for $2 per share** with new institutional investors. We believe this corroborates investors' underlying confidence in Oragenics' potential drug candidates and management. We view Oragenics as a unique high risk, high reward investment opportunity based on the current development stage of its drug candidates. Based on an equal weighting of a discounted cash flow and comparable company analysis model, *our valuation models indicate a fair value of $3.50 per share, 250% above current levels*

Company Description

Oragenics Inc. works primarily on developing new antibiotics and treatment for OM. It is developing AG013 (currently in phase 2 clinical trials for treatment of OM) and OG716 (a new-generation antibiotic candidate for treatment of CDI). The company was founded in 1996 and is headquartered in Tampa, Florida.

Price-Volume History



Key Statistics

Closing Price (As of 06/19/2018)	$1.44
Valuation	$3.50
52-Week Range	$0.60-$6.80
Average Daily Volume (th)	214
Shares Outstanding (th)	6,087
Market Capitalization (M)	$8.40
Number of Analysts Covering	2
Enterprise Value/Revenue	N/A

Revenue ($ in millions)

Dec. FY	2017A	2018E	2019E
1Q	0.00A	0.00A	0.00E
2Q	0.00A	0.00E	0.00E
3Q	0.00A	0.00E	0.00E
4Q	0.00A	0.00E	0.00E
FY	0.00A	0.00E	0.00E

EPS ($)

Dec. FY	2017A	2018E	2019E
1Q	(0.40)A	(0.42)A	(0.26)E
2Q	(0.25)A	(0.36)E	(0.25)E
3Q	(0.42)A	(0.31)E	(0.24)E
4Q	(0.30)A	(0.27)E	(0.24)E
FY	(1.37)A	(1.08)E	(0.86)E

Investment Thesis

Antibiotic resistance is a major healthcare crisis, with antibiotic-resistant bacteria already present in at least two million individuals in the U.S. alone, with this number projected to increase exponentially in the coming decades [1]. Meanwhile, an impaired microbiota, due to broad-spectrum antibiotic use or other environmental factors, has been firmly linked to several disorders, such as gastrointestinal inflammation [2]. Therefore, new solutions are needed which consider both the symbiotic and pathogenic roles bacteria may play. With few companies focused on developing novel drugs to meet this need, we think Oragenics is a *high-growth investment opportunity for investors interested in more careful drug design for both probiotic and antibiotic purposes.* Oragenics focuses on lantibiotics, a unique class of antibiotics that targets bacterial mechanisms, different from traditional treatments. The company's platform has led to the development of MU1140 and its variant OG716, a proprietary antibiotic therapy for clostridium difficile infection (CDI), which the U.S. Center for Disease Control and Prevention (CDC) has labeled an urgent threat to antibiotic resistance [3].

Oragenics is a high-growth investment opportunity for investors interested in more careful drug design for both probiotic and antibiotic purposes

Oragenics also has a later stage program in place to develop a probiotic therapy for oral mucositis (OM) – a debilitating condition affecting more than 500,000 cancer patients annually in the U.S. Its proprietary drug, AG013, demonstrated efficacy in its phase 1B clinical trials, and Oragenics is currently conducting its 200-patient phase 2 trial, recently completing its interim safety analysis of 20 patients. The preliminary safety and efficacy results announced in May 2018 were positive, with the final trial results set to be released in early 2019. With the absence of effective treatments for OM, the addressable global market is large – more than 2.2 million cases a year – and provides an opportunity for over $1.5 billion in sales for Oragenics at a penetration rate of just 20-25%. We believe Oragenics has a clear competitive advantage due to its approach in developing a comprehensive therapy by considering the entire OM spectrum (WHO grades 1-4) rather than just the severe OM grades (grades 3-4). The FDA granted AG013 Fast Track status in November 2016, and the drug holds an orphan drug designation in the European Union. Oragenics has an exclusive global license to develop and commercialize AG013 to treat OM in cancer patients.

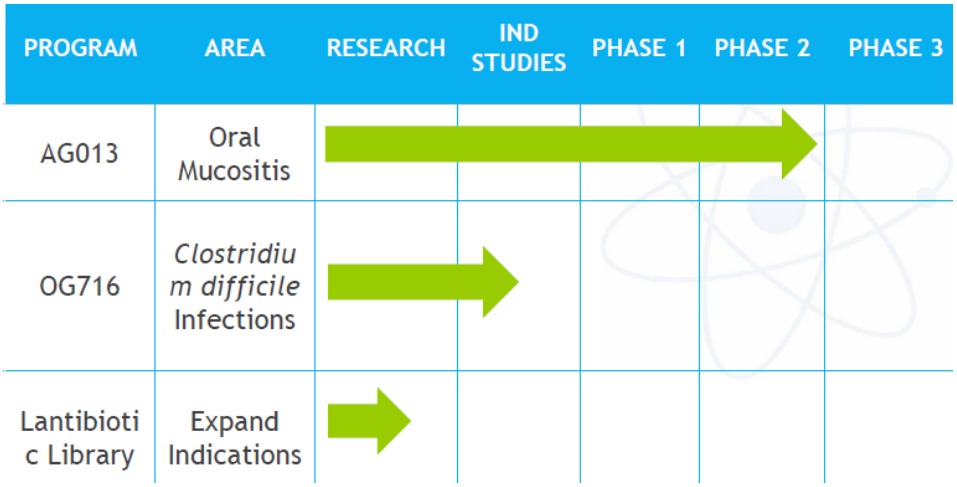
Oragenics should benefit from analytical support and manufacturing expertise from Intrexon during the targeted commercialization of AG013 in 2021

Oragenics is positioning itself to penetrate multi-billion-dollar markets. A major value driver for the company is its current collaboration with Intrexon Corporation (XON), which provides it access to key proprietary technologies to accelerate ongoing R&D, and offsets development costs. Intrexon owns 25% of Oragenics' common stock and also provides additional non-dilutive financing. Oragenics should also benefit from Intrexon's strategic relationships and manufacturing oversight during the targeted commercialization of the AG013 solution in 2021.

Company Overview

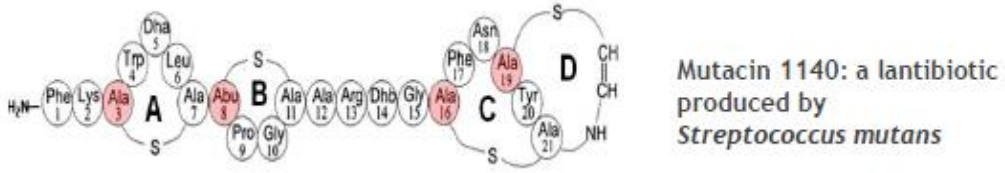
Oragenics, Inc. was founded in 1996 by Dr. Jeffrey Hillman and Dr. Robert Zahradnik, to develop novel therapies to combat harmful bacteria with probiotics. Since its founding, Oragenics has focused on this concept of replacement therapy and has developed platforms relevant for both probiotic and antibiotic treatments. It originally investigated the mechanism of Streptococcus mutans to be used as an oral supplement to prevent dental cavities. The investigation led to the development of MU1140, a unique antibiotic from the lantibiotics class. The company is also developing AG013 – an oral rinse probiotic for the treatment of OM.

Oragenics out-licensed its weight-loss candidate LPT3-04 to LPThera LLC for further commercial development. It is looking for a similar out-licensing partner for its oral care candidate SMaRT Replacement Therapy



Oragenics Development Pipeline, Source: Oragenics Management

Lantibiotics are a type of antimicrobial peptides. They are produced by gram-positive bacteria and undergo extensive posttranslational modifications, resulting in the synthesis of otherwise uncommon amino acids [4]. Lantibiotics are accordingly sub-classified based on their mechanisms of action and underlying amino acid sequence. These peptides are known to be inhibitory towards other gram-positive bacteria and are thus identified as a class 1 bacteriocin [6].



Mutacin 1140, Source: Oragenics Management Presentation

Lantibiotics are most commonly known for their commercial use in food preservation, but are now being considered for use in medicine, especially as an alternative to traditional antibiotics. The value of lantibiotics stems from their unique modes of action that are often distinct from the mechanisms in typical antibiotic treatment [6]. For instance, lipid II is a common target for several lantibiotics. Lipid II functions as an essential intermediate in the synthesis of peptidoglycan within the cell envelope of bacteria. Although traditional antibiotics, such as vancomycin, also target lipid II, lantibiotics do so through separate mechanisms, where inhibition is maintained even in vancomycin-resistant bacteria. Interestingly, there are few examples of naturally occurring lantibiotic resistance, making this class a strong candidate for treating otherwise resistant bacteria [5].

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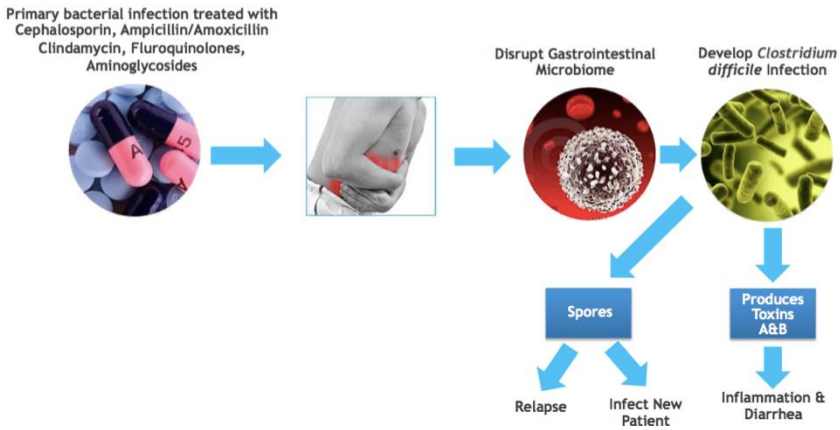
Besides their distinct mechanisms of action, lantibiotics also confer many other benefits compared to traditional treatment regimens. Lantibiotics have low levels of toxicity, evident in their frequent use as a food preservative [6]. Several studies have demonstrated consistently low toxicity within the lantibiotics class [7, 8]. Since they are peptide-based compounds, they are also malleable to bioengineering methods, such as gene manipulation [6]. Engineered versions of these compounds can potentially improve specificity and stability or evade resistance. Lantibiotics also have an interesting alternative mechanism for delivery, since they are natively produced by bacteria, the peptides can be produced in situ by probiotic bacteria.

MU1140 and CDI

CDI is the most common hospital-acquired infection, classified by the CDC as an urgent threat. It was estimated to have caused about 500,000 infections in the U.S. alone in 2011, resulting in 29,000 deaths. Current costs of medical care attributed to this pathogen exceed $1 billion a year in the U.S. and are expected to be much higher in the coming years due to the rise of more virulent and drug-resistant strains.

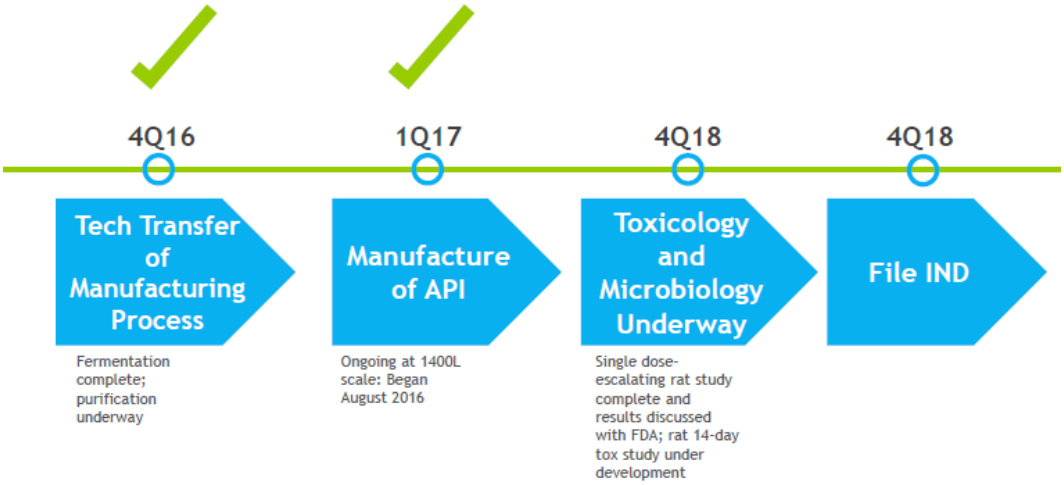
Oragenics has developed a lantibiotic drug discovery platform to potentiate the antimicrobial effects of MU1140, while maintaining its novel lipid abduction mechanism and specificity to CDI



Clostridium difficile infection, Source: Oragenics Management Presentation

MU1140 is a lantibiotic with a distinct mechanism of action termed lipid II abduction. It binds to a highly conserved ancestral sequence on lipid II that is required for bacterial cell wall synthesis and survival.

Vancomycin also targets lipid II, but does so at a different binding site, which can be chemically rearranged in bacteria without compromising cell wall integrity. Thus, it is possible for bacteria to develop vancomycin resistance with a disruption of their binding site. However, doing so will not disrupt the MU1140 mechanism of action. Oragenics has developed a lantibiotic drug discovery platform to potentiate the antimicrobial effects of MU1140, while maintaining its novel lipid abduction mechanism and specificity to CDI.

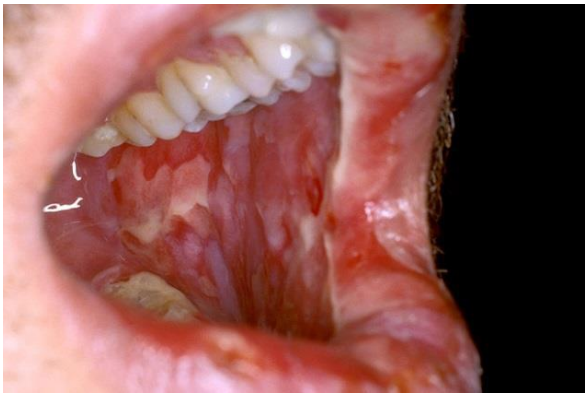


OG716 – Key milestones, Source: Oragenics Management Presentation

OG716 was selected as a potent orally active MU1140 derivative in pre-clinical studies for the treatment of CDI in standard animal models of infection. Specificity of OG716 to CDI has the potential to be less disruptive of the host microbiota, reducing risk of recurrence. Oragenics currently holds intellectual property rights to second-generation derivatives that extend into the late 2030s, and single-dose toxicology screenings are underway in rats, to be discussed with the FDA. In May 2018, the company was granted a patent covering the unique variants of MU1140 and other lantibiotics with improved pharmacological properties and structural features, and the methods of using such compositions to treat and prevent different bacterial infections and diseases. Oragenics plans to file for an IND for OG716 by the end of this year and is in regular interaction with the FDA to complete the filing efficiently.

AG013 and OM

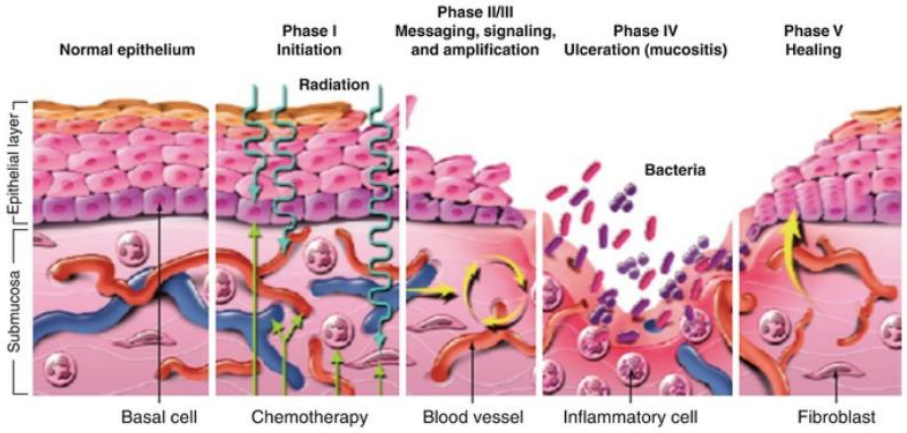
OM is a painful ulcerative inflammatory condition of the mouth that afflicts a significant number of cancer patients undergoing radiation and chemotherapy. The occurrence of ulcerative lesions often forces the interruption of radiation and chemotherapy treatment plans, ultimately leading to a worse clinical outcome.



OM in cancer patients, Source: Oragenics Management Presentation

Patients treated with AG013 had 35% fewer days of being afflicted with ulcerative OM than the placebo group, resulting in an improved quality of life over the course of treatment

AG013 is an oral rinse probiotic formulation of L. lactis that acts as a prophylactic and therapeutic agent for chemotherapy and radiation-induced OM. It works by delivering supplemental trefoil factor 1 (TFF1), a protein normally secreted by the human body to protect mucosal membranes and to promote healing of the mucosal epithelium.

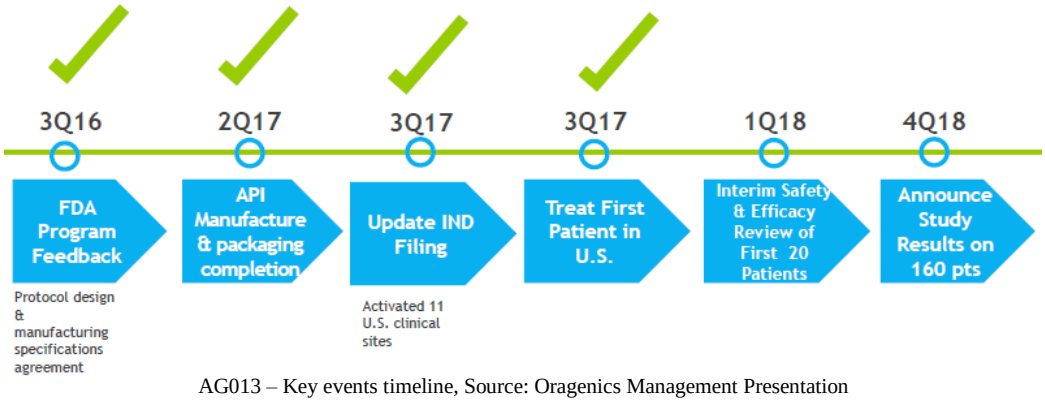


Pathophysiology of OM, Source: Oncohema Key

High TFF1 levels have been shown to significantly reduce mucositis severity in children undergoing cancer therapy [9], and pre-clinical studies in a golden hamster OM model found a dose-dependent reduction in oral lesions with no safety issues observed [10].

These preliminary studies led Oragenics to conduct a single-blind phase 1B clinical program to test the efficacy of AG013 in human subjects. The subjects were selected from newly diagnosed patients with locally advanced head and neck cancer, who were scheduled to receive two cycles of induction chemotherapy. AG013 administration was restricted to subjects who experienced mouth or throat soreness twice or more during the first chemotherapy cycle. This was based on the observation that patients who experience signs of OM during the first round of treatment develop more severe lesions during subsequent cycles. The subjects were split into three groups of seven each, with five on active therapy and two on placebo treatments. AG013 was administered either 1x, 3x, or 6x daily. Safety assessments – such as full blood count, complete metabolic panel, and AG013 bacteria in blood – were performed at the baseline, weekly over the course of the trial, and one year after completion of the trial. AG013 was found to be a safe and efficacious therapy for reducing incidence of ulcerative OM in the patients involved in this study. No adverse effects were reported in patients treated with AG013 that were distinguishable from the placebo group. Patients treated with AG013 had 35% fewer days of being afflicted with ulcerative OM than the placebo group, resulting in an improved quality of life over the course of treatment. This was also evident in fewer patients of the treated group than the placebo group making unplanned emergency room visits.

AG013 was found to be a safe and efficacious therapy for reducing the incidence of ulcerative OM in its phase 1b clinical trial and is expected to be commercialized in 2021-2022



AG013 – Key events timeline, Source: Oragenics Management Presentation

The overall positive outcome of AG013 administration as a treatment for OM and its high safety, efficacy, and ease of application have prompted Oragenics to advance it to a double-blind, placebo-controlled phase 2 clinical trial. The study is currently being conducted in the US, with an arm in Europe, and Oragenics plans to enroll up to 200 patients with head and neck cancer being treated with a chemo radiotherapy regime. It will subsequently pursue financing of $20-25 million to complete the clinical trials. Oragenics expects the study to be completed in early 2019, to be followed by a phase 3 trial in 2019-2020 with the commercialization of AG013 in 2021-2022.

AG013: Future Milestones

- 2Q 2018: Published preliminary results of the interim safety and efficacy review of AG013 use in the enrolled group of 20 patients –shares up over 60% on press release
- 4Q 2018: Publish results of the interim study of 20 patients initially registered for the phase 2 clinical trial of AG013
- 2019: Complete phase 2 clinical trials and publish results
- 2019-20: Initiate the phase 3 trial and complete trial by 2020
- 2020: Receive FDA approval of New Product Application prior to commercial sale of AG013 in 2021
- *2021-22: Commence commercial sale of AG013 in the U.S. and later in Europe*

Corporate Timeline

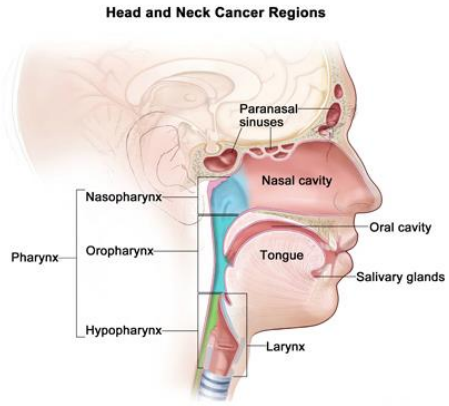
- May 2018: Oragenics reported positive results from the interim safety analysis of its phase 2 clinical trial of AG013 for the treatment of OM- reported positive results on May 30th, stock price rose by 67%
- May 2018: Oragenics and Texas A&M University System granted important U.S. patent for MU1140 and variants
- April 2018: Oragenics announced pricing of $1.8 million registered direct offering
- March 2018: Oragenics completed enrollment of the interim analysis cohort for its phase 2 clinical trial of AG013 for the treatment of OM
- March 2018: Oragenics announced peer-reviewed publication examining efficacy of MU1140 lantibiotic variants against CDI
- January 2018: Oragenics announced a reverse stock split at a ratio of 1 for 10
- November 2017: Oragenics announced closing of a $3.3 million preferred stock private placement and a $3.4 million debt conversion into equity
- September 2017: Oragenics presented at the 19th Annual Rodman & Renshaw Global Investment Conference
- August 2017: Oragenics doses first patient in phase 2 clinical trial of AG013 for OM
- July 2017: Oragenics announces completion of second closing of a $3.0 million preferred stock private placement
- June 2017: Oragenics presented development of novel lantibiotic against CDI at the ICAAC Conference
- May 2017: Oragenics announced a $3.0 million preferred stock private placement and a $2.4 million loan

Large Market Opportunity

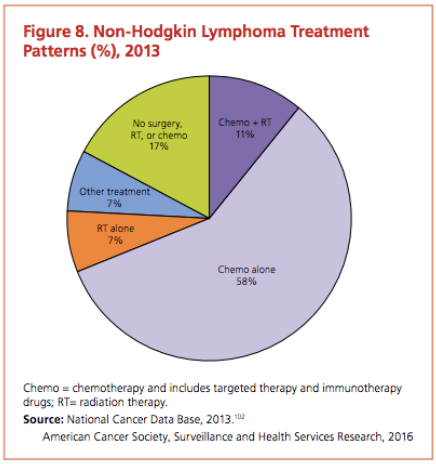
AG013 – Oral rinse to treat large patient population worldwide

AG013 has a large addressable market worldwide, especially in the U.S., due to an increasing number of cancer patients who undergo chemotherapy and could potentially benefit from the efficacy, safety, and convenience of this probiotic treatment. According to the CDC, more than 500,000 newly diagnosed cancer patients (including but not limited to breast, head and neck, and stem cell cancer patients) receive chemotherapy in the U.S. annually. Current chemotherapies include cisplatin (carboplatin to a lesser extent), 5 fluorouracil, irinotecan, methotrexate, cytarabine, and radiation therapy. Patients receiving such chemotherapies face a high risk of developing OM; this is especially true for patients with head and neck cancer, which is treated using the synergistic method.

Current chemotherapies increase the probability of developing OM, especially for those patients with head and neck cancers

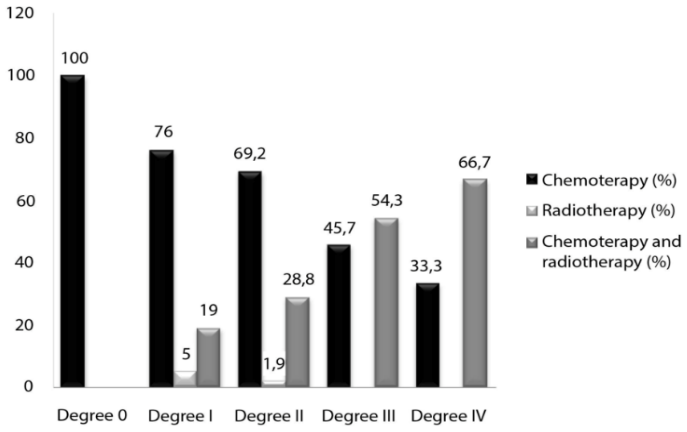


Source: National Cancer Institution



Source: Cancer Org

Several studies show that OM incidence in cancer patients depends on the type of cancer and chemotherapy regimen used to treat it. Specifically, 90-100% of patients with head and neck cancer undergoing chemotherapy develop OM, compared with about 40% of patients with other cancers. Furthermore, evidence from previous studies shows that two groups of patients are at high risk of developing severe OM – head and neck cancer patients undergoing radiotherapy (incidence: approximately 90% overall and 75-85% with severe OM) and patients with hematological malignancies undergoing myeloablative conditioning prior to hematopoietic stem cell transplants (incidence: about 80% with severe OM).



Incidence of cancer patients developing OM, classified by degree of severity, Source: Scielo

The value of the OM therapeutics market has grown significantly since 2010. AG013 could generate $1.5 billion of sales and capture considerable market share

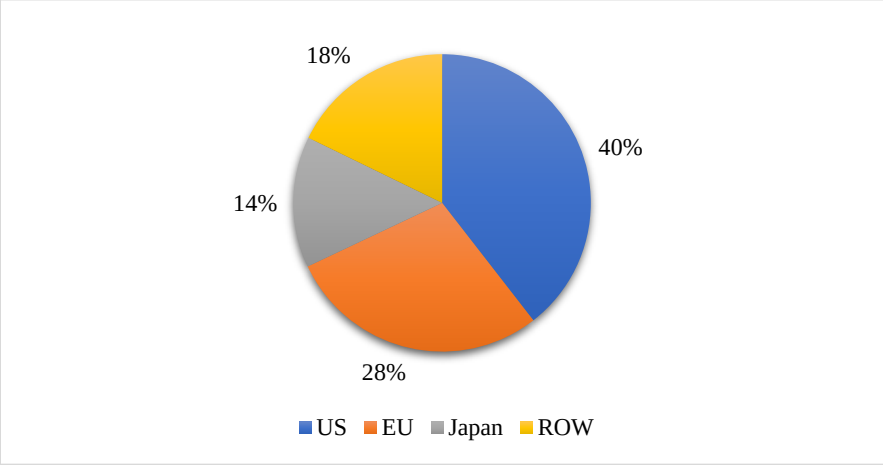
The OM therapeutics market was valued at $813.2 million in 2010 and is expected to grow at a compound annual growth rate (CAGR) of 5.2% to $1,156 million in 2017, according to GlobalData. Despite a large potential market, only a few treatments – such as Kepivance and Healios – are available. Palifermin (trade name: Kepivance) is a chemoprotective drug used to treat and prevent swelling, irritation, sores, and ulcers in the mouth caused by cancer treatment. It is estimated that the palliative care market generates $600 million annually, Kepivance accounts for roughly $300 million of annual sales, with only around 20,000 patients of the addressable market in the U.S. (bone marrow transplantation patients undergoing induction chemotherapy). However, this drug requires inpatient treatment since it is an intravenous solution, increasing costs and complications versus using oral rinse solutions such as AG013.

	AG013	Kepivance®
Sales	TBD	~$300MM/year
Patient Addressable Market	~500,000 /year (U.S.)	20,000 / year (U.S.) (BMT induction chemo only)
Treatment Method	oral rinse	intravenous
Convenience	outpatient	inpatient

Source: Oragenics Management Presentation

Based on market research and favorable clinical results, Oragenics expects **AG013 sales to reach $1.5 billion annually** (U.S.: $635 million, EU: $458 million, Japan: $229 million, rest of the world: $286 million), accounting for **20-25% of global market share**. The company expects AG013 to cost $100 per day and believes the 90% gross margin is achievable.

AG013 – Projected sales



Source: Oragenics Management Presentation

OG716 – Novel antibiotic to treat global threat of CDI

The number of annual CDI cases is rising, with potential risks of recurrence and death. Amid rising resistance to existing drugs, the second generation of lantibiotics 'OG716' emerges as an innovative and promising method of treatment

According to the CDC, in 2017, 500,000 were infected with CDI – an infection of the colon due to production of toxins that damage the lining of the colon which causes 29,000 deaths annually. Even among survivors, 83,000 will experience at least one recurrence. CDI-related deaths have risen a sharp 400% since 2000, primarily due to the lack of effective treatments. Greater incidence is seen in hospitals and nursing homes, and less in the community in general (hospital onset: 37%, nursing home onset: 36%, community onset: 27%). Current treatment for CDI-associated diarrhea requires one to two weeks of hospital stay. However, the recent rapid increase in bacterial resistance to current therapies has become the most potent threat; around 8% of CDI cases are associated with the onset of simultaneous vancomycin-resistant enterococci (VRE) infection.

The lantibiotic platform provides potential for crucial drug development to treat multidrug-resistant gram-positive infections, including methicillin-resistant staphylococcus aureus (MRSA), VRE and virulent CDI.

GlobalData expects $426 million in sales for the treatment of CDI in the U.S. in 2019. There are only five approved therapies in the market at present – metronidazole, vancomycin, fidaxomicin, rifaximin, and zinplava (a monoclonal antibody). Most of the other treatments – including OG716 – are under development. In early-stage studies, OG716 was proven to be better at preventing CDI deaths owing to its beneficial characteristics being orally active, more favorable microbiology profile than previous compounds, and higher potency against CDI in the standard animal infection model. Oragenics owns intellectual property rights to such second-generation compounds until the late 2030s. It recently received a U.S. patent for MU1140 and its variants.

Drug Resistant Pathogen (yellow = gram (+) Tan = 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

Antibiotic-resistant threats, 2017 (cases/year, USA), Source: Oragenics Management Presentation

Competition

Patients are at risk of contracting CDI during or after treatment with broad-spectrum antibiotics. CDI is currently treated with oral metronidazole or vancomycin for 10-14 days. Severe or otherwise resistant cases may require intravenous therapy of metronidazole or oral dosage of fidaxomicin. Several alternative therapies are being developed to treat CDI, as the number of highly resistant strains rises. Merck has completed phase 3 clinical trials of surotomycin. Actelion's cadazolid is currently in phase 3 trials, while Summit Pharmaceuticals' ridinilazole has completed phase 2 trials [11]. We believe Oragenics' novel antibiotic platform is more capable of treating multidrug-resistant infections than the competition.

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Current therapies to prevent OM can have serious side effects. One gold-standard therapy for OM is palifermin, a recombinant protein therapy administered intravenously on an inpatient basis. This treatment comes with serious, yet common, side effects such as swelling, pain and high blood pressure that can increase hospital stay and associated medical costs. Palliative care products such as sedative sprays and gels provide only temporary relief, resulting in an insignificant improvement in patients' quality of life. Other prophylactic and preventative mouthwashes under development, such as Ectoin, have proven ineffective compared to oral rinses [12], making AG013 a competitive product for the treatment and management of OM.

Intrexon: Primary Strategic Partner

Intrexon (NYSE: XON) is a leading biotechnology company whose integrated technology suites provide its partners with industrial-scale design and development of complex biological systems. Oragenics started this collaboration in 2012 with an intent to develop lantibiotics for commercial production. It has since agreed to two exclusive channel collaborations (ECCs) with Intrexon, which under certain terms provides worldwide license to use Intrexon's patents and other intellectual property.

Oragenics' strategic partnership with Intrexon will continue providing exclusive access to major proprietary technologies to accelerate R&D and reduce funding costs, which should enhance shareholder value

Currently, the companies work as specifically defined under the two ECCs, namely their Oral Mucositis ECC and Lantibiotic ECC. Oragenics received the rights to develop and commercialize AG013 from ActoBiotics, a wholly owned subsidiary of Intrexon. Under the terms of the two ECCs, Oragenics is required to make stated one-time payments on achieving significant product milestones (such as filing for commercial sale of new drugs) and quarterly payments of an agreed percentage of net sales to Intrexon. Intrexon owns around 25% of Oragenics' common stock through Third Security LLC, a company founded by Randal J. Kirk, chairman and CEO of Intrexon.

Oragenics utilizes Intrexon's UltraVector DNA construction architecture to design and assemble genetic components into complex gene expression programs, along with using other gene engineering and related proprietary technology. Intrexon is also responsible for technology discovery efforts, cell-engineering development, a few aspects of the manufacturing process, and the costs of filing, prosecution and maintenance of patents.

Exclusive Licensed Intellectual Property

Exclusive licensing of intellectual property is the most essential requirement in the current fast-paced and competitive research environment. Oragenics has made valiant efforts to protect its unique probiotic and lantibiotic research through several exclusive worldwide licenses.

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University of Florida Research Foundation (UFRF) licenses

Oragenics holds several exclusive worldwide intellectual property licenses and patents for MU1140 with UFRF for manufacturing, usage, and sale of products and covered processes. The patents are valid in the US, Australia, Canada, France, Germany, Ireland, Italy, Spain, Sweden, and the UK.

Texas A&M University licenses

Particularly in May this year, Oragenics received the patent for variants of the MU1140 and other lantibiotics with improved pharmacological properties and structural features. The company believes the structural changes available from this license could improve the bioactivity of MU1140. It received another patent for replacement therapy for dental caries in 2016, effective up to 2036.

Intrexon (ActoBio Therapeutics, Inc.) licenses

Oragenics holds an exclusive worldwide license from Intrexon and its wholly owned subsidiary, ActoBiotics, to use their intellectual property to develop and commercialize AG013 for the treatment of OM. Intrexon recently assigned its interest in the license agreement to a wholly owned subsidiary, ActoBio Therapeutics, Inc. Oragenics also has an exclusive worldwide license from Intrexon to use its technology to develop lantibiotics.

Valuation

Oragenics is an early-stage biotechnology company using significant cash resources to develop products for multi-billion dollar markets. It is challenging to value the company using a single method of traditional valuation, as it has yet to earn revenue from operations. We believe it cannot be compared directly with other biotechnology companies given their diverse therapies in different development stages. We have therefore valued it using discounted cash flow analysis and comparable company analysis using public companies in similar stages of development. Our valuation models indicate that the company's shares are significantly undervalued, with large potential upside.

Oragenics appears undervalued using both comparable company analysis and discounted cash flow valuation methods

Comparable early-stage biotech and pharmaceuticals companies

Ticker	Company Name	Key Focus Area	Early Stage drugs	Late Stage drugs	Market Cap ($mn)	M. Cap/drug ($mn)
SNGX	Soligenix, Inc.	Rare diseases	4	2	$13.3	$2.2
CATB	Catabasis Pharmaceuticals	Rare diseases	3		$50.5	$16.8
ONXEO	Onxeo S.A.	Oncology	4	1	$74.7	$14.9
IPIX	Innovation Pharmaceuticals Inc	Oncology	5		$66.8	$13.4
CBLI	Cleveland BioLabs, Inc.	Oncology	4		$31.5	$7.9
CALA	Calithera Biosciences	Oncology	2		$188.2	$94.1
ALDX	Aldeyra Therapeutics, Inc.	Antibodies for infections	2	3	$168.9	$33.8
CFRX	ContraFect Corp.	Antibodies for infections	1		$142.9	$142.9
SBPH	Spring Bank Pharmaceuticals	Viral diseases	3		$177.8	$59.3
LIFE	aTyr Pharma	Genetic disorders	2		$27.0	$13.5
FCSC	Fibrocell Science	Gene Therapies	1		$14.5	$14.5
OGEN	**Oragenics, Inc.**	**Antibodies for infections**	1		***$9.1***	***$9.1***
	Average Market Capitalization per drug under development					***$37.6***
	Median Market Capitalization per drug under development					***$14.9***

Source: Diamond Equity Research Analysis/FactSet Data Systems

In the above model, we selected 11 public listed companies, based primarily on their early development stages and their drugs' lead indications. We compared Oragenics with competitors targeting similar markets, including Soligenix and Innovation Pharmaceuticals in the OM space, and ContraFect and Aldeyra in the antibiotics market. However, we think direct comparison with any of these companies is not accurate, as competitors sometimes have numerous candidates in their pipeline. To arrive at a meaningful conclusion, we compute the market value of each unique drug under development by dividing total market capitalization by the number of unique drugs in the clinical trial stage. The table also shows each company's key focus area, based on their current R&D.

We estimate a forward-looking market value using the peer group average and median market value of each unique drug in the clinical trial stage ranging from $15-38 million. Oragenics' **could shares should therefore be valued at $2.50-$6.40**, based on their number of shares outstanding (including the latest issue of 900,000 shares). *Even the conservative side of the range indicates significant upside from current trading levels*. We acknowledge the difficulty of direct comparison due to the limited number of public listed companies engaged in the development of OM therapies.

To strengthen our fair-value estimate, we created a discounted cash flow model to analyze the intrinsic value of the business, based on the large addressable market and abovementioned market studies. Our discounted cash flow assumptions are conservative, and we forecasted five years as part of that process, with only two years of revenue for Oragenics. We created a top-down model to value the business given its early stage. We project sales from 2021, as guided by management for starting commercialization activities after the company expects to have completed advanced-stage clinical trials in 2020.

We assume the company will be able to commercialize only AG013 during the forecast period, thus there is substantial upside if they commercialize OG716. AG013 is scheduled to be launched in stages, starting in the U.S. in 2021 and in Europe by 2022. We expect the addressable global market of 2.2 million patients to grow 1% per year. We believe Oragenics will be able to achieve the target peak market penetration rate of 25% by year-end 2026. We list our core assumptions in the following table.

Market Metrics	FY18E	FY19E	FY20E	FY21E	FY22E
We've assumed that AG013 is launched in the United States in 2021 and Europe in 2022					
AG013 Drug					
Global Oral Mucositis patients (annual)	2,200,000	2,222,000	2,244,220	2,266,662	2,289,329
Market growth rate (y/y)	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Penetration rate (%)	-	-	-	*0.50%*	*2.00%*
Oragenics market share (annual)	-	-	-	11,333	45,787
Sales ($ million)	-	-	-	$28	$117
Price per patient ($ annual)	-	-	-	$2,500	$2,550
Price growth rate (y/y)	-	-	-		*2.0%*
Gross Margin (as % of sales)	-	-	-	70.0%	70.0%
Cost of goods sold ($ million)	-	-	-	$8	$35

According to our estimates, Oragenics should price AG013 anywhere in the range of $2,500-3,000 per patient, a range computed using the latest market studies. That said, we keep our assumption of prices at $2,500 in the initial years of launch, while we expect a narrower operating margin due to aggressive selling and marketing of the product. We believe the company could achieve $1.5 billion in sales by 2026. We expect the margins to start at 70% in 2021 and to reach 90% by 2024, driven by management expectations of a lower cost base. Our model also provides for payments of $27.5 million to Intrexon related to the completion of major milestones for AG013 in 2020.

Revenue assumptions

	FY18E	FY19E	FY20E	FY21E	FY22E
Oragenics Market Share	-	-	-	11,333	45,787
% growth	-	-	-	*100.0%*	*304.0%*
Price per patient ($)	-	-	-	$ 2,500	$ 2,550
% growth	-	-	-	-	*2.0%*
Total Sales ($'000)	-	-	-	28,333	116,756
% growth	-	-	-	-	*312.1%*
Cost of goods sold	-	-	-	(8,500)	(35,027)
% growth	-	-	-	-	*312.1%*
Gross Profit	-	-	-	19,833	81,729
% Margin	-	-	-	*70.0%*	*70.0%*

Operating cost assumptions

$'000	FY17A	FY18E	FY19E	FY20E	FY21E	FY22E
R&D expenses	3,540	5,305	7,099	7,809	10,152	13,197
% growth	*-25.6%*	*49.9%*	*33.8%*	*10.0%*	*30.0%*	*30.0%*
G&A expenses	3,179	3,182	3,182	5,568	6,403	10,886
% growth	*-16.1%*	*0.1%*	*0.0%*	*75.0%*	*15.0%*	*70.0%*
Selling & Marketing expenses	-	-	-	2,000	4,000	6,000
% growth	-	-	-	-	*100.0%*	*50.0%*
Total Operating expenses	**6,718**	**8,487**	**10,281**	**15,377**	**20,555**	**30,083**
% growth	*-21.4%*	*26.3%*	*21.1%*	*49.6%*	*33.7%*	*46.4%*
As % share of total sales	-	-	-	-	*72.5%*	*25.8%*

Our forecast five-year discounted cash flow analysis provides a fair-value estimate of $4.60 per share, based on the above revenue and cost assumptions. We provide a summary of our analysis below. Please refer to the Appendix for detailed capital assumptions and price, cost of capital, and growth sensitivity analyses.

Discounted cash flow analysis

S'000	FY16A	FY17A	FY18E	FY19E	FY20E	FY21E	FY22E
Operating Income (EBIT)	(8,543)	(6,718)	(8,487)	(10,281)	(15,377)	(722)	51,646
Less: CAPEX	18	0	24	32	103	104	248
Add: D & A	75	66	31	32	2,507	2,261	2,040
Current Assets excl. cash	141	1,027	887	905	594	5,546	33,597
Less: Current Liabilities	1,343	899	1,179	1,578	2,204	2,923	4,247
Working Capital	(1,202)	129	(292)	(673)	(1,610)	2,623	29,351
Increase/ (Decrease) in Working Capital:		1,331	(421)	(381)	(937)	4,232	26,728
Less: Taxes	0	0	0	0	0	(180)	12,911
Free Cash Flow for the Firm/Equity =	**(8,485)**	**(7,983)**	**(8,060)**	**(9,900)**	**(12,036)**	**(2,617)**	**13,798**
Terminal Value =							**99,422**
Present Value of Free Cash Flows =			**(7,409)**	**(7,693)**	**(7,904)**	**(1,453)**	**53,110**

Source: Diamond Equity Research Analysis

We arrive at a combined target price of $3.50, based on the average of comparable and discounted cash flow analysis valuation techniques

($ in thousands except per Share data)	
Total Present Value of Free Cash Flows =	**28,651**
Add: Cash & cash equivalents =	4,758
Less: PV of Total Debt o/s (latest filings) =	68
Less: Preferred Shares	6,100
Less: Minority Interest	0
Equity Value (Present Value) =	**27,241**
Number of Shares outstanding (in thousands)=	6,100
DCF Fair Value per Share ($)=	**4.5**
Comparable Analysis Fair Value per Share ($)=	**2.5**
Combined Fair Value per Share ($)=	**3.5**

Source: Diamond Equity Research Analysis

Experienced Management Team

Oragenics' management team brings years of experience in growing established businesses and start-ups in the pharmaceutical industry. We are encouraged by Alan Joslyn serving as the company's chief executive officer given his substantial experience in developing treatments for gastroenterological and other infectious diseases.

Alan Joslyn, Ph.D. (59, President, Chief Executive Officer, Director): Dr. Joslyn has served as a director since June 2016 and brings over two decades of experience in the pharmaceutical industry. He began his career at Johnson & Johnson, where he held several leadership positions focusing on the development of gastroenterology products including Propulsid®, Motilium®, Aciphex® and prucalopride from 1995 to 2004. He then served as president, chief executive officer, senior vice president and director of Penwest Pharmaceuticals, Mt. Cook Pharma, Edusa Pharmaceuticals, and Sentinella Pharmaceuticals, respectively, from 2004 to 2014. Since 2009, Dr. Joslyn has served as a board member of Synergy Pharmaceuticals (NASDAQ: SGYP) since 2014 and is a partner at Lazarus Pharmaceuticals. We believe Dr. Joslyn's unique experience in the pharmaceutical industry and his extensive expertise in gastroenterology and developing treatments for gastrointestinal and other infectious diseases make him an ideal fit to lead and execute strategies at Oragenics.

Dr. Joslyn is experienced in the pharmaceutical industry and has extensive expertise in developing treatments for gastroenterological and other infectious diseases

Michael Sullivan (61, Chief Financial Officer, Secretary, Treasurer): 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. From October 30, 2014 to June 5, 2016, Mr. Sullivan served as the interim principal executive officer of Oragenics and has served as Chief Financial Officer, secretary and treasurer of the company since February 6, 2012. Prior to this, he held senior-level financial positions at several publicly and privately held companies, including Utek Corporation, eANGLER, and HSN Direct International Limited. Most recently, he was group financial officer of the Investigative Services and Litigation Consulting Services segment of First Advantage Corporation, a firm specializing in talent acquisition solutions. We view Mr. Sullivan's early public company experience as extremely valuable and demonstrates his ability to assist Oragenics in reaching its next financial milestones.

Dr. Martin Handfield (46, Senior Vice President of Discovery Research): Dr. Handfield has strong research abilities and is experienced in commercializing related technologies. He is senior vice president of Discovery Research at Oragenics, and previously served as director of Research and Development since January 2009. Prior to joining Oragenics, Dr. Handfield worked as a 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. Dr. Handfield holds a Bachelor of Science in Biochemistry and a Master of Science and Ph.D. in Microbiology and Immunology from the Université Laval College of Medicine in Canada; he followed postdoctoral training at the University of Florida. We view Dr. Handfield's involvement with Oragenics as an important advantage given his significant scientific achievements in the field of biochemistry.

Dr. Handfield has a strong research background and is experienced in commercializing healthcare technologies

Ownership Profile

Third Security LLC (a company beneficially owned by Randal J. Kirk, chairman of Intrexon) owns around 25% of Oragenics' common stock, closely followed by Koski Family LP, with a 21.1% share. Individual shareholders are Christine L. Koski (2.5%) and Robert C. Koski (2.6%).

Other major institutional investors also hold shares, including Sabby Capital, a known private investment firm (7.4%), and Fidelity Management & Research Company (2.74%). The company also has an active retail investor base.

Third Security LLC (a company owned and founded by Randal J. Kirk, chairman of Intrexon) owns around 25% of Oragenics' common stock

Top 15 shareholders

Top 15 Institutions / Top 5 Insiders/Stakeholders

Rank	Type	%OS	Position (000)	Pos Chg (000) [Recent]	Mkt Val (MM)	% Port	Activism	Report Date	Source
-	**Total**	**64.77**	**3,942**	**372**	**5**	-	-	-	-
-	Institutions	10.79	657	362	1	-	-	-	-
1	Sabby Capital LLC	7.39	450	450	1	0.30	Very Low	04/06/2018	13G
2	Fidelity Management & Research Co.	2.74	167	-0	0	0.00	Very Low	03/31/2018	13F Form
3	The Bank of New York Mellon Corp. (Investment Management)	0.33	20	0	0	0.00	Very Low	03/31/2018	13F Form
4	Virtu Financial BD LLC	0.18	11	5	0	0.00	Very Low	03/31/2018	13F Form
5	IFP Advisors, Inc.	0.05	3	0	0	0.00	Very Low	03/31/2018	13F Form
6	UBS Securities LLC	0.04	2	0	0	0.00	Very Low	03/31/2018	13F Form
7	Barclays Bank Plc (Private Banking)	0.04	2	2	0	0.00	Very Low	03/31/2018	13F Form
8	BlackRock Fund Advisors	0.01	1	0	0	0.00	Low	03/31/2018	13F Form
9	Citigroup Global Markets, Inc. (Investment Management)	0.01	1	1	0	0.00	Very Low	03/31/2018	13F Form
10	BNY Mellon Capital Markets LLC	0.01	0	0	0	0.00	Very Low	03/31/2018	13F Form
11	RBC Dominion Securities, Inc.	0.00	0	0	0	0.00	Very Low	03/31/2018	13F Form
12	Citadel Advisors LLC	0.00	0	-4	0	0.00	Medium	03/31/2018	13F Form
13	Deutsche Asset Management Investment GmbH	0.00	0	-1	0	0.00	Very Low	03/31/2018	13F Form
14	Geode Capital Management LLC	0.00	0	-90	0	0.00	Very Low	03/31/2018	13F Form
15	Guggenheim Funds Investment Advisors LLC	0.00	0	-2	0	0.00	Very Low	03/31/2018	13F Form
-	Insiders / Stakeholders	53.97	3,285	10	5	-	-	-	-
1	Third Security Llc	25.43	1,548	0	2	0.15	-	03/31/2018	13F Form
2	Koski Family Lp	21.13	1,286	0	2	1.65	-	04/30/2018	Proxy
3	Koski Robert C	2.59	158	0	0	37.81	-	04/30/2018	Proxy
4	Koski Christine L	2.58	157	0	0	8.29	-	04/30/2018	Proxy
5	Telling Frederick W	2.23	136	10	0	31.95	-	04/30/2018	Proxy

Source: Factset, June 2018

Risk Factors

- Oragenics does not generate revenue, as it sold its consumer probiotics business in June 2016. Prior to the sale, revenue from ProBiora3 product sales was its sole source of product revenue
- Oragenics has incurred losses and negative cash flow since inception. It continues to allocate significant financial resources to R&D and therefore expects to incur losses for the foreseeable future; this will likely have an adverse effect on its shareholders' equity and working capital
- Financing is also a major risk, as Oragenics will require additional capital to complete the development and commercialization of its product candidates and to operate its business. It has no assurance that such financing will be available or that it will be on terms favorable to the company
- Oragenics may not be successful in developing and commercializing its planned product candidates, as R&D involves a high degree of risk and may take several years
- The company's product candidates under its lantibiotics and OM programs have not received regulatory approval in any jurisdiction and may never receive approval; if approvals are obtained, there is still a risk the products may never be commercialized
- Oragenics' financial results vary significantly from quarter to quarter due to a variety of uncontrollable factors and are difficult to predict. Its operating results may also not meet expectations of research analysts or investors, and the price of its common stock could decrease significantly because of the volatility
- The company relies on the rich experience and specialized expertise of its senior management and scientific team. Therefore, a loss of service of senior management or key employees could harm the company's ability to develop and commercialize its pipeline
- Oragenics' auditor, an independent registered public accounting firm, has expressed substantial doubt about the company's ability to continue as a going concern. Absent sufficient additional financing, the company may be unable to remain a going concern
- Oragenics' product candidates, if approved, will likely face significant competition within the pharmaceutical industry. Such competition could lead to reduced market share for the company's product candidates and contribute to downward pressure on pricing of its product candidates, harming the company's business, financial condition, operating results, and prospects.
- The likely continued sale of equity securities will result in dilution for current common shareholders and may decrease the price of the common stock

For a full list of risk factors, please read Oragenics' latest prospectus and/or annual filings

Appendix

Income statement – Assumptions:

Oragenics is mainly focused on developing AG013 and OG716, while developing lantibiotics for other treatments. In line with current strategy, the company has already out-licensed LPT3-04 and is looking for a similar out-licensing partner for its oral care candidate SMaRT Replacement Therapy. We do not project licensing revenue from these candidates in our revenue model. Based on Oragenics' milestones achieved, we believe OG716 will not be ready for commercialization in the five-year forecast period ending 2022. Hence, we estimate only AG013 sales in 2021. We expect Oragenics to use third-party manufacturers – a cost-effective and asset-light model widely used in the industry. We forecast less market penetration initially, as we expect the company to capture only around 0.5% of the total addressable market in 2021, as it launches its product only in the U.S. We expect it to launch its product in Europe in 2022, capturing 2% of global market share. The latest market studies shared in Oragenics' management presentation helped us to calculate the unit sale price: we forecast initial pricing of $2,500 per patient to support rapid penetration and expect this to grow 2% annually. We project revenue of $28 million in 2021 and $117 million in 2022.

Oragenics – Income statement

$'000	FY17A	FY18E	FY19E	FY20E	FY21E	FY22E
Total Sales	-	-	-	-	28,333	116,756
Gross Profit	-	-	-	-	19,833	81,729
% Margin	-	-	-	-	*70.0%*	*70.0%*
Total Operating expenses	6,718	8,487	10,281	15,377	20,555	30,083
% growth	*-21.4%*	*26.3%*	*21.1%*	*49.6%*	*33.7%*	*46.4%*
EBITDA	**(6,653)**	**(8,456)**	**(10,249)**	**(12,871)**	**1,539**	**53,686**
Depreciation & amortization	(66)	(31)	(32)	(2,507)	(2,261)	(2,040)
EBIT	**(6,718)**	**(8,487)**	**(10,281)**	**(15,377)**	**(722)**	**51,646**
Net interest income (expense)	(206)	0	0	0	0	0
PBT	(6,924)	(8,487)	(10,281)	(15,377)	(722)	51,646
Taxes	0	0	0	0	180	(12,911)
Net Income	**(6,924)**	**(8,487)**	**(10,281)**	**(15,377)**	**(541)**	**38,734**
Diluted EPS ($/share)	**(1.41)**	**(1.08)**	**(0.86)**	**(0.57)**	**(0.02)**	**1.44**
Shares outstanding ('000)	4,926	7,891	11,891	26,891	26,891	26,891

Oragenics projects gross margins of around 90% for AG013. However, we assume a slightly lower margin for the first two years, discounting for the uncertainty surrounding initial negotiations of terms with third-party manufacturers. We expect the company to achieve the target margin by 2024.

Gross margin (as a percentage of sales)

Year	Gross margin
2021	70%
2022	70%
2023	80%
2024	90%

Operating expenses:

i. R&D expenses:

Oragenics has incurred significant R&D expenses in the past, and we expect it to continue to do so given the number of potential disruptive technologies in its pipeline that could expand its drug portfolio. We believe Intrexon will provide significant support for R&D of MU1140 and its variants. Oragenics would need to incur sizeable costs to complete clinical trials for AG013. Based on results of its interim analysis, it plans to pursue rounds of financing in the near term. Although it expects R&D expenses to grow, R&D expenses as a percentage of sales should decline: the we model expesnses at around 36% of sales in 2021 and just 11% in 2022, primarily due to robust revenue growth expectations.

R&D expenses (in $ thousands)

Year	Assumption
2018	5,305
2019	7,099
2020	7,809
2021	10,152
2022	13,197

ii. Selling, general and administrative (SG&A) expenses (excl. depreciation and amortization; D&A):

Our assumptions for SG&A expenses are based on the expectation that Oragenics would start spending on sales and marketing efforts one year prior to the commercialization, targeting an increased presence and general sales efforts as AG013 nears production. SG&A costs are also likely to rise as the company manages rapid growth in operational revenue. While we expect SG&A expenses to keep around 12% of sales, we believe the share will be higher in 2021 (29% of sales) as Oragenics prepares to launch AG013.

SG&A expenses (excl. D&A) (in $ thousands)

Year	Assumption
2018	3,151
2019	3,150
2020	5,062
2021	8,142
2022	14,846

iii. D&A

We assume that D&A will average approximately 2% of fixed assets during the forecast period. We also amortize the milestone payment of $27.5 million to Intrexon in 2020 upon receipt of FDA approval of a New Product Application (the regulatory requirement for commercial sales). According to ECC terms, we expect payment to be made by issue of common stock to Intrexon. We created an asset to be amortized at the rate of 10% per annum, and include the associated expense under D&A.

Tax rate:

We assume an effective tax rate of 25% from 2021 onwards, based on US corporate tax rates. The company has incurred losses in the past, and we believe tax benefits of these losses could be realized in the coming years. However, we do not estimate a tax benefit in our model.

Accounts receivable/payable:

We assume accounts receivable at 10% of sales in 2021 and 15% of sales in 2022. We expect accounts payable at around 14%, the average of the past two years.

Property, plant and equipment:
Considering the large payment, the company is required to make to Intrexon within six months of receiving FDA approval, we have created an asset in 2020 to be amortized over the years, so as not to place an immediate financial burden on the income statement. We expect Oragenics to issue only common stock, so it could maintain the working cash requirement prior to incurring operational revenue.

Shareholders' equity:
We also assume that the company will raise funds via common stock issuance in 2018 until AG013 sales commence in 2021. We expect the number of shares outstanding to increase along with the continued increase in equity. We believe Oragenics will issue common stock to Intrexon in lieu of the one-time payment of $27.5 million agreed upon in 2017. We expect it to pursue all possible avenues of financing available, so it will have the necessary working capital before 2021.

WACC in DCF:

- **Risk premium:** We use the S&P US Pharmaceutical Index, as we believe it is the best proxy for the relevant market index
- Risk-free rate: We use the five-year US Treasury rate
- Beta: 1.39
- Cost of debt: We assume the interest rate on debt at 0%, in line with our expectations of common stock issuance to meet working capital requirements
- Long-term growth rate: We use the global GDP growth rate forecast for 2018 published by International Monetary Fund (IMF)

WACC Inputs	
Risk-free rate	2.8%
Total Equity Risk Premium	11.4%
Beta	1.39
Cost of Equity (CAPM)	**18.6%**
Cost of Debt	-1.1%
Statutory Tax rate	25.0%
Debt / Capital	1.5%
After Tax Cost of Debt	-0.85%
WAC (Debt)	**0.0%**
Cost of Equity (CAPM)	18.6%
Equity / Capital	98.5%
WAC (equity)	**18.3%**
WACC Conclusion	**18.32%**
Long term growth rate (assumed) =	3.9%

Sensitivity Analysis					
Change in Target Price with a 1% change in WACC					
WACC	16.32%	17.32%	18.32%	19.32%	20.32%
Terminal Growth %	3.90%	3.90%	3.90%	3.90%	3.90%
Target Price ($ / Share)	6.38	5.34	**4.47**	3.72	3.08
Change in Target Price with a 0.5% change in Terminal Growth %					
WACC	18.32%	18.32%	18.32%	18.32%	18.32%
Terminal Growth %	2.90%	3.40%	3.90%	4.40%	4.90%
Target Price ($ / Share)	3.90	4.17	**4.47**	4.78	5.11

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