Oramed Pharmaceuticals Inc (ORMP)

Price: $9.16 | BUY | Price Target: $23.00

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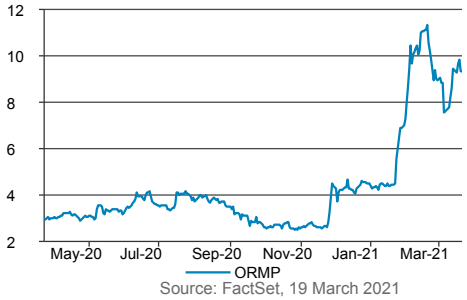
Market Data

Dividend Yield	0.00%
Average Daily Volume	585,051
Shares Out. (MM)	29.4
52 Week Range	$2.40 - $11.71
Market Cap ($M)	$269.0
Enterprise Value ($M)	$183.8

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		31.6x		NM	

Price Performance



Source: FactSet, 19 March 2021

Pursuing Oral COVID-19 Vaccine

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 Medicines. 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. On March 19, Oramed announced it started 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. Given early stage of development, we do not incorporate any revenue from COVID-19 program in our forecast. 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. We are reiterating our BUY rating and $23.00 target price.

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Investment Appraisal

On March 19, 2021, Oramed Pharmaceuticals announced that it has entered into definitive agreements to form a joint venture focused on the development of novel oral COVID-19 vaccines. The new company, Oravax Medical Inc., will focus 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 becomes the largest shareholder in Oravax. Together with Premas, the companies will combine 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.

Use of Oramed's POD technology to develop a COVID-19 vaccine

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 have 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 and Brazilian SARS-CoV-2 variants. 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.

Oramed's management plans to commence Phase I clinical trials on the use of its lead COVID-19 oral vaccine candidate in Q2/2021. Management expects to complete the study in three months. 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. Vaxart's management plans to start Phase II clinical trials in Q2/2021.

Update on Diabetes Program

Oramed Pharmaceuticals is seeking to revolutionize the treatment of diabetes through its proprietary lead candidate, ORMD-0801, which has the potential to become the first commercial oral insulin capsule for the treatment of diabetes. The Company is currently conducting two Phase III clinical trials on the use of ORMD-0801 for the treatment of type 2 diabetes, and it has completed multiple Phase II clinical trials under an Investigational New Drug application with the U.S. Food and Drug Administration. On March 16, 2021, Oramed provided an update on its Phase III clinical program. Management mentioned that it has enrolled and randomized 25% of the 675 patients in its Phase III ORA-D-013-1 clinical trial on the use of its oral insulin capsule ORMD-0801 for the treatment of type 2 diabetes. 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.

Reiterating BUY rating

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. Assuming FDA approval of ORMD-0801 in 2024, we forecast revenue, net income and fully diluted EPS of $77.6 mm, $41.9 mm and $1.57 in F2025 (the first full year of ORMD-0801 commercialization). We value Oramed using a risk-adjusted discounted cash flow model based on a WACC of 13%. Based on our model, we calculate an implied risk-adjusted equity value of $492 mm. 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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Distribution of Ratings				
			Investment Banking*	
Rating	#	%	#	%
BUY	23	82.14%	5	21.74%
NEUTRAL	5	17.86%	1	20.00%
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