Zacks Small-Cap Research

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August 17, 2018
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Oragenics, Inc. (OGEN-AMEX)

OGEN: Positive DSMB Review for Phase 2 Trial of AG013 …

Based on our probability adjusted DCF model that takes into account potential future revenues from AG013 and OG716, OGEN is valued at $5.00/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 (08/17/18)	$0.45
Valuation	**$5.00**

OUTLOOK

Oragenics, Inc. (OGEN) recently announced a positive review by the Data and Safety Monitoring Board (DSMB) for the Phase 2 clinical trial of AG013. The company is now expanding patient enrollment to 45 centers in both the U.S. and E.U. We anticipate topline data from this trial in the second half of 2019.

The company also recently announced an agreement with EKF Diagnostics Holdings plc for the manufacturing of lantibiotic bulk drug substances to be used in preclinical and early stage clinical trials.

In July 2018, the company announced a public financing that resulted in net proceeds to the company of $12.3 million. We believe the company has sufficient capital to fund operations through the second quarter of 2019.

SUMMARY DATA

52-Week High	**$5.40**
52-Week Low	**$0.45**
One-Year Return (%)	**-86.70**
Beta	**1.02**
Average Daily Volume (sh)	**611,101**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**30**
Insider Ownership (%)	**35**
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	**-0.3**
P/E using 2019 Estimate	**-0.5**

Risk Level	**High**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.40 A	-$0.25 A	-$0.42 A	-$0.30 A	-$1.37 A
2018	-$0.42 A	-$0.38 A	-$0.21 E	-$0.20 E	-$1.06 E
2019					-$0.50 E
2020					-$0.35 E

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WHAT'S NEW

Business Update

Phase 2 Trial of AG013 Continues

Oragenics, Inc. (OGEN) is currently conducting a Phase 2, double blind, placebo controlled clinical trial of AG013 (NCT03234465). AG013 is an oral mouth rinse composed of a recombinant *L. lactis* strain that contains the coding sequence for human trefoil family factor 1 (hTFF1), which is continually secreted by the bacteria. The trefoil factor family (TFF) is a family of three different peptides secreted by epithelial cells of the gastrointestinal tract in response to injury (Hoffman, 2004). Their presence has been implicated in reducing chemotherapy- and radiation-induced injury, both in preclinical studies (Beck *et al*., 2004) and in clinical trials (Peterson *et al*., 2009).

Approximately 160-180 subjects with head and neck cancer receiving chemotherapy will receive either AG013 (2.0×10^{11} CFU) or placebo administered three times a day over 7-9 weeks (depending on the subject's chemotherapy 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.

On August 15, 2018, Oragenics announced that the Phase 2 trial was resuming following positive results from an interim safety analysis conducted by a Data and Safety Monitoring Board (DSMB) from 19 patients enrolled in the study. Safety was evaluated based on treatment-emergent adverse events, vital signs, weight, physical examinations, clinical assessments, and the presence/absence of AG013 in the blood. The Data Safety Monitoring Board (DSMB) concluded that the trial can continue with no changes to the study protocol. The incidence of adverse events between AG013 and placebo-treated patients was the same. Reports of serious adverse events were typical for a population of head and neck cancer patients undergoing chemotherapy and there were no reports of sepsis or bacteremia. Of particular note is the fact that only a few patients discontinued due to the development of severe OM, which could be an early indication of efficacy. We anticipate study enrollment being completed in the second quarter of 2019 and topline data to be reported in the second half of 2019.

Manufacturing Agreement for Lantibiotic Production

On July 19, 2018, Oragenics announced the signing of an exclusive agreement with EKF Diagnostics Holdings plc for the manufacture of lantibiotic bulk drug substances for preclinical and early stage clinical trials. Oragenics is currently developing OG716 as the lead development product and, assuming funding is available to initiate Phase 1 studies, we anticipate an Investigational New Drug (IND) application being filed in the second quarter of 2019.

Financial Update

On August 13, 2018, Oragenics filed form 10-Q with financial results for the second quarter of 2018. As expected, the company did not record any revenues. The company reported a net loss in the second quarter of 2018 of $2.3 million, or $0.38 per share. R&D expenses for the second quarter of 2018 totaled $1.3 million compared to $0.6 million for the second quarter of 2017. The increase was primarily due to increased costs associated with the exclusive channel collaborations (ECC's) with Intrexon. G&A expenses totaled $1.0 million for the second quarter of 2018 compared to $0.8 million for the second quarter of 2017. The increase was primarily due to increased salary costs, filing fees, and legal costs.

As of June 30, 2018, the company had approximately $3.9 million in cash and cash equivalents. Subsequent to the end of the quarter, Oragenics announced the closing of an underwritten public offering that resulted in net proceeds to the company of $12.3 million. This included the full exercise of the underwriter's over-allotment option to buy additional shares and warrants. We estimate the company currently has approximately $16 million in cash and cash equivalents, which should be enough to fund operations through the second quarter of 2019.

As of Aug. 8, 2016, Oragenics had approximately 11.8 million shares of stock outstanding and when factoring in the Preferred shares, warrants, and stock options a fully diluted share count of approximately 39.7 million.

Conclusion

We were glad to see the positive review by the DSMB regarding the ongoing Phase 2 trial of AG013. Following the company's recent financing, we anticipate the full allotment of 45 centers opening such that enrollment of the expected 160-180 patients can take place by the end of the second quarter of 2019. This would then lead to topline data later in the second half of 2019. Our valuation is currently $5.00 per share, and with a market cap of only $6 million and a drug in Phase 2 testing we believe that the company is very undervalued and could offer the chance for outsized returns in the run up to data in 2019.

PROJECTED FINANCIALS

Oragenics, Inc.	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 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	$3.5	$1.3	$1.3	$1.5	$1.6	$5.7	$6.0	$6.4
General & Administrative	$3.2	$0.8	$1.0	$1.0	$1.0	$3.8	$4.0	$4.0
Other Operating Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6.7)	($2.1)	($2.3)	($2.5)	($2.6)	($9.5)	($10.0)	($10.4)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($6.7)	($2.1)	($2.3)	($2.5)	($2.6)	($9.5)	($10.0)	($10.4)
Income Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($6.7)	($2.1)	($2.3)	($2.5)	($2.6)	($9.5)	($10.0)	($10.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.37)**	**($0.42)**	**($0.38)**	**($0.21)**	**($0.20)**	**($1.06)**	**($0.50)**	**($0.35)**
YOY Growth	-	-	-	-	-	*-23%*	*-53%*	*-31%*
Basic Shares Outstanding	4.9	5.0	6.0	11.8	13.0	9.0	20.0	30.0

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

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