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Annual Update November 30, 2019

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, to better control type 1 and 2 diabetes 2) ORMD-0901- an orally ingestible GLP-1 receptor agonist/exenatide capsule which better balances blood sugar.

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Oramed announced on positive results from its Phase IIb study in oral Insulin for Type 2 Diabetes patients; The company appointed Mr. Joshua Hexter, to serve as Chief Operating and Business Officer. Oramed's Clinical development remains on track; Target price unchanged

Stock Exchange: NASDAQ / TASE

Symbol: ORMP

Sector: Healthcare

Sub-sector: Pharmaceuticals

Stock price target: NIS 53.2

As of 28 November 2019 (source: TASE website):

Closing Price: NIS 13.7

Market Cap: NIS 238.4M

# of Shares: 17.4M

Stock Performance (last 12 months): -14%

Average Daily Trading Volume: NIS 98K

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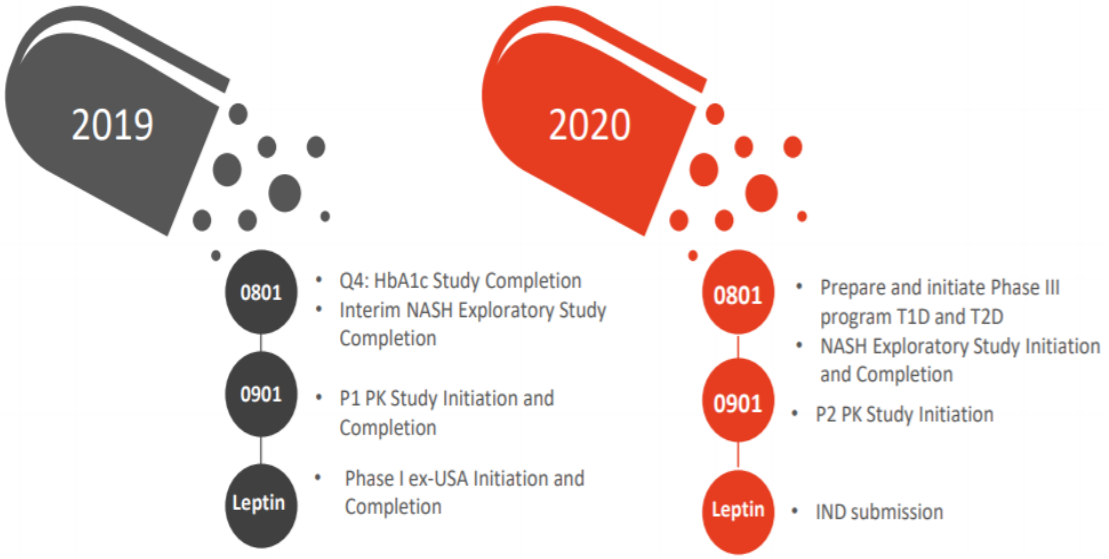
Highlights

On November 12th, Oramed announced on positive results from its initial cohort of the Phase IIb trial evaluating the efficacy and safety of its lead oral insulin candidate, ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of diabetes. Patients were randomized to three administration regimens, the once-daily ORMD-0801 trial achieved a reduction in mean A1C of 0.60% from baseline (0.54% adjusted for placebo (p value = 0.036)). This reduction in A1C is considered clinically meaningful, reflecting an improved glucose control that would result in reduced risk of developing diabetes-related complications.

The Phase IIb double-blind, randomized study for type 2 diabetes was designed to identify the optimal dose to take into Phase III studies. The primary endpoints of the trial are to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90 day treatment period. **Top-line data for Cohort B are expected in Q1-2020.**

After completion of the phase II trial, the company aims to schedule an end of Phase II meeting with the FDA while already designing the Phase III trial protocol and promote the trial alone or with a strategic partner.

On November 21th the company announced that their protease inhibitor technology patent was granted by the Japanese Patent Office.



Financially, Oramed is stable with strong ability to promote its clinical/regulatory plans. As company activities are proceeding as planned, we maintain Oramed's valuation 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.

Annual update

Financial updates *Fiscal year end for the company is August 31st*

Revenues for fiscal 2019 increased by 10% to $2,703,000 from $2,449,000 for fiscal 2018. The increase is mainly attributed to milestone payments received during fiscal 2019 in connection with the License Agreement.

Cost of revenues Cost of revenues for fiscal 2019 increased to $90,000 compared to income of $86,000 for fiscal 2018. The increase is attributed to an adjustment that was made during fiscal 2018 and related to a decrease in the royalty rate Oramed is obligated to pay to the Innovation Authority from 3.5% to 3% due to the amendment of the applicable regulations.

Research and development expenses for fiscal 2019 increased by 13% to $13,522,000 from $11,979,000 for fiscal 2018. The increase is mainly attributed to expenses related to the Phase IIb three-month dose-ranging clinical trial and the oral leptin development and is partially offset by a decrease in expenses related to toxicology studies and scale-up process development and production of the oral capsule ingredients. During fiscal 2019, stock-based compensation costs totaled $231,000, as compared to $575,000 during fiscal 2018. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods.

General and administrative expenses decreased by 9% from $4,083,000 for fiscal 2018 to $3,722,000 for fiscal 2019. The decrease in costs incurred related to general and administrative activities during fiscal 2019, is primarily attributable to a decrease in stock-based compensation costs and is partially offset by an increase in salaries and related expenses. During fiscal 2019, as part of Oramed general and administrative expenses, we incurred expenses of $591,000 related to stock-based compensation costs, as compared to $972,000 during fiscal 2018. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods and to option forfeitures during the period.

Net loss for 2019 was $14,355,000 compare to $12,727,000 in 2018.

Cash and cash equivalents during fiscal 2019 decreased to $3,329,000 from $4,996,000 (as of August 31, 2019).

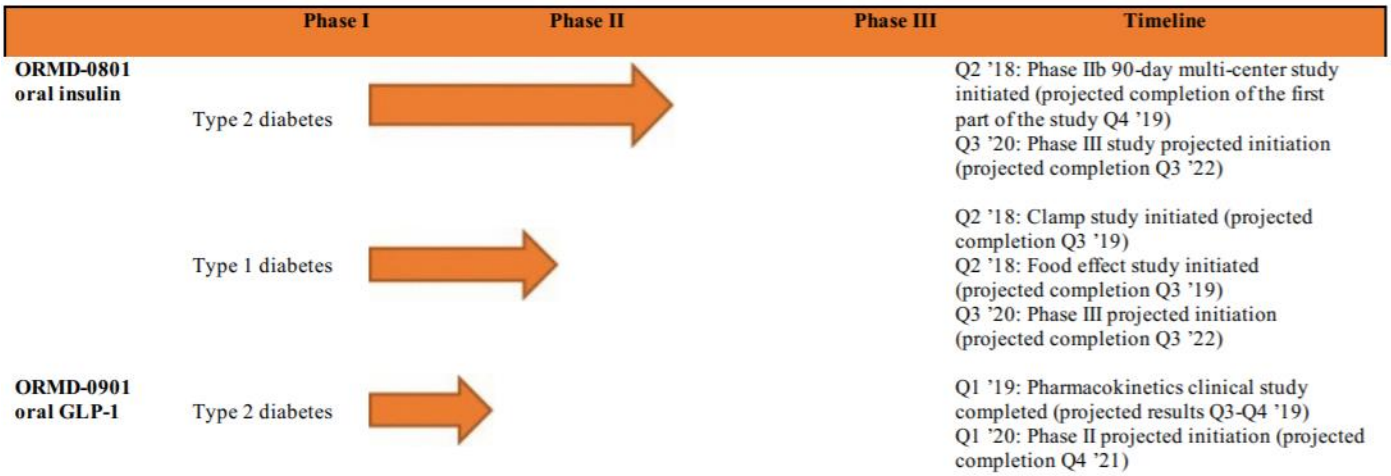
	2019	2018	2017	2016	2015
	(in thousands of dollars except share and per share data)				
Statements of Comprehensive Loss:					
Revenues	$ 2,703	$ 2,449	$ 2,456	$ 641	$ -
Cost of revenues (income)	90	(86)	187	490	-
Research and development expenses	13,522	11,979	10,281	7,709	4,781
General and administrative expenses	3,722	4,083	2,759	2,452	2,602
Financial income	1,061	903	792	474	168
Financial expenses	485	103	101	93	18
Loss before taxes on income	14,055	12,727	10,080	9,629	7,233
Taxes on income (Tax benefit)	300	-	400	1,335	(1)
Net loss for the year	$ 14,355	$ 12,727	$ 10,480	$ 10,964	$ 7,232
Loss per common share – basic and diluted	$ 0.82	$ 0.86	$ 0.79	$ 0.87	$ 0.67
Weighted average common shares outstanding	17,454,489	14,882,356	13,309,372	12,624,356	10,820,465

	As of August 31,				
	2019	2018	2017	2016	2015
	in thousands of dollars except share and per share data				
Balance Sheet Data:					
Cash, cash equivalents, short-term deposits, restricted cash and marketable securities	$ 32,282	$ 30,463	$ 20,138	$ 31,032	$ 17,245
Other current assets	1,042	574	159	198	127
Long-term deposits and other assets	1	13,575	16,262	11,070	8,042
Long-term marketable securities	1,295	2,785	2,151	530	940
Total assets	34,663	47,397	38,712	42,830	26,354
Current liabilities	5,308	4,553	5,165	3,621	1,489
Long-term liabilities	9,962	11,732	14,309	13,019	37
Stockholders' equity	19,393	31,112	19,238	26,190	24,828

Source: annual financial reports

Oramed's Clinical Landscape

Product Pipeline, timeline is presented in calendar quarters (Source: Oramed Quarterly Report)



ORMD-0801(Oral Insulin)

In mid-May, Oramed completed enrollment and randomization of patients in the primary cohort for its 90-day dose-ranging Phase IIb HbA1c clinical study of its oral insulin capsule, ORMD-0801, for Type 2 diabetes. In the initial cohort, 269 U.S. based patients were enrolled and treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32mg per day), twice-daily (64mg per day), thrice-daily (96mg per day). There was a corresponding placebo for each treatment arm. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment).

The Phase IIb double-blind, randomized study for Type 2 diabetes is designed to identify the optimal dose to take into Phase III evaluation. The Phase IIb study will assess the primary efficacy endpoint of reduction in HbA1c as well as safety endpoints.

The first Cohort of the study (higher doses) were vert succesfull, and provides statistically significant efficacy data which, coupled with no reported hypoglycaemia, support a unique mechanism of action of Oramed's oral insulin. The intestinal absorption of insulin enables direct delivery of insulin to the liver mimicking the natural transport of insulin in the body. The result is a more physiologic replacement of insulin, leading to an effective treatment with less risk of hypoglycaemia and weight gain.

Patients randomized in the trial to once-daily ORMD-0801 achieved a reduction in mean A1C of 0.60% from baseline, or a reduction of 0.54% adjusted for placebo (p value = 0.036). This 0.54% reduction in A1C is considered clinically meaningful, reflecting an improved glucose control that would result in reduced risk of developing diabetes-related complications.

Following the results of the primary cohort Oramed plans to initiate an end of Phase II meeting with the FDA to discuss Phase III protocol. In addition, Oramed initiated a secondary cohort of patients within the 90-day Phase IIb HbA1C clinical study to evaluate potential efficacy of ORMD-0801 at lower doses. The results are expected in Q1 2020.

Should Oramed's Phase IIb three-month dose-ranging clinical trial successfully meet its primary or secondary endpoints (completion scheduled for Q4 2019), they anticipate to begin a phase III clinical study on both type 1 and type 2 diabetic patients, following which they expect to file a BLA with potential FDA approval by the end of the first half of calendar year 2024.

In June 2018, Oramed also initiated a food effect trial in the United States for ORMD-0801. This single-blind, five period, randomized, placebo controlled crossover trial is evaluating the pharmacokinetics and pharmacodynamics of ORMD-0801 taken at different times in relation to meals in healthy volunteers and patients with type 1 diabetes. 48 patients are enrolled, including 24 healthy volunteers and 24 patients with type 1 diabetes. Completion of the study is also expected in Q3 2019.

In March 2019, Oramed completed a six month dosing toxicology study of its oral insulin formulation, which was initiated in September 2018 following the FDA's request. The Company expects to get the results of this study in the first quarter of calendar year 2020.

ORMD-0901 (Oral GLP-1 Analog / Exenatide Capsule)

In addition to its flagship product, the ORMD-0801 insulin capsule, Oramed is using its technology for an orally ingestible GLP-1/exenatide capsule, or ORMD-0901. In September 2018, the FDA cleared its IND application for human trials of ORMD-0901. In February 2019, Oramed completed a Phase I pharmacokinetic trial which was initiated in January 2019 to evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. Results are expected in the second half of calendar year 2019. This study was conducted pursuant 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.

Other Products

Leptin, known as the "obesity hormone," is a protein that regulates hunger; It helps inhibit hunger and regulate energy balance, so the body does not trigger hunger responses when it does not need energy. In April 2017, Israel's Ministry of Health approved the commencement of a proof of concept single dose study for Oramed's oral leptin drug candidate to evaluate its pharmacokinetic and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients (glucagon level in type 1 diabetes patients is high). Obesity and diabetes are highly correlated. The study is projected to be initiated in calendar year 2019 and be completed during Q4 2019.

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 30 patients with NASH. As requested by Israel's Ministry of Health, the first part of the study will be conducted on 10 participants and is expected to be completed during calendar year 2019.

Investment Thesis

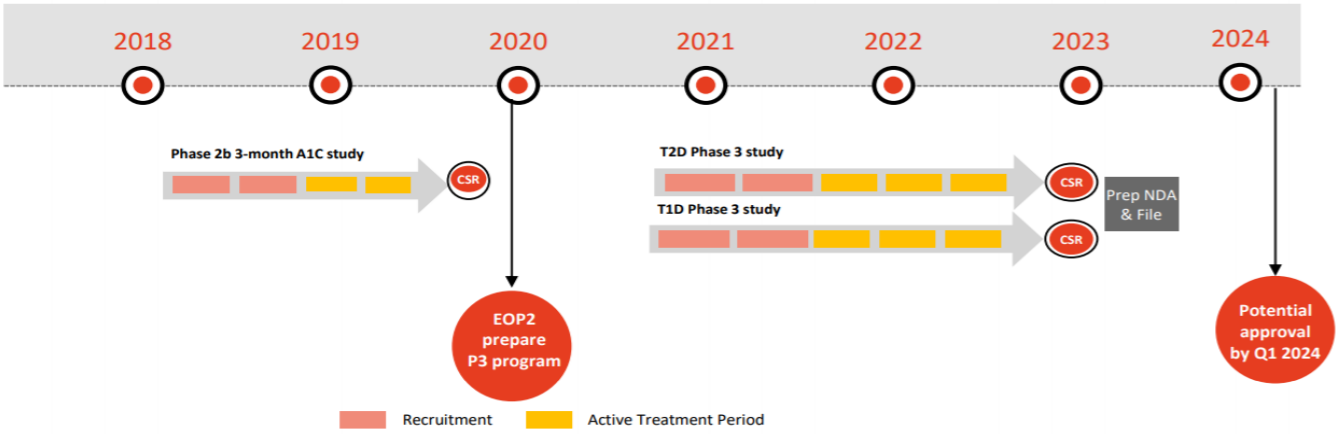
Oramed is an emerging player in the orally delivered therapeutics segment of the global diabetes care market. According to Frost & Sullivan, with a CAGR of 8.8% since 2016, this segment is estimated to reach a value of $42.3 billion by 2022. Insulin, and afterwards GLP-1, account for the overwhelming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

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 $18.1 and has as of Feb 28, 2018 cash, cash equivalents, deposits and investments totaling $40.8M that and 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. See our full initiation report for a comprehensive breakdown of the company, the industry it participates in and our valuation methodology: https://ww2.frost.com/files/2215/4642/7928/Frost_and_Sullivan_Oramed_Initiation_ENG_30122018_isa_1.pdf

Anticipated Clinical Development Timeline of ORMD-0801



Source: Oramed Corporate presentation, October 2019

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 the first part of Phase IIb 90-day multi-center study	High	Q4 2019	Achieved
		Initiated second low dose cohort in Phase IIb HbA1c trial for oral insulin capsule ORMD-0801 to evaluate potential efficacy of lower doses	High	Q1 2020	On track
		Initiation of Phase III trials	High	H2- 2020	On track
		Completion of Phase III trials	High	Q3 2022	On track
		FDA marketing approval	High	Late 2024	Expected
	Type 1 diabetes	Initiation of Clamp study	Low	Q2 2018	Achieved
		Completion of Clamp study	High	Q3 2019	On track
		Food effect trial PK/PD initiation	High	Q2 2018	Achieved
		Food effect trial PK/PD completion	High	Q3 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	High	Mid 2018	Achieved
		Completion of part I of study	High	Q4 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 and projected results	High	H1 2019	On track
		Phase II projected initiation	High	Q1 2020	On track
		Phase II projected completion	High	Q4 2021	On track
Oral Leptin		Completion of P.O.C. study	High	Late 2019	On track

Credit to Experts: Dr. Hadar Cohen-Halevy, Chen Yakar

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