

Update for the quarter ending 31 May 2018

24 July, 2018



Sufficient funds for clinical development activity over the next 24 months; several clinical milestones are scheduled for 2018 and 2019; as Oramed's clinical progress meets our expectations, stock target price remains at NIS 53.2.

Primary Exchange: NASDAQ

Secondary exchange: TASE

Ticker: NASDAQ/ TLV: ORMP

Sector: Pharmaceuticals

Industry: Drug Development

Data as at 24 July, 2018

(Source: TASE)

Closing price: NIS 20.7

Market cap: NIS 358.7M

of shares: 17.4M

Stock performance (12 mos.): -41%

Daily-trading-vol. (12 mos.): NIS 175k

Stock target price: NIS 53.2

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Company Overview

Oramed Pharmaceuticals Inc. (NASDAQ/TASE: ORMP) (hereinafter 'Oramed') is a biomedical company engaged in pharmaceutical research and development of protein and peptide molecules, that are currently only available by injection. The company's initial pipeline targets the diabetes care market. The company advances two independent clinical programs that target diabetes patients; 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 ORMD-0901 an oral GLP-1 agonist, which enhances physiological insulin secretion.

Highlights & Analysis

A strong financial position with sufficient capital to fund scheduled clinical trials and associated expenses for the next 24 months.

- As of 31 May 2018, Oramed had capital resources of approx. \$34.4M, which in conjunction with recent capital raised is enough to support planned clinical and regulatory activity till mid-2020.
- On 6 July 2018, Oramed announced the successful sale of 2,892,000 shares of common stock, along with warrants to purchase up to 2,892,000 shares from six-months after their issuance till three-and-a-half years thereafter. Each share of common stock and warrant were bundled together as 'units' with each unit being sold for \$6.25. **Net of fees Oramed has raised approx. \$16.5M.**

Oramed released its report for the quarterly period ending 31 May 2018 on 13 July, 2018 detailing the following:

Over the past three months, and as we forecasted, Oramed has met an important milestone:

- In June 2018, Oramed initiated a glucose clamp study which will quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801.

Revenues from licensing deals with no cost of revenues have partially offset R&D expenses.

- Research and development expenses for the quarter ending May 31, 2018 increased by approx. 80% to \$4.2 million for the corresponding quarter in 2017.
- Comprehensive Net loss for the quarter ending May 31, 2018 increased to \$4.5 from \$1.7 million for the corresponding period in 2017.

We maintain our valuation as per our [quarterly report of 26 April 2018](#). Oramed's estimated equity value remains at \$200.7M (NIS 708.3M) corresponding to a target price ranging between NIS 49.8 and NIS 56.6; a mean of NIS 53.2.

Updates for the quarterly period ending 31 May 2018

Financial Results

Revenues consist of proceeds related to its licensing agreement; these totaled \$1,832,000 for the nine month period ending May 31, 2018, consistent with the \$1,838,000 for the nine month period ending May 31, 2017. Revenues, for the quarter ending May 31, 2018 totaled \$617,000 equal to the \$617,000 for the corresponding quarter in 2017.

Cost of Revenues for the nine month period ending May 31, 2018 decreased by \$273,000 to income of \$86,000 compared to a cost of \$187,000 for the corresponding period in 2017. Cost of revenues, for the quarter ending May 31, 2018 totaled income of \$86,000 a decrease from Cost of revenues of zero for the corresponding quarter in 2017. The decrease is attributed to a decrease in the royalties Oramed are obligated to pay to the Israel Innovation Authority.

Research and development expenses for nine month period ending May 31, 2018 increased by 19% to \$9,245,000 from \$7,745,000 for the corresponding period in 2017. The increase is mainly due to expenses related to the Phase IIb three-month treatment clinical trial and is partially offset by a decrease in expenses related to the scale-up process development and production of oral capsule ingredients. R&D costs for the three months ending May 31, 2018 increased by 85% to \$4,194,000 from \$2,267,000 for the corresponding period in 2017. The increase is attributable to the same factors as those responsible for increased expenditure over the nine month period.

General and administrative expenses for the nine months ending May 31, 2018 increased by 67% to \$3,050,000 from \$1,824,000 for the nine months ending May 31, 2017. The increase is primarily attributable to increases in stock-based compensation, travel expenses and in the opening of an executive office in New York. General and administrative expenses for the quarter ending May 31, 2018 increased 106% to \$1,043,000 compared to \$505,000 for the corresponding period in 2017.

Comprehensive Net loss for the nine months ending May 31, 2018 totaled \$10,004,000 an increase from corresponding period in 2017. Net loss for the quarter ending May 31, 2018 increased by to \$4,354,000 from \$1,965,000 from for the corresponding period in 2017. The increased net loss is attributable to the increased costs outlined above and partially offset by no taxes being paid on income in either the nine month or three month periods ending May 31, 2018.

R&D highlights

ORMD-0801 (Oral insulin for Type 2 diabetes):

The company has begun recruiting patients for its phase IIb clinical trial. The trial is designed to explore the efficacy of ORMD-0801 when given in different regimens across a dose range of up to 12 weeks in subjects with type 2 diabetes mellitus (T2DM). This placebo controlled, multi-center, randomized, 90 day treatment clinical trial is being conducted on approximately 240 type 2 diabetic patients in multiple centers throughout the U.S. Pursuant to an Investigational New Drug application (hereinafter

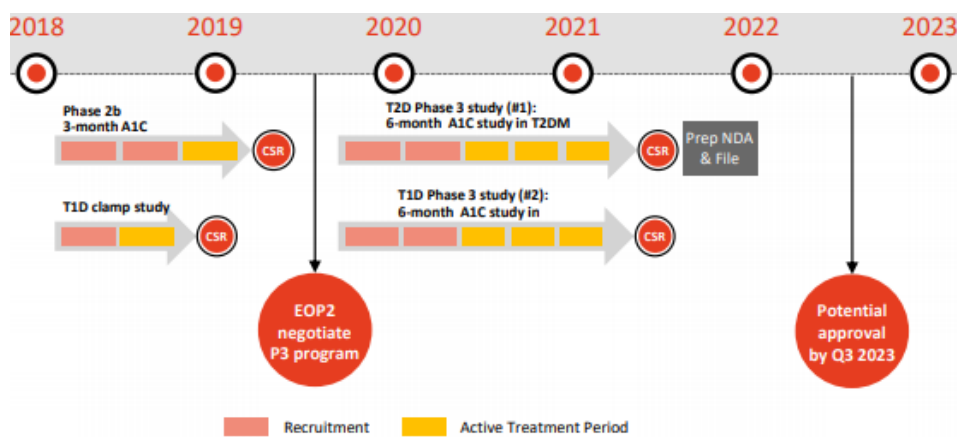


Figure 1: Anticipated Clinical Development Timeline for ORMD-0801

Source: Oramed Pharmaceuticals Inc.

'IND') with the U.S. Food and Drug Administration (hereinafter 'FDA'). The aims of this study are to assess the safety (adverse events, hypoglycemic) and the effect of ORMD-0801 (at different dosing regimens) on change in HbA1c level over 90 days. Secondary aims of the trial include measurements of fasting plasma glucose (FPG), post-prandial glucose (PPG levels) during a mixed-meal tolerance test (MMTT) and weight.

ORMD-0801 (Oral insulin for Type 1 diabetes): A glucose clamp study is used to characterize the exposure-response profiles of type 1 diabetic patients treated with ORMD-0801 began in June 2018. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. Patients with HbA1c levels of 10% or below, aged 18-50, are enrolled in the study for 6-8 months.

Should the Phase IIb three-month dose-ranging clinical trial successfully meet its primary endpoints, we anticipate the initiation of two, six-month Phase III clinical trials on both type 1 and type 2 diabetic patients in early 2020, with potential FDA approval by the third calendar quarter of 2023.

ORMD-0801 (Oral insulin for NASH): In November 2017, Israel's Ministry of Health approved the initiation of an exploratory clinical study of Oramed's oral insulin capsule, ORMD-0801, in patients with nonalcoholic steatohepatitis (NASH). The proposed three-month treatment study will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. The study is expected to begin in the third calendar quarter of 2018. 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 subjects with type 1 diabetes. Up to 48 subjects will be enrolled, including up to 24 healthy volunteers and 24 subjects with type 1 diabetes.

ORMD-0901 (GLP-1 analog for Type 2 Diabetes): GLP-1 analog is a hormone peptide that enhances the secretion of insulin and decreases blood sugar levels. It preserves beta cells function, effectively reduces HbA1c levels, promotes weight loss and is currently given via injection. We expect Oramed to file an IND during the second calendar quarter of 2018 and move directly into a small pharmacokinetics study on healthy volunteers followed by a large Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND. We expect the study to commence in H1-2019.

Oral Leptin: During the first quarter of calendar 2017, Oramed began developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule, and in April 2017, Israel's Ministry of Health approved commencement of a proof of concept single dose study for oral leptin to evaluate its pharmacokinetic and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients. Oramed expects to initiate the study in the second half of 2018 and complete the study in mid-2019.

Analysis

Oramed has continued to cement its position as a leader and disruptor in the Diabetes Care Market, thus endorsing the optimistic conclusions reached in our [Initiation of Coverage](#), published at the end of 2017, and reaffirmed in our [quarterly report published in April 2017](#).

The quarterly period ending May 31, 2018 was very positive from a clinical development point of view with initiation of a glucose clamp study which will quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801. Additionally, the expected initiation of the exploratory study using ORMD-0801 for NASH is a noteworthy indicator of the company's potential to expand its clinical pipeline to reach a wider patient population.

Capital Raising

The price paid per unit which includes both a share in the company and an option to purchase another share within four years, is slightly below the trading price of a single share at the date of announcement (\$6.26). The exercisable price of the options at \$7.25 is relatively close to the market price at the time of the capital raising, inferring that the company raised capital at discount.

As of 31 May 2018, Oramed had cash and cash equivalents of approx. \$34.4M. After the capital raising announced in early July 2018, we estimate Oramed's cash balance at about \$47M including on going burn rate.

IPO of Entera Bio ([NASDAQ:ENTX](#))

As of May 31, 2018 Oramed held approximately 6.9% of D.N.A's ([TASE:DNA](#)) outstanding ordinary shares. [On June 28 2018 Entera began trading on the NASDAQ](#) and closed at \$6.28. DNA has a 27.5% fully diluted stake in Entera. Oramed will also be entitled to 3% of any future net revenues from Entera. Thus, it represents \$1.5M value for Oramed at the time of Entera's IPO.

Looking Forward

H2-2018 is set to be an important period for the company with five clinical trials running in parallel. The initiation of early stage trials of ORMD-0801 for NASH and Oral Leptin for obesity are promising indicators of the potential for the company to expand their proprietary oral drug delivery platform to new products, and also to treat further indications using the existing products in its pipeline.

Oramed has increased revenues, and this is expected to continue until at least June 2023 (based on its signed licensing agreement). In addition, the company's improved financial income has seen net losses decrease even further. Providing this expense management is sustained in the year ahead, Oramed's stable financial position, strengthened by recent net capital raising of approx. \$16.5M, will be sufficient to fund clinical development scheduled for 2018-2019 with capital raising only becoming a necessity in the second calendar quarter of 2020.

We maintain our valuation as per our [initiation of coverage report of 23 December 2017](#). Oramed's estimated equity value remains \$200.7M (NIS 708.3M) corresponding to a target price ranging between NIS 49.8 and NIS 56.6; a mean of NIS 53.2.

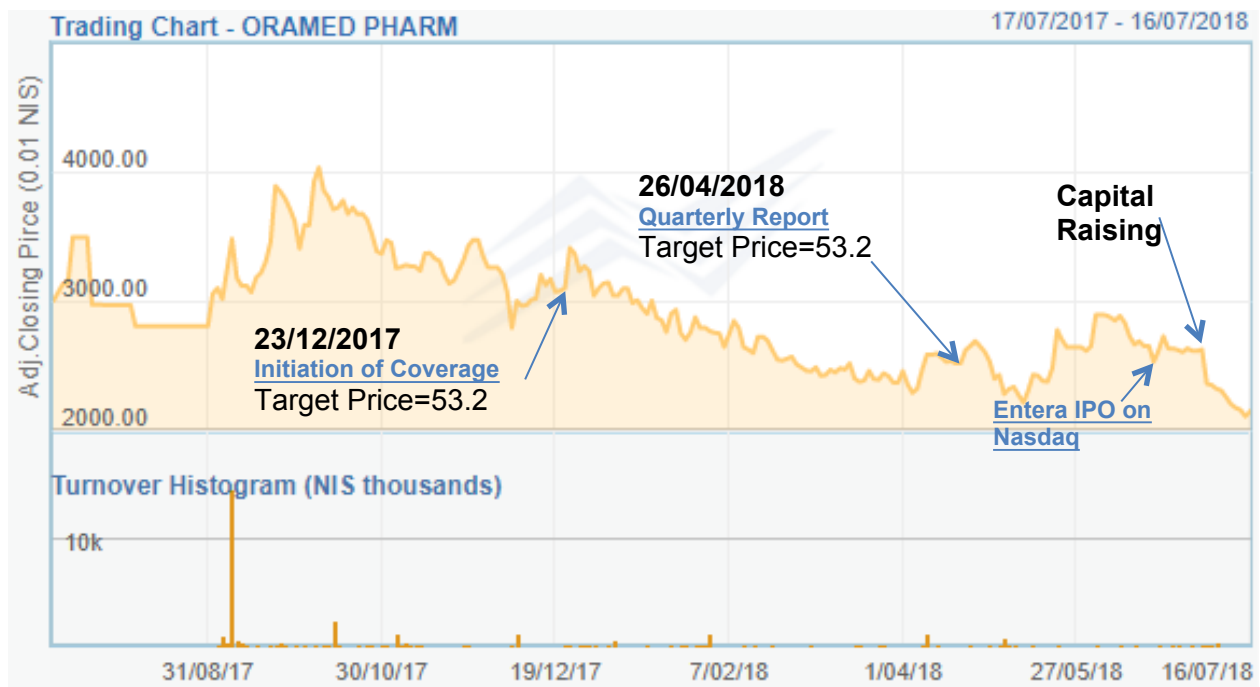
Upcoming Potential Catalysts

Program	Indication	Event	Significance	Timeline	Status
ORMD-0801 (Oral Insulin)	Type 2 diabetes	Initiation of Phase IIb 90-day multi-center study	High	Mid 2018	Achieved
		Completion of Phase IIb 90-day multi-center study	High	Mid 2019	On track
		Initiation of Phase III trials	High	Early 2020	On track

		Completion of Phase III trials	High	Late 2022	On track
		FDA marketing approval	High	Late 2023	Expected
	Type 1 diabetes	Initiation of Clamp study	Low	Mid 2018	Achieved
		Completion of Clamp study	High	Late 2018	On track
		Initiation of Phase III trials	High	Early 2020	On track
		Completion of Phase III trials	High	Late 2022	On track
	NASH	FDA marketing approval	High	Late 2023	Expected
		Initiation of exploratory clinical study	Low	Mid 2018	On track
		Completion of exploratory clinical study	Low	Mid 2019	On track
		Initiation of Phase III trials	High	Early 2020	On track
ORMD-0901 (Oral GLP-1)	Type 2 diabetes	Initiation of Pharmacokinetics clinical study	Low	Late 2018	On track
		Completion of Pharmacokinetics clinical study	Low	Early 2019	On track
		Phase II projected initiation	High	Mid 2019	On track
		Phase II projected completion	High	Late 2020	On track
		Initiation of P.O.C. study	Low	Late 2018	On track
Oral Leptin	Obesity	Initiation of P.O.C. study	Low	Late 2018	On track
		Completion of P.O.C. study	Low	Late 2019	On track

Sources: Frost & Sullivan Analysis; Oramed Pharmaceuticals Inc.

12-month Stock Performance



Source: Tel Aviv Stock Exchange

Appendix

Appendix I - Financial Reports

Balance Sheet (USD 000s)	28.02.2018	31.05.2018
Current Assets		
Cash and cash equivalents	3,295	3,673
Short-term bank deposits	14,379	15,990

Prepaid expenses and other current assets	1224	209
Restricted Cash	-	-
Marketable Securities	3,229	3,710
Total current assets	21,127	23,582
Non-Current Assets		
Long term deposits and investments	13,788	8,752
Long term prepaid expenses	3,306	
Marketable Securities	-	2,293
Net PPE	18	17
Employees rights upon retirement	15	15
Total non-current assets	17,127	11,077
Total assets	38,254	34,659
Current Liabilities		
Accounts payable and accruals	2,156	3,143
Deferred revenues	2,449	2,449
Those payable to related parties	113	45
Total current liabilities	4,718	5,637
Non-Current Liabilities		
Deferred revenues	12,622	12,005
Employees rights upon retirement	19	19
Provision for uncertain tax position	11	11
Other liabilities	404	330
Total non-current liabilities	13,056	12,365
Total liabilities	17,774	18,002
Total equity	20,480	16,657
Total liabilities and equity	38,254	34,659

Profit and Loss Statement, USD 000s	Three months ending	
	31.05.2017	31.05.2018
Revenues	(617)	(617)
Cost of Revenues	0	(86)
Research and Development Expenses	2,267	4,194
General and Administrative Expenses	505	1,043
Operating Loss	2,155	4,534
Financial Income	(210)	209
Financial Expenses	20	29
Net Loss	1,965	4,354
Loss (gain) on shares in DNA Biomedical Solutions Ltd.	(286)	115
Comprehensive Loss	1,679	4,469
Loss per ordinary share – basic and diluted	0.15	0.30

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