Zacks Small-Cap Research
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# Oragenics, Inc. (OGEN-AMEX)

## *OGEN: Phase 2 Trial of AG013 More Than 2/3rd Enrolled…*

Based on our probability adjusted DCF model that takes into account potential future revenues from AG013 and OG716, OGEN is valued at $3.00/share. This model is highly dependent upon the continued clinical success of those programs and will be adjusted accordingly based upon future clinical outcomes.

| | |
|---|---|
| Current Price (10/02/19) | $0.51 |
| **Valuation** | **$3.00** |

## OUTLOOK

On September 25, 2019, Oragenics, Inc. (OGEN) announced that 158 of a planned 200 patients have been enrolled in the ongoing Phase 2 trial of AG013 for the treatment of severe oral mucositis (SOM). The Data Safety and Monitoring Board (DSMB) recently met and determined there were no safety concerns and the trial could proceed as scheduled. We estimate that enrollment will complete by the end of 2019.

The company also recently presented a poster regarding the Phase 2 trial at the European Society for Medical Oncology (ESMO) Congress 2019. Blinded efficacy data shows an overall incidence of SOM of 47%, which is lower than would be expected in a head and neck cancer patient population, and SOM was only reported in 13.1% (110 of 842) of evaluable visits. While it's not possible to determine efficacy outcomes based on this data, we believe the lower overall low incidence of SOM is encouraging.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$3.57** |
| **52-Week Low** | **$0.36** |
| **One-Year Return (%)** | **-85.82** |
| **Beta** | **1.58** |
| **Average Daily Volume (sh)** | **1,813,159** |
| **Shares Outstanding (mil)** | **46** |
| **Market Capitalization ($mil)** | **$23** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **14** |
| **Insider Ownership (%)** | **8** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2018 Estimate** | **-1.7** |
| **P/E using 2019 Estimate** | **-1.8** |

| | |
|---|---|
| **Risk Level** | **High** |
| **Type of Stock** | **Small-Value** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2018 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2019 | 0 A | 0 A | 0 E | 0 E | 0 E |
| 2020 | | | | | 0 E |
| 2021 | | | | | 0 E |

**Earnings Per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2018 | -$0.42 A | -$0.38 A | -$0.35 A | -$0.09 A | -$0.87 A |
| 2019 | -$0.11 A | -$0.10 A | -$0.06 E | -$0.06 E | -$0.33 E |
| 2020 | | | | | -$0.23 E |
| 2021 | | | | | -$0.22 E |

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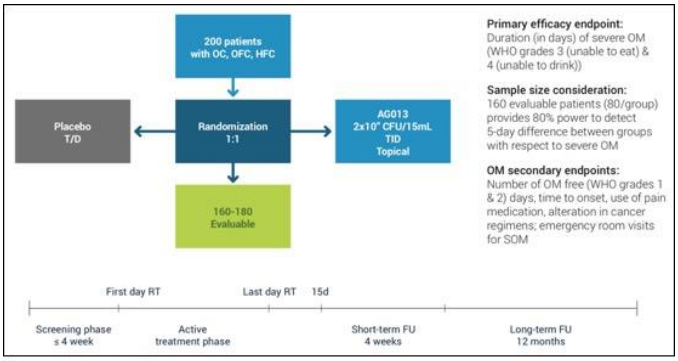
## Business Update

*Poster on Phase 2 Trial of AG013 Presented at ESMO 2019*

On September 30, 2019, Oragenics, Inc. (OGEN) announced the presentation of a poster discussing the ongoing Phase 2 clinical trial of AG013 in severe oral mucositis (SOM) at the European Society for Medical Oncology (ESMO) Congress 2019. The company also recently announced that 158 patients have been enrolled in the trial and that the Data Safety and Monitoring Board (DSMB) determined there were no safety concerns and the trial could proceed as scheduled.

The Phase 2 trial (NCT03234465) is expected to enroll approximately 200 subjects with head and neck cancer receiving chemotherapy and radiation who will receive either AG013 (2.0 x $10^{11}$ CFU) or placebo administered three times a day over 7-9 weeks (depending on the subject's treatment plan). This will be followed by a four-week follow-up phase with a long-term follow up until 12 months past the end of chemotherapy treatment. OM will be assessed at the start of chemotherapy treatment and will continue until the subject has completed the short-term follow up phase or until OM resolves (WHO score ≤ 1). The purpose of the long-term follow up is to assess whether AG013 has any effect on the tumor response to chemotherapy treatment. The trial design is depicted in the following figure.




*Source*: Singh *et al.*, 2019

The trial remains blinded, however an evaluation of blinded efficacy data (which included any patient with SOM after 1 week and those who received a cumulative dose of 55 Gy) demonstrated an overall SOM incidence of 47%, which is less than the expected rate of approximately two-thirds of head and neck cancer patients (Elting *et al.*, 2007). In addition, the overall rate of SOM was reported in only 13.1% (110 of 842) evaluable visits. The following table lists the type and incidence of adverse events.

| Adverse Event | % of Adverse Events |
|---|---|
| Anaemia | 5% |
| WBC count decreased | 6% |
| Sepsis | 0% * |
| Anorexia | 5% |
| Fatigue | 14% |
| Confusion | 1% |
| Abdominal distention | 0% |
| Abdominal pain | 0% |
| Constipation | 12% |
| Nausea | 22%** |
| Diarrhea | 7% |
| Dysguesia | 10% |
| Dyspepsia | 8% |
| Odynophagia | 2% |
| Acute kidney disease | 2% |
| Cough | 4% |
| Acute pulmonary embolism | 0% |

* Unrelated to IMP
** 17% possibly related to IMP

*Source*: Singh *et al.*, 2019

Based on the current rate of enrollment, we estimate that the trial will be fully enrolled before the end of 2019 and topline results should be announced in the first half of 2020.

**Valuation**

We value Oragenics using a probability adjusted discounted cash flow model that takes into account future revenues from AG013 and OG716. For modeling purposes, we anticipate AG013 entering a Phase 3 trial in 2020, an NDA filing in 2022, and approval in 2023 in the U.S. and Europe, with approval one year later in Japan. For OG716, we forecast for clinical trials to start in 2020, an NDA filing in 2024, and approval in 2025.

There are approximately 700,000 newly diagnosed cancer patients in the U.S. that could potentially develop OM, with another 1.3 million in the E.U. and 20,000 in Japan. Patients who develop OM currently have few treatment options available to them outside of palliative care. We believe that a successful treatment that both prevented the incidence of OM and also decreased the incidence of severe OM in those that develop it would be very appealing to oncologists. An effective OM therapy could also decrease rates of hospitalizations for patients suffering severe OM and limit the need to decrease or stop therapy. We use a very conservative 5% peak market share, an average length of use of 60 days, and a cost of $100/day in the U.S. ($70/day and $75/day for the E.U. and Japan, respectively) to arrive at peak worldwide sales of approximately $350 million. Using a 13% discount rate and a 40% chance of approval leads to a net present value of $210 million.

For OG716, we estimate peak market share of 10% of the approximately 500,000, 200,000, and 100,000 *C. difficile* infections each year in the U.S., E.U., and Japan, respectively. We estimate the cost of treatment of $3,000, $2,000, and $2,250 for the U.S., E.U., and Japan, respectively. This leads to peak worldwide revenues of approximately $275 million. Using a 13% discount rate and a 25% chance of approval leads to a net present value of $14 million.

Combining the net present values for AG013 and OG716 along with the company's current cash position and potential cash from warrant exercises leads to a net present value for the company of $276 million. Dividing by the fully diluted share count of 78.8 million plus an additional 15 million shares for future dilution leads to a current value of $3.00 per share.

## PROJECTED FINANCIALS

| Oragenics, Inc. | 2018 A | Q1 A | Q2 A | Q3 E | Q4 E | 2019 E | 2020 E | 2021 E |
|---|---|---|---|---|---|---|---|---|
| **AGO13 (Oral Mucositis)** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| **OG716** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| **Licensing & Royalties** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| **Total Revenues** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | - | - | - | - | - | - | - | - |
| Research & Development | $6.0 | $2.4 | $3.9 | $1.7 | $1.7 | $9.7 | $7.0 | $7.3 |
| General & Administrative | $4.0 | $1.0 | $1.0 | $1.2 | $1.2 | $4.4 | $4.7 | $5.0 |
| Other Operating Expenses | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Operating Income | ($10.0) | ($3.4) | ($4.9) | ($2.9) | ($2.9) | ($14.1) | ($11.7) | ($12.3) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Non-Operating Expenses (Net) | $0.1 | $0.1 | $0.1 | $0.0 | $0.0 | $0.2 | $0.0 | $0.0 |
| Pre-Tax Income | ($9.9) | ($3.3) | ($4.8) | ($2.9) | ($2.9) | ($13.9) | ($11.7) | ($12.3) |
| Income Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Deemed Dividend of Series D Preferred | $1 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Net Income | ($11.3) | ($3.3) | ($4.8) | ($2.9) | ($2.9) | ($13.9) | ($11.7) | ($12.3) |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.87)** | **($0.11)** | **($0.10)** | **($0.06)** | **($0.06)** | **($0.33)** | **($0.23)** | **($0.22)** |
| *YOY Growth* | *-36%* | - | - | - | - | *-62%* | *-29%* | *-4%* |
| Basic Shares Outstanding | 13.0 | 30.6 | 46.1 | 46.3 | 46.4 | 42.3 | 50.0 | 55.0 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

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## HISTORICAL STOCK PRICE




*Source*: Zacks Investment Research

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