

ORAMED PHARMACEUTICALS INC.

Form 10-K

November 14, 2014

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended August 31, 2014

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 000-50298

ORAMED PHARMACEUTICALS INC.  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of Incorporation or  
Organization)

98-0376008

(I.R.S. Employer Identification No.)

Hi-Tech Park 2/4  
Givat-Ram  
P.O. Box 39098  
Jerusalem, Israel  
(Address of Principal Executive Offices)

91390  
(Zip Code)

+972-2-566-0001

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act: None  
Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter was \$128,906,265, based on a price of \$14.86, being the last price at which the shares of the registrant's common stock were sold on The Nasdaq Capital Market prior to the end of the most recently completed second fiscal quarter.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 10,106,305 shares of common stock issued and outstanding as of November 12, 2014.

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ORAMED PHARMACEUTICALS INC.

FORM 10-K

(FOR THE FISCAL YEAR ENDED AUGUST 31, 2014)

TABLE OF CONTENTS

<u>PART I</u>		2
	<u>ITEM 1. BUSINESS.</u>	2
	<u>ITEM 1A. RISK FACTORS.</u>	12
	<u>ITEM 1B. UNRESOLVED STAFF COMMENTS.</u>	21
	<u>ITEM 2. PROPERTIES.</u>	21
	<u>ITEM 3. LEGAL PROCEEDINGS.</u>	21
	<u>ITEM 4. MINE SAFETY DISCLOSURES.</u>	21
<u>PART II</u>		22
	<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.</u>	22
	<u>ITEM 6. SELECTED FINANCIAL DATA.</u>	22
	<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.</u>	25
	<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	33
	<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.</u>	33
	<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.</u>	34
	<u>ITEM 9A. CONTROLS AND PROCEDURES.</u>	34
	<u>ITEM 9B. OTHER INFORMATION.</u>	34
<u>PART III</u>		35
	<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.</u>	35
	<u>ITEM 11. EXECUTIVE COMPENSATION.</u>	39
	<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.</u>	48
	<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.</u>	52
	<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.</u>	52

PART IV

53

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT  
SCHEDULES.

53

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As used in this Annual Report on Form 10-K, the terms “we,” “us,” “our,” the “Company,” and “Oramed” mean Oramed Pharmaceuticals Inc. and our wholly-owned Israeli subsidiary, Oramed Ltd., unless otherwise indicated. All dollar amounts refer to U.S. Dollars unless otherwise indicated.

On August 31, 2014, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.568 to \$1.00. Unless indicated otherwise by the context, statements in this Annual Report on Form 10-K that provide the dollar equivalent of NIS amounts or provide the NIS equivalent of dollar amounts are based on such exchange rate.

On January 10, 2013, we effected a reverse stock split of our shares of common stock at a ratio of one-for-twelve. All share and per share amounts included in this Annual Report on Form 10-K have been adjusted retroactively to reflect the effects of the reverse stock split.

#### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (including the section regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements within the meaning of the federal securities laws regarding our business, clinical trials, financial condition, expenditures, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “planned expenditures,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading “Item 1A. Risk Factors” below, as well as those discussed elsewhere in this Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-K. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report on Form 10-K which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

## PART I

### ITEM 1. BUSINESS.

#### DESCRIPTION OF BUSINESS

##### Research and Development

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills for delivery of other polypeptides.

**Oral insulin:** We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD-0801). Having completed Phase IIa clinical trials in patients with both type 1 and type 2 diabetes, we anticipate the initiation of Phase IIb clinical trials in approximately 180 patients with type 2 diabetes under an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, in the first quarter of calendar year 2015. Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables its passage in a more physiological manner than current delivery methods of insulin. Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

**Diabetes:** Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life. The cause of diabetes is attributed both to genetics (type 1 diabetes) and, most often, to environmental factors such as obesity and lack of exercise (type 2 diabetes). According to the World Health Organization, or WHO, an estimated 347 million people worldwide suffered from diabetes in 2010. In 2004, an estimated 3.4 million people died from consequences of high blood sugar, and the WHO projects that diabetes deaths will increase by two thirds between 2008 and 2030. According to the American Diabetes Association, or ADA, in the United States there were approximately 29.1 million people with diabetes, or 9.3% of the United States population in 2012. Diabetes is a leading cause of blindness, kidney failure, heart attack, stroke and amputation.

**Intellectual property:** We own a portfolio of patents and patent applications covering our technologies and we are aggressively protecting these technology developments on a worldwide basis.

**Management:** We are led by a highly-experienced management team knowledgeable in the treatment of diabetes. Our Chief Medical and Technology Officer, Miriam Kidron, PhD, is a world-recognized pharmacologist and a biochemist and the innovator primarily responsible for our oral insulin technology development and know-how.

**Scientific Advisory Board:** Our management team has access to our internationally recognized Scientific Advisory Board whose members are thought-leaders in their respective areas. The Scientific Advisory Board is comprised of Dr. Nir Barzilai, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Derek LeRoith, Dr. John Amatruda and Dr. Michael Berelowitz acting as Chairman.

##### Strategy

##### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins," which we acquired from Hadasit Medical Research Services

and Development Ltd., or Hadasit, in 2006 and which is pending in various foreign jurisdictions, as well as the other patents we have filed in various foreign jurisdictions since then, as discussed below under “—Patents and Licenses” and below under “Item 1A. Risk Factors.” Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin or other proteins, such as exenatide, for the treatment of diabetes. The enzymes and vehicles that are added to the proteins in the formulation process must not modify the proteins chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We originally filed an IND with the FDA in December 2012 for clearance to begin a Phase II clinical trial of ORMD-0801, in order to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. Because the identical formulation of ORMD-0801 had not yet been studied in humans at bedtime, in February 2013 the FDA noted concerns about mitigating potential risks of severe hypoglycemia and requested that we perform a sub-study in a controlled in-patient setting for a one-week period prior to beginning the larger multi-centered Phase II trial. As a result, we withdrew the original IND and, in April 2013, we submitted a new IND for the Phase IIa sub-study. Following the FDA’s clearance to proceed in May 2013, we began the Phase IIa sub-study in July 2013. As we announced in January 2014, the Phase IIa sub-study met all primary and secondary endpoints. Specifically, the Phase IIa study evaluated the pharmacodynamic effects of ORMD-0801 on mean nighttime glucose (determined using a continuous glucose monitor). The results showed that ORMD-0801 exhibited a sound safety profile, led to reduced mean daytime and nighttime glucose readings and lowered fasting blood glucose concentrations, when compared to placebo. In addition, no serious adverse events occurred during this study, and the only adverse events that occurred were not drug related. In light of these results, we believe that we should move forward with the Phase IIb clinical trial on approximately 180 type 2 diabetic patients, which we are preparing to initiate in the first quarter of calendar year 2015. This double-blind, randomized, 28-day study clinical trial will be designed to assess the safety and efficacy of ORMD-0801 and will be conducted in approximately 30 sites in the United States.



In February 2014, we submitted a protocol to the FDA to initiate a Phase IIa trial of our oral insulin capsule for type 1 diabetes volunteers. The protocol was submitted under our existing IND to include both type 1 and type 2 diabetes indications. The double-blind, randomized, placebo controlled, seven-day study design was carried out at an inpatient setting on 25 type 1 diabetic patients. We began this study in March 2014. As we announced in October 2014, the results showed that ORMD-0801 oral insulin given before meals appeared to be safe and well-tolerated for the dosing regimen in this study. Although the study was not powered to show statistical significance, there were internally consistent trends observed. Consistent with the timing of administration, the data showed a decrease in rapid acting insulin, a decrease in post-prandial glucose, a decrease in daytime glucose by continual glucose monitoring and an increase in post-prandial hypoglycemia in the active group.

Clinical trials are planned in order to substantiate our results as well as for purposes of making future filings for drug approval. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

The table below gives an overview of our product pipeline:

ORMD-0801	Type 2 oral insulin diabetes	Q4 '13: Phase IIa completed Q1 '15: Phase IIb multi-center study projected initiation Q3 '14: Phase IIa completed
	Type 1 diabetes	
ORMD-0901	Type 2 oral GLP-1 diabetes	Q3, '14: Preclinical/IND studies initiated Q1, '15: Phase Ia and Ib ex-US study projected initiation. Q3, '15: Phase II multi-center study projected initiation

### Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.



## Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

## Product Development

### Research and Development Summary

We devote the majority of our efforts to research and development, including clinical studies for our lead clinical product candidates, as described below.

### Orally Ingestible Insulin

During fiscal 2007, we conducted several clinical studies of our orally ingestible insulin that were intended to assess both the safety/tolerability and absorption properties of our proprietary oral insulin. Based on the pharmacokinetic and pharmacologic outcomes of these trials, we decided to continue the development of our oral insulin product.

During fiscal 2008, we successfully completed animal studies and non-FDA approved clinical trials using our oral insulin capsule, including a Phase Ib clinical trial in healthy human volunteers with the intent of dose optimization; a Phase IIa study to evaluate the safety and efficacy of our oral insulin capsule in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem; and a Phase IIa study to evaluate the safety and efficacy of our oral insulin capsule on type 1 diabetic volunteers.

Our successful non-FDA clinical trials continued in fiscal 2009, with a Phase IIb study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers.

In March 2011, we reported that we successfully completed a comprehensive toxicity study for our oral insulin capsule. The study was completed under conditions prescribed by the FDA Good Laboratory Practices regulations.

In September 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This completed exploratory study was a proof of concept study for defining a novel indication for ORMD-0801. We believe the encouraging results justify further clinical development of ORMD-0801 capsule application toward management of uncontrolled diabetes.

As described above, we began FDA-approved clinical trials of ORMD-0801 in July 2013, with the Phase IIa sub-study, which evaluated the pharmacodynamic effects of ORMD-0801 on mean nighttime glucose (determined using a continuous glucose monitor) in volunteers with type 2 diabetes. As we announced in January 2014, the results showed that ORMD-0801 exhibited a sound safety profile, led to reduced mean daytime and nighttime glucose readings and lowered fasting blood glucose concentrations, when compared to placebo. In light of these results, we intend to move forward with the Phase IIb clinical trial on approximately 180 type 2 diabetic patients, which we are preparing to initiate in the first quarter of calendar year 2015. This double-blind, randomized, 28-day study will be designed to assess the safety and efficacy of ORMD-0801 and will be conducted in approximately 30 sites in the United States.



In March 2014, we began an FDA-approved Phase IIa trial of ORMD-0801 in volunteers with type 1 diabetes. As we announced in October 2014, the results showed that ORMD-0801 oral insulin given before meals appeared to be safe and well-tolerated for the dosing regimen in this study. Although the study was not powered to show statistical significance, there were internally consistent trends observed. Consistent with the timing of administration, the data showed a decrease in rapid acting insulin, a decrease in post-prandial glucose, a decrease in daytime glucose by continual glucose monitoring and an increase in post-prandial hypoglycemia in the active group.

We utilize Clinical Research Organizations, or CROs, to conduct our clinical studies. We currently have an agreement with Integrium LLC to act as CRO for the Phase IIb clinical trial of ORMD-0801 in volunteers having type 2 diabetes, described above.

### GLP-1 Analog

Glucagon-like peptide-1, or GLP-1, is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. In addition to stimulating insulin release, GLP-1 was found to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.

During fiscal 2009 we completed pre-clinical trials of ORMD-0901, an analog for GLP-1, which included animal studies that suggested that the GLP-1 analog (exenatide-4), when combined with Oramed's absorption promoters, is absorbed through the gastrointestinal tract and retains its biological activity.

In December 2009, we completed non-FDA approved clinical trials of an oral GLP-1 analog in healthy, male volunteers conducted at Hadassah University Medical Center in Jerusalem. This study tested the safety and efficacy of ORMD-0901, an encapsulated oral GLP-1 analog formulation. The results of the study indicated that ORMD-0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

In January 2013, we began a clinical trial for our oral exenatide capsule on healthy volunteers and type 2 diabetic patients. Based on this study, we decided make slight adjustments in the manufacturing of these capsules and have begun toxicology studies on the new capsules. In parallel to the toxicology studies we intend on initiating a follow-on clinical trial in the first quarter of calendar year 2015.

In September 2013, we submitted a pre-IND package to the FDA for ORMD-0901, our oral exenatide capsule, for a Phase II clinical trial on healthy volunteers and type 2 diabetic patients. We expect to begin non-U.S. based Phase Ia and Ib trials and IND-enabling studies in the first quarter of calendar year 2015.

### Combination Therapy

In June 2012, we presented an abstract, which reported on the impact of our oral insulin capsule ORMD-0801 delivered in combination with our oral exenatide capsule ORMD-0901. The work that was presented assessed the safety and effectiveness of a combination of oral insulin and oral exenatide treatments delivered to pigs prior to food intake. The drug combination resulted in significantly improved blood glucose regulation when compared to administration of each drug separately.

In February 2013, we commenced a first human clinical trial on type 2 diabetic volunteers with our oral insulin capsule delivered in combination with our oral exenatide capsule. In the near term, we are focusing our efforts on the development of the Company's flagship products, oral insulin and oral exenatide. Once these two products have progressed further in clinical trials, we intend on running further studies with the oral combination therapy.

## Raw Materials

Our oral insulin capsule is currently manufactured by Catalent Pharma Solutions, LLC.

One of our oral capsule ingredients is being developed and produced by an Indian company.

In July 2010, Oramed Ltd. entered into the Manufacturing and Supply Agreement, or MSA, with Sanofi-Aventis Deutschland GMBH, or Sanofi-Aventis. According to the MSA, Sanofi-Aventis will supply Oramed Ltd. with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

We purchase, pursuant to separate agreements with third parties, the raw materials required for the manufacturing of our oral capsule. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions if we would need to change suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could have a material adverse effect on our business, prospects, financial condition and results of operations.

## Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 28 patent applications currently pending, with respect to various compositions, methods of production and oral administration of proteins and exenatide. Expiration dates for pending patents, if granted, will fall between 2026 and 2034.

We hold 24 patents, sixteen of which were issued in fiscal 2014, including patents issued by the Swiss, German, French, U.K., Italian, Netherland, Spanish, Australian, Israeli, Japanese, Russian, Canadian and Hong Kong Patent Offices that cover a part of our technology which allows for the oral delivery of proteins and patents issued by the Australian and Israeli Patent Offices that cover part of our technology for the oral delivery of exenatide.

Consistent with our strategy to seek protection in key markets worldwide, we have been and will continue to pursue the patent applications and corresponding foreign counterparts of such applications. We believe that our success will depend on our ability to obtain patent protection for our intellectual property.

Our patent strategy is as follows:

Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate,

Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology, and

Establish comprehensive coverage in the United States and in all relevant foreign markets in anticipation of future commercialization opportunities.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. Our policy is to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, our board of directors, or our Board, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during

the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of our Company. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.



## Out-Licensed Technology

In June 2010, Oramed Ltd. entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd., or D.N.A, for the establishment of Entera Bio LTD, or Entera.

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP-1 analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis. The license was royalty-free unless our ownership interest in Entera decreased to 30% or less of its outstanding share capital, in which case royalties would have been payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may have received ownership of the licensed technology, in which case we would have received a license back on the same terms.

D.N.A initially invested \$600,000 in Entera, and Entera was initially owned in equal parts by Oramed and D.N.A. Entera's Chief Executive Officer, Dr. Phillip Schwartz, was granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital, upon full exercise.

In March 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, we received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, to be paid within four months after closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$581,977 as of March 31, 2011 (\$296,375 as of November 12, 2014). Of the ordinary shares of D.N.A we received, we sold 7,875,989 shares, for which we received aggregate sale proceeds of \$307,955, and currently hold only 528,678 shares. The promissory note was secured by a personal guarantee of the D.N.A majority shareholders and its term was extended in August 2011. D.N.A paid off the promissory note in November 2011. The ordinary shares of D.N.A were restricted for six months from the closing. Pursuant to the Israel Securities Law, the ordinary shares of D.N.A that we own are subject to certain additional restrictions on sale, which expired on March 31, 2013. The market price for D.N.A's ordinary shares is subject to market fluctuations and may, at times, have a price below the value on the date we acquired such shares. The closing price for D.N.A's ordinary shares was \$0.035 per share, on November 12, 2014. In addition, the ordinary shares of D.N.A have historically experienced low trading volume; as a result there is no guarantee that we will be able to resell the ordinary shares of D.N.A at the prevailing market prices. In addition, D.N.A invested \$250,000 in our private placement investment round, which closed in March 2011, for which it received 65,105 shares of our common stock and five-year warrants to purchase 22,787 shares of our common stock at an exercise price of \$6.00 per share.

As part of the transaction with D.N.A, we entered into a patent transfer agreement (to replace the original license agreement upon closing) pursuant to which Oramed assigned to Entera all of its right, title and interest in and to the patent application that it had licensed to Entera in August 2010. Under this agreement, Oramed Ltd. is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza.

In March 2011, Oramed Ltd., Entera and D.N.A terminated the joint venture agreement entered into in June 2010 in connection with the formation of Entera.

In April 2014, Entera announced that it obtained orphan status from the FDA for its oral treatment for hypoparathyroidism. Orphan drug designation qualifies a company for several benefits under the Orphan Drug Act of 1983, as amended. These benefits include a 7-year period of orphan drug exclusivity upon product approval, a tax

credit for certain clinical testing expenses for the orphan drug, written guidance on the non-clinical and clinical studies needed to obtain marketing approval of an orphan drug, and orphan drug grants.

#### Government Regulation

##### The Drug Development Process

Regulatory requirements for the approval of new drugs vary from one country to another. In order to obtain approval to market our drug portfolio, we need to go through a different regulatory process in each country in which we apply for such approval. In some cases information gathered during the approval process in one country can be used as supporting information for the approval process in another country. As a strategic decision, we decided to first explore the FDA regulatory pathway. The following is a summary of the FDA's requirements.

7

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The FDA requires that pharmaceutical and certain other therapeutic products undergo significant clinical experimentation and clinical testing prior to their marketing or introduction to the general public. Clinical testing, known as clinical trials or clinical studies, is either conducted internally by life science, pharmaceutical, or biotechnology companies or is conducted on behalf of these companies by contract research organizations, or CROs.

The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. Below we describe the principal framework in which clinical studies are conducted, as well as describe a number of the parties involved in these studies.

Protocols. Before commencing human clinical studies, the sponsor of a new drug or therapeutic product must submit an IND application to the FDA. The application contains, among other documents, what is known in the industry as a protocol. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

- Who must be recruited as qualified participants,
- How often to administer the drug or product,
- What tests to perform on the participants, and
- What dosage of the drug or amount of the product to give to the participants.

Institutional Review Board. An institutional review board is an independent committee of professionals and lay persons which reviews clinical research studies involving human beings and is required to adhere to guidelines issued by the FDA. The institutional review board does not report to the FDA, but its records are audited by the FDA. Its members are not appointed by the FDA. All clinical studies must be approved by an institutional review board. The institutional review board's role is to protect the rights of the participants in the clinical studies. It approves the protocols to be used, the advertisements which the company or CRO conducting the study proposes to use to recruit participants, and the form of consent which the participants will be required to sign prior to their participation in the clinical studies.

Clinical Trials. Human clinical studies or testing of a potential product are generally done in three stages known as Phase I through Phase III testing. The names of the phases are derived from the regulations of the FDA. Generally, there are multiple studies conducted in each phase.

Phase I. Phase I studies involve testing a drug or product on a limited number of healthy or patients participants, typically 24 to 100 people at a time. Phase I studies determine a product's basic safety and how the product is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year.

Phase II. Phase II trials involve testing of no more than 300 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. Phase II studies may be split into Phase IIa and Phase IIb sub-studies. Phase IIa studies may be conducted with patient volunteers and are exploratory (non-pivotal) studies, typically designed to evaluate clinical efficacy or biological activity. Phase IIb studies are conducted with patients defined to evaluate definite dose range and evaluate efficacy. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will generally continue to review the substance in Phase III studies.

Phase III. Phase III studies involve testing large numbers of participants, typically several hundred to several thousand persons. The purpose is to verify effectiveness and long-term safety on a large scale. These studies generally last two to three years. Phase III studies are conducted at multiple locations or sites. Like the other phases, Phase III requires the site to keep detailed records of data collected and procedures performed.

New Drug Approval. The results of the clinical trials are submitted to the FDA as part of a new drug application, or NDA. Following the completion of Phase III studies, assuming the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of its product, the sponsor will generally submit an NDA to the FDA requesting that the product be approved for marketing. The application is a comprehensive, multi-volume filing that includes the results of all clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging and labeling the product. The FDA's review of an application can take a few months to many years, with the average review lasting 18 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA.

Phase 4. The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase 4 studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase 4 studies usually involve thousands of participants. Phase 4 studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug.

The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials.

#### Other Regulations

Various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, the environment and the purchase, storage, movement, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research are applicable to our activities. They include, among others, the U.S. Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation. The compliance with these and other laws, regulations and recommendations can be time-consuming and involve substantial costs. In addition, the extent of governmental regulation which might result from future legislation or administrative action cannot be accurately predicted and may have a material adverse effect on our business, financial condition, results of operations and prospects.

#### Competition

##### Competition in General

Competition in the area of biomedical and pharmaceutical research and development is intense and significantly depends on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain regulatory approval for testing, manufacturing and marketing. Our competitors include major pharmaceutical, medical products, chemical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the treatment of the diseases and health conditions that we have targeted for product development. We can provide no assurance that developments by others will not render our technology obsolete or noncompetitive, that we will be able to keep pace with new technological developments or that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The foregoing factors could have a material adverse effect on our business, prospects, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

Competition within our sector is increasing, so we will encounter competition from existing firms that offer competitive solutions in diabetes treatment solutions. These competitive companies could develop products that are superior to, or have greater market acceptance, than the products being developed by us. We will have to compete

against other biotechnology and pharmaceutical companies with greater market recognition and greater financial, marketing and other resources.

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Our competition will be determined in part by the potential indications for which our technology is developed and ultimately approved by regulatory authorities. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our potential corporate partners, can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, develop and implement production and marketing plans, obtain and maintain patent protection and secure adequate capital resources. We expect our technology, if approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, value and patent position.

#### Competition for Our Oral Insulin Capsule

We anticipate the oral insulin capsule to be a competitive diabetes drug because of its anticipated efficacy and safety profile. The following are treatment options for type 1 and type 2 diabetic patients:

- Insulin injections,
- Insulin pumps, or
- A combination of diet, exercise and oral medication which improve the body's response to insulin or cause the body to produce more insulin.

Several entities who are actively developing oral insulin capsules and/or alternatives to insulin are thought to be: Novo Nordisk (Denmark), Biocon Limited (India) and Midatech (UK).

#### Scientific Advisory Board

We maintain a Scientific Advisory Board consisting of internationally recognized scientists who advise us on scientific and technical aspects of our business. The Scientific Advisory Board meets periodically to review specific projects and to assess the value of new technologies and developments to us. In addition, individual members of the Scientific Advisory Board meet with us periodically to provide advice in their particular areas of expertise. The Scientific Advisory Board consists of the following members, information with respect to whom is set forth below: Professor Avram Hershko, Professor Nir Barzilai, Professor Ele Ferrannini, Professor Derek LeRoith, Dr. John Amatruda and one of our directors, Dr. Michael Berelowitz, acting as Chairman.

We have entered into an agreement with Dr. Berelowitz pursuant to which we will pay him certain fees as compensation for serving as Chairman. See "Item 10. Directors, Executive Officers and Corporate Governance" and "Item 11. Executive Compensation—Director Compensation" for certain information about Dr. Berelowitz.

Professor Avram Hershko, MD, PhD, joined the Oramed Scientific Advisory Board in July 2008. He earned his MD degree (1965) and PhD degree (1969) from the Hebrew University- Hadassah Medical School of Jerusalem. Professor Hershko served as a physician in the Israel Defense Forces from 1965 to 1967. After a post-doctoral fellowship with Gordon Tomkins at the University of San Francisco (1969-72), he joined the faculty of the Haifa Technion becoming a professor in 1980. He is now Distinguished Professor in the Unit of Biochemistry in the B. Rappaport Faculty of Medicine of the Technion. Professor Hershko's main research interests concern the mechanisms by which cellular proteins are degraded, a formerly neglected field of study. Professor Hershko and his colleagues showed that cellular proteins are degraded by a highly selective proteolytic system. This system tags proteins for destruction by linkage to a protein called ubiquitin, which had previously been identified in many tissues, but whose function was previously

unknown. Subsequent work by Professor Hershko and many other laboratories has shown that the ubiquitin system has a vital role in controlling a wide range of cellular processes, such as the regulation of cell division, signal transduction and DNA repair. Professor Hershko was awarded the Nobel Prize in Chemistry (2004) jointly with his former PhD student Aaron Ciechanover and their colleague Irwin Rose. His many honors include the Israel Prize for Biochemistry (1994), the Gairdner Award (1999), the Lasker Prize for Basic Medical Research (2000), the Wolf Prize for Medicine (2001) and the Louisa Gross Horwitz Award (2001). Professor Hershko is a member of the Israel Academy of Sciences (2000) and a Foreign Associate of the U.S. Academy of Sciences (2003).



Professor Derek LeRoith, MD, PhD, joined the Oramed Scientific Advisory Board in January 2007. He is currently the Director of Research in the Division of Endocrinology, Diabetes and Bone Diseases at Mt. Sinai School of Medicine in New York, and Director of the Diabetes and Metabolism Clinical Research Center of Excellence Clinical Research Institute at Rambam (LHCRIR) Rambam Health Care Campus. Professor LeRoith has worked at the National Institute of Health, or NIH, since 1979 in the field of Endocrinology and Diabetes and rose to be Chief of Diabetes Branch at the MDNIH in Bethesda, Maryland, a position he held until 2005. His main interests have focused on the role of insulin and the insulin-like growth factors, or IGFs, in normal physiology and disease states. In these areas he has published over 600 peer-reviewed articles and reviews in high profile journals. He is also the senior editor of a textbook on diabetes, now in its third edition, and has edited books on IGFs. Professor LeRoith has made major contributions in our understanding of the basic pathophysiology of type 2 diabetes and also the role of the IGFs in various disorders, especially in cancer, and is considered a worldwide expert on these topics. In recognition of his contributions he has received many lecturing positions worldwide and has been the plenary speaker at numerous national and international symposia. He is the editor of a number of diabetes- and growth factor-related journals, has been on the advisory boards of a number of companies and co-chairs two national committees involved in the education of endocrinologist and primary care physicians.

Professor Ele Ferrannini, MD, joined the Oramed Scientific Advisory Board in February 2007. He is a past President to the, European Association for the Study of Diabetes, which supports scientists, physicians and students from all over the world who are interested in diabetes and related subjects in Europe, and performs functions similar to that of the ADA in the United States. Professor Ferrannini has worked with various institutions including the Department of Internal Medicine, University of Pisa School of Medicine, and CNR (National Research Council) Institute of Clinical Physiology, Pisa, Italy; and the Diabetes Division, Department of Medicine, University of Texas Health Science Center at San Antonio, Texas. He has also had extensive training in internal medicine and endocrinology, and has specialized in diabetes studies. Professor Ferrannini has received a Certificate of the Educational Council for Foreign Medical Graduates from the University of Bologna, and with cum laude honors completed a subspecialty in Diabetes and Metabolic Diseases at the University of Torino. He has published over 500 original papers and 50 book chapters and he is a “highly cited researcher,” according to the Institute for Scientific Information.

Professor Nir Barzilai, MD, joined the Oramed Scientific Advisory Board in January 2007. He is the Director of the Institute for Aging Research at the Albert Einstein College of Medicine, New York and the Director of the Nathan Shock Center of Excellence for the Biology of Aging and the Glenn Center for the Biology of Human Aging. He currently holds the Rennert Chair (cathedra) for Aging Research, and is a Professor in the Department of Medicine and Molecular Genetics. He is a member of the Einstein Diabetes Research Center and is a member of the Divisions of Endocrinology and Geriatrics. His interests focus on several basic mechanisms in the biology of aging, including the metabolic deterioration of aging and the genetic determinants of life span. He established several cohorts of families of centenarians and has identified several longevity genes. Professor Barzilai has been the recipient of numerous prestigious awards, including the Beeson Fellow for Aging Research, the Senior Ellison Foundation Award, the Paul Glenn Foundation Award, the NIA- Nathan Shock Award, the 2010 Irving S. Wright Award of Distinction in Aging Research Award and the Rifkin Lectureship for Diabetes. Professor Barzilai has had a strong career in diabetes studies in Israel, London and the United States. He has worked for such esteemed institutions as Hadassah Research Hospital, NIH, and many esteemed U.S. based university hospitals, including Cornell and Yale.

Dr. John Amatruda, MD, joined the Oramed Scientific Advisory Board in February 2010. He graduated from Yale University, received his MD degree from the Medical College of Wisconsin and did his internship and residency in Internal Medicine and Fellowship in Endocrinology and Metabolism at The Johns Hopkins Hospital. He is board certified in Internal Medicine and Endocrinology and Metabolism. From 1977 to 1992, Dr. Amatruda was at The University of Rochester School of Medicine, where he was a Professor of Medicine, head of the Clinical Research Center, fully funded as principle investigator on two NIH grants, and acting Head of the Endocrine Metabolism Unit. In 1992 Dr. Amatruda left the University of Rochester to start and run a drug discovery group at Bayer Corp. where he

served as Vice President and Therapeutic Area Research Head, as well as a Professor of Medicine Adjunct at Yale University School of Medicine. He assisted in the approval of Acarbose, an anti-diabetic drug distributed by Bayer AG used to treat type 2 diabetes, and his group put several compounds into clinical development including the first glucagon receptor antagonist. From 2002 to 2009, Dr. Amatruda held various positions at Merck & Co. Inc., including Vice President, Clinical Research, Metabolism and Atherosclerosis and acting Therapeutic Area head for Cardiovascular. These groups filed NDAs for the drugs Vytorin, Januvia and Janumet. Most recently Dr. Amatruda was Senior Vice President and Franchise Head for Diabetes and Obesity and a member of the Research Management Committee at Merck. Dr. Amatruda is an author of over 150 papers, abstracts, reviews and book chapters, primarily in the areas of insulin action in vitro systems and in clinical diabetes and obesity. He is currently a consultant and an Adjunct Professor of Medicine at Columbia University.

## Employees

We have been successful in retaining experienced personnel involved in our research and development program. In addition, we believe we have successfully recruited the clinical/regulatory, quality assurance and other personnel needed to advance through clinical studies or have engaged the services of experts in the field for these requirements. As of August 31, 2014, we have contracted with ten individuals for employment or consulting arrangements. Of our staff, four are senior management, three are engaged in research and development work, and the remaining three are involved in administration work.

## Additional Information

Additional information about us is contained on our Internet website at [www.oramed.com](http://www.oramed.com). Information on our website is not incorporated by reference into this report. Under the “Investors”, under the “SEC Filings” section of our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our reports filed with the Securities and Exchange Commission, or SEC, are also made available to read and copy at the SEC’s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. You may obtain information about the Public Reference Room by calling the SEC at 1-800-SEC-0330. Reports filed with the SEC are also made available on its website at [www.sec.gov](http://www.sec.gov). The following Corporate Governance documents are also posted on our website: Code of Ethics and the Charters for each of the Audit Committee and Compensation Committee of our Board of Directors.

## ITEM 1A.

## RISK FACTORS.

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this Annual Report on Form 10-K before making an investment decision. Our business, prospects, financial condition, and results of operations may be materially and adversely affected as a result of any of the following risks. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in “Item 1A. Risk Factors” are forward-looking statements. The following risk factors are not the only risk factors facing our Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

### Risks Related to Our Business

We continue and expect to incur losses in the future.

Successful completion of our development programs and our transition to normal operations are dependent upon obtaining necessary regulatory approvals from the FDA prior to selling our products within the United States, and foreign regulatory approvals must be obtained to sell our products internationally. There can be no assurance that we will receive regulatory approval of any of our product candidates, and a substantial amount of time may pass before we achieve a level of revenues adequate to support our operations, if at all. We also expect to incur substantial expenditures in connection with the regulatory approval process for each of our product candidates during their respective developmental periods. Obtaining marketing approval will be directly dependent on our ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. We cannot predict the outcome of these activities.

Based on our current cash resources and commitments, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months and beyond, although no assurance can be given that we will not need additional funds prior to such time. If there are unexpected increases in our operating expenses, we may need to seek additional financing during the next 12 months.

We will need substantial additional capital in order to satisfy our business objectives.

To date, we have financed our operations principally through offerings of securities exempt from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for at least the next 12 months from the date of this Annual Report on Form 10-K. We will require substantial additional financing at various intervals in order to continue our research and development programs, including significant requirements for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals, and for commercialization of our products. We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. In the event that we are unable to obtain such financing, we will not be able to fully develop and commercialize our technology. Our future capital requirements will depend upon many factors, including:

- Continued scientific progress in our research and development programs,
- Costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions,
  - Competing technological and market developments,
  - Our ability to establish additional collaborative relationships, and
- Effects of commercialization activities and facility expansions if and as required.

If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize ourselves. In such event, our business, prospects, financial condition, and results of operations may be adversely affected as we may be required to scale-back, eliminate, or delay development efforts or product introductions or enter into royalty, sales or other agreements with third parties in order to commercialize our products.

We have a history of losses and can provide no assurance as to our future operating results.

We have no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which could generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of August 31, 2014, August 31, 2013 and August 31, 2012, we had working capital of \$20,805,000, \$8,146,000 and \$4,632,000, respectively, and stockholders' equity of \$20,793,000, \$8,131,000 and \$3,778,000, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through August 31, 2014, the year ended August 31, 2012, the year ended August 31, 2013 and the year ended August 31, 2014, we incurred net losses of \$27,820,000, \$3,344,000, \$4,232,000 and \$5,696,000, respectively. We may never achieve profitability and expect to incur net losses in the foreseeable future. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

We rely upon patents to protect our technology.

The patent position of biopharmaceutical and biotechnology firms is generally uncertain and involves complex legal and factual questions. We do not know whether any of our current or future patent applications will result in the issuance of any patents. Even issued patents may be challenged, invalidated or circumvented. Patents may not provide

a competitive advantage or afford protection against competitors with similar technology. Competitors or potential competitors may have filed applications for, or may have received patents and may obtain additional and proprietary rights to compounds or processes used by or competitive with ours. In addition, laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

Patent litigation is becoming widespread in the biopharmaceutical and biotechnology industry and we cannot predict how this will affect our efforts to form strategic alliances, conduct clinical testing or manufacture and market any products under development. If challenged, our patents may not be held valid. We could also become involved in interference proceedings in connection with one or more of our patents or patent applications to determine priority of invention. If we become involved in any litigation, interference or other administrative proceedings, we will likely incur substantial expenses and the efforts of our technical and management personnel will be significantly diverted. In addition, an adverse determination could subject us to significant liabilities or require us to seek licenses that may not be available on favorable terms, if at all. We may be restricted or prevented from manufacturing and selling our products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses.

We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies. We currently hold several pending patent applications in the United States for our technologies covering oral administration of insulin and other proteins and oral administration of exenatides and proteins, corresponding patent applications filed in Canada, Europe, Japan, China, Russia, Israel, Brazil, Australia, South Africa, New Zealand, Hong Kong and India and 24 patents issued by the Australian, Canadian, Chinese, Israeli, Japanese, New Zealand, South African, Russian, Hong Kong, Swiss, German, Spanish, French, United Kingdom, Italy and the Netherlands (for our technologies covering oral administration of insulin and other proteins) and New Zealand, South African, Australian and Israeli (for our technologies covering oral administration of insulin and other proteins and oral administration of exenatides) patent offices. Further, we intend to rely on a combination of trade secrets and non-disclosure and other contractual agreements and technical measures to protect our rights in our technology. We intend to depend upon confidentiality agreements with our officers, directors, employees, consultants, and subcontractors, as well as collaborative partners, to maintain the proprietary nature of our technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid our confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. We believe that our technology is not subject to any infringement actions based upon the patents of any third parties; however, our technology may in the future be found to infringe upon the rights of others. Others may assert infringement claims against us, and if we should be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on terms acceptable to us, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition, and results of operations.

Our commercial success will also depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Patent applications are, in many cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications are filed. In the event of infringement or violation of another party's patent, we may be prevented from pursuing product development or commercialization. See "Item 1. Business—Description of Business—Patents and Licenses."

At present, our success depends primarily on the successful commercialization of our oral insulin capsule.

The successful commercialization of oral insulin capsule is crucial for our success. At present, our principal product is the oral insulin capsule. Our oral insulin capsule is in a very early stage of clinical development and faces a variety of risks and uncertainties. Principally, these risks include the following:

- Future clinical trial results may show that the oral insulin capsule is not well tolerated by recipients at its effective doses or is not efficacious as compared to placebo,
- Future clinical trial results may be inconsistent with previous preliminary testing results and data from our earlier studies may be inconsistent with clinical data,
- Even if our oral insulin capsule is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices,





- Our ability to complete the development and commercialization of the oral insulin capsule for our intended use is significantly dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, the oral insulin capsule on a worldwide basis,
- Even if our oral insulin capsule is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance of our product, and
- Our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues.

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully commercialize our oral insulin capsule for some other reason, it would likely seriously harm our business.

We have limited experience in conducting clinical trials.

Clinical trials must meet FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We have entered into agreements with Integrium- to assist us in designing, conducting and managing our various clinical trials in the United States, as more fully described in “Item 1. Business—Description of Business—Partnerships and Collaborative Agreements”. Any failure of Integrium or any other consultant to fulfill their obligations could result in significant additional costs as well as delays in designing, consulting and completing clinical trials on our products.

Our clinical trials may encounter delays, suspensions or other problems.

We may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks or if we or they find deficiencies in the clinical trial process or conduct of the investigation. If clinical trials of any of the product candidates fail, we will not be able to market the product candidate which is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials, which would result in increased costs and significant development delays. Our failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development could delay or prevent regulatory approval of the product candidate and could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We can provide no assurance that our products will obtain regulatory approval or that the results of clinical studies will be favorable.

The testing, marketing and manufacturing of any of our products will require the approval of the FDA or regulatory agencies of other countries. We have completed certain non-FDA clinical trials and pre-clinical trials for our products. In addition, we have completed Phase IIa clinical trials of ORMD-0801 in patients with both type 1 and type 2 diabetes under an IND with the FDA, and we anticipate the initiation of Phase IIb clinical trials in patients with type 2 diabetes under IND with the FDA in the first quarter of calendar year 2015. However, success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, a number of

companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials.

We cannot predict with any certainty the amount of time necessary to obtain regulatory approvals, including from the FDA or other foreign regulatory authorities, and whether any such approvals will ultimately be granted. In any event, review and approval by the regulatory bodies is anticipated to take a number of years. Preclinical and clinical trials may reveal that one or more of our products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require the testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition, and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event we may be required to withdraw such product from the market. See "Item 1. Business—Description of Business—Government Regulation."

We are dependent upon third party suppliers of our raw materials.

We are dependent on outside vendors for our entire supply of the oral insulin capsule and do not currently have any long-term agreements in place for the supply of oral insulin capsules. While we believe that there are numerous sources of supply available, if the third party suppliers were to cease production or otherwise fail to supply us with quality raw materials in sufficient quantities on a timely basis and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct testing and clinical trials would be materially adversely affected.

We are highly dependent upon our ability to enter into agreements with collaborative partners to develop, commercialize, and market our products.

Our long-term strategy is to ultimately seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) and sales and marketing of our oral insulin capsule and other products. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere.

While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. We currently lack the resources to manufacture any of our product candidates on a large scale and we have no sales, marketing or distribution capabilities. In the event we are not able to enter into a collaborative agreement with a partner or partners, on commercially reasonable terms, or at all, we may be unable to commercialize our products, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. These industries are highly competitive, and this competition comes both from biotechnology firms and from major pharmaceutical and chemical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products).

We also experience competition in the development of our products from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our products may be subject to competition from products developed using other technologies. See “Item 1. Business—Description of Business—Competition.”

We have limited senior management resources and may be required to obtain more resources to manage our growth.

We expect the expansion of our business to place a significant strain on our limited managerial, operational, and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train, and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition, and results of operations. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human, and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition, and results of operations will be materially adversely affected. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Item 1. Business—Description of Business—Strategy” and “—Employees.”

We depend upon our senior management and skilled personnel and their loss or unavailability could put us at a competitive disadvantage.

We currently depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants and other key personnel, including Dr. Miriam Kidron, our Chief Medical and Technology Officer. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition, and results of operations. We do not maintain “key man” life insurance policies for any of our senior executives. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. There is currently a shortage of employees with expertise in developing, manufacturing and commercialization of products and related clinical and regulatory affairs, and this shortage is likely to continue. Competition for skilled personnel is intense and turnover rates are high. Our ability to attract and retain qualified personnel may be limited. Our inability to attract and retain qualified skilled personnel would have a material adverse effect on our business, prospects, financial condition, and results of operations.

Healthcare policy changes, including pending legislation recently adopted and further proposals still pending to reform the U.S. healthcare system, may harm our future business.

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators and third-party payors to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for the products that we are developing, or the amounts of reimbursement available for these products from governmental agencies or third-party payors. These limitations could in turn reduce the amount of revenues that we will be able to generate in the future from sales of our products and licenses of our technology.

In March 2010, the U.S. Congress enacted and President Obama signed into law healthcare reform legislation that may significantly impact the pharmaceutical industry. In addition to requiring most individuals to have health insurance and establishing new regulations on health plans, this legislation will require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the legislation imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the legislation on our business is unclear and there can be no assurance that our business will not be materially adversely affected. In addition, these and other ongoing initiatives in the United States have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product that we may successfully develop.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government’s role in the U.S. healthcare industry may lower the future revenues for the products we are developing and adversely affect our future business, possibly materially.

We are exposed to fluctuations in currency exchange rates.

A considerable amount of our expenses are generated in dollars or in dollar-linked currencies, but a significant portion of our expenses such as some clinical studies and payroll costs are generated in other currencies such as NIS, Euro and British pounds. Most of the time, our non-dollar assets are not totally offset by non-dollar liabilities. Due to the foregoing and to the fact that our financial results are measured in dollars, our results could be adversely affected as a result of a strengthening or weakening of the dollar compared to these other currencies. During fiscal 2011, 2013 and 2014, the dollar depreciated in relation to the NIS, which raised the dollar cost of our Israeli based operations and

adversely affected our financial results, while during fiscal 2010 and 2012 the dollar increased in relation to the NIS, which reduced the dollar cost of our Israeli based operations costs. In addition, our results could also be adversely affected if we are unable to guard against currency fluctuations in the future. Although we may in the future decide to undertake foreign exchange hedging transactions to cover a portion of our foreign currency exchange exposure, we currently do not hedge our exposure to foreign currency exchange risks. These transactions, however, may not adequately protect us from future currency fluctuations and, even if they do protect us, may involve operational or financing costs we would not otherwise incur.

## Risks Related to our Common Stock

As the market price of our common stock may fluctuate significantly, this may make it difficult for you to sell your shares of common stock when you want or at prices you find attractive.

The price of our common stock is currently listed on The Nasdaq Capital Market, or Nasdaq, and constantly changes. In recent years, the stock market in general has experienced extreme price and volume fluctuations. We expect that the market price of our common stock will continue to fluctuate. These fluctuations may result from a variety of factors, many of which are beyond our control. These factors include:

- Clinical trial results and the timing of the release of such results,
- The amount of cash resources and our ability to obtain additional funding,
- Announcements of research activities, business developments, technological innovations or new products by us or our competitors,
  - Entering into or terminating strategic relationships,
  - Changes in government regulation,
  - Departure of key personnel,
  - Disputes concerning patents or proprietary rights,
  - Changes in expense level,
  - Future sales of our equity or equity-related securities,
  - Public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
    - Activities of various interest groups or organizations,
      - Media coverage, and
      - Status of the investment markets.

Future sales of common stock or the issuance of securities senior to our common stock or convertible into, or exchangeable or exercisable for, our common stock could materially adversely affect the trading price of our common stock, and our ability to raise funds in new equity offerings.

Future sales of substantial amounts of our common stock or other equity-related securities in the public market or privately, or the perception that such sales could occur, could adversely affect prevailing trading prices of our common stock and could impair our ability to raise capital through future offerings of equity or other equity-related securities. We anticipate that we will need to raise capital through offerings of equity and equity related securities. We can make no prediction as to the effect, if any, that future sales of shares of our common stock or equity-related securities, or the availability of shares of common stock for future sale, will have on the trading price of our common stock.

Our stockholders may experience significant dilution as a result of any additional financing using our equity securities.

To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Sale of additional equity securities at prices below certain levels may trigger anti-dilution provisions with respect to certain securities we have previously sold.

18

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Future sales of our common stock by our existing stockholders could adversely affect our stock price.

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of November 12, 2014, we had outstanding 10,106,305 shares of common stock, a large majority of which are freely tradeable. Giving effect to the exercise in full of all of our outstanding warrants and options, including those currently unexercisable, we would have outstanding 12,030,746 shares of common stock.

Our issuance of warrants and options to investors, employees and consultants may have a negative effect on the trading prices of our common stock as well as a dilutive effect.

We have issued and may continue to issue warrants, options and convertible notes at, above or below the current market price. As of August 31, 2014, we had outstanding warrants and options exercisable for 1,924,491 shares of common stock at a weighted average exercise price of \$5.99. In addition to the dilutive effect of a large number of shares of common stock and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares of common stock may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.

Delaware law could discourage a change in control, or an acquisition of us by a third party, even if the acquisition would be favorable to you, and thereby adversely affect existing stockholders.

The Delaware General Corporation Law contains provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our Company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with “interested stockholders.” These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares of common stock over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

Because we will not pay cash dividends, investors may have to sell shares of our common stock in order to realize their investment.

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements which we may enter into with institutional lenders or otherwise may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our Board and will be dependent upon our financial condition, results of operations, capital requirements, and any other factors that our Board decides is relevant. See “Item 5. Market Price for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.”

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of November 12, 2014, our directors, executive officers and principal affiliated stockholders beneficially own approximately 13.2% of our outstanding shares of common stock, excluding shares issuable upon the exercise of options and warrants. As a result, these stockholders, should they act together, may have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, should they act together,

may have the ability to control our management and affairs. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- Delaying, deferring or preventing a change in corporate control,
- Impeding a merger, consolidation, takeover or other business combination involving us, or
- Discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

## Risks Related to Conducting Business in Israel

We are affected by the political, economic, and military risks of locating our principal operations in Israel.

Our operations are located in the State of Israel, and we are directly affected by political, economic, and security conditions in that country. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. In addition, acts of terrorism, armed conflicts or political instability in the region could negatively affect local business conditions and harm our results of operations. We cannot predict the effect on the region of any diplomatic initiatives or political developments involving Israel or the Palestinians or other countries and territories in the Middle East. Recent political events, including political uprisings, social unrest and regime change, in various countries in the Middle East and North Africa have weakened the stability of those countries and territories, which could result in extremists coming to power. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. This situation has escalated in the past and may potentially escalate in the future to violent events which may affect Israel and us. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

All adult male permanent residents of Israel, unless exempt, may be required to perform military reserve duty annually. Additionally, all such residents are subject to being called to active duty at any time under emergency circumstances. Some of our officers, directors, and employees currently are obligated to perform annual military reserve duty. We can provide no assurance that such requirements will not have a material adverse effect on our business, prospects, financial condition, and results of operations in the future, particularly if emergency circumstances occur.

Because we received grants from the Israeli Office of the Chief Scientist, we are subject to ongoing restrictions.

We received royalty-bearing grants from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the OCS, for research and development programs that meet specified criteria. We recognized grants in the amounts of \$373,000, \$297,000 and \$428,000 in the years ended August 31, 2012, 2013, 2014, respectively. Due to reductions of the budget of the OCS, the amount of grants we receive from the Israeli government in the future might be lower than in prior years, if we receive any at all. The terms of the OCS grants limit our ability to transfer know-how developed under an approved research and development program outside of Israel, regardless of whether the royalties were fully paid.

It may be difficult to enforce a U.S. judgment against us or our officers and directors and to assert U.S. securities laws claims in Israel.

Almost all of our directors and officers are nationals and/or residents of countries other than the United States. As a result, service of process upon us, our Israeli subsidiary and our directors and officers, may be difficult to obtain within the United States. Furthermore, because the majority of our assets and investments, and most of our directors and officers are located outside the United States, it may be difficult for investors to enforce within the United States any judgments obtained against us or any such officers or directors. Additionally, it may be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to such claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

Subject to specified time limitations and legal procedures, under the rules of private international law currently prevailing in Israel, Israeli courts may enforce a U.S. judgment in a civil matter, including a judgment based upon the civil liability provisions of the U.S. securities laws, as well as a monetary or compensatory judgment in a non-civil matter, provided that the following key conditions are met:

- subject to limited exceptions, the judgment is final and non-appealable;

- the judgment was given by a court competent under the laws of the state in which the court is located and is otherwise enforceable in such state;
- the judgment was rendered by a court competent under the rules of private international law applicable in Israel;
- the laws of the state in which the judgment was given provides for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to present his arguments and evidence;
- the judgment and its enforcement are not contrary to the law, public policy, security or sovereignty of the State of Israel;
- the judgment was not obtained by fraud and does not conflict with any other valid judgment in the same matter between the same parties; and
- an action between the same parties in the same matter was not pending in any Israeli court at the time the lawsuit was instituted in the U.S. court.

If any of these conditions are not met, Israeli courts will likely not enforce the applicable U.S. judgment.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

#### ITEM 2. PROPERTIES.

Our principal executive offices are comprised of approximately 168 square meters of leased office space in Givat-Ram, Jerusalem, Israel. The current lease term is from November 4, 2013 until November 3, 2016. The aggregate annual base rent for this space is currently \$25,000, and is linked to the increase in the Israeli consumer price index. We believe that our existing facilities are suitable and adequate to meet our current business requirements. In the event that we should require additional or alternative facilities, we believe that such facilities can be obtained on short notice at competitive rates.

As security for our obligations under the lease agreement, we have provided a bank guarantee in an amount equal to three monthly lease payments, valid until November 30, 2016.

#### ITEM 3. LEGAL PROCEEDINGS.

From time to time we may become subject to litigation incidental to our business. We are not currently a party to any material legal proceedings.

#### ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

## Market Price for our Common Stock

On February 11, 2013, our common stock began trading on Nasdaq under the symbol "ORMP." Until then it was quoted on the OTCQB under the same symbol. The quarterly high and low reported bid prices for our common stock as quoted on the OTCQB or the high and low sales price on Nasdaq, as applicable, for the periods indicated are as follows:

	High	Low
Year Ended August 31, 2013		
Three Months Ended November 30, 2012	\$3.96	\$3.12
Three Months Ended February 28, 2013	\$9.61	\$3.60
Three Months Ended May 31, 2013	\$10.68	\$6.10
Three Months Ended August 31, 2013	\$9.35	\$5.00
Year Ended August 31, 2014		
Three Months Ended November 30, 2013	\$11.49	\$7.31
Three Months Ended February 28, 2014	\$15.95	\$6.72
Three Months Ended May 31, 2014	\$31.73	\$6.83
Three Months Ended August 31, 2014	\$8.64	\$6.12

The foregoing quotations for periods prior to February 11, 2013 were provided by Yahoo! Finance and the quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

The last reported sale price per share of common stock as quoted on Nasdaq was \$7.14 on November 12, 2014.

## Holders

As of November 12, 2014, there were 10,106,305 shares of our common stock issued and outstanding held of record by approximately 60 registered stockholders. We believe that a significant number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories and are therefore not included in the number of stockholders of record.

## Dividend Policy

We have never paid any cash dividends on our capital stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of our Board and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our Board deems relevant.

## Unregistered Sales of Equity Securities and Use of Proceeds

On August 1, 2014, we issued 142,814 shares of our common stock upon exercise of a warrant previously issued in 2007 to one of our founders for an aggregate exercise price of \$2,000.

On August 31, 2014, we issued 3,750 shares of our common stock, valued at \$38,000, in the aggregate, to a service provider as remuneration for services provided.

These issuances and sales were exempt under Section 4(a)(2) of the Securities Act.

### Comparative Stock Performance Graph

The following graph shows how an initial investment of \$100 in our common stock would have compared to an equal investment in the Nasdaq Composite Index and the NASDAQ Biotechnology Index during the period from September 1, 2009 through August 31, 2014. The performance shown is not necessarily indicative of future price performance.

### ITEM 6. SELECTED FINANCIAL DATA.

The selected data presented below under the captions “Statements of Operations Data,” “Statements of Cash Flows Data” and “Balance Sheet Data” for, and as of the end of, each of the fiscal years in the five-year period ended August 31, 2014, are derived from, and should be read in conjunction with, our audited consolidated financial statements.



The selected information contained in this table should also be read in conjunction with “Management's Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the years ended August 31, 2014, 2013 and 2012 and the selected consolidated balance sheet data as of August 31, 2014 and 2013, are derived from the audited consolidated financial statements included elsewhere in this Annual Report. The statement of operations data for the years ended August 31, 2011 and 2010 and the balance sheet data as of August 31, 2012, 2011 and 2010 are derived from audited financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	2014	2013	2012	2011	2010
	in thousands of dollars except share and per share data				
<b>Statements of Comprehensive Income</b>					
<b>(Loss):</b>					
Research and development expenses, net	\$ 3,277	\$ 2,272	\$ 1,681	\$ 1,159	\$ 1,464
General and administrative expenses	2,629	2,032	1,203	1,276	1,508
Impairment of available- for-sale securities	-	-	184	197	-
Gain on sale of investment	-	-	-	(1,033)	-
Financial expenses (income), net	(214)	133	186	(14)	(10)
Loss before taxes on income	5,692	4,437	3,254	1,585	2,962
Taxes on income (Tax benefit)	4	(205)	90	(24)	15
Net loss for the period	\$ 5,696	\$ 4,232	\$ 3,344	\$ 1,561	\$ 2,977
Loss per common share – basic and diluted	\$ 0.62	\$ 0.59	\$ 0.57	\$ 0.29	\$ 0.62
<b>Weighted average common shares</b>					
outstanding	9,244,059	7,209,283	5,884,595	5,417,278	4,782,499

	As of August 31				
	2014	2013	2012	2011	2010
	in thousands of dollars except share and per share data				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, short-term deposits, restricted cash and marketable securities	\$ 21,306	\$ 8,491	\$ 5,101	\$ 3,716	\$ 1,317
Other current assets	472	153	175	568	81
Long-term assets	24	16	19	42	53
Total assets	21,802	8,660	5,295	4,326	1,451
Current liabilities	973	498	644	441	459
Long-term liabilities	36	31	873	161	162
Stockholders' equity	20,793	8,131	3,778	3,724	830

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes included elsewhere herein and in our consolidated financial statements.

In addition to our consolidated financial statements, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in "Cautionary Statement Regarding Forward-Looking Statements" and "Item 1A. Risk Factors."

### Overview of Operations

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills for delivery of other polypeptides.

**Oral Insulin:** We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD-0801). Having completed Phase IIa clinical trials in patients with both type 1 and type 2 diabetes, we anticipate the initiation of Phase IIb clinical trials in patients with type 2 diabetes under an IND with the FDA, in the fourth quarter of calendar year 2014.

**GLP-1 Analog:** Our second pipeline product (ORMD-0901) is an orally ingestible exenatide (GLP-1 analog) capsule, which aids in the balance of blood-sugar levels and decreases appetite. In January 2013, we began a clinical trial for our oral exenatide capsule on healthy volunteers and type 2 diabetic patients. Based on this study, we decided make slight adjustments in the manufacturing of these capsules and have begun toxicology studies on the new capsules. In parallel to the toxicology studies we intend on initiating a follow-on clinical trial in the first quarter of calendar year 2015. In September 2013, we submitted a pre-IND, package to the FDA for ORMD-0901, our oral exenatide capsule, for a Phase II clinical trial on healthy volunteers and type 2 diabetic patients. We expect to begin non-U.S. based Phase Ia and Ib trials and IND-enabling studies in the firstquarter of calendar year 2015.

**Combination of Oral Insulin and GLP-1 Analog:** Our third pipeline product is a combination of our two primary products, oral insulin and oral exenatide. In February 2013, we commenced a first human clinical trial on type 2 diabetic volunteers with our oral insulin capsule delivered in combination with our oral exenatide capsule. In the near term, we are focusing our efforts on the development of the Company's flagship products, oral insulin and oral exenatide. Once these two products have progressed further in clinical trials, we intend on running further studies with the oral combination therapy.

### Results of Operations

#### Critical accounting policies

Our significant accounting policies are more fully described in the notes to our accompanying consolidated financial statements. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Valuation of options and warrants: We grant options to purchase shares of our common stock to employees and consultants and issue warrants in connection with some of our financings and to certain other consultants.

We account for share-based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is based on the Black Scholes option-pricing model and is recognized as an expense over the requisite service period, net of estimated– forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the options granted is measured on each reporting date, and the gains (losses) are recorded to earnings over the related service period using the straight-line method.

Valuation of warrants issued as part of capital raisings that are classified as a liability: Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the statement of financial position. The liability is measured both initially and in subsequent periods in fair value, with changes in fair value are charged to finance expenses, net.

The fair value of the warrants is determined by using Monte Carlo type model based on the risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issue dates, then for each path to use the Black-Scholes model to estimate the value of the warrants on the last issue date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant delay in this input would result in a higher fair value measurement.

Taxes on income: Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence and the Company's clinical program, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to our deferred tax assets.

Regarding our subsidiary, Oramed Ltd., relevant accounting guidance prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the above-mentioned differences were not reflected in the computation of deferred tax assets and liabilities.

Uncertainty in income tax: We follow a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. Our policy is to include interest and penalties related to unrecognized tax benefits within income tax expenses.



## Comparison of Fiscal 2014 to Fiscal 2013 and Fiscal 2013 to Fiscal 2012

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2014, 2013 and 2012:

Operating Data:	Year ended August 31,		
	2014	2013	2012
Research and development expenses, net	\$3,277	\$2,272	\$1,681
General and administrative expenses	2,629	2,032	1,203
Impairment of available- for-sale securities	--	--	184
Financial expenses (income), net	(214 )	133	186
Loss before taxes on income	5,692	4,437	3,254
Taxes on income (Tax benefit)	4	(205 )	90
Net loss for the period	5,696	4,232	3,344
Loss per common share – basic and diluted	\$0.62	\$0.59	\$0.57
Weighted average common shares outstanding	9,244,059	7,209,283	5,884,595

## Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, supplies, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

Clinical trial and pre-clinical trial expenses include regulatory and scientific consultants' compensation and fees, research expenses, purchase of materials, cost of manufacturing of the oral insulin capsules and payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

In August 2009, Oramed Ltd. was awarded a government grant amounting to a total net amount of NIS 3.1 million (approximately \$813,000), from the OCS. This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and oral GLP-1-analog. In December 2010, Oramed Ltd. was awarded a second grant, or the Second Grant, amounting to a total net amount of NIS 2.9 million (approximately \$720,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to November 2011. As a result of a delay in the research and development plan, as of November 30, 2011, Oramed Ltd. had used only NIS 1,473,000 (approximately \$365,000) of the Second Grant. In May 2012, Oramed Ltd. was awarded an extension of

nine months to use the funds of the Second Grant until August 2012. In addition, in May 2012, Oramed Ltd. was granted a third grant amounting to a total net amount of NIS 595,000 (approximately \$148,000) from the OCS, which was designated for research and development expenses for the period of September 2012 to December 2012. In May 2013, Oramed Ltd. was awarded a fourth grant amounting to a total net amount of NIS 975,000 (approximately \$265,000) from the OCS, which was designated for research and development expenses for the period of January 2013 to December 2013. In March 2014, the OCS accepted Oramed Ltd.'s application to shorten that period to ten months, due to the rapid utilization of the grant, ending October 31, 2013. In March 2014, Oramed Ltd. was also granted a fifth grant amounting to a total amount of NIS 1,206,990 (approximately \$345,000) from the OCS, which was designated for research and development expenses for the period of November 2013 to October 2014. In September 2014, this period was extended in two months until December 2014. We used the funds to support further research and development and clinical studies of our oral insulin capsule and oral GLP-1 analog. The five grants are subject to repayment according to the terms determined by the OCS and applicable law. See “—Government grants” below.

Research and development expenses, for the year ended August 31, 2014 increased by 44% to \$3,277,000 from \$2,272,000 for the year ended August 31, 2013. The increase is attributed to expenses related to clinical trials, as well as to the increase in research and development staff and to cash bonuses to research and development staff for the Company's 2013 achievements, as well as to the increase in stock based compensation costs, which is attributed to awards granted to officers and directors in April 2014. During the year ended August 31, 2014, stock based compensation costs totaled \$905,000, as compared to \$347,000 during the year ended August 31, 2013.

Research and development expenses for the year ended August 31, 2013 increased by 35% to \$2,272,000 from \$1,681,000 for the year ended August 31, 2012. The increase is mainly attributed to expenses related to clinical trials as well as to the increase in stock based compensation costs. The research and development costs include stock based compensation costs, which during the year ended August 31, 2013 totaled \$347,000, as compared to \$99,000 during the year ended August 31, 2012. The increase is mainly attributable to the options granted to employees and directors of the company in August 2012.

#### Government grants

The Government of Israel encourages research and development projects through the OCS, pursuant to the Law for the Encouragement of Industrial Research and Development, 1984, as amended, or the R&D Law. Under the R&D Law, a research and development plan that meets specified criteria is eligible for a grant of up to 50% of certain approved research and development expenditures. Each plan must be approved by the OCS.

In the years ended August 31, 2014, 2013 and 2012, we recognized research and development grants in an amount of \$428,000, \$297,000 and \$373,000, respectively. As of August 31, 2014, we had no contingent liabilities to the OCS.

Under the terms of the grants we received from the OCS, we are obligated to pay royalties of 3% to 3.5% on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licensed ancillary services. Pursuant to a proposed amendment to the R&D Law, our royalty rate may be 3% to 6% per annum. Royalties are payable up to 100% of the amount of such grants, or up to 300% as detailed below, linked to the U.S. Dollar, plus annual interest at LIBOR.

The R&D Law generally requires that a product developed under a program be manufactured in Israel. However, upon notification to the OCS (and provided that the OCS does not object within 30 days), up to 10% of a company's approved Israeli manufacturing volume, measured on an aggregate basis, may be transferred outside of Israel. In addition, upon the approval of the OCS, a greater portion of the manufacturing volume may be performed outside of Israel, provided that the grant recipient pays royalties at an increased rate, which may be substantial, and the aggregate repayment amount is increased up to 300% of the grant, depending on the portion of the total manufacturing volume that is performed outside of Israel. The R&D Law further permits the OCS, among other things, to approve the transfer of manufacturing rights outside of Israel in exchange for an import of different manufacturing into Israel as a substitute, in lieu of the increased royalties. The R&D Law also allows for the approval of grants in cases in which the applicant declares that part of the manufacturing will be performed outside of Israel or by non-Israeli residents and an OCS research committee is convinced that doing so is essential for the execution of the program. This declaration will be a significant factor in the determination of the OCS as to whether to approve a program and the amount and other terms of benefits to be granted. For example, an increased royalty rate and repayment amount might be required in such cases.

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred to third parties in Israel without the approval of the research committee. Such approval is not required for the sale or export of any products resulting from such research or development. The R&D Law further provides that the know-how developed under an approved research and development program may not be transferred



to any third parties outside Israel absent OCS approval which may be granted under special circumstances such as those noted in the following cases: (a) the grant recipient pays to the OCS a portion of the sale price paid in consideration for such OCS-funded know-how or the price paid in consideration for the sale of the grant recipient itself, as the case may be (according to certain formulas; the portion to be paid in respect of a sale of the grant recipient itself changed under the applicable rules that came into effect in November 2012); (b) the grant recipient receives know-how from a third party in exchange for its OCS-funded know-how; or (c) such transfer of OCS-funded know-how arises in connection with certain types of cooperation in research and development activities.

The R&D Law imposes reporting requirements with respect to certain changes in the ownership of a grant recipient. The R&D Law requires the grant recipient and its controlling shareholders and foreign interested parties to notify the OCS of any change in control of the recipient or a change in the holdings of the means of control of the recipient that results in a non-Israeli becoming an interested party in the recipient, and requires the new interested party to undertake to the OCS to comply with the R&D Law. In addition, the rules of the OCS may require additional information or representations in respect of certain such events. For this purpose, “control” is defined as the ability to direct the activities of a company other than any ability arising solely from serving as an officer or director of the company. A person is presumed to have control if such person holds 50% or more of the means of control of a company. “Means of control” refers to voting rights or the right to appoint directors or the chief executive officer. An “interested party” of a company includes a holder of 5% or more of its outstanding share capital or voting rights, its chief executive officer and directors, someone who has the right to appoint its chief executive officer or at least one director, and a company with respect to which any of the foregoing interested parties owns 25% or more of the outstanding share capital or voting rights or has the right to appoint 25% or more of the directors.

Failure to meet the R&D Law’s requirements may subject us to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings. In addition, the Israeli government may from time to time audit sales of products which it claims incorporate technology funded through OCS programs which may lead to additional royalties being payable on additional products.

#### Grants from Bio-Jerusalem

The Bio-Jerusalem fund was founded by the Jerusalem Development Authority in order to support the biomed industry in Jerusalem. We are committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grants received by the Company (Israeli CPI linked) in the total aggregate amount of \$65,000 as of August 31, 2014. For the years ended August 31, 2014 and 2012, there were no grants received from the Bio-Jerusalem fund, and for the year ended August 31, 2013, we received \$12,000, from the Bio-Jerusalem fund. As we have not yet realized any revenues since inception, we have not incurred any royalty liability to the Bio-Jerusalem fund.

#### General and administrative expenses

General and administrative expenses include the salaries and related expenses of our management, consulting costs, legal and professional fees, traveling, business development costs, insurance expenses and other general costs.

General and administrative expenses increased by 29% from \$2,032,000 for the year ended August 31, 2013 to \$2,629,000 for the year ended August 31, 2014. The increase in costs incurred related to general and administrative activities during the year ended August 31, 2014, reflects an increase in salaries and related expenses resulting from cash bonuses to employees for the Company's 2013 achievements, that was partially offset by a decrease in professional expenses. During the year ended August 31, 2014, as part of our general and administrative expenses, we incurred \$563,000 related to stock options granted to employees and consultants, as compared to \$372,000 during the year ended August 31, 2013.

General and administrative expenses increased by 69% from \$1,203,000 for the year ended August 31, 2012 to \$2,032,000 for the year ended August 31, 2013. The increase in costs incurred related to general and administrative activities during the year ended August 31, 2013, reflects an increase in stock based compensation costs of \$200,000, arising from options granted to employees and consultants, as well as an increase in legal fees and consulting expenses mainly in connection with our listing on Nasdaq in February 2013. During the year ended August 31, 2013, as part of our general and administrative expenses, we incurred \$372,000 related to stock options granted to employees and consultants, as compared to \$172,000 during the year ended August 31, 2012.



#### Financial income/expense, net

Net financial income was \$190,000 for the year ended August 31, 2014 as compared to net financial expense of \$133,000 for the year ended August 31, 2013. This was mainly due to the decrease of warrant liabilities attributable to warrants held by Regals Fund LP, or Regals, and a corresponding increase in stockholders' equity on November 29, 2012, as a result of the removal of the anti-dilution provisions of the warrants, which resulted in a net cost of \$297,000, and from an increase in interest income on available cash and cash equivalents primarily due to the increase in cash and cash equivalents balance that resulted from public offerings completed in July and December 2013.

Net financial expense decreased from \$186,000 for the year ended August 31, 2012 to \$133,000 for the year ended August 31, 2013. The decrease is mainly due to changes in the fair value of warrant liabilities offset by the exchange of the warrant liabilities attributable to warrants held by Regals, as described above, and by a gain on sale of marketable securities of \$90,000 in fiscal 2013.

#### Taxes on income / Tax benefit

We had taxes on income of \$4,000 for the year ended August 31, 2014 as compared to a tax benefit of \$205,000 for the year ended August 31, 2013, as a result of additional accrual for uncertain tax position in fiscal 2014.

Taxes on income decreased from taxes on income of \$90,000 for the year ended August 31, 2012 to a benefit of \$205,000 for the year ended August 31, 2013. The decrease is a result of recognizing and measuring uncertain tax positions, as the statute of limitations with respect to the 2008 tax year of Oramed Ltd. expired in the year ended August 31, 2013.

#### Other comprehensive income

A subsequent increase in the fair value of available for sale securities previously written down as impaired for the year ended August 31, 2014 of \$34,000 resulted from the increase in fair value of the ordinary shares of D.N.A, that we hold. Reclassification adjustments for gains included in net loss for the year ended August 31, 2014 of \$80,000, resulted from the sale of 2,625,989 of our D.N.A ordinary shares in October and November 2013 and January and March 2014. Unrealized gains on available for sale securities for the year ended August 31, 2014 of \$194,000, resulted from the increase in fair value of our D.N.A ordinary shares.

A subsequent increase in the fair value of available for sale securities previously written down as impaired for the year ended August 31, 2013 of \$131,000 resulted from the increase in fair value of our D.N.A ordinary shares. Reclassification adjustments for gains included in net loss for the year ended August 31, 2013 of \$90,000, resulted from the sale of 7,000,000 of our D.N.A ordinary shares in February and March 2013. Unrealized gain on available for sale securities for the year ended August 31, 2013 of \$263,000, resulted from the increase in fair value of our D.N.A ordinary shares.

Impairment of available for sale securities for the year ended August 31, 2012 of \$184,000 resulted from the decrease in fair value of our D.N.A ordinary shares.

#### Liquidity and Capital Resources

From inception through August 31, 2014, we have incurred losses in an aggregate amount of \$27,820,000. During that period we have financed our operations through several private placements of our common stock, as well as public offerings of our common stock in July and December 2013, raising a total of \$35,747,000, net of transaction costs. During that period we also received cash consideration of \$1,862,000 from the exercise of warrants and

options. We will seek to obtain additional financing through similar sources in the future as needed. As of August 31, 2014, we had \$1,762,000 of available cash, \$18,481,000 of short term bank deposits and \$1,047,000 of marketable securities. We anticipate that we will require approximately \$11.3 million to finance our activities during the 12 months following August 31, 2014.

Management continues to evaluate various financing alternatives for funding future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors, including the investor in connection with the private placement entered into in November 2014, and existing stockholders, future public offerings, and additional funding from the OCS. Based on our current cash resources and commitments, including cash received in public offerings in the period ended August 31, 2014, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months and beyond.

As of August 31, 2014, our total current assets were \$21,778,000 and our total current liabilities were \$973,000. On August 31, 2014, we had a working capital surplus of \$20,805,000 and an accumulated loss of \$27,820,000. As of August 31, 2013, our total current assets were \$8,644,000 and our total current liabilities were \$498,000. On August 31, 2013, we had a working capital surplus of \$8,146,000 and an accumulated loss of \$22,124,000. The increase from August 31, 2014 to August 31, 2013 was primarily due to proceeds from our public offering completed in December 2013.

During the year ended August 31, 2014, cash and cash equivalents decreased by \$510,000 from the \$2,272,000 reported as of August 31, 2013, which is due to the reasons described below.

Operating activities used cash of \$4,068,000 in the year ended August 31, 2014 and \$3,396,000 in the year ended August 31, 2013. Cash used for operating activities in the year ended August 31, 2014 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments, while cash used by operating activities in the year ended August 31, 2013 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments and exchange of warrants.

During the year ended August 31, 2014, we received \$408,000 in OCS grants towards our research and development expenses as compared to \$327,000 during the year ended August 31, 2013. We recognized the amount of \$428,000 during the year ended August 31, 2014 as compared to \$309,000 in the year ended August 31, 2013. This increase was primarily due to the timing of the grant utilization.

Investing activities used cash of \$13,088,000 in the year ended August 31, 2014, as compared to \$4,569,000 provided by investing activities in the year ended August 31, 2013. Cash used for investing activities in the years ended August 31, 2014 and 2013 consisted primarily of the purchase of short-term bank deposits.

Financing activities provided cash of \$16,640,000 in the year ended August 31, 2014 and \$5,824,000 in the year ended August 31, 2013. Cash provided by financing activities during both periods consisted of proceeds from our issuance of common stock, warrants and options. During fiscal 2014, warrants were exercised for cash and resulted in the issuance of 261,665 shares of common stock and options were exercised for cash and resulted in the issuance of 307,016 shares of common stock, 280,114 of which were exercised by our Chief Medical and Technology Officer. The cash consideration received for exercise of warrants was \$1,570,000 and the cash consideration received for exercise of options was \$183,000. During fiscal 2013, a total of 10,180 warrants were exercised via a "cashless" manner, resulting in the issuance of 3,787 shares of common stock to our investors. In addition 11,262 warrants were exercised for cash and resulted in the issuance of 11,262 shares of common stock to our investors and 8,334 options were exercised for cash and resulted in the issuance of 8,334 shares of common stock. The cash consideration received for exercise of warrants was \$68,000 and the cash consideration received for exercise of options was \$42,000.

During fiscal 2014 and fiscal 2013 we issued a total of 47,459 shares of common stock to various third party vendors for services rendered. The aggregate value of those shares was approximately \$347,000. In fiscal 2013 we also consummated a private placement, in which we sold 349,396 "units" at a purchase price of \$4.44 per unit, for total net consideration of \$1,423,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.50 of a share of common stock at an exercise price of \$6.00 per share. In July 2013, we sold 658,144 shares of common stock, at a price of \$7.00 per share, to various investors in a registered direct offering, for aggregate net proceeds of approximately \$4,239,000. The placement agents in this offering received aggregate cash compensation in the amount of approximately \$255,000, and approximately \$30,000 as reimbursement for unaccountable expenses. In December 2013, we sold 1,580,000 shares of common stock, at a price of \$10.00 per share, to two institutional investors in a registered direct offering, for aggregate net proceeds of approximately \$14,887,000. The placement agent in this offering received aggregate cash compensation in the amount of approximately \$815,500, including

reimbursement for unaccountable expenses.

31

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In November 2013 and August 2014, we issued a total of 13,750 shares of our common stock, valued at \$102,000, in the aggregate, to a certain service provider as remuneration for services rendered.

In May 2014, we issued 2,252 shares of common stock, valued at \$19,000 to Regals as payment of liquidated damages related to certain registration rights contained in a 2012 securities purchase agreement.

In November 2014, we entered into a Stock Purchase Agreement with an investor pursuant to which we have agreed to sell 696,378 shares of common stock at a price of \$7.18 per share, which is equal to the closing price of the Company's common stock on the Nasdaq Capital Market on October 31, 2014, for an aggregate gross proceeds of approximately \$5 million. In connection with this private placement, we will pay a finder's fee of up to \$150,000. This private placement is expected to close on or about November 28, 2014, subject to the payment of the purchase price. If within 30 days after November 28, 2014, the closing does not occur because of a default or breach by the investor or we have not yet been paid the full purchase price for the shares, then the investor has agreed to pay a break-up fee of \$1 million to us. If we do not deliver a stock certificate evidencing the shares to the investor within 30 days of receiving full payment of the purchase price for the shares, then we have agreed to pay a break-up fee of \$1 million to the investor.

#### Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments at August 31, 2014, and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations	Total	Less than 1			Over 5
		year	1-3 years	3-5 years	
Clinical research study obligations	\$ 3,588	\$ 2,694	\$ 894	\$ -	\$ -
Purchase obligations	962	918	44	-	-
Operating lease obligations	84	43	41	-	-
Accrued Severance Pay, net	9	-	-	-	9
<b>Total</b>	<b>\$ 4,643</b>	<b>\$ 3,655</b>	<b>\$ 979</b>	<b>\$ -</b>	<b>\$ 9</b>

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

#### Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning September 1, 2014 are as follows (in thousands of dollars):

Category	Amount
Research and development, net of OCS funds	\$ 8,584
General and administrative expenses	2,712
<b>Total</b>	<b>\$ 11,296</b>

In December 2012 and April 2013, we filed IND applications with the FDA for our orally ingested insulin and we are conducting, or planning to conduct, further clinical studies with our oral exenatide capsule and the combination



therapy, respectively, and others. Our ability to complete these expected activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us and receiving additional grants from the OCS.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to a variety of risks, including changes in interest rates, foreign currency exchange rates, changes in the value of our marketable securities and inflation.

As of August 31, 2014, we had \$1.7 million in cash and cash equivalents, \$18.5 million in short-term bank deposits and restricted deposits and \$1 million in marketable securities.

We aim to preserve our financial assets, maintain adequate liquidity and maximize return while minimizing exposure to market risks. Such policy further provides that we should hold most of our current assets in bank deposits. As of today, the currency of our financial assets is mainly in U.S. dollars.

## Marketable securities

We own 20,416,289 common shares of D.N.A, which are presented in our financial statements as marketable securities. Marketable securities are presented at fair value and their realization is subject to certain limitations if sold through the market, and we are therefore exposed to market risk. There is no assurance that at the time of sale of the marketable securities the price per share will be the same or higher, nor that we will be able to sell all of the securities at once given the volume of securities we hold. The shares are traded on the Tel Aviv Stock Exchange and the shares' price is denominated in NIS. We are also exposed to changes in the market price of D.N.A shares, as well as to exchange rates fluctuations in the NIS currency compared to the U.S dollar.

## Interest Rate Risk

We invest a major portion of our cash surplus in bank deposits in banks in Israel. Since the bank deposits typically carry fixed interest rates, financial income over the holding period is not sensitive to changes in interest rates. However, our interest gains from future deposits may decline in the future as a result of changes in the financial markets. In any event, given the historic low levels of the interest rate, we estimate that a further decline in the interest rate we are receiving will not result in a material adverse effect to our business.

## Foreign Currency Exchange Risk and Inflation

A significant portion of our expenditures, including salaries, clinical research expenses, consultants' fees and office expenses relate to our operations in Israel. The cost of those Israeli operations, as expressed in U.S. dollars, is influenced by the extent to which any increase in the rate of inflation in Israel is not offset (or is offset on a lagging basis) by a devaluation of the NIS in relation to the U.S. dollar. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. In addition, as of August 31, 2014, we own net balances in NIS of approximately \$1,229,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate gain of approximately \$112,000, while assuming a 10% devaluation of the NIS against the U.S. dollars, we would experience an exchange rate loss of approximately \$137,000.

The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Year Ended August 31,		
	2012	2013	2014
Average rate for period	3.809	3.718	3.494
Rate at period-end	4.028	3.614	3.568

We do not use any currency hedging transactions of options or forwards to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See Item 15 of this Annual Report on Form 10-K.

33

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of August 31, 2014. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act. The Company's internal control over financial reporting is defined as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting as of August 31, 2014 based on the current framework for Internal Control-Integrated Framework (2013) set forth by The Committee of Sponsoring Organizations of the Treadway Commission.

Based on this evaluation, our management concluded that the Company's internal control over financial reporting was effective as of August 31, 2014 at a reasonable assurance level.

Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, the independent registered public accounting firm has audited our fiscal 2014 consolidated financial statements included in this Annual Report on Form 10-K, our internal control over financial reporting. The report appears elsewhere herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended August 31, 2014 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

34

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## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Set forth below is certain information with respect to the individuals who are our directors and executive officers.

Name	Age	Position
Nadav Kidron	40	President, Chief Executive Officer and Director
Miriam Kidron	74	Chief Medical and Technology Officer and Director
Leonard Sank	49	Director
Harold Jacob	61	Director
Michael Berelowitz	70	Director and Chairman of the Scientific Advisory Board
Gerald Ostrov	64	Director
Yifat Zommer	40	Chief Financial Officer, Treasurer and Secretary
Joshua Hexter	44	Chief Operating Officer and VP Business Development

Dr. Miriam Kidron is Mr. Nadav Kidron's mother. There are no other directors or officers of our Company who are related by blood or marriage.

#### Business Experience

The following is a brief account of the education and business experience during at least the past five years of each director and our only executive officer who is not a director, indicating the principal occupation during that period, and the name and principal business of the organization in which such occupation and employment were carried out.

Mr. Nadav Kidron was appointed President, Chief Executive Officer and director in March 2006. He is also a director of Entera (of which the Company owns 2.3% of the outstanding shares). In 2009, he was a fellow at the Merage Foundation for U.S.-Israel Trade Programs for executives in the life sciences field. From 2003 to 2006, he was the managing director of the Institute of Advanced Jewish Studies at Bar Ilan University. From 2001 to 2003, he was a legal intern at Wine, Mishaiker & Ernstoff Law Offices in Jerusalem, Israel. Mr. Kidron holds an LL.B. and an International MBA from Bar Ilan University, Israel, and is a member of the Israel Bar Association.

We believe that Mr. Kidron's qualifications to serve on our Board include his familiarity with the Company as its founder, his experience in capital markets, as well as his knowledge and familiarity with corporate management.

Dr. Miriam Kidron was appointed Chief Medical and Technology Officer and director in March 2006. Dr. Kidron is a pharmacologist and a biochemist with a Ph.D. in biochemistry. From 1990 to 2007, Dr. Kidron was a senior researcher in the Diabetes Unit at Hadassah University Hospital in Jerusalem, Israel. During 2003 and 2004, Dr. Kidron served as a consultant to Emisphere Technologies Inc., a company that specializes in developing broad-based proprietary drug delivery platforms. Dr. Kidron was formerly a visiting professor at the Medical School at the University of Toronto (Canada), and is a member of the American, European and Israeli Diabetes Associations. Dr. Kidron is a recipient of the Bern Schlanger Award.

We believe that Dr. Kidron's qualifications to serve on our Board include her expertise in the Company's technology, as it is based on her research, as well as her experience and relevant education in the fields of pharmacology and diabetes.

Mr. Leonard Sank was appointed a director in October 2007. Mr. Sank is a South African entrepreneur and businessman, who is devoted to entrepreneurial endeavors and initiatives. He has over 20 years of experience playing important leadership roles in developing businesses. Since December 2011, Mr. Sank has served as a director in Eastvaal Motors Pty Ltd., a diversified retail motor business, and served as a director there in the past. Since 2010, Mr. Sank has served as a director in Bradbury Finance Pty Ltd. From 2000 to 2007, Mr. Sank served as a director in Vecto Finance Pty Ltd., a credit lending business. For the past fifteen years Mr. Sank has served as a director of Macsteel Service Centres SA Pty Ltd., South Africa's largest private company. He also serves on the boards of small businesses and local non-profit charity organizations in Cape Town, where he resides.

We believe that Mr. Sank's qualifications to serve on our Board include his years of experience in development stage businesses, as well as his experience serving as a director of many entities.

Dr. Harold Jacob was appointed a director in July 2008. Since 1998, Dr. Jacob has served as the president of Medical Instrument Development Inc., a company which provides a range of support and consulting services to start-up and early stage companies as well as patenting its own proprietary medical devices. Since 2011, Dr. Jacob has also served as an attending physician at Hadassah University Medical Center, where he has served as the director of the gastrointestinal endoscopy unit since September 2013. Dr. Jacob has advised a spectrum of companies in the past and he served as a consultant and then as the Director of Medical Affairs at Given Imaging Ltd., from 1997 to 2003, a company that developed the first swallowable wireless pill camera for inspection of the intestine. He has licensed patents to a number of companies including Kimberly-Clark Corporation. Since 2013, Dr. Jacob has served as the Chief Medical Officer and a director of NanoVibronix, Inc., a medical device company using surface acoustics to prevent catheter acquired infection as well as other applications, where he served as Chief Executive Officer from 2004 to 2013. He practiced clinical gastroenterology in New York and served as Chief of Gastroenterology at St. John's Episcopal Hospital and South Nassau Communities Hospital from 1986 to 1995, and was a Clinical Assistant Professor of Medicine at SUNY from 1983 to 1990. Dr. Jacob founded and served as Editor in Chief of Endoscopy Review and has authored numerous publications in the field of gastroenterology.

We believe that Dr. Jacob's qualifications to serve on our Board include his years of experience in the biomed industry, his experience serving in management roles of various companies, as well as his knowledge and familiarity with gastroenterology.

Dr. Michael Berelowitz was appointed a director in June 2010 and Chairman of our Scientific Advisory Board in June 2011. Since 2011, Dr. Berelowitz has been self-employed as a biopharmaceutical consultant. From 2009 to 2011, Dr. Berelowitz served as Senior Vice President and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit at Pfizer, Inc. From 1996 to 2009, he served in various other roles at Pfizer, Inc., beginning as a Medical Director in the Diabetes Clinical Research team and then assuming positions of increasing responsibility until being appointed to his present role. Prior to that, Dr. Berelowitz spent a number of years in academia. Dr. Berelowitz

also serves on the board of directors of Recro Pharma Inc., a NASDAQ-listed clinical stage specialty pharmaceutical company. Among his public activities, Dr. Berelowitz has served on the board of directors of the American Diabetes Association, the Clinical Initiatives Committee of the Endocrine Society, and has chaired the Task Force on Research of the New York State Council on Diabetes. He has also served on several editorial boards, including the Journal of Clinical Endocrinology and Metabolism and Endocrinology, Reviews in Endocrine and Metabolic Disorders and Clinical Diabetes. Dr. Berelowitz has authored and co-authored more than 100 peer-reviewed journal articles and book chapters in the areas of pituitary growth hormone regulation, diabetes and metabolic disorders. Dr. Berelowitz holds adjunct appointments as Professor of Medicine in the Divisions of Endocrinology and Metabolism at SUNY – Stony Brook and Mt. Sinai School of Medicine in New York.

We believe that Dr. Berelowitz’s qualifications to serve on our Board include his years of experience in management roles in the pharmaceuticals industry, as well as his vast skill and expertise in the fields of endocrinology and diabetes.

Mr. Gerald Ostrov was appointed a director in September 2012. Mr. Ostrov currently serves on the board of directors of Orasure Technologies Inc., a NASDAQ listed company which develops, manufactures, markets and sells oral fluid diagnostic products and specimen collection devices, is a founder and a member of the board of directors of Adlens Beacon, a privately held company developing self-adjustable reading glasses, serves on the board of directors of the Robert Wood Johnson University Hospital Foundation and serves on the Johnson & Johnson Corporate Contributions Committee. From 2008 to 2010, Mr. Ostrov served as Chairman and Chief Executive Officer of Bausch & Lomb Incorporated, where he helped to stabilize and restructure the business following its privatization. From 1998 to 2006, Mr. Ostrov acted as Company Group Chairman for Johnson & Johnson’s Worldwide Vision Care businesses. Mr. Ostrov began his career with Johnson & Johnson’s Health Care Division in 1976. In 1982, he left Johnson & Johnson to become Vice President of Marketing for Ciba-Geigy’s Consumer Pharmaceuticals Company, where he was named President of Ciba Consumer Pharmaceuticals in 1985 and served in that capacity until rejoining Johnson & Johnson in 1991 as President of the corporation’s Personal Products Company. Mr. Ostrov holds a Bachelor of Science degree with distinction in Industrial Engineering and Operations Research from Cornell University and holds an M.B.A. from Harvard University.



We believe that Mr. Ostrov's qualifications to serve on our Board include his years of experience in management roles in the pharmaceuticals industry, as well as his experience serving as a director of many entities.

Ms. Yifat Zommer was appointed Chief Financial Officer, Treasurer and Secretary in April 2009. From 2007 to 2008, Ms. Zommer served as Chief Financial Officer of Witech Communications Ltd., a subsidiary of IIS Intelligence Information Systems Ltd., a company operating in the field of video transmission using wireless communications. From April 2006 to April 2007, Ms. Zommer acted as Chief Financial Officer for CTWARE Ltd., a telecommunication company. Prior to that she was an audit manager in Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, where she served for five years. Ms. Zommer holds a Bachelor of Accounting and Economics degree from the Hebrew University, a Business Administration degree (MBA) from Tel-Aviv University and a Masters degree in Law (LL.M.) from Bar-Ilan University, Israel. Ms. Zommer is a certified public accountant in Israel.

Mr. Joshua Hexter was appointed Chief Operating Officer in April 2013. From 2007 to 2013, Mr. Hexter was a Director or Executive Director in BioLineRx Ltd. ("BioLineRx"), a TASE-listed biopharmaceutical development company dedicated to identifying, in-licensing and developing innovative therapeutic candidates. Prior to his employment with BioLineRx, Mr. Hexter was a member of the board of directors and CEO of Biosensor Systems Design, Inc., a company developing market-driven biosensors. Mr. Hexter holds a bachelor's degree from the University of Wisconsin and a master's degree in management from Boston University.

#### Board of Directors

There are no agreements with respect to the election of directors. Each director is elected for a period of one year at our annual meeting of stockholders and serves until the next such meeting and until his or her successor is duly elected or until his or her earlier resignation or removal. The Board may also appoint additional directors. A director so chosen or appointed will hold office until the next annual meeting of stockholders and until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. The Board has determined that Michael Berelowitz, Harold Jacob, Gerald Ostrov and Leonard Sank, are independent as defined under the rules promulgated by NASDAQ. Other than Dr. Berelowitz, none of the independent directors has any relationship with us besides serving on our Board. We have entered into an agreement with Dr. Berelowitz pursuant to which we pay him certain fees as compensation for serving as Chairman of our Scientific Advisory Board. See "Item 10. Directors, Executive Officers and Corporate Governance" and "Item 11. Executive Compensation—Director Compensation" for certain information about Dr. Berelowitz.

We have determined that each of the directors is qualified to serve as a director of the Company based on a review of the experience, qualifications, attributes and skills of each director. In reaching this determination, we have considered a variety of criteria, including, among other things: character and integrity; ability to review critically, evaluate, question and discuss information provided, to exercise effective business judgment and to interact effectively with the other directors; and willingness and ability to commit the time necessary to perform the duties of a director.

#### Board Meeting Attendance

During the year ended August 31, 2014, our Board held nine meetings and took actions by written consent on two occasions. No director attended fewer than 75% of the aggregate of: (i) the total number of meetings of the Board (during the period for which such director served as a director); and (ii) the total number of meetings held by all committees of the Board on which such director served (during the period for which such director served on such committees). Board members are encouraged to attend our annual meetings of stockholders.



## Committees

### Audit Committee and Audit Committee Financial Expert

The members of our Audit Committee are Leonard Sank, Harold Jacob and Gerald Ostrov. Our Board has determined that Gerald Ostrov is an “audit committee financial expert” as set forth in Item 407(d)(5) of Regulation S-K and that all members of the Audit Committee are “independent” as defined by the rules of the SEC and the Nasdaq rules and regulations. The Audit Committee operates under a written charter that is posted on the “Investors” section of our website, [www.oramed.com](http://www.oramed.com). The primary responsibilities of our Audit Committee include:

- Appointing, compensating and retaining our registered independent public accounting firm;
- Overseeing the work performed by any outside accounting firm;
- Assisting the Board in fulfilling its responsibilities by reviewing: (i) the financial reports provided by us to the SEC, our stockholders or to the general public, and (ii) our internal financial and accounting controls; and
- Recommending, establishing and monitoring procedures designed to improve the quality and reliability of the disclosure of our financial condition and results of operations.

### Compensation Committee

The members of our Compensation Committee are Leonard Sank, Michael Berelowitz and Gerald Ostrov. The Board has determined that all of the members of the Compensation Committee are “independent” as defined by the rules of the SEC and Nasdaq rules and regulations. The Compensation Committee operates under a written charter that is posted on the “Investors” section of our website, [www.oramed.com](http://www.oramed.com). The primary responsibilities of our Compensation Committee include:

- Reviewing, negotiating and approving, or recommending for approval by our Board of the salaries and incentive compensation of our executive officers;
- Administering our equity based plans and making recommendations to our Board with respect to our incentive–compensation plans and equity–based plans; and
- Periodically reviewing and making recommendations to our Board with respect to director compensation.

### Section 16(a) Beneficial Ownership Reporting Compliance

Based solely upon a review of Forms 3, 4 and 5, and amendments thereto, furnished to us during fiscal 2014, we believe that during fiscal 2014, our executive officers, directors and all persons who own more than ten percent of a registered class of our equity securities complied with all Section 16(a) filing requirements, except as follows:

- Harold Jacob, a director, failed to timely file a Form 4 reporting his April 14, 2014 acquisition of 700 shares of our common stock. Mr. Jacob filed a Form 4 reporting this transaction on April 18, 2014.
- Harold Jacob also failed to timely file a Form 4 reporting a sale of an aggregate of 834 shares of our common stock on December 30, 2013. Mr. Jacob filed a Form 4 reporting this transaction on January 29, 2014.

### Code of Ethics

We have adopted a Code of Ethics and Business Conduct for our senior officers, directors and employees. A copy of the Code of Ethics and Business Conduct is located at our website at [www.oramed.com](http://www.oramed.com).

38

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## ITEM 11. EXECUTIVE COMPENSATION.

### Compensation Discussion and Analysis

This section explains the policies and decisions that shape our executive compensation program, including its specific objectives and elements, as it relates to our “named executive officers,” or NEOs. Our NEOs for fiscal 2014 are those four individuals listed in the "Summary Compensation Table" below. The Compensation Committee believes that our executive compensation is appropriately designed to incentivize our named executive officers to work for our long-term prosperity, is reasonable in comparison with the levels of compensation provided by comparable companies, and reflects a reasonable cost. We believe our named executive officers are critical to the achievement of our corporate goals, through which we can drive stockholder value.

The Compensation Committee of our Board is comprised solely of independent directors as defined by NASDAQ and non-employee directors as defined by Rule 16b-3 under the Exchange Act. The Compensation Committee has the authority and responsibility to review and approve the compensation of our Chief Executive Officer, or CEO, and other executive officers. Other information concerning the structure, roles and responsibilities of our Compensation Committee is set forth in "Board Meetings and Committees—Compensation Committee" section.

Our executive compensation program and our NEOs' compensation packages are designed around the following objectives:

- αττραχτ, ηιρε, ανδ ρεταιιν ταλεντεδ ανδ εξπειρευχεδ εξεχυτιωεσ;
- motivate, reward and retain executives whose knowledge, skills and performance are critical to our success;
- focus executive behavior on achievement of our corporate objectives and strategy; and
- align the interests of management and stockholders by providing management with longer-term incentives through equity ownership.

The Compensation Committee reviews the allocation of compensation components regularly to ensure alignment with strategic and operating goals, competitive market practices and legislative changes. The Compensation Committee does not apply a specific formula to determine the allocation between cash and non-cash forms of compensation. Certain compensation components, such as base salaries, benefits and perquisites, are intended primarily to attract, hire, and retain well-qualified executives. Other compensation elements, such as long-term incentive opportunities, are designed to motivate and reward performance. Long-term incentives are intended to reward NEOs for our long-term performance and executing our business strategy, and to strongly align NEOs' interests with those of stockholders.

With respect to equity compensation, the Compensation Committee makes awards to executives under our Amended and Restated 2008 Stock Incentive Plan, or 2008 Plan. Executive compensation is paid or granted based on such matters as the Compensation Committee deems appropriate, including our financial and operating performance and the alignment of the interests of the executive officers and our stockholders.

### Elements of Compensation

Our executive officer compensation program is comprised of: (i) base salary or monthly compensation; (ii) discretionary bonus; (iii) long-term equity incentive compensation in the form of stock option and restricted stock unit, or RSU, grants; and (iv) benefits and perquisites.



In establishing overall executive compensation levels and making specific compensation decisions for our NEOs in fiscal 2014, the Compensation Committee considered a number of criteria, including the executive's position, scope of responsibilities, prior base salary and annual incentive awards and expected contribution.

Generally, our Compensation Committee reviews and, as appropriate, approves compensation arrangements for the NEOs from time to time but not less than once a year. The Compensation Committee also takes into consideration the CEO's recommendations for executive compensation of the other three NEOs. The CEO generally presents these recommendations at the time of our Compensation Committee's review of executive compensation arrangements.

#### Base Salary

The Compensation Committee performs a review of base salaries and monthly compensation for our NEOs from time to time as appropriate. In determining salaries, the Compensation Committee members also take into consideration independent third party market data, such as compensation surveys to industry, individual experience and performance and contribution to our clinical, regulatory, commercial and operational performance. None of the factors above has a dominant weight in determining the compensation of our named executive officers, and our Compensation Committee considers the factors as a whole when considering such compensation. In addition, our Compensation Committee uses comparative data regarding compensation paid by peer companies in order to obtain a general understanding of current trends in compensation practices and ranges of amounts being awarded by other public companies, and not as part of an analysis or a formula.

In each of fiscal 2014 and 2013, we conducted an analysis of salaries and monthly compensation received by our NEOs' respective counterparts in companies in the biotechnology industry and other comparable companies in Israel and outside of Israel. During fiscal 2014, the Compensation Committee received consulting services from Brightman Almagor Zohar & Co., a member firm of Deloitte Touche Tohmatsu Limited with regard to management compensation. The Committee engaged the consultant solely to collect and analyze data regarding management compensation at other companies comparable to the Company. The consultant collected data from companies in the biomed sector that are publicly traded on The NASDAQ Stock Market, in the biomed sector and having similar (within 50%) market cap, total assets, total revenue, net income, and/or location of operations (in Israel) to the Company. The comparable companies that were chosen by the consultants were Amicus Therapeutics, Inc.; Columbia Laboratories Inc.; Enxo Biochem, Inc.; Navidea Biopharmaceuticals Inc.; Pluristem Therapeutics Inc.; Rexhan Pharmaceuticals, Inc.; Sorrento Therapeutics, Inc.; Stemline Therapeutics, Inc.; and Synergy Pharmaceuticals Inc. The Committee looked at the fixed and variable compensation of each of the comparable NEOs and for directors.

We believe that a competitive base salary and monthly compensation is a necessary element of any compensation program that is designed to attract and retain talented and experienced executives. We also believe that attractive base salaries can motivate and reward executives for their overall performance. Base salary and monthly compensation are established in part based on the individual experience, skills and expected contributions to our performance, as well as such executive's performance during the prior year. Compensation adjustments are made occasionally based on changes in an executive's level of responsibility, company progress or on changed local and specific executive employment market conditions.

In fiscal 2013, we increased the base salary of Nadav Kidron, our CEO, Miriam Kidron, our Chief Medical and Technology Officer, and Yifat Zommer, our Chief Financial Officer and recruited Joshua Hexter to serve as our the Chief Operating Officer. In fiscal 2014 our NEOs' salaries and monthly compensation did not change from the previous year as we believe they fell within the range of salaries received by our NEOs' respective counterparts in companies in the biotechnology industry and other comparable companies in Israel.

#### Performance Based Bonus

Our NEOs are eligible to receive discretionary annual bonuses based upon performance. The amount of annual bonus to our NEOs is based on various factors, including, among others, the achievement of scientific and business goals and our financial and operational performance. The committee takes into account the overall performance of the individuals as well as the overall performance of the Company over the period being reviewed and recommendation of management. We do not have a written bonus plan setting forth these criteria in advance. The overall payment is also based on historic compensation of the NEOs.



We believe that annual bonuses payable based on the achievement of short-term corporate goals incentivize our NEOs to create stockholder value and attain short-term performance objectives.

#### Long-term Equity Incentive Compensation

Long-term incentive compensation allows the NEOs to share in any appreciation in the value of our common stock. The Compensation Committee believes that stock participation aligns executive officers' interests with those of our stockholders. The amounts of the awards are designed to reward past performance and create incentives to meet long-term objectives. Awards are made at a level expected to be competitive within the biotechnology industry, as well as with Israeli-based companies. We do not have a formula relating to, and did not conduct any analysis of, the level of awards that is competitive within the biotechnology industry and Israeli-based companies. Awards are made on a discretionary basis and not pursuant to specific criteria set out in advance. In determining the amount of each grant, the Compensation Committee also takes into account the number of shares held by the executive prior to the grant. The vesting schedule for NEOs is based on monthly installments for periods of no longer than three years. The Compensation Committee believes that time-based vesting encourages recipients to build stockholder value over a long period of time.

RSU awards provide our NEOs with the right to purchase shares of our common stock at a par value of \$0.012, subject to continued employment with our company. In November 2014, the Compensation Committee awarded RSUs for the first time. We chose to grant RSU awards and not options because RSU awards, once vested, always have an immediate financial value to the holder thereof, unlike options where the exercise price might be above the current market price of the shares and therefore not have any intrinsic value to the holder thereof. In addition, because vested RSU awards always have financial value, as opposed to options, we were able to limit the number of securities issued to our NEOs and other employees, directors and consultants. RSUs generally vest over a period of no longer than three years. The Compensation Committee believes that time-based vesting encourages recipients to build stockholder value over a long period of time.

#### Benefits and Perquisites

Generally, benefits available to NEOs are available to all employees on similar terms and include welfare benefits, paid time-off, life and disability insurance and other customary or mandatory social benefits in Israel. We provide our NEOs with a phone and a company car which are customary benefits in Israel to managers and officers.

During 2014, the Compensation Committee approved the payment to Mr. Kidron of approximately \$7,000 per month for a of approximately five-month period during which Mr. Kidron was in the United States. This payment replaced per diem payments for that business travel. The Compensation Committee determined that this amount reflects the difference in the cost of living between Israel and the United States.

We do not believe that the benefits and perquisites described above deviate materially from the customary practice for compensation of executive officers by other companies similar in size and stage of development in Israel. These benefits represent a relatively small portion of the executive officers' total compensation.

#### Say-on-Pay Vote

Our stockholders approved, on an advisory basis, our executive compensation program at our at our annual meeting of our stockholders held on July 23, 2014, or the 2014 Annual Meeting. Besides this approval, we did not seek or receive any specific feedback from our stockholders concerning our executive compensation program during the past year. The Compensation Committee did not specifically rely on the results of the vote in making any compensation-related decisions during fiscal 2014.



## COMPENSATION COMMITTEE REPORT

The Compensation Committee has reviewed and discussed the foregoing Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with our management and, based on such review and discussions, the Compensation Committee recommended to our Board that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K and in our proxy statement relating to our next annual meeting of stockholders.

## Compensation Committee Members:

Leonard Sank  
Michael Berelowitz  
Gerald Ostrov

## SUMMARY COMPENSATION TABLE

The following table shows the particulars of compensation paid to our NEOs, for the fiscal years ended August 31, 2014, 2013 and 2012.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
	(1)	(2)	(2)(3)	(4)	(2)(5)	(6)
Nadav Kidron	2014	261,338	120,000	390,696	31,770	803,804
President and CEO and director (6)	2013	182,510	60,000	-	29,152	271,662
	2012	159,136	-	186,783	17,989	363,908
Miriam Kidron	2014	206,315	65,000	390,696	12,076	676,739
Chief Medical and Technology Officer and director (7)	2013	168,410	20,000	-	14,728	200,486
	2012	159,136	-	186,783	13,200	359,119
Yifat Zommer	2014	143,769	50,000	-	39,806	233,575
CFO, Treasurer and Secretary	2013	83,387	15,000	-	29,086	127,473
	2012	58,686	-	136,233	29,719	224,639
Joshua Hexter	2014	174,162	25,000	-	42,857	242,019
COO and VP Business Development(8)	2013	48,426	-	519,785	10,019	578,230

(1) The information is provided for each fiscal year, which begins on September 1 and ends on August 31.

(2) Amounts paid for Salary, Bonus and All Other Compensation were originally denominated in NIS and were translated into U.S. Dollars at the then current exchange rate for each payment.

(3) Bonuses were granted at the discretion of the Compensation Committee.

(4) The amounts reflect the grant date fair value, as calculated pursuant to FASB ASC Topic 718, of these option awards. The assumptions used to determine the fair value of the option awards for fiscal years ended August 31, 2014, 2013 and 2012 are set forth in Note 9 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our named executive officers will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.

(5) See "All Other Compensation Table" below.

(6) Mr. Kidron receives compensation from Oramed Ltd. through KNRV, Ltd., an Israeli entity owned by Mr. Kidron, or KNRV. See "—Employment and Consulting Agreements" below.

(7)

Dr. Kidron receives compensation from Oramed Ltd. through KNRY. See “—Employment and Consulting Agreements” below.

(8) Mr. Hexter joined the Company in April 2013 and his base salary for fiscal 2013 was \$128,000.

## All Other Compensation Table

The “All Other Compensation” amounts set forth in the Summary Compensation Table above consist of the following:

Name	Year	Automobile- Related Expenses (\$)	Manager’s Insurance* (\$)	Education Fund* (\$)	Business Travel** (\$)	Total (\$)
Nadav Kidron	2014	13,050	--	--	18,720	31,779
	2013	11,992	--	--	17,160	29,152
	2012	17,989	--	--	--	17,989
Miriam Kidron	2014	14,728	--	--	--	14,728
	2013	12,076	--	--	--	12,076
	2012	13,200	--	--	--	13,200
Yifat Zommer	2014	15,440	16,263	8,103	--	39,806
	2013	10,507	12,416	6,163	--	29,086
	2012	12,976	11,024	5,719	--	29,719
Joshua Hexter	2014	12,784	20,157	9,916	--	42,857
	2013	3,536	3,998	2,485	--	10,019

\*Manager’s insurance and education funds are customary benefits provided to employees based in Israel. Manager’s insurance is a combination of severance savings (in accordance with Israeli law), defined contribution tax-qualified pension savings and disability insurance premiums. An education fund is a savings fund of pre-tax contributions to be used after a specified period of time for educational or other permitted purposes.

\*\* Business travel represent the addition compensation of approximately \$5,000 and \$4,000 per month in fiscal 2014 and 2013, respectively, for the period during which Mr. Kidron was in the United States. This payment was in addition to per diem payments for that business travel. The Compensation Committee determined that this amount reflects the difference in the cost of living between Israel and the United States.

## Employment and Consulting Agreements

On July 1, 2008, Oramed Ltd. entered into a consulting agreement with KNRY, whereby Mr. Nadav Kidron, through KNRY, provides services as President and Chief Executive Officer of both the Company and Oramed Ltd., or the Nadav Kidron Consulting Agreement. Additionally, on July 1, 2008, Oramed Ltd. entered into a consulting agreement with KNRY whereby Dr. Miriam Kidron, through KNRY, provides services as Chief Medical and Technology Officer of both the Company and Oramed Ltd., or the Miriam Kidron Consulting Agreement. We refer to the Miriam Kidron Consulting Agreement and Nadav Kidron Consulting Agreement collectively as the Consulting Agreements.

The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNRY (1) will be paid, under each of the Consulting Agreements, in a gross amount of NIS 50,400 per month and (2) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements. Pursuant to the Consulting Agreements, KNRY, Nadav Kidron and Miriam Kidron each agree that during the term of the Consulting Agreements and for a 12 month period thereafter, none of them will

compete with Oramed Ltd. nor solicit employees of Oramed Ltd.

43

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On July 17, 2013, the Consulting Agreements were amended, such that the monthly consulting fee was increased to NIS 75,000 and NIS 60,000 for the services of Nadav Kidron and Miriam Kidron, respectively, effective July 1, 2013.

We, through Oramed Ltd., have entered into an employment agreement with Yifat Zommer as of April 19, 2009, pursuant to which Ms. Zommer was appointed as Chief Financial Officer, Treasurer and Secretary of the Company and Oramed Ltd. In accordance with the employment agreement, as amended, Ms. Zommer's current gross monthly salary is NIS 31,460. In addition, Ms. Zommer is provided with a cellular phone and a company car pursuant to the terms of her agreement.

We, through Oramed Ltd., have entered into an employment agreement with Joshua Hexter as of April 14, 2013, pursuant to which Mr. Hexter was appointed as Chief Operating Officer and VP Business Development of the Company and Oramed Ltd. In accordance with the employment agreement, Mr. Hexter's current gross monthly salary is NIS 38,500. In addition, Mr. Hexter is provided with a cellular phone and a company car pursuant to the terms of his agreement.

We have entered into indemnification agreements with our directors and officers pursuant to which we agreed to indemnify each director and officer for any liability he or she may incur by reason of the fact that he or she serves as our director or officer, to the maximum extent permitted by law.

#### Potential Payments upon Termination or Change-in-Control

We have no plans or arrangements in respect of remuneration received or that may be received by our named executive officers to compensate such officers in the event of termination of employment (as a result of resignation, retirement, change-in-control) or a change of responsibilities following a change-in-control.

#### Pension, Retirement or Similar Benefit Plans

We have no arrangements or plans under which we provide pension, retirement or similar benefits for directors or executive officers. Our directors and executive officers may receive stock options, RSUs or restricted shares at the discretion of our Compensation Committee in the future.

## GRANTS OF PLAN-BASED AWARDS

The following table shows grants of plan-based equity awards made to our NEOs during fiscal 2014: Neither Ms. Zommer nor Mr. Hexter received any awards during fiscal 2014.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)(1)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)
Nadav Kidron	4/9/14	47,134	12.45	390,695
Miriam Kidron	4/9/14	47,134	12.45	390,695

(1) These options were granted under our 2008 Plan and vested with respect to 15,710 shares of common stock on April 30, 2014 and the remainder vests in eight equal monthly installments, commencing on May 31, 2014. These options have an expiration date of April 9, 2024.

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information concerning stock options and stock awards held by the NEOs as of August 31, 2014.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Nadav Kidron	72,000(1)	-	6.48	5/7/18
	72,000(2)	-	5.88	4/20/20
	72,000(3)	-	4.08	8/8/22
	31,422(4)	15,712(7)	12.45	4/9/24
Miriam Kidron	72,000(1)	-	6.48	5/7/18
	72,000(2)	-	5.88	4/20/20
	72,000(3)	-	4.08	8/8/22
	31,422(4)	15,712(7)	12.45	4/9/24
Yifat Zommer	33,334(5)	--	5.64	10/19/19
	43,750(6)	7,000(5)	4.08	8/8/22
Joshua Hexter	46,200(7)	54,600(6)	7.88	3/14/23



- (1) On May 7, 2008, 72,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$6.48 per share; 12,000 of such options vested immediately on the date of grant and the remainder vested in twenty equal monthly installments, commencing on June 30, 2008. The options have an expiration date of May 7, 2018.
- (2) On April 21, 2010, 72,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$5.88 per share; 9,000 of such options vested immediately on the date of grant and the remainder vested in twenty-one equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.

- (3) On August 8, 2012, 72,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$4.08 per share; 21,000 of such options vested immediately on the date of grant and the remainder vested in seventeen equal monthly installments, commencing on August 31, 2012. The options have an expiration date of August 8, 2022.
- (4) On April 9, 2014, 47,134 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$12.45 per share; 15,710 of such options vested on April 30, 2014 and the remainder vests in eight equal monthly installments, commencing on May 31, 2014. The options have an expiration date of April 9, 2024.
- (5) On June 3, 2009, 33,334 options were granted to Yifat Zommer under the 2008 Plan at an exercise price of \$5.64 per share; the options vests in three equal annual installments, commencing October 19, 2010, and expire on October 19, 2019.
- (6) On August 8, 2012, 50,750 options were granted to Yifat Zommer under the 2008 Plan at an exercise price of \$4.08 per share; the options vested in twenty-nine equal monthly installments, commencing on August 31, 2012, and expire on August 8, 2022.
- (7) On April 14, 2013, 100,800 options were granted to Joshua Hexter under the 2008 Plan at an exercise price of \$7.88 per share; the options vest in 35 consecutive equal installments during a 3-year period commencing on May 31, 2013, and two installments of 1,400 each, that will vest on April 30, 2013 and April 14, 2016, and expire on April 14, 2023.

## OPTIONS EXERCISED AND STOCK VESTED

The following table sets forth information with respect to the NEOs concerning the exercise of stock options or similar instruments during fiscal 2014. Other than Dr. Kidron, none of our NEOs exercised any options or similar instruments or had any stock grants that vested.

Name	Option Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)
Miriam Kidron(1)	280,114	2,799,757

(1) On August 14, 2007, we granted Dr. Miriam Kidron a warrant to purchase up to 280,114 shares of our common stock at an exercise price of \$.012 per share; the warrant vested immediately and had an expiration date of December 31, 2012. On August 8, 2012, our Board resolved to extend the term of Dr. Kidron's warrant until August 6, 2014.

## Compensation Committee Interlocks and Insider Participation

During fiscal 2014, Mr. Sank, Dr. Berelowitz, and Mr. Ostrov served as the members of our Compensation Committee. None of the members of our Compensation Committee is, or has been, an officer or employee of ours.

During the last year, none of our NEOs served as: (1) a member of the compensation committee (or other committee of the Board performing equivalent functions or, in the absence of any such committee, the entire board of directors) of another entity, one of whose executive officers served on the compensation committee; (2) a director of another entity, one of whose executive officers served on the compensation committee; or (3) a member of the compensation committee (or other committee of the board of directors performing equivalent functions or, in the absence of any such committee, the entire board of directors) of another entity, one of whose executive officers served as a director on our Board.

## DIRECTORS COMPENSATION

The following table provides information regarding compensation earned by, awarded or paid to each person for serving as a director who is not an executive officer during fiscal 2014:

Name of Director	Fees Earned or Paid in Cash (\$)	Option Awards (2) (\$)	All Other Compensation (\$)	Total (\$)
Nadav Kidron (1)	-	-	-	-
Miriam Kidron (1)	-	-	-	-
Leonard Sank	10,000	90,028	-	100,028
Harold Jacob	10,000	90,028	-	100,028
Michael Berelowitz	10,000	84,719	26,664(4)	121,383
Gerald Ostrov	10,000	90,411	-	100,411

- (1) Please refer to the Summary Compensation Table for executive compensation with respect to the named individual.
- (2) The amounts reflect the grant date fair value, as calculated pursuant to FASB ASC Topic 718, of these option awards. The assumptions used to determine the fair value of the option awards for fiscal 2014 are set forth in Note 9 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our directors will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.
- (3) At August 31, 2014, our non-employee directors held options to purchase shares of our common stock as follows:

Name of Director	Aggregate Number of Shares Underlying Stock Options
Leonard Sank	58,094
Harold Jacob	58,094
Michael Berelowitz	31,994
Gerald Ostrov	33,094

(4) Michael Berelowitz serves as the Chairman of our Scientific Advisory Board. In this role, Dr. Berelowitz is actively involved in our scientific decisions, clinical strategy, and partnership negotiations. Dr. Berelowitz was paid a fee of \$3,333 per month from December 1, 2013 to August 31, 2014, and prior to that he was compensated at an hourly rate of \$300, up to \$1,500 per day, as compensation for serving in this position.

Our directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our Board. Each independent director is entitled to receive as remuneration for his or her service as a member of the Board a sum equal to \$10,000 per annum, to be paid quarterly and shortly after the close of each quarter. Our executive officers did not receive additional compensation for service as directors. The Board may award special remuneration to any director undertaking any special services on behalf of us other than services ordinarily required of a director. Beginning December 1, 2014, our directors will receive an annual compensation of \$12,000.

Other than as described above, we have no present formal plan for compensating our directors for their service in their capacity as directors. Other than indicated above, no director received and/or accrued any compensation for his services as a director, including committee participation and/or special assignments during fiscal 2014.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

### Stock Option Plans

#### Amended and Restated 2008 Stock Incentive Plan

On May 5, 2008, our Board adopted the 2008 Plan in order to attract and retain quality personnel. The 2008 Plan provides for the grant of stock options, restricted stock, restricted stock units and stock appreciation rights, collectively referred to as “awards.” Stock options granted under the 2008 Plan may be either incentive stock options under the provisions of Section 422 of the Internal Revenue Code, or non-qualified stock options. Under the 2008 Plan, as amended, 1,000,000 shares were reserved for the grant of awards, which may be issued at the discretion of our Board from time to time.

At the 2014 Annual Meeting, our stockholders approved the adoption of our Amended and Restated 2008 Stock Incentive Plan, amending the 2008 Plan in order to order to (1) increase the aggregate number of shares authorized for issuance under the 2008 Plan by 400,000 shares to 1,400,000 shares of common stock, (2) provide specific terms for the issuance of restricted stock and restricted stock units under the 2008 Plan and (3) permit awards to be based on performance-based criteria that will allow us to maximize its ability to pay deductible compensation for U.S. federal income tax purposes.



As of August 31, 2014, options with respect to 1,384,199 shares have been granted, of which 86,167 have been forfeited, 35,236 have been exercised and 291,674 have expired.

Other

On August 14, 2007, we granted Dr. Miriam Kidron a warrant to purchase up to 280,114 shares at an exercise price of \$0.012 per share; the warrant vested immediately and had an expiration date of August 14, 2012. On August 8, 2012, our Board resolved to extend the term of Dr. Kidron's warrant until August 6, 2014. The warrant was exercised in full during fiscal 2014.

The following table sets forth additional information with respect to our equity compensation plans (consisting solely of the 2008 Plan) as of August 31, 2014:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weight-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,036,289	\$ 6.72	393,642
Equity compensation plans not approved by security holders	--	--	--
<b>Total</b>	<b>1,036,289</b>	<b>\$ 6.72</b>	<b>393,642</b>

## Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our common stock as of November 12, 2014 by: (1) each person who is known by us to own beneficially more than 5% of our common stock; (2) each director; (3) each of our named executive officers listed above under “Summary Compensation Table”; and (4) all of our directors and executive officers as a group. On such date, we had 10,106,305 shares of common stock outstanding.

As used in the table below and elsewhere in this form, the term “beneficial ownership” with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following November 12, 2014. Inclusion of shares in the table does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares. Unless otherwise indicated, (1) each person or entity named in the table has sole voting power and investment power (or shares that power with that person’s spouse) with respect to all shares of common stock listed as owned by that person or entity and (2) the address of each of the individuals named below is: c/o Oramed Pharmaceuticals Inc., Hi-Tech Park 2/4 Givat Ram, PO Box 39098, Jerusalem 91390, Israel.

Name and Address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Regals Fund LP 767 Fifth Ave. New York, NY 10153	1,453,637(1)	13.6%
Special Situations Fund 527 Madison Ave., Suite 2600 New York, NY 10022	790,000(2)	7.8%
Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd. 1# Industrial Road, Wuzhou Industrial Park Wuzhou City, Guangxi Province, 543000	696,378(3)	6.4%
Nadav Kidron #+	1,119,590(4)	10.8%
Miriam Kidron #+	358,092(5)	3.5%
Leonard Sank #	568,717(6)	5.6%
Harold Jacob #	58,794(7)	*
Michael Berelowitz #	31,994(8)	*
Gerald Ostrov #	33,094(9)	*
Yifat Zommer +	80,584(10)	*
Joshua Hexter +	51,800(11)	*
All current executive officers and directors, as a group (eight persons)	2,302,665(12)	21.0%

\* Less than 1%

#

Director

+

Named Executive Officer

(1)



Includes warrants to purchase 557,274 shares of common stock. Regals Capital Management LP is the investment manager of Regals, the owner of record of these shares of common stock. Mr. David M. Slager is the managing member of the general partner of Regals Capital Management LP. All investment decisions are made by Mr. Slager, and thus the power to vote or direct the votes of these shares of common stock, as well as the power to dispose or direct the disposition of such shares of common stock is held by Mr. Slager through Regals Capital Management LP. The foregoing is based on information known to us.

- (2) Consists of 440,000 shares of common stock owned by Special Situations Fund III QP, L.P., 150,000 shares of common stock owned by Special Situations Cayman Fund, L.P. and 200,000 shares of common stock owned by Special Situations Life Sciences Fund, L.P. Austin W. Marxe, or Marxe, David M. Greenhouse, or Greenhouse, and Adam C. Stettner, or Stettner, are members of SSCayman LLC, the general partner of Special Situations Cayman Fund, L.P. Marxe, Greenhouse and Stettner are controlling principals of AWM Investment Company, Inc., the general partner of MGP Advisers Limited Partnership, the general partner of Special Situations Fund III QP, L.P. Marxe, Greenhouse and Stettner are also members of LS Advisers L.L.C., the general partner of Special Situations Life Sciences Fund, L.P. The foregoing is based on a Schedule 13G filed jointly by Marxe, Greenhouse and Stettner on February 12, 2014.

- (3) Consists of 696,378 shares of common stock issuable pursuant to a Stock Purchase Agreement entered into by the Company and between Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd.
- (4) Includes 255,278 shares of common stock issuable upon the exercise of outstanding stock options.
- (5) Includes 255,278 shares of common stock issuable upon the exercise of outstanding stock options.
- (6) Includes: (a) 243,000 shares of common stock and warrants to purchase 23,265 shares of common stock held by Mr. Sank, (b) 78,125 shares of common stock and a warrant to purchase 27,344 shares of common stock held by Mr. Sank's wife, (c) 58,094 shares of common stock issuable to Mr. Sank upon the exercise of outstanding stock options, and (d) 138,889 shares of common stock owned by a company wholly owned by a trust of which Mr. Sank is a trustee. Mr. Sank disclaims beneficial ownership of the securities referenced in (b) and (d) above.
- (7) Includes 700 shares of common stock indirectly acquired through a corporation wholly-owned by Mr. Jacob, and 58,094 shares of common stock issuable upon the exercise of outstanding stock options.
- (8) Consists of common stock issuable upon the exercise of outstanding stock options.
- (9) Consists of common stock issuable upon the exercise of outstanding stock options.
- (10) Consists of common stock issuable upon the exercise of outstanding stock options.
- (11) Consists of common stock issuable upon the exercise of outstanding stock options.
- (12) Includes 848,637 shares of common stock issuable upon the exercise of options beneficially owned by the referenced persons.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

During fiscal 2014, we did not participate in any transaction, and we are not currently participating in any proposed transaction, or series of transactions, in which the amount involved exceeded \$120,000, and in which, to our knowledge, any of our directors, officers, five percent beneficial security holders, or any member of the immediate family of the foregoing persons had, or will have, a direct or indirect material interest.

Our policy is to enter into transactions with related persons on terms that, on the whole, are no less favorable than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred. All related person transactions are approved by our Board.

See “Item 11. Executive Compensation—Director Compensation” above for information as to one of our directors and the Chairman of our Scientific Advisory Board, Michael Berelowitz.

The Board has determined that Leonard Sank, Harold Jacob, Michael Berelowitz and Gerald Ostrov are independent as defined under the rules promulgated by Nasdaq.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The aggregate fees billed by Kesselman & Kesselman, independent registered public accounting firm, and member firm of PricewaterhouseCoopers International Limited, for services rendered to us during the fiscal years ended August 31, 2014 and 2013:

Summary:	2014	2013
Audit Fees(1)	\$ 91,000	\$ 100,000
Tax Fees(2)	5,000	10,000
Total Fees	\$ 96,000	\$ 110,000

(1) Amount represents fees paid for professional services for the audit of our consolidated annual financial statements, review of our interim condensed consolidated financial statements included in quarterly reports, audit of our internal control over financial reporting, assistance with review of our response to SEC comments on our Annual Report on Form 10-K for the fiscal year ended August 31, 2013 and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings or engagements.

(2) Amount represents fees paid for consulting services to assist us with our implementation of FASB ASC Topic 740-10 (formerly FIN 48), “Income Taxes,” relating to uncertain tax positions.

The Board established our Audit Committee on September 28, 2012. The Audit Committee pre-approves all services provided by our independent auditors. All of the above services and fees were reviewed and approved by the Audit Committee before the services were rendered.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Index to Financial Statements

The following financial statements are filed as part of this Annual Report on Form 10-K:

	Page
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - Report of Kesselman &amp; Kesselman</u>	F - 1
CONSOLIDATED FINANCIAL STATEMENTS:	
<u>Balance sheets</u>	F - 2
<u>Statements of comprehensive loss</u>	F - 3
<u>Statements of changes in stockholders' equity</u>	F - 4
<u>Statements of cash flows</u>	F - 5
<u>Notes to financial statements</u>	F - 6 - F - 30

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of

Oramed Pharmaceuticals Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of comprehensive loss, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Oramed Pharmaceuticals Inc. and its subsidiary (the "Company") at August 31, 2014 and 2013, and the result of its operations and its cash flows for each of the three years in the period ended August 31, 2014, 2013 and 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of August 31, 2014, based on criteria established in Internal Control - Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits, (which was an integrated audit in 2014). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Tel Aviv, Israel  
November 13, 2014

/s/ Kesselman & Kesselman  
Kesselman & Kesselman  
Certified Public Accountants (Isr.)

A member firm of  
PricewaterhouseCoopers  
International Limited

F - 1

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ORAMED PHARMACEUTICALS INC.  
CONSOLIDATED BALANCE SHEETS  
U.S. Dollars in thousands (except share and per share data)

	August 31	
	2014	2013
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,762	\$ 2,272
Short term deposits (note 2)	18,481	5,247
Marketable securities (note 3)	1,047	956
Restricted cash (note 11)	16	16
Prepaid expenses and other current assets	64	90
Related parties (note 12)	330	5
Grants receivable from the chief scientist	78	58
<b>Total current assets</b>	<b>21,778</b>	<b>8,644</b>
<b>LONG TERM DEPOSITS AND INVESTMENT AMOUNTS FUNDED IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT (note 6)</b>	<b>3</b>	<b>5</b>
<b>PROPERTY AND EQUIPMENT, NET (note 4)</b>	<b>7</b>	<b>5</b>
<b>Total assets</b>	<b>\$ 21,802</b>	<b>\$ 8,660</b>
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES -</b>		
Accounts payable and accrued expenses	\$ 926	\$ 434
Related Parties (note 12c)	47	64
<b>Total current liabilities</b>	<b>973</b>	<b>498</b>
<b>LONG TERM LIABILITIES:</b>		
Employee rights upon retirement (note 6)	9	8
Provision for uncertain tax position (note 11e)	27	23
	36	31
<b>COMMITMENTS (note 7)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$ 0.012 par value (30,000,000 and 16,666,667 authorized shares as of August 31, 2014 and 2013, respectively; 10,102,555 and 7,937,872 shares issued and outstanding as of August 31, 2014 and 2013, respectively)	121	95
Accumulated other comprehensive income	452	304
Additional paid-in capital	48,040	29,856
Accumulated loss	(27,820 )	(22,124 )
<b>Total stockholders' equity</b>	<b>20,793</b>	<b>8,131</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 21,802</b>	<b>\$ 8,660</b>

The accompanying notes are an integral part of the financial statements.



ORAMED PHARMACEUTICALS INC.  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
U.S. Dollars in thousands (except share and per share data)

	2014	Year ended August 31 2013	2012
RESEARCH AND DEVELOPMENT EXPENSES, NET	\$ 3,277	\$ 2,272	\$ 1,681
GENERAL AND ADMINISTRATIVE EXPENSES	2,629	2,032	1,203
OPERATING LOSS	5,906	4,304	2,884
FINANCIAL INCOME (note 10a)	(225 )	(180 )	(13 )
IMPAIRMENT OF AVAILABLE-FOR-SALE SECURITIES	-	-	184
FINANCIAL EXPENSES (note 10b)	11	313	199
LOSS BEFORE TAXES ON INCOME	5,692	4,437	3,254
INCOME TAX EXPENSES (BENEFIT) (note 11)	4	(205 )	90
NET LOSS FOR THE YEAR	\$ 5,696	\$ 4,232	\$ 3,344
SUBSEQUENT INCREASE IN THE FAIR VALUE OF AVAILABLE FOR SALE SECURITIES PREVIOUSLY WRITTEN DOWN AS IMPAIRED	(34 )	(131 )	-
RECLASSIFICATION ADJUSTMENT FOR GAINS INCLUDED IN NET LOSS	80	90	-
UNREALIZED GAIN ON AVAILABLE FOR SALE SECURITIES	(194 )	(263 )	-
TOTAL OTHER COMPREHENSIVE INCOME	(148 )	(304 )	-
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$ 5,548	\$ 3,928	\$ 3,344
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ 0.62	\$ 0.59	\$ 0.57
WEIGHTED AVERAGE NUMBER OF COMMON SHARES USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	9,244,059	7,209,283	5,884,595

The accompanying notes are an integral part of the financial statements.

ORAMED PHARMACEUTICALS INC.  
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
U.S. Dollars in thousands (except share and per share data)

	Common Stock Shares In thousands	\$	Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
BALANCE AS OF AUGUST 31, 2011	5,844	\$70	\$18,201	\$ -	\$ (14,548 )	\$ 3,723
SHARES AND WARRANTS ISSUED FOR CASH, NET(see note 8b)	802	10	2,985	-	-	2,995
SHARES AND WARRANTS TO BE ISSUED FOR CASH (see note 8b)	-	-	25	-	-	25
SHARES ISSUED FOR SERVICES	29	*	108	-	-	108
STOCK BASED COMPENSATION EXPENSE	-	-	271	-	-	271
NET LOSS	-	-	-	-	(3,344 )	(3,344 )
BALANCE AS OF AUGUST 31, 2012	6,675	80	21,590	-	(17,892 )	3,778
SHARES AND WARRANTS ISSUED FOR CASH, NET(see note 8c)	349	4	1,418	-	-	1,422
SHARES ISSUED FOR CASH, NET (see note 8d)	658	8	4,231	-	-	4,239
SHARES ISSUED FOR MARKETABLE SECURITIES (see note 8b)	199	2	626	-	-	628
SHARES ISSUED FOR SERVICES	34	*	244	-	-	245
EXCHANGE OF WARRANTS (see note 5)	-	-	918	-	-	918
EXERCISE OF WARRANTS AND OPTIONS	23	*	110	-	-	110
STOCK BASED COMPENSATION EXPENSE	-	-	719	-	-	719
NET LOSS	-	-	-	-	(4,232 )	(4,232 )
OTHER COMPREHENSIVE INCOME	-	-	-	304	-	304
BALANCE AS OF AUGUST 31, 2013	7,938	\$95	\$29,856	\$ 304	\$ (22,124 )	\$ 8,131
SHARES ISSUED FOR CASH, NET (see note 8g)	1,580	19	14,868	-	-	14,887
	16	*	102	-	-	102

SHARES ISSUED (see notes 7f)						
EXERCISE OF WARRANTS AND OPTIONS	569	7	1,746	-	-	1,753
STOCK BASED COMPENSATION EXPENSE	-	-	1,468	-	-	1,468
NET LOSS	-	-	-	-	(5,696 )	(5,696 )
OTHER COMPREHENSIVE INCOME	-	-	-	148		148
BALANCE AS OF AUGUST 31, 2014	10,103	\$121	\$48,040	\$ 452	\$ (27,820 )	\$ 20,793

\* Represents an amount of less than \$1.

The accompanying notes are an integral part of the financial statements

ORAMED PHARMACEUTICALS INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
U.S. Dollars in thousands (except share and per share data)

	Year ended August 31		
	2014	2013	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(5,696 )	\$(4,232 )	\$(3,344 )
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6	5	15
Exchange differences and interest on deposits	(29 )	19	62
Stock based compensation	1,468	719	271
Common stock issued for services	102	244	108
Gain on sale of investment	(80 )	(50 )	-
Impairment of available for sale securities	-	-	184
Exchange of warrants	-	297	-
Changes in fair value of warrant liabilities	-	(45 )	143
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(319 )	(3 )	(31 )
Accounts payable and accrued expenses	475	(146 )	203
Liability for employee rights upon retirement	1	1	(2 )
Provision for uncertain tax position	4	(205 )	90
Total net cash used in operating activities	(4,068 )	(3,396 )	(2,301 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(14 )	(6 )	(2 )
Purchase of short term deposits	(55,750 )	(5,847 )	(475 )
Proceeds from sale of short term deposits	42,539	1,054	1,800
Proceeds from sale of marketable securities	137	227	450
Funds in respect of employee rights upon retirement	(2 )	(2 )	(4 )
Other	2	5	-
Total net cash used in investing activities	(13,088 )	(4,569 )	1,769
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock and warrants - net of issuance expenses*	14,887	5,715	3,489
Proceeds from exercise of warrants and options	1,753	109	-
Total net cash provided by financing activities	16,640	5,824	3,489
EFFECT OF EXCHANGE RATE CHANGES ON CASH	6	(18 )	(39 )
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(510 )	(2,159 )	2,918
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,272	4,431	1,513
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 1,762	\$ 2,272	\$ 4,431
<b>Material non cash investing and financing activities:</b>			
Exchange of warrants	-	918	-
Shares issued for marketable securities	-	628	-
Shares and warrants to be issued for cash	-	-	25

\* See notes 8a, 8b and 8d.

The accompanying notes are an integral part of the financial statements.

F - 5

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General

1) Incorporation and operations

Oramed Pharmaceuticals Inc. (the “Company”) was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd (“Hadasit”) to acquire the provisional patent related to orally ingestible insulin capsule to be used for the treatment of individuals with diabetes.

On March 11, 2011, the Company was reincorporated from the State of Nevada to the State of Delaware.

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd., which is engaged in research and development. Unless the context indicates otherwise, the term “Group” refers to Oramed Pharmaceuticals Inc. and its Israeli subsidiary, Oramed Ltd. (the “Subsidiary”).

2) Development and liquidity risks

The Group is engaged in research and development in the biotechnology field for innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules for delivery of other polypeptides, and has not generated any revenues from its operations. Continued operation of the Company is contingent upon obtaining sufficient funding until it becomes profitable.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the FDA prior to selling its products within the United States, and foreign regulatory approvals must be obtained to sell its products internationally. There can be no assurance that the Company will receive regulatory approval of any of its product candidates, and a substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all. The Company also expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during their respective developmental periods. Obtaining marketing approval will be directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. The Company cannot predict the outcome of these activities.

Based on its current cash resources and commitments, and cash received in private and public offerings in the years ended August 31, 2014 and 2013, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months and beyond after the date that the financial statements are issued, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing during the next 12 months.

3) Reverse stock split

On January 10, 2013, the Company's Board of Directors approved a reverse stock split at a ratio of one-for-twelve, effective January 22, 2013, which decreased the number of common shares issued and outstanding as of January 23, 2013, from approximately 86.5 million shares to approximately 7.2 million shares and the number of authorized common shares from 200 million shares to approximately 16.7 million shares. All share and per share data were retrospectively adjusted as a result of the split.

b. Accounting principles

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

c. Use of estimates in the preparation of financial statements

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the financial statements date and the reported expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to stock based compensation.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Functional currency

The currency of the primary economic environment in which the operations of the Company and its Subsidiary are conducted is the U.S. dollar (“\$” or “dollar”). Therefore, the functional currency of the Company and its Subsidiary is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions - exchange rates at transaction dates or average rates and (2) for other items (derived from non-monetary balance sheet items such as depreciation) - historical exchange rates. The resulting transaction gains or losses are carried to financial income or expenses, as appropriate.

e. Principles of consolidation

The consolidated financial statements include the accounts of the Company and its Subsidiary. All inter-company transactions and balances have been eliminated in consolidation.

f. Income taxes

1. Deferred taxes

Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has provided a full valuation allowance with respect to its deferred tax assets.

Regarding the Subsidiary, the recognition is prohibited for deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the abovementioned differences were not reflected in the computation of deferred tax assets and liabilities.



ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Taxes that would apply in the event of disposal of investments in the Subsidiary have not been taken into account in computing deferred taxes, as it is the Company's intention to hold this investment, not to realize it.

2. Uncertainty in income tax

The Company follows a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. The Company's policy is to include interest and penalties related to unrecognized tax benefits within income tax expenses.

g. Research and development, net

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, employee benefits, the cost of supplies, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses and the full cost of manufacturing drug for use in research and preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as Contract Research Organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, clinical trial costs are expensed immediately.

Grants received from the OCS and from Bio-Jerusalem are recognized as grant income when the grants become receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grants are deducted from the related research and development expenses as the costs are incurred and are presented in R&D expenses, net. See also notes 7(j) and 7(k).

h. Cash equivalents

The Company considers all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents.

i. Loss per common share

Basic and diluted net loss per common share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding. Outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented.

The total number of common stock options and warrants excluded from the calculation of diluted net loss was 1,924,491 for the year ended August 31, 2014 (2,343,972 and 1,892,180 for the years ended August 31, 2013 and 2012, respectively).

F - 9

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

j. Stock based compensation

Equity awards granted to employees are accounted for using the grant date fair value method. The fair value of share based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. The expected service period is estimated using the simplified method due to insufficient specific historical information of employees' exercise behavior. The forfeitures are estimated based on historical experience and anticipated future conditions. The Company elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach. When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

k. Warrants issued as part of capital raisings that are classified as a liability

Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the statement of financial position.

The liability is measured both initially and in subsequent periods at fair value, with changes in fair value charged to finance expenses, net. See note 5.

l. Fair value measurement:

Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of August 31, 2014 the assets or liabilities measured at fair value comprise of available for sale securities (level 1).

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible.



ORAMED PHARMACEUTICALS INC.  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
 U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The Company has placed a restricted deposit with a certain bank in an amount of \$16 as security for its credit card activity.

Available-for-sale securities are reported at fair value, with unrealized gains and losses, net of related tax recorded as a separate component of other comprehensive income in equity until realized. Unrealized losses that are considered to be other-than-temporary are charged to statement of operations as an impairment charge and are included in the consolidated statement of operations under impairment of available-for-sale securities.

The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost, and the Company's ability and intent to hold the investment. Realized gains and losses on sales of the securities are included in the consolidated statement of operations as financial income or expenses.

m. Concentration of credit risks

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents, short term deposit and marketable securities which are deposited in major financial institutions. The Company is of the opinion that the credit risk in respect of these balances is remote.

n. Property and equipment

Property and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the assets.

Annual rates of depreciation are as follows:

	%
Computers and peripheral equipment	33
Office furniture and equipment	15-33

Leasehold improvements are amortized over the term of the lease which is shorter than the estimated useful life of the improvements.

o. Newly issued and recently adopted accounting pronouncements:

1. In August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Currently, there is no guidance under U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in ASU 2014-15 provide that guidance. In doing so,

the amendments should reduce diversity in the timing and content of footnote disclosures. This new standard requires management to assess the entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 will be effective prospectively for annual reporting periods ending after the first annual period ending after December 15, 2016 and interim periods therein. Early application of the standard is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued. The Company has elected to early adopt the provisions of ASU 2014-15 in fiscal year 2014.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

2. In June 2014, the FASB issued ASU 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (“ASU 2014-10”). This update removes the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The amendments also clarify that the guidance in Topic 275, Risks and Uncertainties, is applicable to entities that have not commenced planned principal operations. The amendments in ASU 2014-10 will be effective retrospectively except for the clarification to Topic 275, which shall be applied prospectively for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early application of each of the amendments is permitted for any annual reporting period or interim period for which the entity’s financial statements have not yet been issued. The Company has elected to adopt the provisions of ASU 2014-10 in the third quarter of fiscal year 2014, and therefore removed the inception to date information and all reference to development. As a result, the adoption of ASU 2014-10 only impacted the consolidated financial statement presentation.
3. In February 2013, the FASB issued ASU 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (“ASU 2013-02”). This update requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, ASU 2013-02 requires presentation, either on the face of the income statement or in the notes, of significant amounts reclassified out of accumulated other comprehensive income by respective line items of net income, but only if the amounts reclassified are required to be reclassified in their entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about these amounts. The amendments in ASU 2013-02 will be effective prospectively for annual reporting periods beginning after December 15, 2012, and interim periods within those annual periods. The Company adopted ASU 2013-02 in the first quarter of fiscal year 2014. The adoption of ASU 2013-02 did not have any material effect on the consolidated financial statement presentation.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 2 - SHORT TERM DEPOSITS:

Amounts that represent bank deposits that do not meet the cash equivalent criteria are the following:

	2014		August 31		2013	
	Annual interest rate	Amount	Annual interest rate	Amount	Annual interest rate	Amount
Dollar deposits	0.12-0.6 %	\$ 18,481	0.6-1.06 %	\$ 5,112		
NIS deposits		-	1.93 %	135		
		\$ 18,481		\$ 5,247		

## NOTE 3 - MARKETABLE SECURITIES:

Available-for-sale securities are reported at fair value, with unrealized gains and losses, recorded as a separate component of other comprehensive income in equity until realized. Unrealized losses that are considered to be other-than-temporary are charged to statement of operations as an impairment charge and are included in the consolidated statement of operations under impairment of available-for-sale securities.

As of August 31, 2014, marketable securities consisted wholly of equity securities of D.N.A Biomedical Solutions Ltd ("D.N.A"). D.N.A. ordinary shares are traded on the Tel Aviv Stock Exchange and have a quoted price. The fair value of those securities is measured at the quoted prices of the securities on the measurement date.

During the years ended August 31, 2014 and 2013, the Subsidiary sold in aggregate 2,625,989 and 5,250,000 of the D.N.A ordinary shares for a total of \$138 and \$170, respectively. In March 2013 the Company sold 1,750,000 of the D.N.A ordinary shares for \$56.

As of August 31, 2014, the Group owns approximately 9.8% of D.N.A's outstanding ordinary shares.

The cost of the securities as of August 31, 2014 and 2013 is \$590 and \$652.

The cost of the securities sold and the amount reclassified out of accumulated other comprehensive income into financial income (amounting to \$80 and \$90 during the years ended August 31, 2014 and 2013, respectively), were determined by specific identification.

As of August 31, 2014 and 2013, the available for sale securities are classified as Level 1.

As of August 31, 2014, the carrying amount of cash and cash equivalents, short term deposits, accounts receivable, other current assets and accounts payables and accrued expenses approximates their fair values due to the short-term maturities of these instruments.

The amounts funded in respect of employee rights are stated at cash surrender value which approximates its fair value.





ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 4 - PROPERTY AND EQUIPMENT, NET:

- a. Composition of property and equipment, grouped by major classifications, is as follows:

	August 31	
	2014	2013
<b>Cost:</b>		
Leasehold improvements	\$ 78	\$ 76
Office furniture and equipment	28	20
Computers and peripheral equipment	38	34
	144	130
Less - accumulated depreciation and amortization	130	124
	\$ 14	\$ 6

- b. Depreciation expenses totaled \$6, \$5 and \$15 in the years ended August 31, 2014, 2013 and 2012, respectively.

## NOTE 5 - WARRANTS

As part of the Company's private placements in 2011 and 2012, three warrants to purchase in aggregate 311,797 shares were granted to a Leading Investor, as defined in note 8a (collectively, the "Warrants"). The Warrants were granted for five years at an initial exercise price of \$6.00 per share. The Warrants included a full ratchet anti-dilution protection from the second year anniversary date after issuing the warrant, subject to certain limitations. In the event the Company was to issue or sell any common stock for a consideration per share lower than the exercise price then in effect, or was to issue or sell any options, warrants or other rights for the purchase or acquisition of such shares at a consideration per share of less than the exercise price then in effect, the warrants were to be amended to (a) reduce the exercise price to an amount equal to the per share consideration payable to the company in such sale or issuance, and (b) the quantity of warrants were to be updated.

As a result of a private placement in August 2012, and the agreement with D.N.A from October 2012, as described in note 8b, the warrant that was issued in 2011 was twice amended in such that its exercise price was reduced to \$3.7656 per share and the number of shares issuable upon its exercise was increased to 290,459.

On November 29, 2012, the Company and the Leading Investor entered into a letter agreement (the "Agreement") in connection with the Warrants, pursuant to the which, the Company and the Leading Investor agreed to amend the Warrants to remove the anti-dilution protection in its entirety. In addition, as to the Warrants issued in August and November 2012, the exercise price was reduced to \$3.7656 per share. On that day, the Company also issued to the Leading Investor an additional warrant to purchase up to 137,311 shares of the Company over a period of four years at an exercise price of \$7.20 per share.

The fair value of the new warrant at the date of grant was \$145, using the following assumptions: dividend yield of 0%, expected term of four years, expected volatility of 62.29% and risk-free interest rate of 0.57%.

The fair value of the warrants was determined by using a Monte Carlo type model based on the risk neutral approach. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant

delay in this input would result in a higher fair value measurement.

F - 14

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 5 – WARRANTS (continued):

In addition to the new warrants, the Company’s President, Chief Executive Officer and director (the “CEO”), in his personal capacity as a shareholder of the Company, undertook and agreed that following the execution and delivery of the Agreement, in the event that an adjustment pursuant to the anti-dilution protection of any of the Warrants, as amended, would have been triggered and the number of shares of common stock of the Company that the Leading Investor would have been able to purchase under the Warrants would have increased by an aggregate number in excess of 137,311 shares, then the Leading Investor shall have the right to purchase from the CEO such number of shares of common stock of the Company owned by the CEO equal to such excess, up to a maximum of 112,690 shares of common stock of the Company (the “CEO Option”). The foregoing right shall survive until the expiration date of such Warrants. The fair value of the CEO Option on the date of grant was \$168, based on the Monte Carlo type model and was recognized as an expense against the stockholders equity.

Following the removal of the anti-dilution protection, the Warrants were no longer classified as liabilities. The Company recognized a financial expense in the amount of \$297 during the three months ended November 30, 2012.

The following table summarizes the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs for the years ended August 31, 2013 and 2012. There were no Level 3 items for the year ended August 31, 2014.

	Year ended August 31,	
	2013	2012
Carrying value at the beginning of the period	\$ 637	\$ -
Additions	28	494
Changes in fair value	(44 )	143
Exchange of warrants	(621 )	-
Carrying value at the end of the period	\$ -	\$ 637

See note 8g with respect to outstanding warrants.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 6 - EMPLOYEES RIGHTS UPON RETIREMENT:

The Subsidiary is required to make a severance payment upon dismissal of an employee, or upon termination of employment in certain circumstances. The severance pay liability to the employees (based upon length of service and the latest monthly salary - one month's salary for each year employed) is recorded on the Subsidiary's balance sheets under "Liability for employee rights upon retirement." The liability is recorded as if it were payable at each balance sheet date on an undiscounted basis.

The liability is funded in part by the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the Subsidiary's balance sheets under "Funds in respect of employee rights upon retirement." These policies are the Subsidiary's assets. However, under labor agreements and subject to certain limitations, any policy may be transferred to the ownership of the individual employee for whose benefit the funds were deposited. In each of the years ended August 31, 2014 and 2013 the Subsidiary deposited \$2, and in the year ended August 31, 2012 deposited \$4 with insurance companies in connection with its severance payment obligations.

In accordance with the current employment agreements with certain employees, the Subsidiary makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's rights upon retirement. The Subsidiary is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the Subsidiary's balance sheets, as the amounts funded are not under the control and management of the Subsidiary and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plans").

The amounts of severance pay expenses were \$26, \$23 and \$6 for the years ended August 31, 2014, 2013 and 2012, respectively. \$26, \$13 and \$7 in the years ended August 31, 2014, 2013 and 2012, respectively, were in respect of a Contribution Plan.

The Subsidiary expects to contribute approximately \$27 in the year ending August 31, 2015 to insurance companies in connection with its severance liabilities for its operations for that year.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 7 - COMMITMENTS:

a. In March 2011, the Subsidiary sold shares of its investee company, Entera Bio Ltd (“Entera”) to D.N.A (see also note 3), retaining a 3% interest, which is accounted for as a cost method investment (amounting \$1). In consideration for the shares sold to D.N.A, the Company received a promissory note issued by D.N.A in the principal amount of \$450, with an annual interest rate of 0.45% that was fully paid in November 2011, and 8,404,667 ordinary shares of D.N.A.

As part of this agreement, the Subsidiary entered into a patent transfer agreement according to which, the Subsidiary assigned to Entera all of its right, title and interest in and to the patent application that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera’s net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. As of August 31, 2014, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary.

b. On September 11, 2011, the Subsidiary entered into an agreement with Hadasit, the Company's Medical and Chief Technology Officer (the “CTO”) and Dr. Daniel Schurr (the “Hadasit Agreement”) to retain consulting and clinical trial services. According to the Hadasit Agreement, Hadasit will be entitled to a consideration of \$200 to be paid by the Company in accordance with the actual progress of the studies, \$95 of which were recognized through August 31, 2014. See also note 1a(1).

c. On February 15, 2011, the Subsidiary entered into a consulting agreement with a third party (the “Consultant”) for a period of five years, pursuant to which the Consultant will provide consultation on scientific and clinical matters. The Consultant is entitled to a fixed monthly fee of \$8, royalties of 8% of the net royalties actually received by the Subsidiary in respect of the patent that was sold to Entera on March 31, 2011 and an option to purchase up to 20,834 shares of the Company at an exercise price of \$6.00 per share. The option vests in five annual installments commencing February 16, 2012 and expires on February 16, 2021. The initial fair value of the option on the date of grant was \$62, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 78.65%; risk-free interest rates of 3.62%; and the remaining expected term of 10 years. The fair value of the option as of August 31, 2014 was \$111, using the following assumptions: dividend yield of 0% and expected term of 6.46 years; expected volatility of 81.31%; and risk-free interest rate of 2.05%. The fair value of the unvested options is remeasured at each balance sheet reporting date and is recognized over the related service period using the straight-line method.

d. On March 18, 2012, the Subsidiary entered into a lease agreement for its facilities in Israel. The lease agreement was for a period of 57 months commencing January 1, 2012.

On April 28, 2013, the Subsidiary entered into a new lease agreement for its office facilities in Israel, which replaced the lease agreement from 2012. The new lease agreement is for a period of 36 months commencing November 4, 2013. The annual lease payment will be NIS 89 from 2014 through 2016, and will be linked to the increase in the Israeli consumer price index (“CPI”) (as of August 31, 2014, the future annual lease payments under the new agreement will be \$25, based on the exchange rate as of August 31, 2014).

The lease expenses for the years ended August 31, 2014, 2013 and 2012 were \$27, \$13 and \$9, respectively.

The future lease payments under the lease agreement are \$25 in each of the years ending August 31, 2015 and 2016, and \$2 for the year ending August 31, 2017.

As security for its obligation under this lease agreement the Company provided a bank guarantee in an amount equal to three monthly lease payments.

e. The Subsidiary has entered into operating lease agreements for vehicles used by its employees for a period of 3 years.

The lease expenses for the years ended August 31, 2014, 2013 and 2012 were \$28, \$30 and \$30, respectively.

F - 17

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 7 - COMMITMENTS (continued):

The future lease payments under the lease agreement are \$18 and \$14 for the years ending August 31, 2015 and 2016, respectively.

As security for its obligation under the lease agreements the Subsidiary deposited \$2, which are classified as long term deposits.

f. On August 15, 2011, the Company entered into a consulting agreement with a third party advisor for a period of nine months, pursuant to which such advisor provided investor relations services and received a monthly cash fee and shares of the Company's common stock that were issued in three equal installments as follows: on each of December 12, 2011, March 14, 2012 and May 15, 2012, the Company issued 6,917 shares at a fair value of \$25, \$27 and \$25, respectively.

On April 15, 2013, the Company entered into an additional consulting agreement with the same third party advisor for a period of twelve months, pursuant to which such advisor provided investor relations services and received a monthly cash fee and 15,000 shares of the Company's common stock. On July 11 and November 4, 2013 the Company issued to such advisor 5,000 and 10,000 shares, respectively. The fair value of the shares at these dates was \$35 and \$64, respectively.

On May 13, 2014, the Company entered into an additional consulting agreement with the same third party advisor for a period of an additional twelve months, pursuant to which such advisor will provide investor relations services and will be entitled to receive a monthly cash fee and 15,000 shares of the Company's common stock that will be issued in four equal installments, on each of August 1, 2014, November 1, 2014, February 1, 2015 and May 1, 2015. As of August 31, 2014 the Company issued to such advisor 3,750 shares. The fair value of the shares at that date was \$38.

- g. On April 29, 2013, the Subsidiary entered into a Clinical Research Organization Service Agreement with a third party, to retain it as a Clinical Research Organization ("CRO"), for its Phase IIa clinical trial for an oral insulin capsule for type 2 diabetes patients. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$333 that will be paid during the term of the engagement and based on achievement of certain milestones, all of which were recognized through August 31, 2014.

On February 6, 2014, the Subsidiary entered into a second agreement with the same CRO, for its Phase IIa clinical trial for an oral insulin capsule for type 1 diabetes patients, which was completed in October 2014. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$280 that will be paid during the term of the engagement and based on achievement of certain milestones, \$182 of which were recognized through August 31, 2014.

On July 22, 2014, the Subsidiary entered into a third agreement with the same CRO, for its Phase 2b clinical trial for an oral insulin capsule for type 2 diabetes patients, which is expected to be begin in the first quarter of calendar year 2015. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$3,290 that will be paid during the term of the engagement and based on achievement of certain milestones, \$64 of which were recognized through August 31, 2014.





ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 7 - COMMITMENTS (continued):

h. On July 23, 2013, the Subsidiary entered into a Master Service Agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of \$102, all of which was recognized through August 31, 2014.

On March 3, 2014, the Subsidiary entered into an additional agreement with the same vendor, for the process development and production of one of its oral capsule ingredients in a different technology in the amount of \$311, \$40 of which was recognized through August 31, 2014, and bonus payments of up to \$600 that will be paid upon achieving certain milestones, as described in the agreement, none of which was recognized through August 31, 2014.

On May 15, 2014, the Subsidiary entered into an additional agreement with the same vendor, for the process development and production of the same capsule ingredients in the amount of \$217, \$103 of which was recognized through August 31, 2014

i. On May 26, 2014, the Subsidiary entered into a supply agreement with a vendor, according to which, the vendor will manufacture insulin capsules for total consideration of \$214, \$47 of which were recognized through August 31, 2014.

j. Grants from Bio-Jerusalem

The Subsidiary is committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received by the Company (Israeli CPI linked) at the total amount of \$65. As of August 31, 2014, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

During the years ended August 31, 2014 and 2012, the Company received no grants from the Bio-Jerusalem fund. For the year ended August 31, 2013, the research and development expenses are presented net of Bio-Jerusalem grants, in the total amount of \$12.

k. Grants from the Chief Scientist Office ("OCS")

Under the terms of the Company's funding from the Israeli Government, royalties of 3%-3.5% are payable on sales of products developed from a project so funded, up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of annual interest at a rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured. In case of failure of a project that was partly financed as above, the Company is not obligated to pay any such royalties.

On August 31, 2014, the Subsidiary had not yet realized any revenues from the said project and did not incur any royalty liability. The total amount that was actually received through August 31, 2014 was \$2,066.

For the years ended August 31, 2014, 2013 and 2012, the research and development expenses are presented net of OCS Grants, in the total amount of \$428, \$297 and \$373, respectively.



ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 8 - STOCKHOLDERS' EQUITY:

In February 2013 the Company's common stock began trading on the Nasdaq Capital Market under the symbol ORMP. Before then it was traded on the Over-The-Counter Bulletin Board.

The following are the significant capital stock transactions that took place during the years ended August 31, 2014, 2013 and 2012:

a. In August 2012, the Company entered into Securities Purchase Agreements with a number of investors for the sale of 801,942 units at a purchase price of \$4.44 per unit for total consideration of \$3,560. Each unit consisted of one share of the Company and one common stock purchase warrant. Each warrant entitles the holder to purchase half a share exercisable for five years at an exercise price of \$6.00 per share. The investors were granted customary registration rights with respect to resales of shares, including the shares underlying the warrants. In addition, one of the investors who was previously defined as a leading investor (the "Leading Investor"), who purchased 225,226 of the units, was granted the right to maintain its percentage of the shares of the Company's common stock outstanding by purchasing more shares whenever the Company proposes to issue certain additional shares to other investors. Such right only exists so long as such investor holds at least 5% of the Company's outstanding common stock. In addition, such investor's warrants contained anti-dilution protection (the "full ratchet anti-dilution protection") and cashless exercise provisions not contained in the other investors' warrants. The other terms of the Leading Investor's Securities Purchase Agreement were substantially the same as those granted to him in 2011 for his first investment. As to the amendment to the 2011 Warrants, see note 5.

In addition, in August 2012, the Company entered into a Securities Purchase Agreement with an investor for the sale of 5,652 units at same terms as describe above. As the payment from said investor was received during September 2012, following which, the Company issued him 5,652 shares of its common stock and a warrant to purchase 2,826 shares of its common stock, the proceeds from that investment, of \$25 were presented as shares and warrants to be issued for cash.

The Company paid cash consideration of \$71 as finders' fees in connection with the Securities Purchase Agreements.

b. Between September and November 2012, the Company entered into Securities Purchase Agreements with a number of investors for the sale of 329,872 units at a purchase price of \$4.44 per unit for total consideration of \$1,464. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase 0.50 a share of common stock exercisable for five years at an exercise price of \$6.00 per share. The investors were granted customary registration rights with respect to resales of shares, including the shares underlying the warrants. In addition, the Leading Investor, who purchased 33,784 of the units, was granted the right to maintain its percentage of the shares of the Company's common stock outstanding by purchasing more shares whenever the Company proposes to issue certain additional shares to other investors. Such right only exists so long as such investor holds at least 5% of the Company's outstanding common stock. In addition, such investor's warrants contained full ratchet anti-dilution protection and cashless exercise provisions not contained in the other investors' warrants. The other terms of the Leading Investor's Securities Purchase Agreement were substantially the same as those granted to him in 2011 for his first investment. As to the amendment to certain Warrants, and the removal of the full ratchet anti-dilution protection see note 5.

As a finder's fee, in connection with the securities purchase agreements, the Company paid cash consideration of \$13, as well as issued 1,127 shares of the Company and 564 common stock purchase warrant to another individual. The Company also issued 12,745 shares of the Company and 6,373 common stock purchase warrants to a director as a finder's fee with respect to the Securities Purchase Agreements described above and to the Securities Purchase Agreements to which the Company had entered into in August 2012.

F - 20

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 8 - STOCKHOLDERS' EQUITY (continued):

- c. On October 30, 2012, the Company entered into a Securities Purchase Agreement with D.N.A, according to which, the Company issued on that day to D.N.A 199,172 shares of its common stock, in consideration for the option to purchase up to 21,637,611 ordinary shares of D.N.A, valued at approximately \$629 at the day of the transaction. The Company exercised the option in February 2013. See also note 3.
- d. On July 10, 2013, the Company entered into a Placement Agency Agreement with Aegis Capital Corp. as representative of the several placement agents (the "Placement Agents"), pursuant to which the Placement Agents agreed to use their reasonable best efforts to arrange for the sale of up to 658,144 shares of the Company's common stock. In connection therewith, on July 10, 2013, the Company also entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell an aggregate of 658,144 shares at a price of \$7.00 per share, to various investors in a registered direct offering (the "Offering"). The Company received all funds and issued all shares in connection with the Offering as of July 17, 2013. The net proceeds to the Company from the offering are approximately \$4,239, after deducting Placement Agents' commissions of \$255 and other offering expenses of the Company.
- e. On December 24, 2013, the Company entered into a Placement Agency Agreement with the Placement Agent, pursuant to which the Placement Agent agreed to use its reasonable best efforts to arrange for the sale of up to 1,580,000 shares of the Company's common stock. In connection therewith, on December 24, 2013, the Company entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell an aggregate of 1,580,000 shares of common stock, at a price of \$10.00 per share, to two institutional investors in a registered direct offering (the "Offering"). The net proceeds to the Company from the Offering were approximately \$14,887, after deducting Placement Agent's commissions of \$816 and other offering expenses of the Company.
- f. On July 23, 2014, the Company's shareholders approved an amendment to the Company's Certificate of Incorporation to increase the Company's authorized common stock from 16,666,667 shares to 30,000,000 shares.
- g. As of August 31, 2014, the Company had outstanding warrants exercisable for 953,369 shares of common stock at exercise prices ranging from \$3.7656 to \$7.20 expiring at various dates between November 11, 2015 and February 2, 2018.

The following table presents the warrant activity for the years ended August 31, 2014, 2013 and 2012:

	2014		2013		2012	
	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price*	Warrants	Weighted-Average Exercise Price*
Warrants outstanding as of September 1	1,215,034	\$ 5.33	883,191	\$ 5.56	352,883	\$ 6.00
Issued	-	-	353,285	\$ 4.79	530,308	\$ 5.28
Exercised	(261,665 )	\$ 6.00	(21,442 )	\$ 6.00	-	-
Warrants outstanding as of	953,369	\$ 5.15	1,215,034	\$ 5.33	883,191	\$ 5.56

August 31

Warrants  
exercisable as of

August 31	952,258	\$ 5	1,213,478	\$ 5.33	852,024	\$ 5.55
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\* See note 5 with regards to the amendment of price of certain warrants during the years ended August 31, 2012 and 2013.

F - 21

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

NOTE 9 - STOCK BASED COMPENSATION:

As of August 31, 2014, the Company has one stock option plan, the Amended and Restated 2008 Stock Incentive Plan, under which, the Company had reserved a pool of 1,400,000 shares of the Company's common stock which may be issued at the discretion of the Company's Board of Directors from time to time. Under this Plan, each option is exercisable into one share of common stock of the Company.

The options may be exercised after vesting and in accordance with vesting schedules which will be determined by the Board of Directors for each grant. The maximum term of the options is 10 years.

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on a historical volatility, by statistical analysis of the weekly share price for past periods. The expected term is the length of time until the expected dates of exercising the options, and is estimated using the simplified method due to insufficient specific historical information of employees' exercise behavior.

The following are the significant stock options transactions with executive and board members made during the years ended August 31, 2014, 2013 and 2012:

- a. On August 8, 2012, options to purchase an aggregate of 144,000 shares of the Company were granted to the CEO and to the CTO, both related parties, at an exercise price of \$4.08 per share (equivalent to the traded market price on the date of grant), the options vested with respect to 42,000 shares of common stock immediately on the date of grant and the remaining shares of common stock will vest in seventeen equal monthly installments of 6,000 each. These options expire on August 7, 2022. The fair value of these options on the date of grant was \$374, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.03%; risk-free interest rates of 0.83%; and expected term of 5.5 years.
- b. On August 8, 2012, options to purchase an aggregate of 43,334 shares of the Company were granted to three Board of Directors members at an exercise price of \$4.08 per share (equivalent to the traded market price on the date of grant). The options vest in two equal annual installments, commencing January 1, 2013, and expire on August 7, 2022. The fair value of these options on the date of grant was \$115, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.03%; risk-free interest rates of 1.0375%; and expected term of 5.75 years.
- c. On August 8, 2012, the Company's Board of Directors approved an extension of the term of the warrants to purchase 280,114 shares of the Company held by the CTO by approximately two years from such approval, expiring on August 6, 2014. The incremental fair value of the warrant extension was negligible.
- d. On December 20, 2012, options to purchase 20,000 shares of the Company were granted to a director at an exercise price of \$6.00 per share (higher than the traded market price on the date of grant). The options vested in two equal annual installments, commencing January 1, 2013, and expire on December 19, 2022. The fair value of these options on the date of grant was \$41, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 64.35%; risk-free interest rates of 1.01%; and expected term of 5.75 years.





ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 9 - STOCK BASED COMPENSATION (continued):

e. On April 9, 2014, options to purchase an aggregate of 94,268 shares of the Company were granted to the CEO and to the CTO, both related parties, at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vested with respect to 31,420 shares of common stock on April 30, 2014, and the remaining shares of common stock vest in eight equal monthly installments of 7,586 each. These options expire on April 9, 2024. The fair value of these options on the date of grant was \$781, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 82.06%; risk-free interest rates of 1.65%; and expected term of 5.21 years.

f. On April 9, 2014, options to purchase an aggregate of 52,376 shares of the Company were granted to four Board of Directors members at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vest in two equal installments, on July 1, 2014 and January 1, 2015, and expire on April 9, 2024. The fair value of these options on the date of grant was \$435, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 82.06%; risk-free interest rates of 1.65%; and expected term of 5.25 years.

The fair value of each option grant is estimated on the date of grant using the Black Scholes option-pricing model with the following assumptions:

	For options granted in the year ended August 31		
	2014	2013	2012
Expected option life (years)	5.21-5.25	5.75-6	5.5-5.75
Expected stock price volatility (%)	82.06	64.35-75.46	76.03
Risk free interest rate (%)	1.65	0.92-1.01	0.83-1.0375
Expected dividend yield (%)	0.0	0.0	0.0

A summary of the status of the stock options granted to employees and directors as of August 31, 2014, 2013 and 2012, and changes during the years ended on those dates, is presented below:

	2014		Year ended August 31, 2013		2012	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	1,049,249	4.13	932,116	3.72	834,116	3.84
Changes during the year:						

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Granted - at market price	149,200	12.45	100,800	7.88	244,334	4.08
Granted - above market price	-	-	24,667	6.00	-	-
Expired	-	-	-	-	(141,667)	5.40
Forfeited	-	-	-	-	(4,667)	5.64
Exercised	(289,548)	0.18	(8,334)	5.04	-	
Options outstanding at end of year	908,901	6.75	1,049,249	4.13	932,116	3.72
Options exercisable at end of year	786,328		870,883		717,088	
Weighted average fair value of options granted during the year	\$ 8.31		\$ 4.55		\$ 2.65	

F - 23

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 9 - STOCK BASED COMPENSATION (continued):

Costs incurred in respect of stock based compensation for employees and directors, for the years ended August 31, 2014, 2013 and 2012 were \$1,422, \$563 and \$201, respectively.

The total intrinsic value of employees options exercised during the years ended August 31, 2014 and 2013 was \$2,847 and \$18, respectively. None of the options were exercised by employees during the year ended August 31, 2012.

The following table presents summary information concerning the options granted to employees and directors outstanding as of August 31, 2014:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price	Aggregate intrinsic value
\$			\$	
4.08 to 6.00	514,901	6.70	4.95	2,672
6.48 to 7.88	244,800	5.72	7.06	755
12.45	149,200	9.61	12.45	-
	908,901	6.91	6.75	3,427

The following table presents summary information concerning the options granted to employees and directors exercisable as of August 31, 2014:

Range of exercise prices	Number exercisable	Weighted Average Remaining Contractual Life Years	Weighted average exercise price	Aggregate intrinsic value
\$			\$	
4.08 to 6.00	505,818	6.67	4.97	2,617
6.48 to 7.88	190,200	4.88	6.82	631
12.45	90,310	9.61	12.45	-
	786,328	6.58	6.27	3,248

As of August 31, 2014 there were \$292 of unrecognized compensation costs related to non-vested options previously granted to employees and directors, to be recorded over the next 20 months.

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 9 - STOCK BASED COMPENSATION (continued):

A summary of the status of the stock options granted to non-employees outstanding as of August 31, 2014, 2013 and 2012, and changes during the years ended on this date, is presented below:

	2014		Year ended August 31 2013		2012	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	79,689	7.21	79,689	7.21	79,689	7.21
Changes during the year:						
Exercised	(17,468 )	7.49	-	-	-	-
Options outstanding at end of year	62,221	7.13	79,689	7.21	79,689	7.21
Options exercisable at end of year	53,888		47,469		54,683	

The Company recorded stock based compensation of \$46, \$156 and \$117 during the years ended August 31, 2014, 2013 and 2012, respectively, related to non-employees awards.

The total intrinsic value of non-employees options exercised during the year ended August 31, 2014, was \$187. None of the options were exercised by non-employees during the years ended August 31, 2013 and 2012.

The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2014:

Range of exercise prices \$	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted Average Exercise Price \$	Aggregate intrinsic value
4.08 to 6.00	37,219	3.94	5.79	162
9.12	25,002	2.99	9.12	25
	62,221	3.56	7.13	187

The following table presents summary information concerning the options granted to non-employee exercisable as of August 31, 2014:

Range of	Number	Weighted	Weighted	Aggregate
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exercise prices	exercisable	Average Remaining Contractual Life	average exercise price	intrinsic value
\$		Years	\$	
4.08 to 6.00	28,886	3.21	5.73	128
9.12	25,002	2.99	9.12	25
	53,888	3.11	7.30	153

As of August 31, 2014 there were \$49 of unrecognized compensation costs related to non-vested non-employee options, to be recorded over the next 18 months.

F - 25

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 10 - FINANCIAL INCOME AND EXPENSES

a.	Financial income		
	Year ended August 31		
	2014	2013	2012
Gain on sale of marketable securities (note 3)	\$ 80	\$ 90	\$ -
Changes in fair value of warrants	-	44	-
Income from interest on deposits	138	19	13
Exchange rate differences	7	-	-
Other	-	27	-
	\$ 225	\$ 180	\$ 13

  

b.	Financial expenses		
	Year ended August 31		
	2014	2013	2012
Exchange of warrants	\$ -	\$ 297	\$ -
Changes in fair value of warrants	-	-	143
Exchange rate differences	-	3	35
Bank commissions	11	13	15
Other	-	-	6
	\$ 11	\$ 313	\$ 199

## NOTE 11 - TAXES ON INCOME:

Taxes on income included in the consolidated statements of operations represent current taxes due to taxable income of the Company and its Subsidiary.

## a. Corporate taxation in the U.S.

The applicable corporate tax rate for the Company is 35%.

As of August 31, 2014, the Company has an accumulated tax loss carryforward of approximately \$6,626 (as of August 31, 2013, approximately \$5,605). Under U.S. tax laws, subject to certain limitations, carryforward tax losses expire 20 years after the year in which incurred. In the case of the Company, subject to potential limitations in accordance with the relevant law, the net loss carryforward will expire in the years 2025 through 2032.

## b. Corporate taxation in Israel:

The Subsidiary is taxed in accordance with Israeli tax laws. The corporate tax rate applicable to 2013 and 2014 is 25% and 26.5%, respectively.

As of August 31, 2014, the Subsidiary has an accumulated tax loss carryforward of approximately \$9,713 (as of August 31, 2013, approximately \$7,664).





ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 11 - TAXES ON INCOME (continued):

## Deferred income taxes:

	2014	August 31 2013	2012
<b>In respect of:</b>			
Net operating loss carryforward	4,890	3,993	3,190
Research and development expenses	688	339	18
Less - valuation allowance	(5,578 )	(4,332 )	(3,208 )
Net deferred tax assets	-	-	-

Realization of deferred tax assets is dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income. As the achievement of required future taxable income is uncertain, the Company recorded a full valuation allowance.

## c. Loss before taxes on income and income taxes included in the income statements of operations:

	2014	Year ended August 31 2013	2012
<b>Loss before taxes on income:</b>			
U.S.	893	1,186	599
Outside U.S.	4,799	3,251	2,655
	\$ 5,692	\$ 4,437	\$ 3,254
<b>Income tax expenses (benefit):</b>			
<b>Current:</b>			
U.S.	-	(13 )	(8 )
Outside U.S.	4	(192 )	98
	\$ 4	\$ (205 )	\$ 90

ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 11 - TAXES ON INCOME (continued):

## d. Reconciliation of the statutory tax benefit to effective tax expense

Following is a reconciliation of the theoretical tax expense, assuming all income is taxed at the regular tax rates applicable to companies in the United States, and the actual tax expense:

	2014	Year ended August 31 2013	2012
Loss before income taxes as reported in the consolidated statement of comprehensive income (loss)	\$ (5,692 )	\$ (4,437 )	\$ (3,254 )
Statutory tax benefit	(1,992 )	(1,552 )	(1,139 )
Increase (decrease) in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax	1,104	902	517
Disallowable deductions	480	374	120
Increase in taxes resulting from different tax rates applicable to the Subsidiary	408	276	502
Uncertain tax position	4	(205 )	90
Taxes on income for the reported year	\$ 4	\$ (205 )	\$ 90

## e. Uncertainty in Income Taxes

Accounting Standards Codification No.740 "Income Taxes" requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company. The Company recognizes interest and penalties related to its tax contingencies as income tax expense. For the three years ended August 31, 2014, the Company did not record any amount for penalties related to tax contingencies.

The following table summarizes the activity of the Company unrecognized tax benefits:

	Year ended August 31		
	2014	2013	2012
Balance at Beginning of Year	\$ 23	\$ 228	138
Increase (decrease) in uncertain tax positions for the current year	4	(205 )	90
Balance at End of Year	\$ 27	\$ 23	\$ 228

The increase in uncertain tax positions for the year ended August 31, 2014, is a result of additional accrual for uncertain tax position.

The Company does not expect unrecognized tax expenses to change significantly over the next 12 months.

The Company is subject to U.S. Federal income tax examinations for the tax years of 2009 through 2014.

The Subsidiary is subject to Israeli income tax examinations for the tax years of 2010 through 2014.

F - 28

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ORAMED PHARMACEUTICALS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
U.S. Dollars in thousands (except share and per share data)

## NOTE 11 - TAXES ON INCOME (continued):

## f. Valuation Allowance Rollforward

	Balance at beginning of period	Year ended August 31 Additions	Balance at end of period
Allowance in respect of carryforward tax losses:			
Year ended August 31, 2014	\$ 4,332	\$ 1,246	\$ 5,578
Year ended August 31, 2013	\$ 3,208	\$ 1,124	\$ 4,332
Year ended August 31, 2012	\$ 1,813	\$ 1,395	\$ 3,208

## NOTE 12 - RELATED PARTIES - TRANSACTIONS:

a. During each of the fiscal years of 2014, 2013 and 2012 the Company paid to directors \$40, \$39 and \$30, respectively, as directors fee.

b. On July 1, 2008, the Subsidiary entered into a consulting agreement with KNRV Ltd. ("KNRV"), an Israeli company owned by the CEO, whereby the CEO, through KNRV, will provide services as President and Chief Executive Officer of both the Company and the Subsidiary (the "CEO's Consulting Agreement"). Additionally, on July 1, 2008, the Subsidiary entered into a consulting agreement with KNRV whereby the CTO, through KNRV, will provide services as Chief Medical and Technology Officer of both the Company and the Subsidiary (the "CTO's Consulting Agreement" and together with the CEO's Consulting Agreement, the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNRV (i) will be paid, under each of the Consulting Agreements, a gross amount of NIS 50,400 per month (\$14) and (ii) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements.

On July 17, 2013, the Subsidiary entered into amendments to the Consulting Agreements with KNRV, according to which, the CEO's annual payment was set at \$250 that will be calculated at an exchange rate of 3.6 NIS per U.S. dollar (actual payment of \$257), and in addition to such payment he will be granted the use of a company car and a one time cash bonus of \$60, and the CTO's annual payment was set at \$200 that will be calculated at an exchange rate of 3.6 NIS per U.S. dollar (actual payment of \$206), and in addition to such payment she was granted the use of a company car and a one time cash bonus of \$20, both effective July 1, 2013.

On February 24, 2014, the compensation committee of the Company's board of directors approved payment of cash bonuses to the CEO and the CTO in the amounts of \$120 and \$65, respectively.

On March 18, 2014, the compensation committee of the Company's board of directors approved a temporary increase of nearly \$7 per month for a specific period in which the CEO stayed in the United States. This payment replaced per diem payments for that business travel.



ORAMED PHARMACEUTICALS INC.  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
 U.S. Dollars in thousands (except share and per share data)

## NOTE 12 - RELATED PARTIES - TRANSACTIONS (continued):

## c. Balances with related parties:

	August 31	
	2014	2013
Receivable	\$ 330	\$ 5
Accounts payable and accrued expenses - KNRV	\$ 47	\$ 64

The receivable is the withholding tax from options exercised on August 1, 2014 which was received by the Company on September 12, 2014.

## d. Expenses to related parties:

	Year ended August 31		
	2014	2013	2012
KNRV	\$ 671	\$ 448	\$ 318

## NOTE 13 - SUBSEQUENT EVENT

In November 2014, the Company entered into a Securities Purchase Agreement with an investor for the sale of 696,378 share of the Company's common stock, at a price of \$7.18 per share, which is equal to the closing price of the Company's common stock on the Nasdaq Capital Market on October 31, 2014. The closing date is expected to be on or before November 28, 2014. In connection with the offering, the Company will pay a finder's fee of up to \$150.

All other schedules for which provision is made in the applicable accounting regulations of the SEC are not required under the related instructions, or are inapplicable, and therefore have been omitted.

(b) Exhibits

- 3.1\* Composite Copy of Certificate of Incorporation, as amended as of January 22, 2013, corrected February 8, 2013 and further amended July 25, 2014.
- 3.2\* Composite Copy of Certificate of Incorporation, as amended as of January 22, 2013, corrected February 8, 2013 and further amended July 25, 2014 (marked copy).
- 3.3 Amended and Restated By-laws (incorporated by reference from our current report on Form 8-K filed February 1, 2013).
- 4.1 Specimen Common Stock Certificate (incorporated by reference from our registration statement on Form S-1 filed February 1, 2013).
- 4.2 Common Stock Purchase Warrant issued to Attara Fund, Ltd. on January 10, 2011, and transferred to Regals Fund LP on March 11, 2012 (incorporated by reference from our quarterly report on Form 10-Q filed January 13, 2011).
- 4.3 Amendment No. 1, dated August 28, 2012, to Common Stock Purchase Warrant transferred to Regals Fund LP on March 11, 2012 (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
- 4.4 Amendment No. 2, dated November 13, 2012, to Common Stock Purchase Warrant transferred to Regals Fund LP on March 11, 2012 (incorporated by reference from our quarterly report on Form 10-Q/A filed December 27, 2012).
- 4.5 Amendment No. 3, dated November 29, 2012, to Common Stock Purchase Warrant transferred to Regals Fund LP on March 11, 2012 (incorporated by reference from our registration statement on Form S-1 filed February 1, 2013).
- 4.6 Form of Common Stock Purchase Warrant used in 2010-2011 private placement (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).
- 4.7 Form of Common Stock Purchase Warrant used in 2012 private placements (incorporated by reference from our annual report on Form 10-K filed December 12, 2012).
- 4.8 Form of Common Stock Purchase Warrant issued to Regals Fund LP (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
- 4.9 Amendment No. 1 to Form of Common Stock Purchase Warrant issued to Regals Fund LP (incorporated by reference from our registration statement on Form S-1 filed February 1, 2013).

- 4.10 Common Stock Purchase Warrant issued to Regals Fund LP on November 29, 2012 (incorporated by reference from our quarterly report on Form 10-Q/A filed December 27, 2012).
- 10.1+ Consulting Agreement by and between Oramed Ltd. and KNRV, Ltd., entered into as of July 1, 2008 for the services of Nadav Kidron (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.2+\* Amendment, dated July 13, 2013, to Consulting Agreement by and between Oramed Ltd. and KNRV, Ltd., entered into as of July 1, 2008 for the services of Nadav Kidron.
- 10.3+\* Amendment, dated November 13, 2014, to Consulting Agreements by and between Oramed Ltd. and KNRV, Ltd., entered into as of July 1, 2008 for the services of Nadav Kidron and Miriam Kidron.



- 10.4+ Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008 for the services of Miriam Kidron (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.5+\*Amendment, dated July 13, 2013, to Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008 for the services of Miriam Kidron.
- 10.6+ Oramed Pharmaceuticals Inc. Amended and Restated 2008 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed on June 17, 2014).
- 10.7+\*Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement.
- 10.8+ Form of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.9+ Employment Agreement dated as of April 19, 2009, by and between Oramed Ltd. and Yifat Zommer (incorporated by reference from our current report on Form 8-K filed on April 22, 2009).
- 10.10+Clinical Trial Agreement dated September 11, 2011, between Oramed Ltd., Hadasit Medical Research Services and Development Ltd., Miriam Kidron and Daniel Schurr (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
- 10.11+Clinical Trial Agreement dated July 8, 2009, between Oramed Ltd., Hadasit Medical Research Services and Development Ltd., Miriam Kidron and Itamar Raz (incorporated by reference from our current report on Form 8-K filed July 9, 2009).
- 10.12 Agreement dated January 7, 2009, between Oramed Pharmaceuticals Inc. and Hadasit Medical Research Services and Development Ltd. (incorporated by reference from our current report on Form 8-K filed January 7, 2009).
- 10.13 Joint Venture Agreement dated June 1, 2010, between Oramed Ltd. and LASER Detect Systems Ltd (now known as D.N.A Biomedical Solutions Ltd.) (incorporated by reference from our quarterly report on Form 10-Q filed July 14, 2010).
- 10.14 Manufacturing and Supply Agreement dated July 5, 2010, between Oramed Ltd. and Sanofi-Aventis Deutschland GMBH (incorporated by reference from our current report on Form 8-K filed July 14, 2010).
- 10.15 Securities Purchase Agreement between Oramed Pharmaceuticals Inc. and Attara Fund, Ltd., dated as of December 21, 2010 (incorporated by reference from our quarterly report on Form 10-Q filed January 13, 2011).

- 10.16 Share Purchase Agreement dated February 22, 2011, between Oramed Ltd. and D.N.A Biomedical Solutions Ltd. (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).
- 10.17 Patent Transfer Agreement dated February 22, 2011, between Oramed Ltd. and Entera Bio Ltd. (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).
- 10.18 Form of Securities Purchase Agreement used in 2010-2011 private placement (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).
- 10.19+Form of Indemnification Agreements dated March 11, 2011, between Oramed Pharmaceuticals Inc. and each of our directors and officers (incorporated by reference from our definitive proxy statement on Schedule 14A filed on January 31, 2011).

- 10.20+ Agreement, dated November 26, 2013, with Dr. Michael Berelowitz (incorporated by reference from our quarterly report on Form 10-Q filed January 14, 2014).
- 10.21+\* Agreement and Amendment No. 1, dated July 16, 2014, with Dr. Michael Berelowitz.
- 10.22 Form of Securities Purchase Agreement used in 2012 private placements (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
- 10.23 Form of Securities Purchase Agreement used in 2012 private placement with Regals Fund LP. (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
- 10.24 Form of Securities Purchase Agreement, dated December 24, 2013, used in December 2013 registered direct offering (incorporated by reference from our current report on Form 8-K filed December 26, 2013).
- 10.25 Securities Purchase Agreement dated October 30, 2012, between Oramed Pharmaceuticals Inc. and D.N.A Biomedical Solutions Ltd. (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
- 10.26 Letter Agreement, dated as of November 29, 2012, between Oramed Pharmaceuticals Inc. and Regals Fund LP. (incorporated by reference from our registration statement on Form S-1 filed February 1, 2013).
- 10.27+ Employment Agreement, dated April 14, 2013, between Oramed Ltd. and Joshua Hexter (incorporated by reference from our current report on Form 8-K filed April 16, 2013).
- 10.28 Form of Securities Purchase Agreement used in 2013 registered direct offering (incorporated by reference from our current report on Form 8-K filed July 10, 2013).
- 10.29 Clinical Research Organization Services Agreement dated July 22, 2014, between Oramed Ltd. and Integrium, LLC. (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission.)
- 10.30 Securities Purchase Agreement between Oramed Pharmaceuticals, Inc. and Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd., dated November 3, 2014 (incorporated by reference from our current report on Form 8-K filed November 4, 2014).
- 21.1 Subsidiary (incorporated by reference from our annual report on Form 10-K filed November 27, 2013).

- 23.1\* Consent of Kesselman & Kesselman, Independent Registered Public Accounting Firm.
- 31.1\* Certification Statement of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 31.2\* Certification Statement of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1\*\* Certification Statement of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
- 32.2\*\* Certification Statement of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350.

101.1\* The following financial statements from the Company's annual report on Form 10-K for the year ended August 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.

- \* Filed herewith.
- \*\* Furnished herewith.
- + Management contract or compensation plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

/s/ NADAV KIDRON  
Nadav Kidron,  
President and Chief Executive Officer

Date: November 13, 2014

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ NADAV KIDRON  
Nadav Kidron,  
President and Chief Executive Officer and  
Director  
(principal executive officer) November 13, 2014

/s/ YIFAT ZOMMER  
Yifat Zommer,  
Chief Financial Officer  
(principal financial and accounting officer) November 13, 2014

/s/ MIRIAM KIDRON  
Miriam Kidron,  
Chief Medical and Technology Officer and  
Director November 13, 2014

/s/ LEONARD SANK  
Leonard Sank,  
Director November 13, 2014

/s/ HAROLD JACOB  
Harold Jacob,  
Director November 13, 2014

/s/ MICHAEL BERELOWITZ  
Michael Berelowitz,  
Director November 13, 2014

/s/ GERALD OSTROV  
Gerald Ostrov,  
Director November 13, 2014