

## Oragenics, Inc.

(OGEN-AMEX)

**OGEN: SARS-CoV-2 Vaccine to Enter the Clinic in Early 2021...**

Based on our probability adjusted DCF model that takes into account potential future revenues from TerraCoV2 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 (09/03/20) \$0.66  
Valuation \$3.00

## OUTLOOK

Oragenics, Inc. (OGEN) recently 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). The vaccine utilizes a recombinant version of the prefusion spike protein that includes two amino acid substitutions to stabilize the protein in the prefusion conformation. Oragenics has submitted grants to the NIH and BARDA, for which they anticipate hearing back in the next few months. We estimate clinical trials will begin in early 2021.

## SUMMARY DATA

52-Week High \$1.49  
52-Week Low \$0.39  
One-Year Return (%) 69.50  
Beta 0.55  
Average Daily Volume (sh) 3,543,647

Shares Outstanding (mil) 61  
Market Capitalization (\$mil) \$40  
Short Interest Ratio (days) N/A  
Institutional Ownership (%) 14  
Insider Ownership (%) 10

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 -1.4  
P/E using 2021 Estimate -2.4

Risk Level High  
Type of Stock Small-Growth  
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 A	0 A	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	-\$0.11 A	-\$0.24 A	-\$0.07 E	-\$0.07 E	-\$0.47 E
2021					-\$0.25 E
2022					-\$0.23 E

## WHAT'S NEW

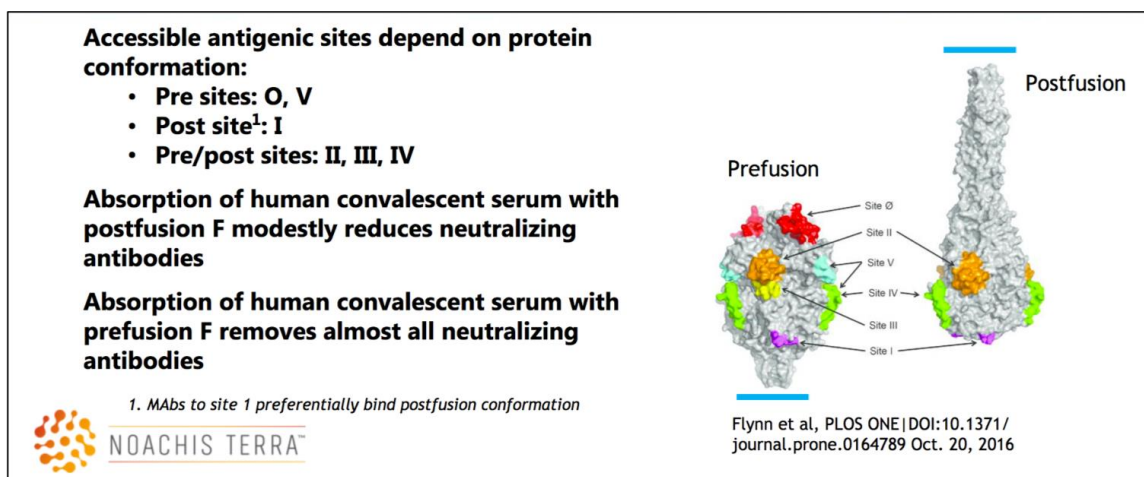
### Business Update

#### *Developing Vaccine Against SARS-CoV-2*

In May 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 ([Wrapp et al., 2020](#)).

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](#)). 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. The following figure gives an example of antigenic sites on the RSV F protein, and how some of those antigenic sites on the prefusion form of the molecule are not present on the postfusion form, thus exemplifying why producing a stable, prefusion form of the S protein is critical for vaccine development ([Flynn et al., 2016](#)).



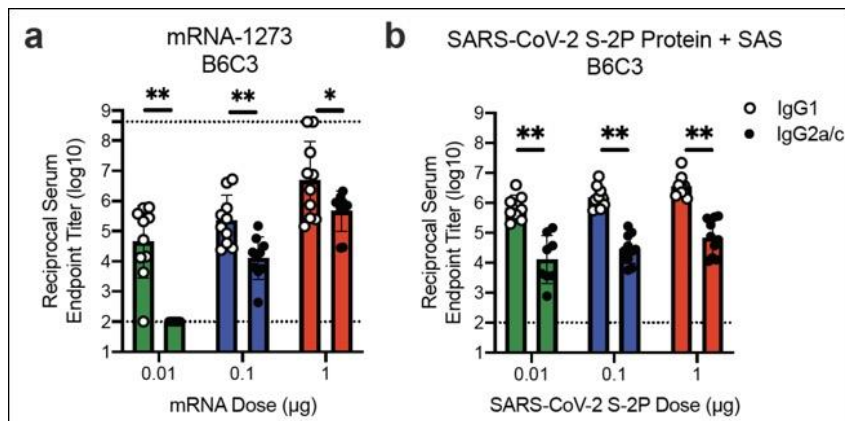
Source: Oragenics, Inc.

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.

Oragenics recently [signed](#) a process development and drug substance manufacturing agreement with Avid Bioservices, Inc., in which Avid will provide analytical method development, process development, and drug substance manufacturing services for TerraCoV2. All of these activities are designed to support the goal of getting TerraCoV2 vaccine candidate into clinical testing in early 2021.

## Robust Antibody Response to SARS-CoV-2 S-2P

A preclinical study examined the immune response to various doses of the stabilized prefusion spike protein (SARS-CoV-2 S-2P) in different strains of mice<sup>1</sup> (Corbett *et al.*, 2020). The following figure shows that immunization with S-2P elicits antibody titers that are similar to those incited by mRNA-1273, the lead SARS-CoV-2 vaccine candidate being developed by Moderna Inc. (MRNA). S-2P was immunized with Sigma Adjuvant System (SAS) as an adjuvant, which is an oil-in-water emulsion that is an alternative to Freund's adjuvant. In addition, the similar levels of both IgG1 and IgG2a/c antibodies is indicative of a balanced Th1/Th2 response.



Source: bioRxiv, June 2020, Kizzmekia Corbett

Immunization with S-2P also elicits robust neutralizing antibody (Nab) titers in BALB/c mice. The following table shows the levels of Nab from three separate serum pools following immunization with S-2P and SAS. These values were similar to the Nab levels induced by mRNA-1273.

Mouse Serum Pool # <sup>1</sup>	Reciprocal IC <sub>50</sub> Titer		Fold Difference <sup>4</sup>
	Pseudovirus Neutralization <sup>2</sup>	PRNT <sup>3</sup>	
1	893.5 +/- 1.4	933.5	1.0
2	211.6 +/- 1.5	314.5	0.7
3	159.8 +/- 1.3	397.1	0.5

1. BALB/c mice were immunized at weeks 0 and 3 with 1 µg SARS-CoV-2 S-2P protein, adjuvanted with SAS. Sera were collected 2 weeks post-boost and pooled (N = 3 mice/pool).  
 2. IC<sub>50</sub> titers were averaged from pseudovirus neutralization assays completed in 5 experimental replicates. (GMT +/- geometric SD)  
 3. IC<sub>50</sub> titer from PRNT assay completed once.  
 4. Fold difference calculated as average pseudovirus neutralization IC<sub>50</sub> titer relative to PRNT IC<sub>50</sub> Titer

Source: bioRxiv, June 2020, Kizzmekia Corbett

## New Board Member Adds Expertise in Vaccine Development

In May 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.

## Financial Update

On August 14, 2020, Oragenics filed form 10-Q with financial results for the second quarter of 2020. As expected, the company did not report any revenues during the second quarter of 2020. R&D expenses were \$11.5 million for the second quarter of 2020, compared to \$3.9 million for the second quarter of 2019. The increase was primarily due to the acquisition of Noachis Terra, Inc. and an increase in costs associated with the TerraCoV2. G&A expenses for the second quarter of 2020 were \$0.8 million, compared to \$1.0 million for the second quarter of 2019.

<sup>1</sup> Kizzmekia Corbett, *et al.*, "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness," *bioRxiv* June 2020[doi: <https://doi.org/10.1101/2020.06.11.145920>]

The decrease was primarily due to decreased filing fees and registration costs, travel and entertainment costs, consulting fees, and stock-based compensation.

Oragenics exited the second quarter of 2020 with approximately \$9.6 million in cash and cash equivalents. Subsequent to the end of the quarter, the company generated gross proceeds of \$5.1 million from the exercise of approximately 5.5 million warrants. We estimate the company has sufficient capital to fund operations into the second quarter of 2021. As of August 7, 2020, Oragenics had approximately 61.0 million shares of common stock outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 89.6 million.

### **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. We believe if successful, TerraCoV2 could attain \$1 billion in revenues in a relatively short amount of time given the urgency to vaccinate the world's population. We also model for OG716 to reach \$275 million in peak sales. Our current valuation for Oragenics is \$3.00.

## PROJECTED FINANCIALS

Oragenics, Inc.	2019 A	Q1 A	Q2 A	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
<b>Total Revenues</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$12.1	\$3.7	\$11.5	\$3.2	\$3.2	\$21.7	\$12.7	\$13.0
General & Administrative	\$3.8	\$1.5	\$0.8	\$1.0	\$1.0	\$4.3	\$4.5	\$5.0
Other Operating Expenses	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Operating Income</b>	<b>(\$15.9)</b>	<b>(\$5.2)</b>	<b>(\$12.4)</b>	<b>(\$4.2)</b>	<b>(\$4.2)</b>	<b>(\$26.0)</b>	<b>(\$17.2)</b>	<b>(\$18.0)</b>
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.3	\$0.0	\$0.0	\$0.1	\$0.1	\$0.2	\$0.0	\$0.0
<b>Pre-Tax Income</b>	<b>(\$15.6)</b>	<b>(\$5.2)</b>	<b>(\$12.3)</b>	<b>(\$4.1)</b>	<b>(\$4.1)</b>	<b>(\$25.7)</b>	<b>(\$17.2)</b>	<b>(\$18.0)</b>
Income Taxes	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Deemed Dividend of Series D Preferred	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Net Income</b>	<b>(\$15.6)</b>	<b>(\$5.2)</b>	<b>(\$12.3)</b>	<b>(\$4.1)</b>	<b>(\$4.1)</b>	<b>(\$25.7)</b>	<b>(\$17.2)</b>	<b>(\$18.0)</b>
<i>Net Margin</i>	-	-	-	-	-	-	-	-
<b>Reported EPS</b>	<b>(\$0.37)</b>	<b>(\$0.11)</b>	<b>(\$0.24)</b>	<b>(\$0.07)</b>	<b>(\$0.07)</b>	<b>(\$0.47)</b>	<b>(\$0.25)</b>	<b>(\$0.23)</b>
<i>YOY Growth</i>	-58%	-	-	-	-	27%	-47%	-8%
Basic Shares Outstanding	42.3	46.1	52.2	61.0	61.0	55.1	70.0	80.0

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

## HISTORICAL STOCK PRICE



Source: Zacks SCR

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