

Oragenics, Inc.

(OGEN-AMEX)

OGEN: Advancement of COVID-19 Vaccine Continues; IND Filing in 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 (12/02/20) \$0.43
Valuation **\$3.00**

OUTLOOK

Oragenics, Inc. (OGEN) is developing TerraCoV2, a vaccine candidate against SARS-CoV-2 (the virus that causes COVID-19) that is based on research licensed 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. Following a successful pre-IND meeting with the FDA, we anticipate the company filing the IND by the end of the second quarter of 2021 and commencing enrollment of a Phase 1 clinical trial shortly thereafter.

SUMMARY DATA

52-Week High \$1.49
52-Week Low \$0.39
One-Year Return (%) -26.62
Beta 0.62
Average Daily Volume (sh) 3,579,945

Shares Outstanding (mil) 75
Market Capitalization (\$mil) \$31
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 A	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	-\$0.08 A	-\$0.06 E	-\$0.46 E
2021					-\$0.20 E
2022					-\$0.20 E

WHAT'S NEW

Business Update

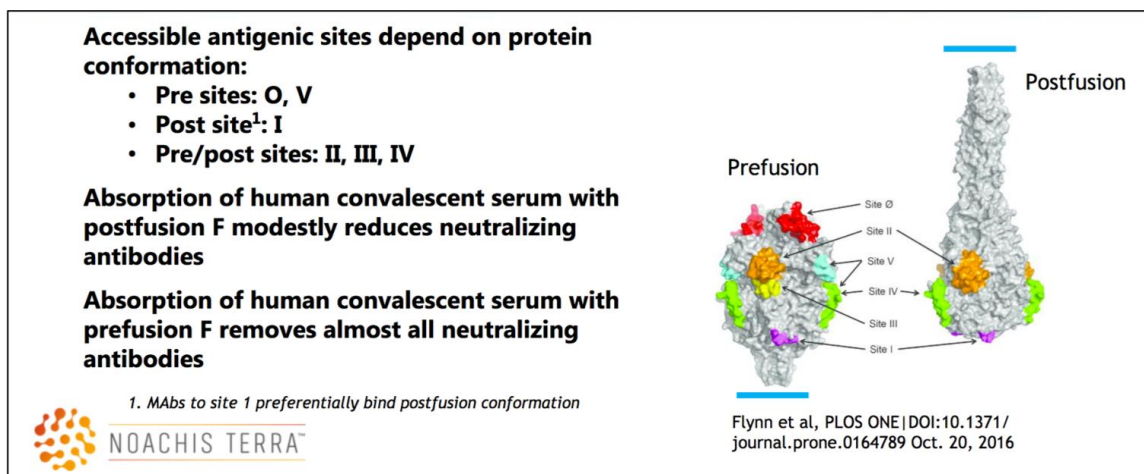
COVID-19 Vaccine Development Continues

Orogenics, Inc. (OGEN) 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). The vaccine candidate is targeted against the prefusion spike (S) protein found on the surface of SARS-CoV-2 (more details below). Since acquiring the rights to the vaccine candidate earlier in 2020, Orogenics has completed the creation of the antigen producing CHO cell line, with purification methods currently under development. In addition, we anticipate the company announcing a deal for an adjuvant to be used with the vaccine in the first quarter of 2021. We also anticipate the completion of various preclinical studies during the first quarter of 2021 that will include mouse immunogenicity studies and hamster challenge studies. Currently, we estimate that the company will file an IND for TerraCoV2 by the end of the second quarter of 2021, with a Phase 1 clinical trial initiating in the third quarter of 2021. The Phase 1 trial will likely take 8-10 weeks to perform and will examine a number of dosing parameters for the vaccine, including the potential for a single dose, which is in contrast to the two doses necessary for the leading vaccine candidates. A successful Phase 1 trial could potentially lead to a Phase 2/3 trial initiating by the end of 2021.

Background on TerraCoV2

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](#)).

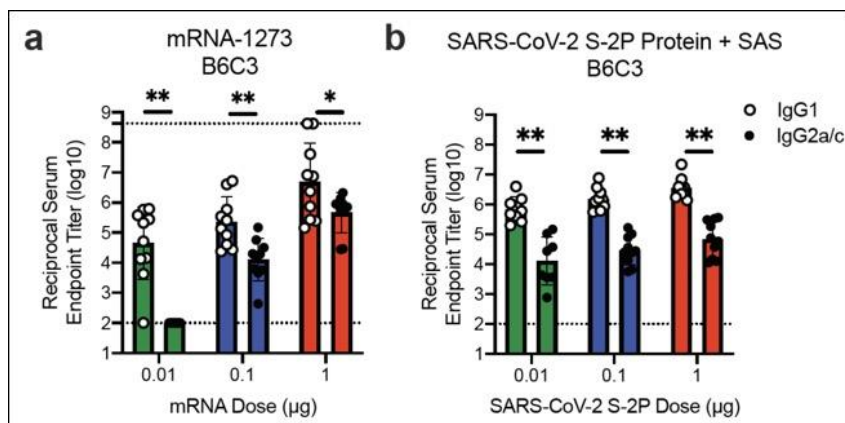
Generating antibodies directed against the spike protein is a preferred strategy for vaccine development, however generating a recombinant spike protein that retains the prefusion conformation is difficult, as the complex can spontaneously change to the membrane fusion form. This is important because 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 Orogenics 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: Orogenics, Inc.

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 mice¹ (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 # ¹	Reciprocal IC ₅₀ Titer		Fold Difference ⁴
	Pseudovirus Neutralization ²	PRNT ³	
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. IC₅₀ titers were averaged from pseudovirus neutralization assays completed in 5 experimental replicates. (GMT +/- geometric SD)
 3. IC₅₀ titer from PRNT assay completed once.
 4. Fold difference calculated as average pseudovirus neutralization IC₅₀ titer relative to PRNT IC₅₀ Titer

Source: bioRxiv, June 2020, Kizzmekia Corbett

Financial Update

On November 10, 2020, Oragenics filed form 10-Q with financial results for the third quarter of 2020. As expected, the company did not report any revenues during the third quarter of 2020. R&D expenses were \$3.5 million for the third quarter of 2020, compared to \$3.1 million for the third quarter of 2019. The increase was primarily due to an increase in costs associated with the development of TerraCoV2. G&A expenses for the third quarter of 2020 were \$1.0 million, compared to \$0.9 million for the third quarter of 2019. The increase was primarily due to increased filing fees and registration costs, travel and entertainment costs, consulting fees, and stock-based compensation.

Oragenics exited the third quarter of 2020 with approximately \$10.0 million in cash and cash equivalents. Subsequent to the end of the quarter, the company generated gross proceeds of \$5.25 million from a public offering of 14.2 million shares at a price of \$0.37 per share. We estimate that the company currently has approximately 75.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 103.8 million.

¹ 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>]

Valuation

We value Orogenics 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 mid-2021 with approval in 2023. Pfizer, Moderna, and AstraZeneca have all reported a high degree of efficacy for their COVID-19 vaccine candidates, however we never envisioned TerraCoV2 competing with the first round of COVID vaccines. Rather, we envision TerraCoV2 being utilized in a “post-pandemic” environment in which its potential characteristics (single dose, pre-filled syringes, storage at 4°C) could prove advantageous over other vaccine candidates. With no changes to our model, our valuation remains at \$3.00.

PROJECTED FINANCIALS

Oragenics, Inc.	2019 A	Q1 A	Q2 A	Q3 A	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
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$12.1	\$3.7	\$11.5	\$3.5	\$3.2	\$22.0	\$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
Operating Income	(\$15.9)	(\$5.2)	(\$12.4)	(\$4.5)	(\$4.2)	(\$26.3)	(\$17.2)	(\$18.0)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.3	\$0.0	\$0.0	\$0.0	\$0.1	\$0.2	\$0.0	\$0.0
Pre-Tax Income	(\$15.6)	(\$5.2)	(\$12.3)	(\$4.5)	(\$4.1)	(\$26.1)	(\$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)	(\$5.2)	(\$12.3)	(\$4.5)	(\$4.1)	(\$26.1)	(\$17.2)	(\$18.0)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.37)	(\$0.11)	(\$0.24)	(\$0.08)	(\$0.06)	(\$0.46)	(\$0.20)	(\$0.20)
<i>YOY Growth</i>	-58%	-	-	-	-	25%	-56%	-1%
Basic Shares Outstanding	42.3	46.1	52.2	59.7	69.0	56.8	85.0	90.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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