

Update for the quarterly period ending 28.2.18

26 April, 2018



Oramed has a sufficient cash balance to fund its clinical development timeline in the near term; several clinical milestones are scheduled for 2018 and 2019; stock target price remains at NIS 53.2.

Primary Exchange: TASE

Secondary exchange: NASDAQ

Ticker: TLV/NASDAQ: ORMP

Sector: Pharmaceuticals

Industry: Drug Development

Data as at 25 April, 2018

(Source: TASE)

Closing price: NIS 26.88

Market cap: NIS 372.5M

of shares: 13,859,041

Stock performance (9 months): -9.3%

Daily-trading-vol. (9 months): NIS 194K

Stock target price: NIS 53.2

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 the diabetes market; 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 receptor agonist, which increases physiological insulin secretion.

Highlights & Analysis

Oramed released its quarterly report for the period ending 28 February 2018 on 9 April, 2018 detailing the following:

A strong financial position with sufficient capital to fund scheduled clinical trials and associated expenses.

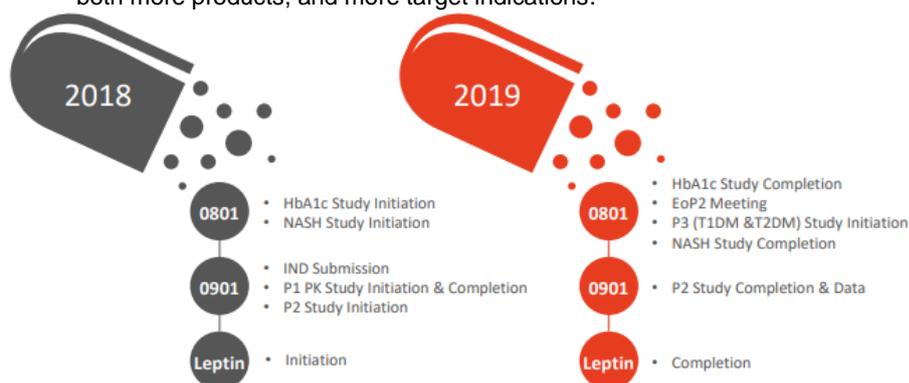
- As of 28 February 2018, Oramed has capital resources of approx. \$38.0M, enough to support 2018 clinical and regulatory plan.

Revenues from licensing deals with no cost of revenues have partially offset heavy R&D expenses to reduce Oramed's burn rate ahead of critical clinical milestones.

- Revenues for the quarter ending February 28, 2018 totaled \$604,000, consistent with \$611,000 for the corresponding quarter in 2017.
- Research and development expenses for the quarter ending February 28, 2018 decreased by 13% to \$2,724,000, from \$3,125,000 for the corresponding quarter in 2017.
- Net losses for the quarter ending February 28, 2018 decreased by 8.4% to \$2,916,000 from \$3,183,000 for the corresponding period in 2017.

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.

- Three critical clinical milestones are expected for 2018, which justify the above valuation.
- Three minor clinical milestones set for 2018 are promising indicators of a long-term expansion of Oramed's pharmaceutical portfolio, in terms of both more products, and more target indications.



Source: Oramed Pharmaceuticals Inc.

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Updates for the quarterly period ending 28.2.18

Financial Results

Revenues consist of proceeds related to the License Agreement; these totaled \$1,215,000 for the six month period ending February 28, 2018, consistent with the \$1,221,000 for the six month period ending February 28, 2017. Revenues for the quarter ending February 28, 2018 totaled \$604,000, consistent with \$611,000 for the corresponding quarter in 2017.

Research and development expenses for the six months ending February 28, 2018 decreased by 8% to \$5,051,000, from \$5,478,000 for the corresponding period in 2017. The decrease is mainly due to reduced expenses in Oramed's scale-up process development and production of oral capsule ingredients as well as progress in toxicology studies and is partially offset by an increase in expenses related to preparations for the Phase IIb three-month treatment clinical trial. Research and development expenses for the quarter ending February 28, 2018 decreased by 13% to \$2,724,000, from \$3,125,000 for the corresponding quarter in 2017, and are attributable to the same factors.

General and administrative expenses for the six months ending February 28, 2018 increased by 52% to \$2,007,000 from \$1,319,000 for the six months ending February 28, 2017. General and administrative expenses for the quarter ending February 28, 2018 increased by 16% to \$991,000 from \$851,000 for the corresponding period in 2017. The increase is mainly attributable to the relocation of Oramed's principal executive office to New York.

Net financial income increased by 15% from net income of \$344,000 for the six month period ending February 28, 2017 to net income of \$396,000 for the six month period ending February 28, 2018. The increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates. Net financial income increased by 7% from net income of \$182,000 for the quarter ending February 28, 2017 to net income of \$195,000 for the quarter ending February 28, 2018, and is attributable to the same factors.

Net loss for the six-months ending February 28, 2018 decreased by 6.4% to \$5,447,000 from \$5,819,000 for the corresponding period in 2017. Net losses for the quarter ending February 28, 2018 decreased by 7.4% to \$2,916,000 from \$3,183,000 for the corresponding period in 2017.

R&D highlights

ORMD-0801 (Oral insulin for Type 2 diabetes): Initiation of a three-month dose-ranging Phase IIb clinical trial of Oramed's proprietary flagship product, an orally ingestible insulin capsule, or ORMD-0801, began in the second calendar quarter of 2018. This placebo controlled, randomized, 90 day treatment clinical trial will be conducted on approximately 240 type 2 diabetic patients in multiple centers throughout the U.S. pursuant to an Investigational New Drug application (hereinafter 'IND') with the U.S. Food and Drug Administration (hereinafter 'FDA'). The aims of the trial are to assess the safety and effect of ORMD-0801 on HbA1c levels over a 90 day period of treatment. 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.

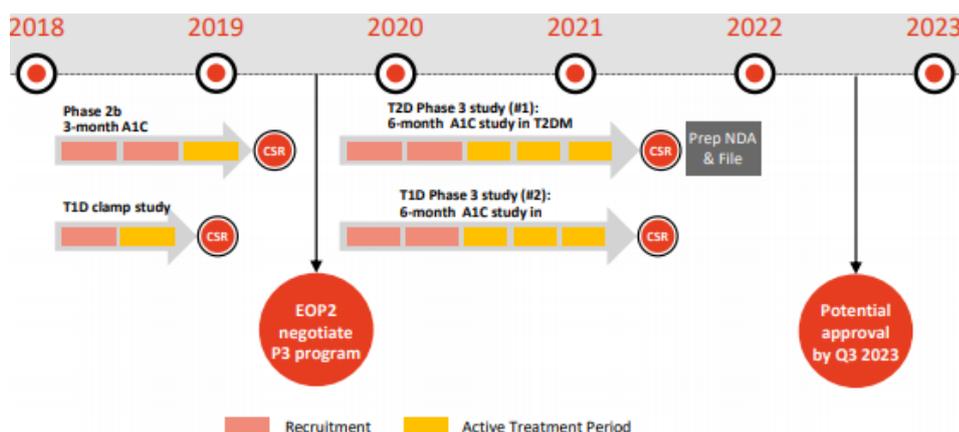


Figure 1: Anticipated Clinical Development Timeline for ORMD-0801

Source: Oramed Pharmaceuticals Inc.

ORMD-0801 (Oral insulin for Type 1 diabetes): We also expect initiation of a glucose clamp study which will quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801 around the second calendar quarter of 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. This exploratory, randomized, double-blind glucose clamp study will

evaluate exposure-response profiles of type 1 diabetes patients dosed with ORMD-0801. Patients with HbA1c levels of 10% or below, aged 18-70, will be enrolled in the study.

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 initiation of an exploratory clinical study of our 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. We expect to initiate the study in the second calendar quarter of 2018 and complete it during 2019.

ORMD-0901 (GLP-1 analog for Type 2 Diabetes): 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.

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. The study is projected to initiate in the third calendar quarter of 2018 and be completed during 2019.

Analysis

Oramed has continued to reaffirm their 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 beginning of the quarter.

2018 is set to be a landmark year for the Company with six forecasted clinical milestones. Of particular significance is the initiation of a three-month dose-ranging clinical trial of ORMD-0801 (oral insulin) and Phase II of ORMD-0901 (oral GLP-1 analog) in type 2 diabetes. In addition, 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 kept revenues stable expected to last until June 2023 (based on out licensing deal). 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, and particularly strong cash balance will mean that funds will be sufficient to see out all clinical milestones scheduled for 2018 with capital raising only set to become a necessity in the medium-long term.

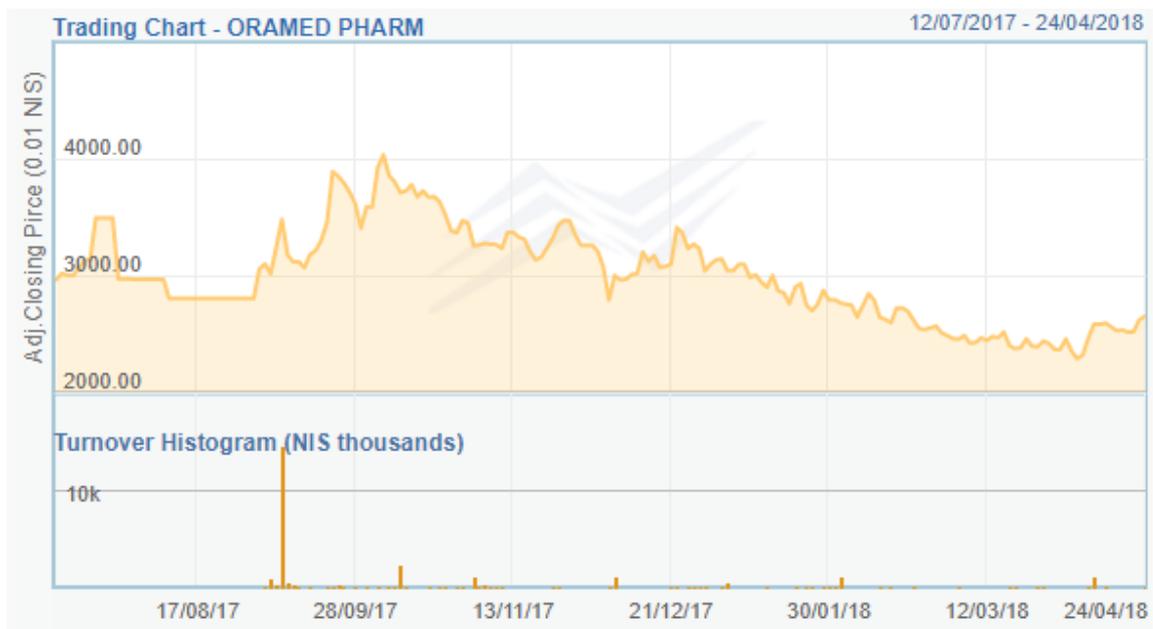
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Upcoming Potential Catalysts

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	On track
		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
		FDA marketing approval	High	Late 2023	Expected
NASH	Initiation of exploratory clinical study	Low	Mid 2018	On track	
	Completion of exploratory clinical study	Low	Mid 2019	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	Late 2018	On track
		Phase II projected initiation	High	Early 2019	On track
		Phase II projected completion	High	Mid 2020	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.

Stock performance since TASE IPO (July 12, 2017)



Appendix

Appendix I - Financial Reports

Balance Sheet (USD 000s)	28.02.2018	28.02.2017
Current Assets		
Cash and cash equivalents	3,295	1,452
Short-term bank deposits	14,379	24,554
Prepaid expenses and other current assets	224	151
Restricted Cash	-	16
Marketable Securities	3,229	3,607
Total current assets	21,127	29,780
Non-Current Assets		
Long term deposits and investments	13,788	11,005
Marketable Securities	3,306	1,023
Net PPE	18	16
Employees rights upon retirement	15	12
Total non-current assets	17,127	12,056
Total assets	38,254	41,836
Current Liabilities		
Accounts payable and accruals	2,156	2,424
Deferred revenues	2,449	2,449
Those payable to related parties	113	60
Total current liabilities	4,718	4,933
Non-Current Liabilities		
Deferred revenues	12,622	15,072
Employees rights upon retirement	19	17
Provision for uncertain tax position	11	11
Other liabilities	404	481
Total non-current liabilities	13,056	15,581
Total liabilities	17,774	20,514
Total equity	20,480	21,322
Total liabilities and equity	38,254	41,836

Profit and Loss Statement, USD 000s	Feb 28, 2018	Feb 28, 2017
Revenues	604	611
Research and Development Expenses, net	(2,724)	(3,125)
General and Administrative Expenses	(991)	(851)
Operating Loss	(3,111)	(3,365)
Financial Income	217	203
Financial Expenses	(22)	(21)
Net Loss	(2,916)	(3,183)
Gain/Loss on shares in DNA Biomedical Solutions Ltd.	(414)	168
Comprehensive Loss	(3,330)	(3,015)
Loss per ordinary share – basic and diluted	(0.20)	(0.24)

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