ORAMED PHARMACEUTICALS INC.
Form FWP
June 17, 2013

Breakthrough
Technology
for a
Brighter Future
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Issuer Free Writing Prospectus
Filed Pursuant to Rule 433
Registration No. 333-187343
June 17, 2013

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## Safe Harbor

Certain statements contained in this material are forward-looking statements. These forward-looking statements are based on the current expectations of the management of Oramed only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; and our ability to obtain additional funding required to conduct our research, development and commercialization activities, and others, all of which could cause the actual results or performance of Oramed to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Oramed undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Oramed, reference is made to Oramed's reports filed from time to time with the Securities and Exchange Commission. which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Please refer to the company's filings with the Securities and Exchange Commission for a comprehensive list of risk factors that could cause actual results, performance or achievements of the company to differ materially from those expressed or implied in such forward-looking statements. Oramed undertakes no obligation to update or revise any forward-looking statements.

Free Writing Prospectus Statement

This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all of the information that you should consider before investing.

We have filed a registration statement (including a prospectus dated March 22, 2013 and a preliminary prospectus supplement dated June 17, 2013) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement, the related preliminary prospectus supplement and other documents we have filed with the SEC for more complete information about us and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at www.sec.gov. Alternatively, we, any underwriter or any dealer participating in the offering will arrange to send you the prospectus and preliminary prospectus supplement if you request it by calling Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: prospectus@aegiscap.com or Maxim Group LLC, 405 Lexington Avenue, 2nd Floor, New York, NY 10174, toll-free telephone: 1-800-724-0761

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| Offering Summary | |
|---|---|
| Issuer | Oramed Pharmaceuticals Inc. |
| Exchange / Ticker | NASDAQ Capital Market / ORMP |
| Offering Size | Approximately $13 million (100% Primary) |
| Over-allotment | 15% (100% Primary) |
| Use of Proceeds | Clinical development of ORMD-0801 and ORMD-0901, working capital & general corporate purposes |
| Book-Runners | Aegis Capital Corp and Maxim Group LLC |

Oramed
An oral solution….
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Oramed Overview

Protein breakdown, low bioavailability
Harsh pH
Protease
threat
Mechanical
challenges
Absorption
barrier
Fate of proteins/peptides in GIT
7

Oramed Technology:
Oramed's delivery platform protects proteins and enhances their absorption, allowing them to reach the bloodstream via the portal vein, thereby establishing a more physiologic protein gradient when compared to other delivery systems.

Versatile
Simple
Competent
Versatile
Supports a
wide range
of protein
sizes and
doses
Simple
Simple
blend of
ingredients
ORAMED DRUG DELIVERY

Regulatory competence
No NCEs; widely applied
pharmacopoeia
9
Oramed Technology

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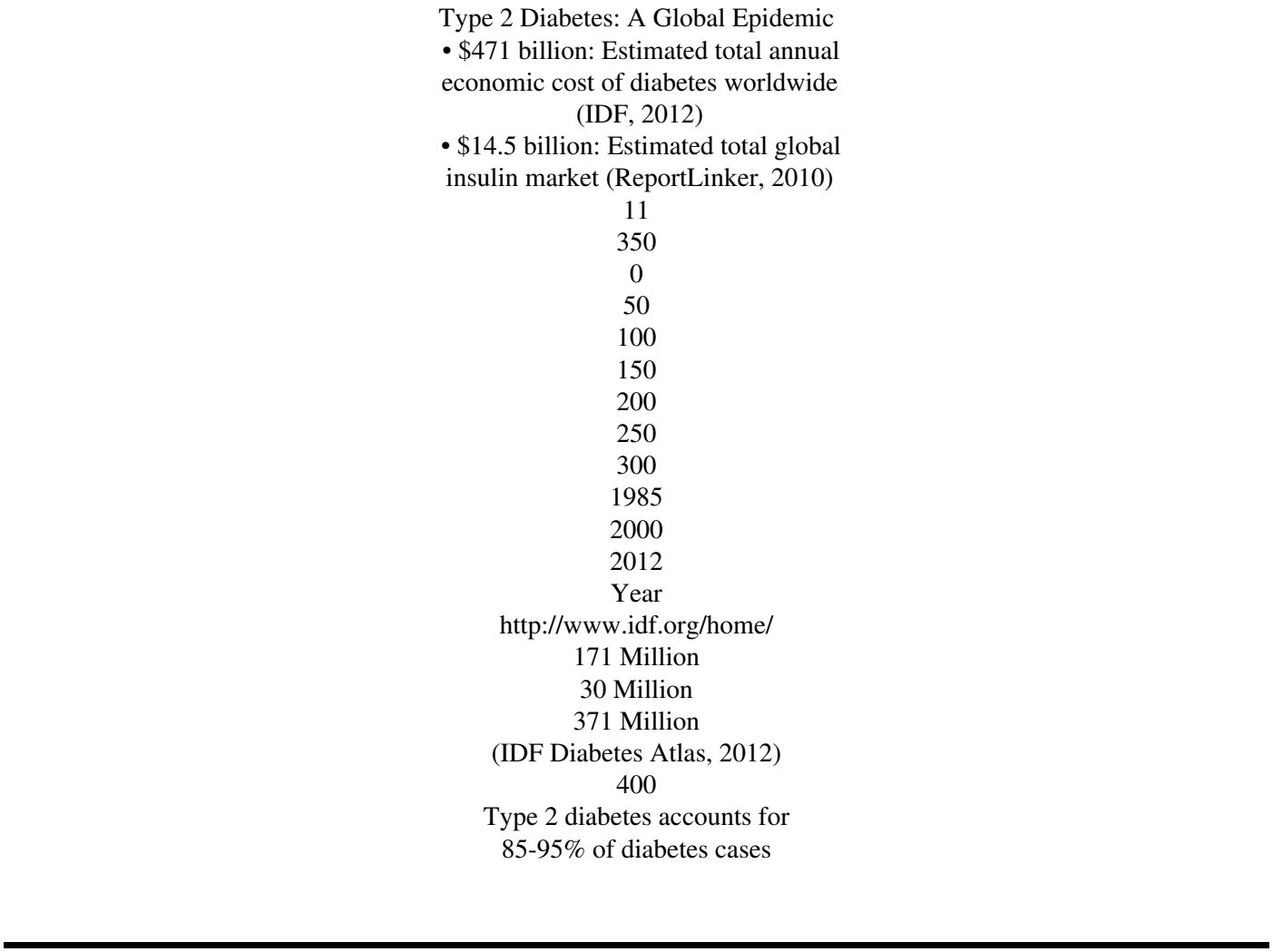
Diabetes:
A Global Epidemic


Type 2 Diabetes: A Global Epidemic
• $471 billion: Estimated total annual economic cost of diabetes worldwide (IDF, 2012)
• $14.5 billion: Estimated total global insulin market (ReportLinker, 2010)
11
350
0
50
100
150
200
250
300
1985
2000
2012
Year
http://www.idf.org/home/
171 Million
30 Million
371 Million
(IDF Diabetes Atlas, 2012)
400
Type 2 diabetes accounts for 85-95% of diabetes cases

Pipeline Overview

| Therapy | Indication | Preclinical | Phase I | Phase II (ex-US) | Phase II (FDA) | Timeline |
|---|---|---|---|---|---|---|
| ORMD - 0801 | T2DM | | | | | Q3, ‘13: Phase IIa “sub-study” projected initiation<br>Q2, ’14: Phase IIb multi-center study projected initiation |
| | T1DM | | | | | Q2, ‘14: Phase II (ex-US) multi-center trial projected initiation |
| ORMD-0901 | T2DM | | | | | Q1 ’13: Phase I/II (ex-US) study initiated |
| Combination Therapy | T2DM | | | | | Q1, ‘13: First-in-human PoC trial initiated |

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ORMD-0801
Oral Insulin

| |
|---|
| Total number of study subjects: 131 |
| Total number of administrations in humans: 1444 |
| 38 |
| 27 |
| 66 |

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ORMD-0801
Type 2 Diabetes

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l Blood glucose - insulin secretion system forms a 'closed-loop'

l Peripheral insulin promotes glucose uptake in fat and muscle

l First-pass hepatic metabolism extracts 80% of secreted insulin

l Systemic exposure is minimized

Portal insulin delivery is physiologic.

Systemic insulin delivery is not.

pancreas

portal vein

liver

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Initial Treatment:

• Lifestyle Modification

• Diet & Exercise

Single & Combination Oral Therapies:

• ORMD-0801

• Reduce insulin resistance

• Stimulate insulin secretion

Final Treatment:

• Insulin Replacement

ORMD-0801 is not a substitute for insulin injections, but rather a new earlier treatment option

Stages of Type 2 Diabetes

Criteria for advancing to next stage:

AIC not at target < 7.0%

Type 2 Diabetes:

Stages & Treatment Options

ORMD-0801 Pre-clinical
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Healthy, non-diabetic, cannulated beagle dogs 60-75% drop in blood glucose levels within 30-100 minutes of treatment
No hypoglycemia or adverse events were observed over the three years of testing
0
20
40
60
80
0
60
120
180
Time (min)
n=4
8 mg insulin
8 mg insulin, no additives
1.5 U NovoRapid
ORMD-0801 (A)
ORMD-0801 (C)
20
ORMD-0801
Preclinical - Dogs

20
40
60
80
-
0
30
60
90
120
NC
0
100
-
10
150
Time (min)
NC; 4 independent test sessions
Fasting
n=2
Pre-
prandial
0
20
40
60
80
100
120
140
0
50
100
150
Time (min)
-20
n=3
NC; 6 independent test sessions
ORMD-0801; 5 independent sessions
8 mg
insulin
21
ORMD-0801
Preclinical - Pigs

Phase II Study (ex-US):
Design: Multi-centered, placebo-controlled, randomized, double-blinded, 29 T2DM patient study to evaluate safety and tolerability of one bedtime orally administered ORMD-0801 formulation (2 capsules containing 8 mg insulin each) as well as its effectiveness in providing glycemic control.
21 T2DM
8 T2DM
Monitor safety parameters
Compare plasma markers at start of study to those at end of study
ORMD-0801
once daily
placebo
once daily
22

T2DM Clinical Results
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Results:

Safety:

• First extended exposure to ORMD-0801 proved safe and tolerable.

• No serious adverse events reported.

• No cumulative effects were observed.

• Only two hypoglycemic events were recorded - both were mild.

Efficacy:

• Reduced glycemia & inflammatory markers

• Percentage of patients demonstrating clinically relevant reductions in insulin, c-peptide, fasting blood glucose (FBG), and Hb1Ac levels was higher in the ORMD-0801 cohort, compared to the placebo.

0

5

10

15

20

25

30

35

40

45

50

FBG

Fructose-
amine

HbA1c

Insulin

c-peptide

CRP

ORMD-0801

Placebo

Phase II Study (ex-US):

FBG, HbA1c, Cardiovascular Disease Risk,
Hypoglycemia

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Upcoming Trial
(under FDA IND)
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ORMD-0801
Type 1 Diabetes

ID:
8
80
100
120
140
160
-10
-5
0
5
10
15
200
240
300
360
180
Time (min)
ID:
9
70
120
170
220
270
-14
-10
-6
-2
0
200
240
300
360
180
Time (min)

Expected rate of increase in fasting blood glucose concentrations among T1DM upon insulin withdrawal: 45.1 ± 9.7 mg/dL·hr-1 (Clement et al, 2002, Diabetes Technol Ther 4(4):459)

| Subject # | Rate of glucose change (mg/dL*hr-1) |
|---|---|
| 2 | 43.7 |
| 3 | -0.7 |
| 4 | -15.5 |
| 5 | 10.9 |

| | |
|---|---|
| 6 | -6.1 |
| 7 | -28.7 |
| 8 | -18.4 |
| 9 | 5.5 |

ORMD-0801 effectively prevented the expected rise in blood glucose concentrations among fasting T1DM subjects

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ORMD-0801 T1DM

DAY
NIGHT
180
200
220
240
260
280
300
pretreatment
treatment
ê 11.5%
50.75
58.3
38
49.7
DAY
NIGHT
pretreatment
treatment
Frequency glucose >200mg/dL
06:00
-
08:59
09:00
-
11:59
12:00
-
13:59
14:00
-
18:59
19:00
-
20:59
21:00
-
23:59
00:00
-
05:59
Time

Design: 7 T1DM, monitor glycemic stability of one orally administered ORMD-0801 formulation (1 capsule (8 mg insulin) before meals, three time daily). Glucose monitored with continuous, blinded glucose monitor

Results: Safe, well tolerated, reduced glycemia.

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ORMD-0801

T1DM

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ORMD-0901
Oral Exenatide
T2DM

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Oral Exenatide (GLP-1 Analog)
30

0
20
40
60
80
100
120
S.C.
AG
4
AG
3
-
+
+
+
+
Exenatide
*
*
*
Glucose

Results: Subcutaneous exenatide delivery amounted to a 51% reduction in mean glucose AUC0-150, while formulations AG4 and AG3 prompted 43% and 29% reductions, respectively (* p = 0.068, demonstrating a treatment-related trend for the sample size).

ORMD-0901 formulations preserved the biological activity of orally delivered exenatide. ORMD-0901 successfully curbed blood sugar excursions following glucose challenge.

Methods:

Ø Healthy, fasting, cannulated dogs

Ø Single dose ORMD-0901 formulations

Ø Administered 30 minutes before a glucose challenge.

Ø Blood samples collected every 15 minutes.

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preprandial
Phase 1
4 Healthy
Placebo-control
150 µg
exenatide
0
40
60
80
100
120
140
Time (min)
-50
0
100
150
n=4
ORMD-0901
placebo
FIRST IN
HUMAN
NO
NAUSEA
32
ORMD-0901
T2DM

Oramed
Corporate Overview
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Nadav Kidron, Esq., MBA - Chief Executive Officer & Director
• Experience in various industries, Including corporate law and technology
• Advisory Board member - EnteraBio, Trendlines Group
Miriam Kidron, PhD - CSO & Director
• Senior Researcher at the Diabetes Unit of Hadassah Medical Center for more than 25 years
• Leading researcher in oral insulin development
Yifat Zommer, MBA - CFO
• Extensive Experience in corporate financial management
• Bachelor of Accounting and Economics from Hebrew University
• MBA from Tel Aviv University, CPA Israel
Josh Hexter - COO, Vice President Business Development
• More than 15 years of prominent leadership and managerial roles in biotech and pharma - most recently with BioLineRX
• Master's degree in management from Boston University
Ehud Arbit, MD - Director of R&D
• Former VP of Medical Research at Emisphere Technologies
• Former Division Head at Memorial Sloan Kettering Cancer Center
Board of Directors
Michael Berelowitz,
PhD
Chairman of SAB
SVP Clinical
Development &
Medical Affairs, Pfizer
(former)
Harold Jacob, MD
Former Chief Medical
Officer, Given Imaging.
Geral Ostrov
CEO, Bausch&Lomb
(former); Senior level
Executive J&J (former)
Leonard Sank
Entrepreneur and
businessman
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Management
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Scientific Advisory Board
Chairman of SAB: Michael Berelowitz, MD
Prof. Derek LeRoith, MD, PhD
• Professor of Medicine and Chief of Endocrinology, Diabetes and Bone Disease Unit, Mount Sinai School of Medicine, NY.
Prof. John Amatruda, MD
• The Former Senior Vice President and Franchise Head of the Diabetes and Obesity Unit at Merck & Co.
Prof. Avram Herskho, MD, PhD
• Distinguished Professor in the Biochemistry Unit in the B. Rappaport Facility of Medicine in the Technion in Haifa.
• Nobel Laureate in Chemistry (2004) for the discovery of ubiquitin-mediated protein degradation.
Prof. Nir Barzilai, MD
• Director for the Institute of Aging Research. Member of Diabetes Research Center, Albert Einstein University College of Medicine.
Prof. Ele Ferrannini, MD, PhD
• Prof. of Internal Medicine, University of Pisa School of Medicine. Professor of Medicine, Diabetes Unit Texas Health Science Center. Past President of the EASD.

Intellectual Property:
Five primary worldwide patents
• Methods and Compositions for Oral Administration of Proteins (2 unique types)
– Expire 2026 & 2028
– Approval granted in Israel, Japan, Australia and New Zealand
– Pending in multiple jurisdictions, including the US
• Methods and Compositions for Oral Administration of Exenatide
– Expires 2028
– Approval granted in New Zealand
– Pending in multiple jurisdictions, including the US
• Methods and Compositions for Treating Diabetes
– Expires in 2032, Pending status, including the US
• Protease inhibitor-containing compositions and compositions comprising same
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Financial Overview 2013*

* As of June 1, 2013

Ticker: NASDAQ: ORMP

• $20.7M raised to date

• No Debt

• Cash and investments: $4.2M

• Shares Issued: 7.2M

• Fully diluted: 9.5M**

** Including outstanding 0.9M options and 1.5M warrants.

*** Including the shares of D.N.A Biomedical Solutions Ltd.

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Capitalization Structure

| Capitalization | Outstanding | % Outstanding |
|---|---|---|
| Common Stock | 7,226,423 | 75.35% |
| Stock Options | 857,158 | 8.94% |
| Warrants | 1,506,410 | 15.71% |
| Fully-diluted Shares Outstanding | 9,589,991 | 100% |

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- Anticipated 2013 expenditures (Q3-Q4): $2.5M
- Anticipated 2014 expenditures (Q1-Q4): $8M

Anticipated Use of Proceeds 2013-2015

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Anticipated Milestones
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Breakthrough Technology for a
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