



Company Overview

Oramed Pharmaceuticals Inc. (NASDAQ/TASE: ORMP) (hereinafter 'Oramed') is a biomedical company engaged in pharmaceutical research and development of a technology platform that enables oral delivery of proteins, that are currently only available by injection. The company's initial pipeline targets the diabetes care market, and its long-term pipeline is strategically guided by this foundation. The company advances two independent clinical programs that target the diabetes market: 1) ORMD-0801, an oral insulin product, which aims to disrupt the treatment paradigm for type 2 diabetes and decrease the number of insulin injections needed for type 1 diabetes, and 2) ORMD-0901-an oral GLP-1 receptor agonist, which better balances blood sugar.

Oramed Pharmaceuticals Inc. is engaged in transforming injectable drugs into oral ones; initiated ORMD-0901 PK study; received additional milestone payment of \$3 million in January 2019; catalyst rich 2019 ahead; we maintain our target price of NIS 53.2.

Stock Exchange: TASE,
NASDAQ

Symbol: ORMP

Sector: Healthcare

Sub-sector: Pharmaceuticals

Stock price target: NIS 53.2

As of 27 January 2019
(source: TASE website):

Closing Price: NIS 13.0

Market Cap: NIS 225.2M

of Shares: 17.4M

Stock Performance
(since TASE IPO): -63%

Average Daily Trading Volume
(since TASE IPO): NIS 103K

Kobi Hazan - Lead Analyst

Frost & Sullivan Research &
Consulting Ltd.

Email:

Equity.Research@frost.com

Tel.: +972-9-9502888

www.frost.com/EquityResearch

Highlights

As of November 30, 2018 the company has cash, cash equivalents, short-term and long-term deposits, and marketable securities of \$42.8M, enough to promote its strategic plan into 2019.

Oramed's persistent and relatively successful focus on oral delivery for the diabetes drug market is a commercially promising strategy with the potential of clinical expansion into other segments in the future. By 2025, the diabetes market size is projected to be about \$170 billion with a CAGR of 12.7% (2020 to 2025). Oral delivery is projected to comprise about one third of the market.

Q1 main updates:

- Through November 30, 2018, Oramed received aggregate milestone payments from its license agreement with HTIT totaling \$17.5 million. An additional milestone payment of \$3 million was received in January 2019, amounting to a total of \$33million received to date from HTIT for both the licensing agreement and the investment in Oramed shares.
- **ORMD-0901:** In September 2018, the FDA cleared Oramed's IND application for human trials of ORMD-0901. In the first quarter of calendar year 2019, the company initiated a Phase I pharmacokinetic trial which will evaluate the safety and pharmacokinetics of ORMD-0901 compared to placebo. This study is being conducted according to the IND and will be followed by a Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

Financially, Oramed is stable with strong ability to promote its clinical and regulatory plans. From a clinical perspective, as planned, Oramed initiated the ORMD-0901 Phase I pharmacokinetic trial. We look for Phase II initiation in Q4 2019.

As company activities are proceeding as planned, we maintain our valuation of Oramed's equity at \$244.7M / NIS 920M; our target price estimation remains in a range between NIS 49.8 and NIS 56.6, a mean of NIS 53.2.

Upcoming Catalyst Roadmap (full list of catalysts on page 6)

Drug Candidate	Indication	Catalyst	Timeline
ORMD-0801 (oral insulin)	Type 2 Diabetes	Completion of Phase IIb 90-day multi-center study	Q4 2019
	Type 1 Diabetes	Completion of Clamp study	Q1 2019
		Food effect trial PK/PD completion	Q2 2019
	Nash	Completion of exploratory clinical study	Late 2019
ORMD-0901 (oral GLP-1)	Type 2 Diabetes	Initiation of Pharmacokinetics clinical study	Q1 2019 (Achieved)
		Completion of Pharmacokinetics clinical study	Q1 2019
		Phase II projected initiation	Q4 2019
Oral Leptin	Obesity	Initiation of P.O.C. study	2019
		Completion of P.O.C. study	Late 2019

Q1 update

Financial updates

Fiscal year end for the company is August 31st.

HTIT update –an additional \$3 million milestone payment was received.

On November 30, 2015, Oramed and Hefei Tianhui Incubator of Technologies (HTIT) entered into a Technology License Agreement. In accordance with the agreement, HTIT received an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong for Oramed's oral insulin capsule, ORMD-0801. HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to Oramed's technology and the ORMD-0801 capsule, and will pay (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the territory, and (ii) an aggregate of \$37.5 million, of which \$3 million was paid immediately, \$8 million was paid subject to entry into certain agreements with certain third parties, and \$26.5 million will be payable upon achievement of certain milestones and conditions. Through November 30, 2018, Oramed received aggregate milestone payments of \$17.5 million and an additional milestone payment of \$3 million was received in January 2019.

Revenues consist of proceeds related to the License Agreement mentioned above. Revenues for the three month period ended November 30, 2018 increased by 10% to \$674,000, from \$611,000 for the three month period ended November 30, 2017.

Cost of revenues for the three month period ended November 30, 2018 increased to \$35,000 compared to no cost of revenues for the three month period ended November 30, 2017. The increase is attributable to the inclusion of additional milestone payments under the License Agreement.

Research and development expenses for the three month period ended November 30, 2018 increased by 87% to \$4,347,000, from \$2,327,000 for the three month period ended November 30, 2017. The increase is primarily due to expenses related to Oramed's Phase IIb three-month treatment clinical trial, food effect and clamp clinical trials, and is partially offset by a decrease in expenses related to the scale-up process development and production of oral capsule ingredients. Stock-based compensation costs for the three month period ended November 30, 2018 totaled \$39,000, as compared to \$171,000 during the three month period ended November 30, 2017. The decrease is mainly attributable to the progress in amortization and the forfeiture of awards granted in prior periods.

General and administrative expenses for the three month period ended November 30, 2018 decreased by 8% to \$932,000 from \$1,016,000 for the three month period ended November 30, 2017.

Cash and cash equivalents - During the three month period ended November 30, 2018, cash and cash equivalents decreased to \$3,861,000 from the \$4,996,000 reported as of August 31, 2018.

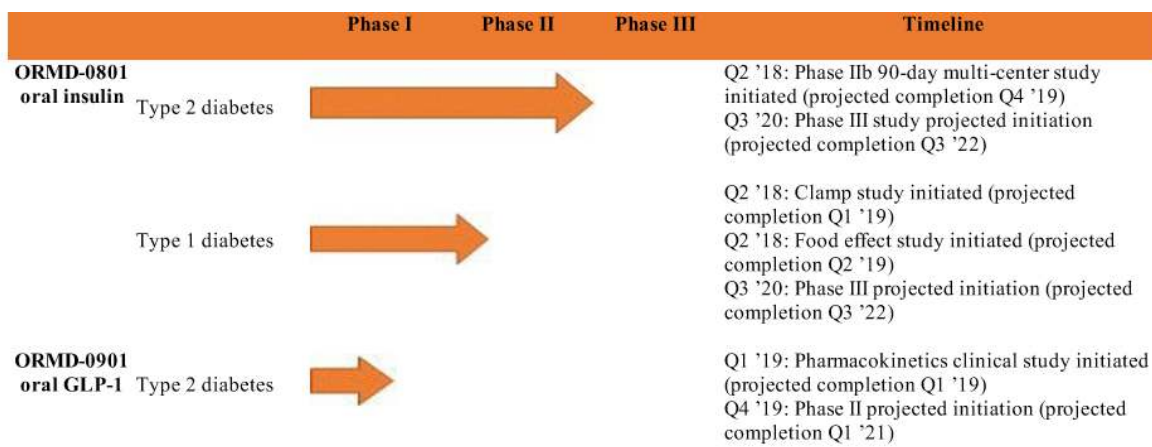
Operating activities used cash totaling \$4,131,000 in the three month period ended November 30, 2018, as compared to \$2,728,000 used in the three month period ended November 30, 2017. Cash used in operating activities in the three month period ended November 30, 2018 resulted in net loss due to research and development and general and administrative expenses, as well as changes in contract liabilities due to the License Agreement and is partially offset by changes in accounts payable and accrued expenses.

New Clinical developments

GLP-1/exenatide capsule, or ORMD-0901: In September 2018, the FDA cleared Oramed’s IND application for human trials of ORMD-0901. In the first quarter of calendar year 2019, the company initiated a Phase I pharmacokinetic trial which will evaluate the safety and pharmacokinetics of ORMD-0901 compared to placebo and an active comparator. This study is being conducted according to the IND and will be followed by a Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

ORMD-0801: In October 2018, Oramed initiated an exploratory clinical study of ORMD-0801 in patients with nonalcoholic steatohepatitis, or NASH. The three-month treatment study, which was approved by Israel’s Ministry of Health, will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. Oramed expects to complete the study during calendar year 2019.

Below is the most recent product pipeline:

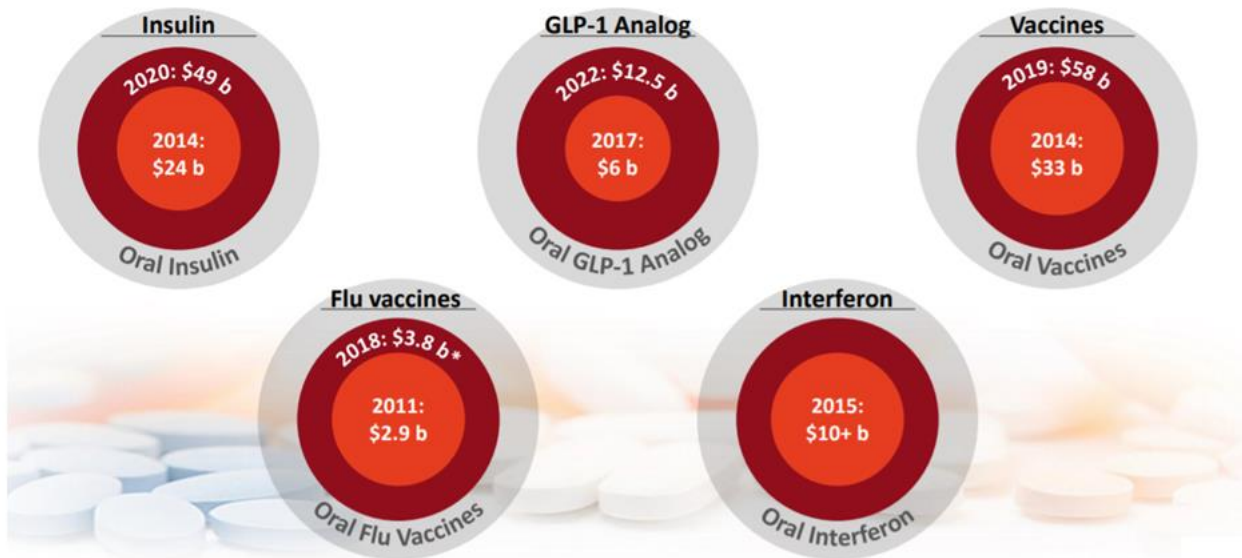


Source: company data, financial report Q1

Executive Summary

Investment Thesis

Oramed is an emerging player in the orally delivered therapeutics segment of the global diabetes care market. According to Frost & Sullivan, with a CAGR of 8.8% since 2016, this segment is estimated to reach a value of \$42.3 billion by 2022. Insulin, and afterwards GLP-1, account for the overwhelming majority of the diabetes market. Oramed's core business is its oral platform which enables the promotion of numerous domains as we present below:



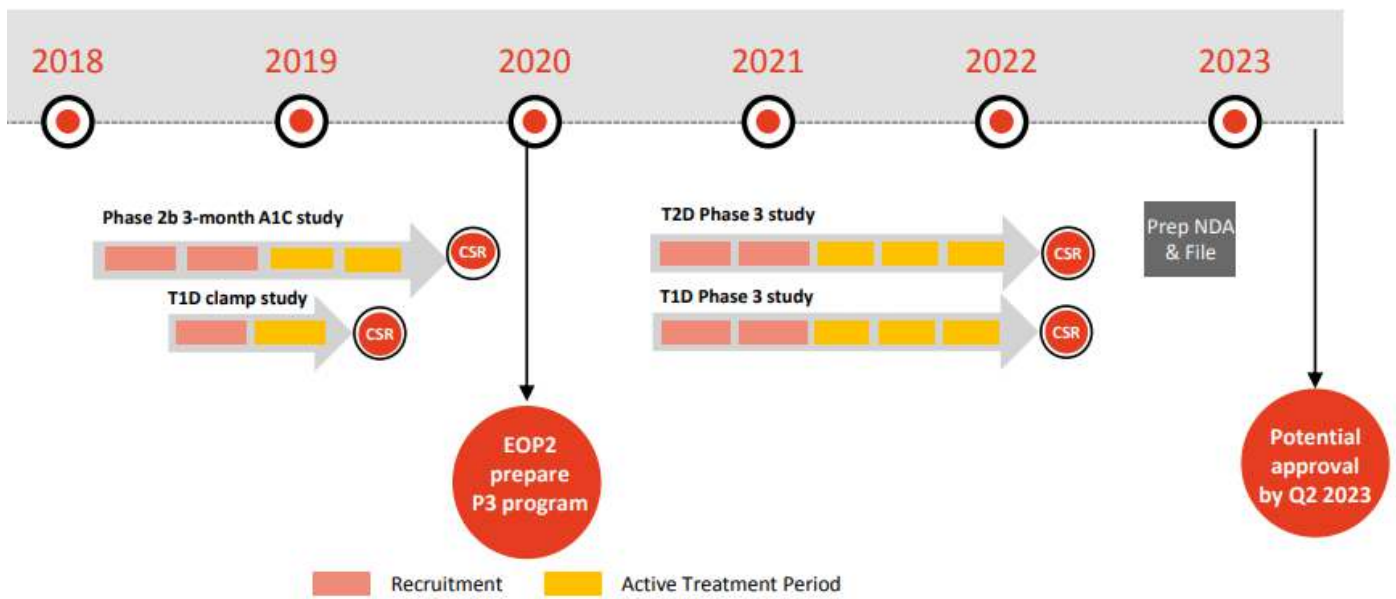
Source: Oramed investor presentation, November 2018

The current target market is very attractive financially, however, is rather competitive given the number of orally deliverable non-insulin solutions which are administered in conjunction with increasingly infrequent insulin injections. In July 2018, Oramed raised a gross \$18.1M and has as of November 30, 2018 cash, cash equivalents, deposits and investments totaling \$42.8M that can support the companies activities into 2019.

Oral insulin administration has an intrinsic physiological advantage in balancing blood sugar versus insulin given by injection. Oramed faces no current significant direct competitors in the oral Insulin market; nevertheless, should the big pharmaceutical players continue succeeding in developing injections which are efficiently administered at increasingly less frequent intervals, the added-value in terms of compliance to patients of oral insulin will decrease accordingly. Additionally, Oramed will be required to conduct a "market education campaign", targeting both patients and physicians when and if its products are approved for market. The probability of this campaign's success is undeterminable at this stage; however Oramed's comfortable cash position and 12-year market exclusivity will prove to be reliable assets in this pursuit.

Thus, we view the investment in Oramed as a great opportunity for investors to participate in the quest for a game changing delivery method, not only in the diabetes domain, but also in a number of other indications that lack easily administered orally delivered solutions. Pending successful completion of the company's clinical trial with ORMD-0801 (the company's oral insulin product), we believe that the stock's potential will significantly increase.

Anticipated Clinical Development Timeline of ORMD-0801



Source: Oramed Investors presentation, November 2018

Upcoming Potential Catalysts

Program	Indication	Event	Significance	Timeline	Status
ORMD-0801 (Oral Insulin)	Type 2 diabetes	Initiation of Phase IIb 90-day multi-center study	High	Q2 2018	Achieved
		Completion of Phase IIb 90-day multi-center study	High	Q4 2019	On track
		Initiation of Phase III trials	High	Q3 2020	On track
		Completion of Phase III trials	High	Q3 2022	On track
		FDA marketing approval	High	Late 2023	Expected
	Type 1 diabetes	Initiation of Clamp study	Low	Q2 2018	Achieved
		Completion of Clamp study	High	Q1 2019	On track
		Food effect trial PK/PD initiation	High	Q2 2018	Achieved
		Food effect trial PK/PD completion	High	Q2 2019	On Track
		Initiation of Phase III trials	High	Q3 2020	On track
		Completion of Phase III trials	High	Q3 2022	On track
		FDA marketing approval	High	Late 2023	Expected
NASH	Initiation of exploratory clinical study	Low	Q4 2018	Achieved	
	Completion of exploratory clinical study	Low	Late 2019	On track	
ORMD-0901 (Oral GLP-1)	Type 2 diabetes	Initiation of Pharmacokinetics clinical study	Low	Q1 2019	Achieved
		Completion of Pharmacokinetics clinical study	Low	Q1 2019	On track
		Phase II projected initiation	High	Q4 2019	On track
		Phase II projected completion	High	Q1 2021	On track
Oral Leptin	Obesity	Initiation of P.O.C. study	Low	2019	On track
		Completion of P.O.C. study	Low	Late 2019	On track

Appendices

Appendix A - Financial Reports

First quarter ending 30.11.18		
Balance Sheet (\$000s)	<u>30.11.2018</u>	<u>31.08.2018</u>
Current assets		
Cash	3,861	4,996
Short term deposits	19,920	20,875
Marketable securities	5,143	4,592
Other assets	727	574
Total current assets	29,651	31,037
Long-term assets		
Long-term deposits	11,613	13,542
Marketable securities	2,290	2,785
Employee rights	16	16
PPE	23	17
Total assets	43,593	47,397
Current liabilities		
Accounts payable	2,982	2,058
Contract liabilities	1,131	2,449
Payable to related parties	51	46
Total current liabilities	4,164	4,553
Long-term liabilities		
Contract liabilities	10,259	11,388
Employee rights	20	20
Others	292	324
Total Liabilities	14,735	16,285
Equity	28,858	31,112

First quarter ending 30.11.18		
Profit and Loss (\$000s)	<u>30.11.2018</u>	<u>30.11.2017</u>
Revenues	674	611
Cost of revenues	35	-
Research and development, net	4,347	2,327
General and administrative	932	1,016
Financial income, net	278	201
Income from changes in fair value of investments	60	-
Net Loss for the period	4,302	2,531

Credit to Experts: Dr. Tiran Rothman, Dr. Hadar Cohen-HaLevy

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Kobi Hazan
T: +972 (0) 9 950 2888
E: equity.research@frost.com

Some of the companies we cover



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