Oramed Pharmaceuticals Inc (ORMP)

Price: $10.93 | BUY | Price Target: $23.00

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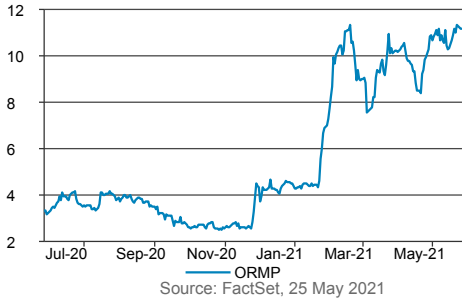
Market Data

Dividend Yield	0.00%
Average Daily Volume	430,062
Shares Out. (MM)	30.2
52 Week Range	$2.40 - $12.73
Market Cap ($M)	$330.4
Enterprise Value ($M)	$239.0

Estimates - Fiscal Year End: 12/31

	2020A		2021E		2022E	
	old	new	old	new	old	new
EBIT - --						
FY	(11.80)A	-	7.90E	-	(20.30)E	-
EPS($) - --						
FY	(0.56)A	-	0.29E	-	(0.76)E	-
P/E	NM		37.7x		NM	

Price Performance



Source: FactSet, 25 May 2021

Diabetes and COVID-19 Programs Remain on Track

Oramed Pharmaceuticals is a platform technology pioneer in the field of oral delivery of protein-based medicines. Oramed is seeking to revolutionize the treatment of diabetes with ORMD-0801, the first oral insulin capsule potentially entering the diabetes market.

Unique Platform Technology to Orally Deliver Protein-based Therapeutics and Vaccines. Oramed has developed a platform technology to deliver proteins through the gastrointestinal tract, preventing degradation in the stomach and stimulating absorption over the intestinal wall.

Expanding Product Pipeline with New COVID-19 Program. Oramed's products are targeting diabetes, obesity and NASH. Lead drug ORMD-0801 targets a market worth an estimated $4.36 billion. Oramed is also developing a novel oral COVID-19 vaccine.

Oral Insulin for the Treatment of Diabetes. ORMD-0801, currently in Phase III trials, is designed to restore glycemic control and prevent disease progression, potentially reducing the need for insulin injections. Based on the analysis of existing data, we believe ORMD-0801 could become the first commercial oral insulin formulation for the treatment of diabetes.

Reiterating BUY rating. Based on our analysis of Phase II clinical results, we believe that ORMD-0801 will meet primary efficacy end points in Phase III clinical trials, which could act as a catalyst for the stock. In our opinion, the value of diabetes and COVID-19 programs is not fully reflected in the current share price. We are reiterating our BUY rating and $23.00 target price.

Published: May 26, 2021 09:44AM EDT Please see Important Disclosures in Appendix.

Investment Appraisal

Oramed Pharmaceuticals yesterday provided an update on its clinical programs as CEO Nadav Kidron issued a letter to shareholders. Oramed is conducting two Phase III clinical trials on the use of oral insulin, ORMD-0801, for the treatment of type 2 diabetes. The ORA-D-013-1 clinical trial has recruited close to 300 of the planned 675 patients, with 75 active clinical sites currently recruiting patients in the United States. The Company expects to complete patient enrolment in ORA-D-013-1 before the end of 2021. The ORA-D-013-1 study is a double-blinded, placebo-controlled, multi-center randomized clinical trial. The primary efficacy end point of the trial is improving glycemic control measured as hemoglobin A1c (HbA1c). The secondary efficacy end point is change from baseline in fasting plasma glucose at 26 weeks post-initiation of treatment. Management expects to release results from this study after all patients have completed the first six-month treatment period, which we expect to occur in the second half of 2022. Oramed's second Phase III clinical trial, ORA-D-013-2, just recently started enrolling patients. If the trial results meet safety and efficacy end points, Oramed plans to submit a Biologics License Application (BLA) to the U.S. FDA seeking approval of ORMD-0801 for the treatment of type 2 diabetes upon completion of ORA-D-013-1 and ORA-D-013-2 clinical trials.

As an expansion of its product pipeline, Oramed announced in March 2021 the launch of a program to develop oral vaccines targeting COVID-19 and other infectious diseases. In our opinion, these programs show the versatility of the Company's platform technology for oral delivery of protein-based therapeutics and vaccines. Back in March, Oramed entered into definitive agreements to form a joint venture focused on the development of novel oral COVID-19 vaccines. The newly formed company, Oravax Medical Inc., is focused on the development of oral COVID-19 vaccines based on Oramed's proprietary POD oral delivery technology and Premas Biotech Pvt. Ltd.'s novel vaccine technology. Oramed Pharmaceuticals became the largest shareholder in Oravax. Together with Premas, the companies are combining their technological knowhow to develop oral COVID-19 vaccines. Premas Biotech brings to the joint venture its expertise in protein expression systems and protein subunit vaccine production, which is critical for Oravax's programs. Premas has developed the D-Crypt technology (based on yeast-expression system), which consists of a protein expression platform designed for high yield production of "difficult-to-express" proteins (DTE-Ps). D-Crypt is designed to reduce the time and costs of vaccine development and production. Oravax will combine Oramed's POD oral delivery technology with Premas Biotech's D-Crypt technology.

In his letter, Oramed's CEO Nadav Kidron mentioned that Oravax's oral COVID-19 vaccine will enter human clinical trials in H2/2021. In experimental models, a single dose of the vaccine induced a significant antibody response, which could protect against emerging variants of SARS-CoV-2. Oramed is in discussions with potential partners for pre-orders of Oravax's oral COVID-19 vaccine candidate. Mr. Kidron mentioned that management is exploring ways to benefit Oramed's shareholders including potentially issuing dividend shares of Oramed's shares in Oravax Medical to Oramed's shareholders, which would make Oravax Medical a publicly held company (Oravax might apply for listing on Nasdaq if eligible). As of April 13, 2021, Oramed had over $75 mm in cash and no debt.

<u>Use of Oramed's POD technology to develop a novel oral COVID-19 vaccine</u>

Oramed’s POD technology utilizes a three-pronged approach consisting of:

- Encapsulation of protein antigens for COVID-19 vaccine;
- Protease inhibition;
- Use of a chelating agent to improve absorption of COVID-19 vaccine antigens through the intestinal wall.

Through encapsulation, COVID-19 vaccine antigens are protected from degradation by hydrolysis in the stomach. Protease inhibitors prevent degradation of vaccine antigens by enzymatic proteolysis in the brush border zone of the small intestine. The chelating agent sequesters calcium, which is required by many proteases, thus further protecting vaccine antigens from enzymatic degradation and facilitating small intestine’s permeability to Oravax's COVID-19 vaccine.

Oravax's lead vaccine candidate consists of a virus like particle (VLP) vaccine comprised of three SARS-CoV-2 protein antigens. SARS-CoV-2 is the coronavirus associated with COVID-19 disease. Oravax's trivalent vaccine is designed to elicit an immune response against three structural proteins of the virus. Oravax's lead vaccine will have the advantage of being delivered by oral route, which we believe could potentially result in higher adoption and compliance due to easier administration. A second potential advantage of Oravax's novel vaccine relative to existing anti-Spike protein COVID-19 vaccines is its versatility, providing protection against a wider number of variant strains of SARS-CoV-2. A third potential advantage of Oravax's oral vaccine is that it might elicit mucosal immunity. Mucosal immunity could potentially result in better protection relative to injectable vaccines.

Structural proteins of SARS-CoV-2, such as Envelope, Membrane and Nucleocapsid proteins, carry a lesser number of mutations than "SARS-CoV-2 Spike protein". The Spike protein is known to be vulnerable to a higher mutation rate (Nature 2020, 579 (7798) p270-273; Nature 2020, 579 (7798) p265-269). A relatively high mutation rate has been detected in the receptor binding domain (RBD) of the Spike protein, which might be due to natural selection of these mutants. Several critical mutations in Spike protein have been identified in several SARS-CoV-2 variants, primarily in South African, British, Brazilian and Indian SARS-CoV-2 variants of concern. In our opinion, the disadvantage of not targeting the RBD domain of the Spike protein is that the vaccine might not interfere with the mechanism of viral entry into human lung cells. SARS-CoV-2 enters type II alveolar epithelial cells through the interaction of the RBD domain of Spike protein with ACE-2 cellular receptor on the surface of these cells. Existing vaccines, such as Pfizer/BioNTech's BNT162b2, Moderna's mRNA-1273 and others induce neutralizing antibodies against RBD domain of Spike protein preventing viral entry into human cells.

In a preclinical experimental model, Oravax's oral COVID-19 vaccine induced both systemic and mucosal immunity. Systemic immunity consists of neutralizing antibodies known as immunoglobulin G (IgG, a type of antibody), which is the most commonly found antibody in blood and bodily fluids. In contrast, mucosal immunity consists of the presence of a protective type of antibody known as immunoglobulin A (IgA, a type of antibody structurally distinct from IgG), which is mainly present in the mucosa or epithelial tissues. Given that COVID-19 is primarily manifested by infection of the respiratory mucosa, mucosal immunity (first barrier of defense) becomes a desire feature of any COVID-19 vaccine. Given the trivalent design of the vaccine, its oral route of administration, and potential induction of mucosal immunity, we believe that Oravax will emerge as a key competitor in the COVID-19 vaccine area. Another competitor, Vaxart, Inc. (Nasdaq: VXRT), is currently in Phase I clinical trials on the use of VXA-CoV2-1 oral COVID-19 vaccine, which targets the Spike and Nucleocapsid proteins of SARS-CoV-2.

Reiterating BUY rating

We believe that Oramed continues to make progress in its clinical programs pursuing diabetes and infectious diseases. In our view, the expansion of Oramed's product pipeline to include an oral COVID-19 vaccine program is a positive development for the Company, which demonstrates the versatility of its proprietary platform technology. Given the early stage of development of COVID-19 program, we are not incorporating any revenue from this program in our forecast. In our view, the value of Oramed’s oral protein delivery platform technologies, and the large commercial potential of its lead products for the treatment of diabetes, obesity, non-alcoholic steatohepatitis (NASH) and prevention of COVID-19 is not fully reflected in the Company’s current share price. Oramed’s ORMD-0801 alone targets a commercial opportunity worth an estimated $4.36 billion. Based on the analysis of results from Phase II clinical trials in diabetes, we believe that ORMD-0801 will meet primary efficacy endpoints in Phase III clinical trials, which could act as a positive catalyst for the stock. We value Oramed using a risk-adjusted discounted cash flow model based on a WACC of 13%. We are reiterating our BUY rating and $23.00 target price on the stock.

Table of Risks

• Oramed is a biotechnology company still developing its candidate medicines in human clinical trials. As such, the Company has incurred significant losses since inception. Oramed will face financial risks as it will have minimal recurring revenues until it commercializes its products, or executes a development and commercialization agreement with a potential partner, which could generate licensing fees, milestone payments, royalties and research funding.

• Oramed will require to raise additional capital to fund its clinical programs. Management might fail to obtain the additional funding required to develop and commercialize their product candidates.

• Oramed and collaborators might fail to protect intellectual property rights.

• Oramed might not be able to retain key personnel to manage its business effectively.

IMPORTANT DISCLOSURES:

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Estimates Disclosures Legend

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Distribution of Ratings				
				Investment Banking*
Rating	#	%	#	%
BUY	22	78.57%	5	22.73%
NEUTRAL	6	21.43%	1	16.67%
SELL	0	0.00%	0	0.00%

**Investment banking services provided in the previous 12 months*

MEANING OF RATINGS:

BUY: the stock is likely to generate a total return of at least 10% over the next 12 months and should outperform relative to the industry.

NEUTRAL: the stock is likely to perform in-line with the industry over the next 12 months.

SELL: the stock is likely to underperform (from a total return perspective) relative to the industry over the next 12 months.

NR: Not Rated

SP: Suspended