Zacks Small-Cap Research

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Oragenics, Inc. (OGEN-AMEX)

OGEN: Acquires Noachis Terra Inc.; Will Develop SARS-CoV-2 Vaccine…

Based on our probability adjusted DCF model that takes into account potential future revenues from TerraCoV2 and OG716, OGEN is valued at $0.90/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 (05/08/20)	$0.50
Valuation	**$0.90**

OUTLOOK

On May 4, 2020, Oragenics, Inc. (OGEN) announced the acquisition of Noachis Terra Inc., which holds a worldwide license to TerraCoV2, a vaccine candidate against SARS-CoV-2 (the virus that causes COVID-19) from the National Institute of Allergy and Infectious Diseases (NIAID). Oragenics is hoping to advance the vaccine candidate into clinical trials by early 2021 and will finance the development of TerraCoV2 with its available cash. Prior to the acquisition, Noachis Terra submitted a funding application to BARDA, and we anticipate Oragenics hearing back on that application in the next couple of months.

SUMMARY DATA

52-Week High	**$0.83**
52-Week Low	**$0.36**
One-Year Return (%)	**0.02**
Beta	**0.28**
Average Daily Volume (sh)	**3,617,683**
Shares Outstanding (mil)	**46**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
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 2020 Estimate	**-1.5**
P/E using 2021 Estimate	**-1.6**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.11 A	-$0.10 A	-$0.08 A	-$0.08 A	-$0.37 A
2020	-$0.08 E	-$0.09 E	-$0.09 E	-$0.09 E	-$0.35 E
2021					-$0.31 E
2022					-$0.30 E

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WHAT'S NEW

Business Update

Developing Vaccine Against SARS-CoV-2

On May 4, 2020, Oragenics, Inc. (OGEN) announced the acquisition of Noachis Terra Inc., which is developing TerraCoV2, a vaccine candidate against SARS-CoV-2 (the virus that causes COVID-19) that is licensed from the National Institute of Allergy and Infectious Diseases (NIAID). We anticipate the vaccine entering the clinic in early 2021.

The vaccine candidate is targeted against the prefusion spike protein found on the surface of SARS-CoV-2. The spike (S) protein is found on all coronaviruses and is used for receptor recognition and entry into target cells (Li, 2016). The S protein is produced as a single amino acid chain before being cleaved into two non-covalently bound subunits, S1 and S2. These subunits then trimerize to form a large prefusion spike protein. The complex undergoes a conformational change in order to bind to cell surface receptors that allows for cell entry.

Generating antibodies directed against the spike protein is a preferred strategy for vaccine development, however generating a recombinant spike protein that retains the prefusion conformation is difficult, as the complex can spontaneously change to the membrane fusion form. This is important because antibodies directed against the prefusion complex can bind the S protein as it exists on the surface of the virus, while antibodies directed against the membrane fusion form are not effective at neutralizing the virus. Multiple studies in this field have advanced our knowledge on producing stable, prefusion spike proteins, as shown by research into vaccines against HIV (Sanders *et al*., 2002) and MERS (Pallesen *et al*., 2017). While we don't know the details, the vaccine acquired by Oragenics utilizes a prefusion form of the S protein for SARS-CoV-2 for vaccination. In addition, it is produced in a mammalian expression system (Chinese Hamster Ovary [CHO] cells), which allows for the proper glycosylation pattern, another important aspect to ensuring an immunogenic antigen.

In addition to the intellectual property acquired with Noachis Terra, Oragenics will be working with Noachis Terra's Consulting Director of Research and Development, Dr. David Zarley, on the development of TerraCoV2. Dr. Zarley was involved in the creation of Flumist® along with vaccine candidates against parainfluenza and rotavirus during his career.

Terms for the acquisition of Noachis Terra Inc. include payments of 1) $1.925 million in cash; 2) 9.2 million shares of common stock; and 3) warrants to purchase 9.2 million shares of common stock with an exercise price of $1.25 per share. The shares of stock are locked until the earliest of a) shares of OGEN closing above $2.50; b) an announcement from the company that it has received funding from BARDA; or c) six months following the close of the transaction. The warrants may not be exercised until the earlier of a) an announcement from the company that is has received funding from BARDA; b) Phase 1 clinical data demonstrating activity; or c) one year from the closing of the transaction.

New Board Member Adds Expertise in Vaccine Development

On May 4, 2020, Oragenics announced it has increased the size of its Board of Directors and added Ms. Kim Murphy to the board. Ms. Murphy has been involved in all aspects of vaccine development from previous experience with GlaxoSmithKline (GSK). At GSK, she led the global influenza vaccine and pandemic preparedness business and also managed a 2,000-employee team responsible for vaccine development, sales, manufacturing, and distribution. Prior to GSK, she held various commercialization and marketing roles within Novartis Vaccines and Diagnostics Inc. and Merck. Her knowledge of vaccine development and experience will be vital to Oragenics as it embarks on developing TerraCoV2.

Phase 2 Trial of AG013 in Oral Mucositis Not Successful

On April 15, 2020, Oragenics, Inc. (OGEN) announced that the Phase 2 trial of AG013 for the treatment of oral mucositis (OM) in patients with head and neck cancer receiving chemoradiation did not meet the primary efficacy endpoint, as there was not a statistically significant difference in duration of severe OM between patients treated with AG013 compared to those treated with placebo.

The company indicated that additional analyses are ongoing to determine if there are signs of efficacy in population subgroups, and we anticipate the results of these analyses to be available over the next few weeks.

Valuation

At this point we have removed AG013 from our valuation model and value the company based on TerraCov2, OG716, the cash on hand, and potential cash from warrant exercises. For modeling purposes, we anticipate the Phase 1 trial of TerraCoV2 initiating in early 2021 with approval in late 2022. For OG716, we model for clinical trials to initiate in 2021, an NDA filing in 2025, and approval in 2026.

For TerraCoV2, we estimate peak sales of the vaccine at $1 billion that will occur two years after approval due to the need to vaccinate as many individuals as possible in the U.S. as quickly as possible. This is a very unique situation and is highly fluid so our model will likely be modified a number of times as more information becomes available. We believe Oragenics would form a commercialization partnership and receive a 13% royalty. We assign a 10% probability of approval due to the fact that no other coronavirus vaccines have been developed, however positive news flow will increase that probability accordingly. Using a 13% discount rate leads to a net present value for TerraCoV2 of $17 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 OG716, TerraCoV2, the company's current cash position, and potential cash from warrants leads to a net present value for the company of $88 million. Dividing by the estimated fully diluted share count of 95.8 million leads to a current value of approximately $0.90 per share.

PROJECTED FINANCIALS

Oragenics, Inc.	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 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	$12.1	$3.0	$3.1	$3.2	$3.2	$12.5	$12.7	$13.0
General & Administrative	$3.8	$1.0	$1.0	$1.0	$1.0	$4.0	$4.5	$5.0
Other Operating Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($15.9)	($4.0)	($4.1)	($4.2)	($4.2)	($16.5)	($17.2)	($18.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.3	$0.1	$0.1	$0.1	$0.1	$0.4	$0.0	$0.0
Pre-Tax Income	($15.6)	($3.9)	($4.0)	($4.1)	($4.1)	($16.2)	($17.2)	($18.0)
Income Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Deemed Dividend of Series D Preferred	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($15.6)	($3.9)	($4.0)	($4.1)	($4.1)	($16.2)	($17.2)	($18.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.37)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.09)**	**($0.35)**	**($0.31)**	**($0.30)**
YOY Growth	*-58%*	-	-	-	-	*-5%*	*-11%*	*-4%*
Basic Shares Outstanding	42.3	46.1	46.1	46.1	46.1	46.1	55.0	60.0

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

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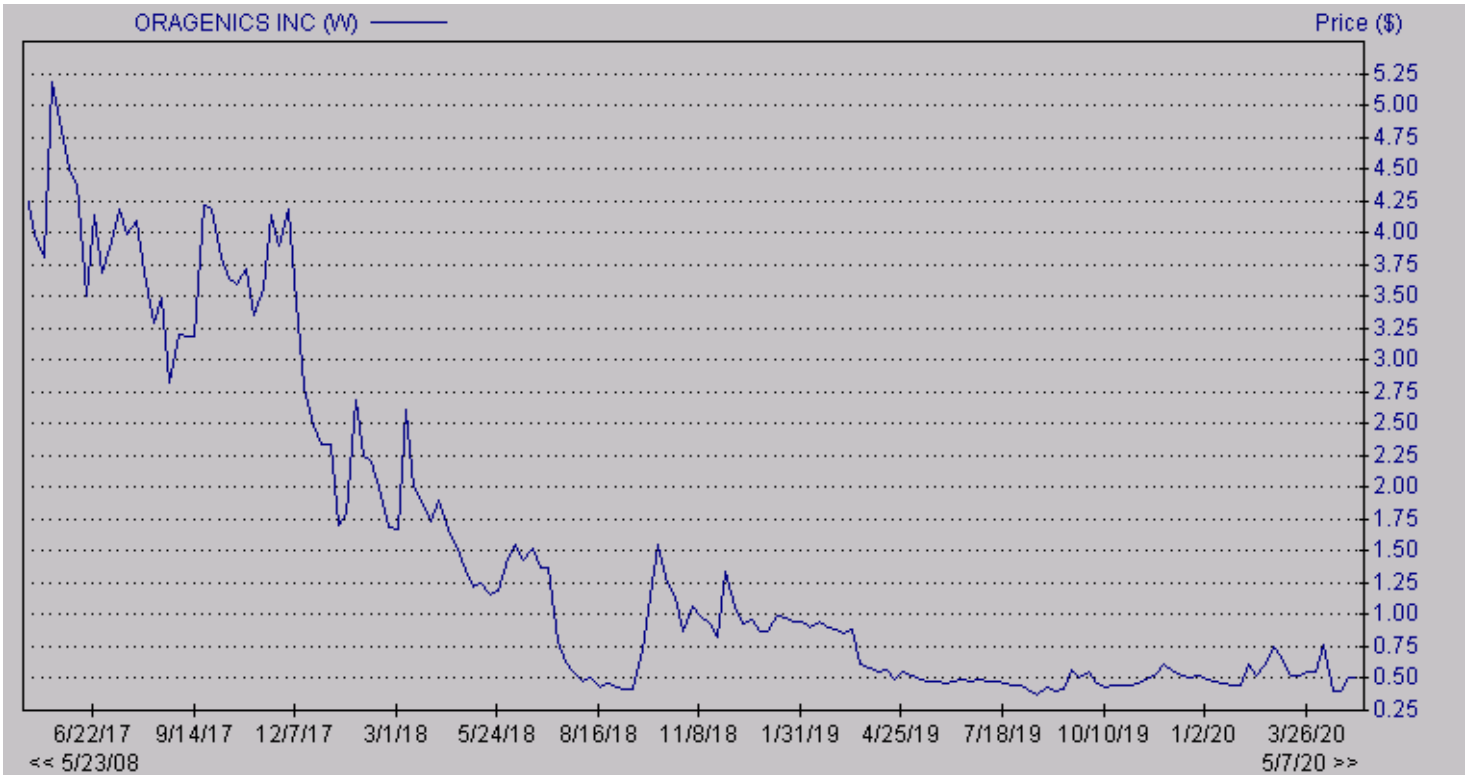
HISTORICAL STOCK PRICE



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