

ORAMED PHARMACEUTICALS INC.

Form 10-K

November 25, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the Fiscal Year Ended August 31, 2015**

or

**o 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) (Zip Code)

**91390**

**+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

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

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 <input type="radio"/>	Accelerated filer <input type="radio"/>
Non-accelerated filer <input type="radio"/>	Smaller reporting company <input checked="" type="radio"/>

(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 \$44,469,184, based on a price of \$4.52, 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: 11,599,825 shares of common stock issued and outstanding as of November 24, 2015.

**ORAMED PHARMACEUTICALS INC.**

**FORM 10-K  
(FOR THE FISCAL YEAR ENDED AUGUST 31, 2015)**

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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, 2015, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.930 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**

The statements contained in this Annual Report on Form 10-K that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Words such as “expects,” “anticipates,” “intends,” “plans,” “planned expenditures,” “believes,” “seeks,” “estimates” and 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. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements appear in Item 1 - “Business” and Item 7 - “Management's Discussion and Analysis of Financial Condition and Results of Operations,” as well as elsewhere in this Annual Report on Form 10-K and include, among other statements, statements regarding the following:

the expected development and potential benefits from our products in treating diabetes;

the prospects of entering into license agreements, or other partnerships or forms of cooperation with other companies or medical institutions, including a stock purchase agreement and licensing agreement with Hefei Life Science & Technology Park Investments and Development Co., Ltd., or HLST;

our research and development plans, including pre-clinical and clinical trials plans and the timing of conclusion of trials;

our belief that our technology has the potential to deliver medications and vaccines orally that today can only be delivered via injection;

the competitive ability of our technology based product efficacy, safety, patient convenience, reliability, value and patent position;

the potential market demand for our products;

our expectation that in the upcoming year our research and development expenses, net, will continue to be our major expenditure;

our expectations regarding our short- and long-term capital requirements;

our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses; and

information with respect to any other plans and strategies for our business.

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 discussed herein, including those risks described in Item 1A. "Risk Factors", and expressed from time to time in our other filings with the Securities and Exchange Commission, or SEC. In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this Annual Report on Form 10-K could be interpreted differently in light of additional research, clinical and preclinical trials results. 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 oral 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 initiated a Phase IIb clinical trial on approximately 180 type 2 diabetic patients that is being conducted in approximately 30 sites in the United States, beginning in June 2015. This double-blind, randomized, 28-day study clinical trial is conducted under an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA. The clinical trial is designed to assess the safety and efficacy of ORMD-0801, will investigate ORMD-0801 over a longer treatment period and will have statistical power to give us greater insight into the drug's efficacy. We anticipate the last patient will complete this trial during the first quarter of calendar year 2016. 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.

**Oral Glucagon-like peptide-1:** Glucagon-like peptide-1, or GLP-1, is an incretin hormone, which is 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. In addition to our flagship product, the insulin capsule, we are using our technology for an orally ingestible GLP-1 capsule (ORMD-0901). In August 2015, we began a non-FDA approved clinical trial for our oral exenatide capsule on type 2 diabetic patients, and we anticipate it will be completed during the first quarter of calendar year 2016.

**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 International Diabetes Federation, or IDF, an estimated 387 million adults worldwide suffered from diabetes in 2014 and the IDF projects this number will increase to 612 million by 2035. Also, according to the IDF, in 2014, an estimated 4.9 million people died from diabetes. 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, in June 2015, we initiated the Phase IIb clinical trial on approximately 180 type 2 diabetic patients. This double-blind, randomized, 28-day study clinical trial will be designed to assess the safety and efficacy of ORMD-0801 and is being 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. Beginning in March 2014, the double-blind, randomized, placebo controlled, seven-day study design was carried out at an inpatient setting on 25 type 1 diabetic patients. 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 are also conducting a glucose clamp study of our oral insulin capsule on type 2 diabetic volunteers that will be performed at The University of Texas Health Science Center at San Antonio and University Health System's Texas Diabetes Institute. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. As previously announced, the first patient has been enrolled and we anticipate completing the study in the second quarter of calendar year 2016.

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:

### ***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 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.

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.

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, in June 2016 we initiated the Phase IIb clinical trial on approximately 180 type 2 diabetic patients. This double-blind, randomized, 28-day study will be designed to assess the safety and efficacy of ORMD-0801 and is being 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.

In April 2015, we began a glucose clamp study of our oral insulin capsule on type 2 diabetic volunteers that will be performed at The University of Texas Health Science Center at San Antonio and University Health System's Texas Diabetes Institute. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. We anticipate completing the study in the second quarter of calendar year 2016.

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*

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 to 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. In August 2015, we began a non-U.S. based Phase Ib study.

In August 2015, we began a non-FDA approved clinical trial for our oral exenatide capsule on type 2 diabetic patients, and we anticipate it will be completed during the first quarter of calendar year 2016.

### ***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.

### ***Feasibility study***

In August 2015, we entered into an agreement with a large international pharmaceutical company, or the Pharma Company, pursuant to which we will conduct a feasibility study, using one of the Pharma Company's propriety injectable compounds. The study will use our proprietary technology in order to deliver the compound orally. The study will provide data required for decision making on whether to enter into a license agreement between the parties.

### ***Raw Materials***

Our oral insulin capsule is currently manufactured by Swiss Caps AG.

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 29 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 26 patents, one of which was issued in fiscal 2015, and one of which was allowed in the United States, 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, which was paid in November 2011, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$581,977 as of March 31, 2011. Of the ordinary shares of D.N.A we received, we sold 5,250,000 shares during February and March 2013 and 2,625,989 shares during October 2013 to March 2014, 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 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. D.N.A consummated a reverse stock split at a ratio of one-for-two, effective October 4, 2015. The closing price for D.N.A's ordinary shares was \$0.066 per share on November 24, 2015. 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 had 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.

In July 2015, Entera announced it had completed a phase 2a study to assess the safety and efficacy of its oral treatment for hypoparathyroidism and that the goals of the study were achieved.

On July 3, 2015, we entered into a non-binding Letter of Intent, or the LoI, which was amended on September 3, 2015 and further amended on October 22, 2015, with HLST. According to the LoI, as amended, we will enter into a Stock Purchase Agreement with HLST pursuant to which HLST will agree to buy and we will agree to sell an aggregate of 1,155,367 shares of our common stock at a price per share of approximately \$10.39 (\$12,000,000 in total), and, in addition, we will grant a commercialization license in the territory of Peoples Republic of China, or the Territory, related to oral insulin, for an aggregate of approximately \$37,500,000, of which \$11,000,000 would be paid up front, and \$26,500,000 would be payable upon achievement of certain milestones and conditions, and royalties of 10% on net sales of the related commercialized products to be sold by HLST in the Territory.

Pursuant to the LoI, HLST paid us a non-refundable amount of \$500,000 as a no-shop fee, and we will commit to negotiate exclusively with HLST regarding an out-licensing and commercialization transaction in the Territory. The no-shop period, as extended on September 3, 2015 and October 22, 2015, expires on December 22, 2015. The parties intend to finalize the definitive agreements by the end of the no-shop period.

## **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.

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.

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 NIH 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 Clinical & Experimental 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 Yale 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, 2015, 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. On our website, under “Investors”, “SEC Filings”, 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, 2015, August 31, 2014 and August 31, 2013, we had working capital of \$15,883,000, \$20,805,000 and \$8,146,000, respectively, and stockholders' equity of \$24,828,000, \$20,793,000 and \$8,131,000, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through August 31, 2015, the year ended August 31, 2013, the year ended August 31, 2014 and the year ended August 31, 2015, we incurred net losses of \$35,052,000, \$4,232,000, \$5,696,000 and \$7,232,000, 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 exenatide and proteins, corresponding patent applications filed in Canada, Europe, Japan, China, Russia, Israel, Brazil, Australia, South Africa, New Zealand, Hong Kong and India, 25 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, and one patent allowed in the United States (for our technologies covering oral administration of insulin and other proteins). 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 LLC to assist us in designing, conducting and managing our various clinical trials in the United States. 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 initiated a Phase IIb clinical trial in patients with type 2 diabetes under an IND with the FDA in June 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 has significantly impacted the pharmaceutical industry. In addition to requiring most individuals to have health insurance and establishing new regulations on health plans, this legislation requires discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the legislation imposes an annual fee, which has increased annually, on sales by branded pharmaceutical manufacturers. There can be no assurance that our business will not be materially adversely affected by these increased rebates, fees and other provisions. In addition, it appears likely that these and other ongoing initiatives in the United States will continue the pressure on drug pricing, especially under the Medicare and Medicaid programs, and may also increase regulatory burdens and operating costs. 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 2012 and 2015 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.

**Our management will have significant flexibility in using the net proceeds of any offering of securities.**

We intend generally to use the net proceeds from any offerings of our securities for expenses related to our clinical trials, research and product development activities, and for general corporate purposes, including general working capital purposes. Our management will have significant flexibility in applying the net proceeds of any such offering. The actual amounts and timing of expenditures will vary significantly depending on a number of factors, including the amount of cash used in our operations and our research and development efforts. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costly to raise funds in the future.

**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 24, 2015, we had outstanding 11,599,825 shares of common stock, a large majority of which are freely tradable. Giving effect to the exercise in full of all of our outstanding warrants, options and restricted stock units, or RSUs, including those currently unexercisable or unvested, we would have outstanding 14,542,789 shares of common stock.

**Our issuance of warrants, options and restricted stock units 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, RSUs and convertible notes at, above or below the current market price. As of November 24, 2015, we had outstanding warrants and options exercisable for 1,879,105 shares of common stock at a weighted average exercise price of \$6.00. We also had outstanding restricted stock units exercisable for 86,116 shares of common stock at no cost. 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 24, 2015, our directors, executive officers and principal affiliated stockholders beneficially own approximately 12.6% of our outstanding shares of common stock, excluding shares issuable upon the exercise of options, warrants and RSUs. 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 \$297,000, \$428,000 and \$49,000 in the years ended August 31, 2013, 2014 and 2015, 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 \$23,000, 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, 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
Year Ended August 31, 2015		
Three Months Ended November 30, 2014	\$10.15	\$5.81
Three Months Ended February 28, 2015	\$6.55	\$4.31
Three Months Ended May 31, 2015	\$9.84	\$3.71
Three Months Ended August 31, 2015	\$7.91	\$4.15

The last reported sale price per share of common stock as quoted on Nasdaq was \$7.65 on November 24, 2015.

**Holder**

As of November 24, 2015, there were 11,599,825 shares of our common stock issued and outstanding held of record by approximately 40 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 each of November 3, 2014, March 4, 2015, May 3, 2015 and August 1, 2015, we issued 3,750 shares of our common stock, valued at \$93,000, in the aggregate, to Corporate Profile, LLC, or Corporate Profile, in payment of a portion of the consulting fee for investor relations services owed to Corporate Profile pursuant to Letter Agreements, dated May 13, 2014 and May 19, 2015, between us.

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, 2010 through August 31, 2015. 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, 2015, 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, 2015, 2014 and 2013 and the selected consolidated balance sheet data as of August 31, 2015 and 2014, 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, 2012 and 2011 and the balance sheet data as of August 31, 2013, 2012 and 2011 are derived from audited financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	2015	2014	2013	2012	2011
	(in thousands of dollars except share and per share data)				
Statements of Comprehensive Income (Loss):					
Research and development expenses, net	\$4,781	\$3,277	\$2,272	\$1,681	\$1,159
General and administrative expenses	2,602	2,629	2,032	1,203	1,276
Impairment of available- for-sale securities	-	-	-	184	197
Gain on sale of investment	-	-	-	-	(1,033 )
Financial income	(168 )	(225 )	(180 )	(13 )	(33 )
Financial expenses	18	11	313	199	19
Loss before taxes on income	7,233	5,692	4,437	3,254	1,585
Taxes on income (Tax benefit)	(1 )	4	(205 )	90	(24 )
Net loss for the period	\$7,232	\$5,696	\$4,232	\$3,344	\$1,561
Loss per common share – basic and diluted	\$0.67	\$0.62	\$0.59	\$0.57	\$0.29
Weighted average common shares outstanding	10,820,465	9,244,059	7,209,283	5,884,595	5,417,278

	As of August 31				
	2015	2014	2013	2012	2011
	in thousands of dollars except share and per share data				
Balance Sheet Data:					
Cash, cash equivalents, short-term deposits, restricted cash and marketable securities	\$17,245	\$21,306	\$8,491	\$5,101	\$3,716
Other current assets	127	472	153	175	568
Long-term assets	8,042	24	16	19	42
Long-term marketable securities	940	-	-	-	-
Total assets	26,354	21,802	8,660	5,295	4,326
Current liabilities	1,489	973	498	644	441
Long-term liabilities	37	36	31	873	161
Stockholders' equity	24,828	20,793	8,131	3,778	3,724

## **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). We completed Phase IIa clinical trials in patients with both type 1 and type 2 diabetes, and in June 2015 initiated a Phase IIb clinical trials in patients with type 2 diabetes under an IND with the FDA.

**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 to 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 began a non-U.S. based Phase Ib trial study in August 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 a 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 2015 to Fiscal 2014 and Fiscal 2014 to Fiscal 2013**

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2015, 2014 and 2013:

Operating Data:	Year ended August 31,		
	2015	2014	2013
Research and development expenses, net	\$4,781	\$3,277	\$2,272
General and administrative expenses	2,602	2,629	2,032
Impairment of available-for-sale securities	-	-	-
Financial expenses (income), net	(150 )	(214 )	133
Loss before taxes on income	7,233	5,692	4,437
Taxes on income (Tax benefit)	(1 )	4	(205 )
Net loss for the period	7,232	5,696	4,232
Loss per common share – basic and diluted	\$0.67	\$0.62	\$0.59
Weighted average common shares outstanding	10,820,465	9,244,059	7,209,283

**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 by 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, 2015 increased by 46% to \$4,781,000 from \$3,277,000 for the year ended August 31, 2014. The increase is attributed to expenses related to clinical trials, as well as to the decrease in OCS grants in the year ended August 31, 2015. During the year ended August 31, 2015, stock based compensation costs totaled \$616,000, as compared to \$905,000 during the year ended August 31, 2014.

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.

### ***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, 2015, 2014 and 2013, we recognized research and development grants in an amount of \$49,000, \$428,000 and \$297,000, respectively. As of August 31, 2015, 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, 2015. For the years ended August 31, 2015 and 2014, 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 decreased by 1% from \$2,629,000 for the year ended August 31, 2014 to \$2,602,000 for the year ended August 31, 2015. The decrease in costs incurred related to general and administrative activities during the year ended August 31, 2015, reflects a decrease in salaries and related expenses resulting from cash bonuses to employees paid in 2014, and from a decrease in professional expenses, that were partially offset by an increase in stock based compensation costs of \$168,000, arising from restricted stock units granted to employees and consultants. During the year ended August 31, 2015, as part of our general and administrative expenses, we incurred \$731,000 related to stock options granted to employees and consultants, as compared to \$563,000 during the year ended August 31, 2014.

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.

***Financial income/expense, net***

Net financial income was \$150,000 for the year ended August 31, 2015 as compared to net financial income of \$214,000 for the year ended August 31, 2014. This was mainly due to the gain on sale of marketable securities of \$80,000 in the year ended August 31, 2014 as compared to no gain on sale of marketable securities in the year ended August 31, 2015, as the Company did not sell any of its D.N.A ordinary shares during that year.

Net financial income was \$214,000 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.

***Taxes on income / Tax benefit***

We had a tax benefit of \$1,000 for the year ended August 31, 2015 as compared to taxes on income of \$4,000 for the year ended August 31, 2014, as a result of a decrease in the accrual for uncertain tax position in fiscal 2015.

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.

***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, 2015 of \$3,000 resulted from the increase in fair value of the ordinary shares of D.N.A that we hold. Unrealized gains on available for sale securities for the year ended August 31, 2015 of \$103,000, 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, 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.

## **Liquidity and Capital Resources**

From inception through August 31, 2015, we have incurred losses in an aggregate amount of \$35,052,000. 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, in November 2014 and in June 2015, raising a total of \$45,460,000, net of transaction costs. During that period we also received cash consideration of \$1,870,000 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, 2015, we had \$3,213,000 of available cash, \$19,945,000 of short term and long term bank deposits and \$3,028,000 of marketable securities. We anticipate that we will require approximately \$11.2 million to finance our activities during the 12 months following August 31, 2015.

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, existing stockholders and future public offerings. Based on our current cash resources and commitments, including cash received in public offerings in the period ended August 31, 2015, 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, 2015, our total assets were \$17,372,000 and our total liabilities were \$1,489,000. On August 31, 2015, we had a working capital surplus of \$15,883,000 and an accumulated loss of \$35,052,000. As of August 31, 2014, our total assets were \$21,778,000 and our total 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. The decrease in working capital surplus from August 31, 2014 to August 31, 2015 was primarily due to the purchase of long-term bank deposits that was partially offset by proceeds from our private offering completed in November 2014 and our public offering completed in June 2015.

During the year ended August 31, 2015, cash and cash equivalents increased by \$1,451,000 from the \$1,762,000 reported as of August 31, 2014, which is due to the reasons described below.

Operating activities used cash of \$4,946,000 in the year ended August 31, 2015 and \$4,068,000 in the year ended August 31, 2014. Cash used for operating activities in the years ended August 31, 2015 and 2014 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments.

During the year ended August 31, 2015, we received \$126,000 in OCS grants towards our research and development expenses as compared to \$408,000 during the year ended August 31, 2014. We recognized the amount of \$49,000 during the year ended August 31, 2015 as compared to \$428,000 in the year ended August 31, 2014. This increase was primarily due to the timing of the grant utilization.

Investing activities used cash of \$3,312,000 in the year ended August 31, 2015, as compared to \$13,088,000 used in investing activities in the year ended August 31, 2014. Cash used for investing activities in the year ended August 31, 2015 consisted primarily of the purchase of short-term and long-term bank deposits as well as the purchase of marketable securities, while cash used for investing activities in the years ended August 31, 2014 consisted primarily of the purchase of short-term bank deposits.

Financing activities provided cash of \$9,721,000 in the year ended August 31, 2015 and \$16,640,000 in the year ended August 31, 2014. Cash provided by financing activities during both periods consisted of proceeds from our issuance of common stock, warrants and options. During fiscal 2015, 1,370 options were exercised for cash and resulted in the issuance of 1,370 shares of common stock. The cash consideration received for exercise of the options was \$8,000. 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 2015 and fiscal 2014, we issued a total of 28,750 shares of common stock to various third party vendors for services rendered. The aggregate value of those shares was approximately \$195,000. In fiscal 2015 we also consummated a private placement, in which we sold 696,378 shares of common stock at a purchase price of \$7.18 per share, for total net consideration of \$5 million, and paid a finder's fee of \$150,000. 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.

In June 2015, we entered into a letter agreement, or the Engagement Letter, pursuant to which the placement agent agreed to serve as exclusive agent, advisor or underwriter in any offering of by us occurring between June 4, 2015 and July 4, 2015. In June 2015, we entered into a Securities Purchase Agreement, pursuant to which we agreed to sell, in a registered direct offering, or the June 2015 Offering: (1) an aggregate of 714,286 shares of our common stock at a price of \$7.50 per share to six investors and (2) at the option of each investor, or the Overallotment Right, additional shares of our common stock, or the Overallotment Shares, up to the number equal to the number of shares purchased by such Purchaser and at a price of \$10.00 per Overallotment Share. The closing of the sale of the 714,286 shares of our common stock occurred on June 10, 2015. The Overallotment Right is exercisable beginning December 10, 2015, and shall remain exercisable until December 10, 2016. Pursuant to the Engagement Letter, the placement agent received, for its services in the June 2015 Offering, a fee equal to 7% of the gross proceeds raised in the June 2015 Offering and an expense allowance of 1% of the gross proceeds raised in the June 2015 Offering, and affiliates of the placement agent received warrants to purchase 28,571 shares of our common stock, exercisable for a period of three years and with an exercise price of \$10.00 per share. Our net proceeds from the June 2015 Offering were approximately \$4,880,000 after deducting the placement agent's expenses and our other offering expenses.

In November 2014 and March, May and August 2015, we issued a total of 15,000 shares of our common stock, valued at \$93,000, 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 issued to the investor an aggregate of 696,378 shares of common stock, at a price of \$7.18 per share, which was equal to the closing price of our common stock on the Nasdaq Capital Market on October 31, 2014, for aggregate gross proceeds of \$5,000,000. Our net proceeds from the offering were approximately \$4,833,000 after deducting a finder's fee of \$150,000 and our other offering expenses. The offering closed on November 28, 2014.

On April 2, 2015, we entered into an at the market issuance sales agreement, or the Sales Agreement, pursuant to which we may issue and sell shares of its common stock having an aggregate offering price of up to \$25,000,000 from time to time, at our option, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3. We will pay the sales agent a commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent. To date, no shares have been sold under the Sales Agreement.

## Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments at August 31, 2015, 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 year	1-3 years	3-5 years	Over 5 years
Clinical research study obligations	\$2,478	\$2,478	\$ -	\$ -	\$ -
Purchase obligations	355	355	-	-	-
Operating lease obligations	47	38	9	-	-
Accrued Severance Pay, net	11	-	-	-	11
Total	\$2,891	\$2,871	\$ 9	\$ -	\$ 11

## Off-Balance Sheet Arrangements

As of August 31, 2015, we had no off balance sheet arrangements that have had or that we expect would be reasonably likely to have a future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## 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, 2015 are as follows (in thousands of dollars):

Category	Amount
Research and development, net of OCS funds	\$9,090
General and administrative expenses	2,060
Total	\$11,150

In June 2015, we initiated a Phase IIb clinical trial for our orally ingested insulin and we are conducting, or planning to conduct, further clinical studies, including those with regard to our oral exenatide capsule. 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.

## **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, 2015, we had \$3.2 million in cash and cash equivalents, \$19.9 million in short and long term bank deposits and restricted deposits and \$3 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, but only the fair value of these instruments. 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, 2015, we own net balances in NIS of approximately \$1,413,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate gain of approximately \$128,000, while assuming a 10% devaluation of the NIS against the U.S. dollars, we would experience an exchange rate loss of approximately \$157,000.

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,		
	2013	2014	2015
Average rate for period	3.718	3.494	3.851
Rate at period-end	3.614	3.568	3.930

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.

**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, 2015. 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, 2015 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, 2015 at a reasonable assurance level.

#### **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, 2015 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION.**

Not applicable.

## **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.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Nadav Kidron	41	President, Chief Executive Officer and Director
Miriam Kidron	75	Chief Medical and Technology Officer and Director
Leonard Sank	50	Director
Harold Jacob	62	Director
Michael Berelowitz	71	Director and Chairman of the Scientific Advisory Board
Gerald Ostrov	66	Director
Yifat Zommer	41	Chief Financial Officer, Treasurer and Secretary
Joshua Hexter	45	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 approximately 2.3% of the outstanding shares) and of Israel Advanced Technology Industries organization. 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, Mishaike & 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, whose interests lie in entrepreneurial endeavors and initiatives, with over 20 years' experience of playing significant leadership roles in developing businesses. For the past sixteen years, Mr. Sank has served as a director of Macsteel Service Centres SA (Pty) Ltd, South Africa's largest private company. Since 2010, Mr. Sank has served as a Director of Bradbury Finance Pty Ltd, and 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 2014, 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 2014. 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. Prior to 1996, Dr. Berelowitz spent a number of years in academia. Dr. Berelowitz also serves on the board of directors of Recro Pharma Inc. and of Kamada Ltd., two NASDAQ-listed pharmaceutical companies. 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 and VP Business Development* in April 2013. From 2007 to 2013, Mr. Hexter was a Director or Executive Director in BioLineRx Ltd., or 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, 2015, our Board held seven meetings and took actions by written consent on six 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 2015, we believe that during fiscal 2015, 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.

### **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).

## 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 2015 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:

attract, hire, and retain talented and experienced executives;

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 RSU grants; and (iv) benefits and perquisites.

In establishing overall executive compensation levels and making specific compensation decisions for our NEOs in fiscal 2015, 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 fiscal 2014, for example, 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. The Committee did not receive any executive compensation consulting services in fiscal 2015.

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 2015, following two years in which the base salaries of our NEOs were not changed, our Compensation Committee decided to increase our NEOs' base salaries by six percent, as the members of our Compensation Committee deemed this to be a reasonable rate in the pharmaceuticals industry based on their experience. 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 and again awarded RSUs in February 2015. 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 two 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.

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 annual meeting of our stockholders held on July 23, 2014, or the 2014 Annual Meeting. We did not seek or receive any specific feedback from our stockholders concerning our executive compensation program during the past fiscal year. The Compensation Committee did not specifically rely on the results of the prior vote in making any compensation-related decisions during fiscal 2015.

**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, 2015, 2014 and 2013.

Name and Principal Position	Year (1)	Salary	Bonus	Stock	Option	All Other	Total (\$)
		(\$) (2)	(\$) (2)(3)	Awards (\$) (4)	Awards (\$) (5)	Compensation (\$) (2)(6)	
Nadav Kidron President and CEO and director (7)	2015	254,318	63,045	431,645	-	16,217	765,225
	2014	261,338	120,000	-	390,696	31,770	803,804
	2013	182,510	60,000	-	-	29,152	271,662
Miriam Kidron Chief Medical and Technology Officer and director (8)	2015	188,466	50,436	431,645	-	13,592	684,139
	2014	206,315	65,000	-	390,696	12,076	676,739
	2013	168,410	20,000	-	-	14,728	200,486
Yifat Zommer CFO, Treasurer and	2015	101,063	26,445	212,314	-	34,899	374,721
	2014	109,684	50,000	-	-	39,806	199,490

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Secretary	2013	83,387	15,000	-	-	29,086	127,473
Joshua Hexter	2015	124,108	32,363	-	-	39,547	196,019
COO and VP Business	2014	159,696	25,000	-	-	42,857	227,553
Development (9)	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.

For RSU awards, the amounts reflect the grant date fair value, as calculated pursuant to FASB ASC Topic 718. The assumptions used to determine the fair value of the RSU awards are set forth in Note 10 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 the award vest and the underlying shares are issued and subsequently sold.

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 are set forth in Note 10 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.

(6) See “All Other Compensation Table” below.

(7) 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.

(8) Dr. Kidron receives compensation from Oramed Ltd. through KNRV. See “—Employment and Consulting Agreements” below.

(9) Mr. Hexter joined the Company in April 2013.

**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	2015	16,217	--	--	--	16,217
	2014	13,050	--	--	18,720	31,779
	2013	11,992	--	--	17,160	29,152
Miriam Kidron	2015	13,592	--	--	--	13,592
	2014	14,728	--	--	--	14,728
	2013	12,076	--	--	--	12,076
Yifat Zommer	2015	12,612	14,879	7,408	--	34,899
	2014	15,440	16,263	8,103	--	39,806
	2013	10,507	12,416	6,163	--	29,086
Joshua Hexter	2015	12,451	18,030	9,066	--	39,547
	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 represents additional 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 KNRV, whereby Mr. Nadav Kidron, through KNRV, 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 KNRV whereby Dr. Miriam Kidron, through KNRV, 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 KNRV (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, KNRV, 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.

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.

On July 1, 2015, the Consulting Agreements were further amended, such that the monthly consulting fee was increased to NIS 79,500 and NIS 63,600 for the services of Nadav Kidron and Miriam Kidron, respectively, effective July 1, 2015.

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 33,347. 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, as amended, Mr. Hexter's current gross monthly salary is NIS 40,810. 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 2015: Mr. Hexter received no awards during fiscal 2015.

Name	Grant Date	All Other	
		Stock Awards:	Grant Date
		Number of Securities Underlying RSUs	Fair Value of Stock Awards (\$)
Nadav Kidron <sup>(1)</sup>	11/13/14	9,788	67,537
Nadav Kidron <sup>(2)</sup>	2/23/15	79,848	364,107
Miriam Kidron <sup>(1)</sup>	11/13/14	9,788	67,537
Miriam Kidron <sup>(2)</sup>	2/23/15	79,848	364,107
Yifat Zommer <sup>(3)</sup>	2/23/15	46,560	212,314

These RSUs were granted under our 2008 Plan and vested in two equal installments, each of 4,894 shares, on (1) November 30 and December 31, 2014. The shares of common stock underlying the RSUs will be issued upon request of the grantee.

These RSUs were granted under our 2008 Plan and vest in 23 installments consisting of one installment of 6,654 (2) shares on February 28, 2015 and 22 equal monthly installments of 3,327 shares each, commencing March 31, 2015. The shares of common stock underlying the RSUs will be issued upon request of the grantee.

These RSUs were granted under our 2008 Plan and vest in 23 installments, consisting of one installment of 3,880 (3) shares on February 28, 2015 and 22 equal monthly installments of 1,940 shares each, commencing March 31, 2015.

**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, 2015.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of shares that have not vested (#)	Market value of shares that have not vested (\$)
Nadav Kidron	72,000 <sup>(1)</sup>	-	6.48	5/7/18		
	72,000 <sup>(2)</sup>	-	5.88	4/20/20		
	72,000 <sup>(3)</sup>	-	4.08	8/8/22		
	47,134 <sup>(4)</sup>	-	12.45	4/9/24		
					53,232 <sup>(8)(9)</sup>	299,164
Miriam Kidron	72,000 <sup>(1)</sup>	-	6.48	5/7/18		
	72,000 <sup>(2)</sup>	-	5.88	4/20/20		
	72,000 <sup>(3)</sup>	-	4.08	8/8/22		
	47,134 <sup>(4)</sup>	-	12.45	4/9/24		
					53,232 <sup>(8)(9)</sup>	299,164
Yifat Zommer	33,334 <sup>(5)</sup>	-	5.64	10/19/19		
	50,750 <sup>(6)</sup>	-	4.08	8/8/22		
					31,040 <sup>(10)</sup>	174,445
Joshua Hexter	79,800 <sup>(7)</sup>	21,000	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 vested 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 vested 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.

(8) On November 13, 2014, 9,788 RSUs, representing a right to receive shares of the Company's common stock, were granted to each of Nadav Kidron and Miriam Kidron. The RSUs vested in two equal installments, each of 4,894 shares, on November 30 and December 31, 2014. The shares of common stock underlying the RSUs will be issued upon request of the grantee.

(9) On February 23, 2015, 79,848 RSUs, representing a right to receive shares of the Company's common stock, were granted to each of Nadav Kidron and Miriam Kidron. The RSUs vest in 23 installments consisting of one installment of 6,654 shares on February 28, 2015 and 22 equal monthly installments of 3,327 shares each, commencing March 31, 2015. The shares of common stock underlying the RSUs will be issued upon request of the grantee.

(10) On February 23, 2015, 46,560 RSUs, representing a right to receive shares of the Company's common stock, were granted to Yifat Zommer. The RSUs vest in 23 installments, consisting of one installment of 3,880 shares on February 28, 2015 and 22 equal monthly installments of 1,940 shares each, commencing March 31, 2015.

## 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 2015.

Name	Stock Awards	
	Number of Shares Acquired on Vesting	Value Realized on Vesting (\$)
Yifat Zommer	15,520	91,510
Nadav Kidron	36,404	208,615
Miriam Kidron	36,404	208,615

(1) Represents shares of common stock not yet issued underlying RSUs that have vested. Such shares will be issued upon request of the grantee.

(2) Represents the value of shares of common stock not yet issued underlying RSUs that have vested. Such shares will be issued upon request of the grantee.

## Compensation Committee Interlocks and Insider Participation

During fiscal 2015, 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.



**DIRECTOR 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 2015:

Name of Director	Fees Earned or Paid in Cash (\$)	Stock Awards(2) (3)(5) (\$)	All Other Compensation (\$)	Total (\$)
Nadav Kidron <sup>(1)</sup>	-	-	-	-
Miriam Kidron <sup>(1)</sup>	-	-	-	-
Leonard Sank	11,667	119,886	-	131,553
Harold Jacob	11,667	119,886	-	131,553
Michael Berelowitz <sup>(4)</sup>	11,667	119,886	39,996	(4) 171,549
Gerald Ostrov	11,667	119,886	-	131,553

(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 RSU awards. The assumptions used to determine the fair value of the RSU awards for fiscal 2015 are set forth in Note 10 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 the underlying shares are sold.

(3) On August 31, 2015, our non-employee directors held options and RSUs to purchase shares of our common stock as follows:

Name of Director	Aggregate Number of Shares Underlying Stock Awards
Leonard Sank	80,272
Harold Jacob	80,272
Michael Berelowitz	54,172

Gerald Ostrov 55,272

Michael Berelowitz serves as the Chairman of our Scientific Advisory Board. In this role, Dr. Berelowitz is (4) actively involved in our scientific decisions, clinical strategy, and partnership negotiations. Dr. Berelowitz was paid a fee of \$3,333 per month as compensation for serving in this position.

On November 13, 2014, the Company granted 2,718 RSUs, representing a right to receive shares of the Company's (5) common stock, to each of Leonard Sank, Harold Jacob, Michael Berelowitz and Gerald Ostrov. The RSUs vested on January 1, 2015.

On February 23, 2015, the Company granted 22,178 RSUs, representing a right to receive shares of the Company's (6) common stock, to each of Leonard Sank, Harold Jacob, Michael Berelowitz and Gerald Ostrov. The RSUs vest in two equal installments, each of 44,356 shares, on December 31, 2015 and December 31, 2016.

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 \$20,000 per annum (effective July 1, 2015 and prior to that \$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.

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 2015.

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

**Stock Option Plans**

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 (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, 2015, options with respect to 1,384,199 shares have been granted, of which 89,464 have been forfeited, 36,606 have been exercised and 313,609 have expired.

As of August 31, 2015, 346,704 RSUs have been granted, of which 39,142 have vested and the shares of common stock underlying RSUs were issued, and 53,232 have vested and the shares of common stock underlying those RSUs will be issued upon request of the grantee.

The following table sets forth additional information with respect to our equity compensation plans (consisting solely of the 2008 Plan) as of August 31, 2015:

Plan category	Number of securities to be issued upon	Weight-average exercise price of	Number of securities remaining available for
---------------	--	----------------------------------	--

	exercise of outstanding options, warrants and rights (a)	outstanding options, warrants and rights (b)	future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	992,161	\$ 6.75	72,170
Equity compensation plans not approved by security holders	--	--	--
Total	992,161	\$ 6.75	72,170

## 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 24, 2015 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 11,599,825 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 24, 2015. 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	1,80,137 (1)	14.9 %
Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd. 1# Industrial Road, Wuzhou Industrial Park Wuzhou City, Guangxi Province, 543000	696,378	6.0 %
Nadav Kidron #+	1,180,358(2)	9.9 %
Miriam Kidron #+	415,660 (3)	3.5 %
Leonard Sank #	582,524 (4)	5.0 %
Harold Jacob #	72,601 (5)	*
Michael Berelowitz #	45,801 (6)	*
Gerald Ostrov #	46,901 (7)	*
Yifat Zommer +	107,364 (8)	*
Joshua Hexter +	91,000 (9)	*
All current executive officers and directors, as a group (eight persons)	2,542,209(10)	20.3 %

\*Less than 1%

#Director

+Named Executive Officer

Includes warrants to purchase 557,274 shares of common stock and options to purchase 426,500 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) Includes 263,184 shares of common stock issuable upon the exercise of outstanding stock options and 49,712 RSUs.

(3) Includes 263,184 shares of common stock issuable upon the exercise of outstanding stock options and 49,712 RSUs.

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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 (4) options, (d) 2,718 shares of common stock issued upon the settlement of RSUs, (e) 11,089 shares of common stock issuable upon the settlement of RSUs and (e) 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 (e) above.

Includes 700 shares of common stock indirectly acquired through a corporation wholly-owned by Mr. Jacob, (5) 58,094 shares of common stock issuable upon the exercise of outstanding stock options and 11,089 shares of common stock issuable upon the settlement of RSUs.

(6) Includes 31,994 common stock issuable upon the exercise of outstanding stock options and 11,089 shares of common stock issuable upon the settlement of RSUs.

(7) Includes 33,094 common stock issuable upon the exercise of outstanding stock options and 11,089 shares of common stock issuable upon the settlement of RSUs.

(8) Includes 84,084 common stock issuable upon the exercise of outstanding stock options and 3,880 shares of common stock issuable upon the settlement of RSUs.

(9) Consists of common stock issuable upon the exercise of outstanding stock options.

(10) Includes 927,637 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 and 2015, 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 the lesser of \$120,000 or one percent of the average of our total assets at year end, 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, 2015 and 2014:

Summary:	2015	2014
Audit Fees <sup>(1)</sup>	\$76,000	\$91,000
Audit-Related Fees	-	-
Tax Fees <sup>(2)</sup>	6,000	5,000
All Other Fees	-	-
Total Fees	\$82,000	\$96,000



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 (1) internal control over financial reporting, review of our responses to SEC comments and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings or engagements.

(2) Tax consulting services.

SEC rules require that before the Independent Auditors are engaged by us to render any auditing or permitted non-audit related service, the engagement be: (1) pre-approved by our Audit Committee; or (2) entered into pursuant to pre-approval policies and procedures established by the Audit Committee, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service, and such policies and procedures do not include delegation of the Audit Committee's responsibilities to management.

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:

	<b>Page</b>
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - Report of Kesselman &amp; Kesselman</u>	F - 1
<b>CONSOLIDATED FINANCIAL STATEMENTS:</b>	
<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 - 33

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders of  
**Oramed Pharmaceuticals Inc.**

We have audited the accompanying consolidated balance sheets of Oramed Pharmaceuticals Inc. and its subsidiary (the “Company”) as of August 31, 2015 and 2014, and the related consolidated statements of comprehensive loss, changes in stockholders’ equity and cash flows for each of the three years in the period ended August 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company and its subsidiary at August 31, 2015 and 2014, and the results of their comprehensive loss, changes in stockholders’ equity and cash flows for each of the three years ended August 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

Tel Aviv, Israel      /s/ Kesselman & Kesselman  
November 25, 2015   Kesselman & Kesselman  
                                 Certified Public Accountants (Isr.)  
                                 A member firm of PricewaterhouseCoopers  
                                 International Limited

**ORAMED PHARMACEUTICALS INC.**  
**CONSOLIDATED BALANCE SHEETS**

U.S. Dollars in thousands (except share and per share data)

	August 31	
	2015	2014
Assets		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$3,213	\$1,762
Short term deposits (note 2)	11,928	18,481
Marketable securities (note 3)	2,088	1,047
Restricted cash	16	16
Prepaid expenses and other current assets	127	64
Related parties (note 13c)	-	330
Grants receivable from the chief scientist	-	78
Total current assets	17,372	21,778
<b>LONG TERM ASSETS:</b>		
Long term deposits and investment (note 4)	8,022	3
Marketable securities (note 3c)	940	-
Amounts funded in respect of employee rights upon retirement (note 7)	9	7
Property and equipment, net (note 5)	11	14
Total long term assets	8,982	24
Total assets	\$26,354	\$21,802
Liabilities and stockholders' equity		
<b>CURRENT LIABILITIES -</b>		
Accounts payable and accrued expenses	\$953	\$926
Advance on account of license agreement (note 1a1)	500	-
Related parties (note 13c)	36	47
Total current liabilities	1,489	973
<b>LONG TERM LIABILITIES:</b>		
Employee rights upon retirement (note 7)	11	9
Provision for uncertain tax position (note 12e)	26	27
	37	36
<b>COMMITMENTS (note 8)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$ 0.012 par value (30,000,000 authorized shares as of August 31, 2015 and 2014; 11,563,077 and 10,102,555 shares issued and outstanding as of August 31, 2015 and 2014, respectively)	138	121
Accumulated other comprehensive income	558	452

Additional paid-in capital	59,184	48,040
Accumulated loss	(35,052)	(27,820)
Total stockholders' equity	24,828	20,793
Total liabilities and stockholders' equity	\$26,354	\$21,802

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

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**ORAMED PHARMACEUTICALS INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

U.S. Dollars in thousands (except share and per share data)

	Year ended August 31		
	2015	2014	2013
RESEARCH AND DEVELOPMENT EXPENSES, NET	\$4,781	\$3,277	\$2,272
GENERAL AND ADMINISTRATIVE EXPENSES	2,602	2,629	2,032
OPERATING LOSS	7,383	5,906	4,304
<b>FINANCIAL INCOME</b> (note 11a)	(168 )	(225 )	(180 )
<b>FINANCIAL EXPENSES</b> (note 11b)	18	11	313
LOSS BEFORE TAXES ON INCOME	7,233	5,692	4,437
<b>INCOME TAX EXPENSES (BENEFIT)</b> (note 12c)	(1 )	4	(205 )
NET LOSS FOR THE YEAR	\$7,232	\$5,696	\$4,232
SUBSEQUENT INCREASE IN THE FAIR VALUE OF AVAILABLE FOR SALE SECURITIES PREVIOUSLY WRITTEN DOWN AS IMPAIRED	(3 )	(34 )	(131 )
RECLASSIFICATION ADJUSTMENT FOR GAINS INCLUDED IN NET LOSS	-	80	90
<b>UNREALIZED GAIN ON AVAILABLE FOR SALE SECURITIES</b>	(103 )	(194 )	(263 )
TOTAL OTHER COMPREHENSIVE INCOME	(106 )	(148 )	(304 )
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$7,126	\$5,548	\$3,928
BASIC AND DILUTED LOSS PER COMMON SHARE	\$0.67	\$0.62	\$0.59
WEIGHTED AVERAGE NUMBER OF COMMON SHARES USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	10,820,465	9,244,059	7,209,283

**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		Additional paid-in capital	Accumulated other comprehensive income		Total Accumulated stockholders' equity
	Shares	\$		income	loss	
	In thousands					
BALANCE AS OF AUGUST 31, 2012	6,675	\$80	\$ 21,590	\$ -	\$ (17,892 )	\$ 3,778
SHARES AND WARRANTS ISSUED (see note 9b)	349	4	1,418	-	-	1,422
SHARES ISSUED (see note 9d)	658	8	4,231	-	-	4,239
SHARES ISSUED FOR MARKETABLE SECURITIES (see note 9c)	199	2	626	-	-	628
SHARES ISSUED FOR SERVICES	34	1	244	-	-	245
EXCHANGE OF WARRANTS (see note 6)	-	-	918	-	-	918
EXERCISE OF WARRANTS AND OPTIONS	23	*	110	-	-	110
STOCK BASED COMPENSATION	-	-	719	-	-	719
OTHER COMPREHENSIVE INCOME	-	-	-	304	-	304
NET LOSS	-	-	-	-	(4,232 )	(4,232 )
BALANCE AS OF AUGUST 31, 2013	7,938	95	29,856	304	(22,124 )	8,131
SHARES ISSUED FOR CASH, NET (see note 9e)	1,580	19	14,868	-	-	14,887
SHARES ISSUED (see note 8f)	16	*	102	-	-	102
EXERCISE OF WARRANTS AND OPTIONS	569	7	1,746	-	-	1,753
STOCK BASED COMPENSATION	-	-	1,468	-	-	1,468
OTHER COMPREHENSIVE INCOME	-	-	-	148	-	148
NET LOSS	-	-	-	-	(5,696 )	(5,696 )
BALANCE AS OF AUGUST 31, 2014	10,103	121	48,040	452	(27,820 )	20,793
SHARES, OPTIONS AND WARRANTS ISSUED FOR CASH, NET (see notes 9f and 9h)	1,411	17	9,696	-	-	9,713
SHARES ISSUED (see note 8f)	15	*	93	-	-	93
EXERCISE OF OPTIONS	1	*	8	-	-	8
STOCK BASED COMPENSATION	33	*	1,347	-	-	1,347
OTHER COMPREHENSIVE INCOME	-	-	-	106	-	106
NET LOSS	-	-	-	-	(7,232 )	(7,232 )
BALANCE AS OF AUGUST 31, 2015	11,563	\$138	\$ 59,184	\$ 558	\$ (35,052 )	\$ 24,828

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

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

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**ORAMED PHARMACEUTICALS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

U.S. Dollars in thousands (except share and per share data)

	Year ended August 31		
	2015	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(7,232 )	\$(5,696 )	\$(4,232)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	4	6	5
Exchange differences and interest on investments	(20 )	(29 )	19
Stock based compensation	1,347	1,468	719
Common stock issued for services	93	102	244
Gain on sale of investment	-	(80 )	(50 )
Exchange of warrants	-	-	297
Changes in fair value of warrant liabilities	-	-	(45 )
Changes in operating assets and liabilities:			
Prepaid expenses, other current assets and related parties	345	(319 )	(3 )
Accounts payable, accrued expenses and related parties	516	475	(146 )
Liability for employee rights upon retirement	2	1	1
Provision for uncertain tax position	(1 )	4	(205 )
Total net cash used in operating activities	(4,946 )	(4,068 )	(3,396)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(1 )	(14 )	(6 )
Purchase of short term and long term deposits	(21,125)	(55,750)	(5,847)
Purchase of held to maturity securities	(1,885 )	-	-
Proceeds from sale of short term deposits	19,701	42,539	1,054
Proceeds from sale of available-for-sale securities	-	137	227
Funds in respect of employee rights upon retirement	(2 )	(2 )	(2 )
Other	-	2	5
Total net cash used in investing activities	(3,312 )	(13,088)	(4,569)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock, options and warrants - net of issuance expenses*	9,713	14,887	5,715
Proceeds from exercise of warrants and options	8	1,753	109
Total net cash provided by financing activities	9,721	16,640	5,824
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(12 )	6	(18 )
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,451	(510 )	(2,159)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	1,762	2,272	4,431
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$3,213	\$1,762	\$2,272

Material non cash investing and financing activities:

Exchange of warrants	-	-	918
Shares issued for marketable securities	-	-	628

\* See notes 9b, 9d, 9e, 9f and 9h.

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

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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 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”).

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

On July 3, 2015, the Company and the Subsidiary entered into a non-binding Letter of Intent (the “LoI”) with Sinopharm Capital Management Co. Ltd. and Hefei Life Science & Technology Park Investments and Development Co., Ltd. (“HLST” and together - “Sinopharm-HLST”), according to which, the Company will enter into a Stock Purchase Agreement with Sinopharm-HLST pursuant to which Sinopharm-HLST will agree to buy and the Company will agree to sell an aggregate of 1,155,367 shares of its common stock, or the Shares, at a price per Share of approximately \$10.39 (and \$12,000 in total), and in addition, the Subsidiary will grant a commercialization license in the territory of Peoples Republic of China (the “Territory”) related to oral insulin, for an aggregate of approximately \$38,000, of which \$18,000 would be paid up front, and \$20,000 would be payable upon achievement of a certain milestone, and royalties of 10% on net sales of the related commercialized products to be sold by Sinopharm-HLST in the Territory.

In July 2015, according to the LoI, Sinopharm-HLST paid the Subsidiary a non-refundable amount of \$500 as a no-shop fee, and the Company and the Subsidiary committed to negotiate exclusively with Sinopharm-HLST regarding an out-licensing and commercialization transaction in the Territory. In the event that the parties enter into a license agreement, the foregoing amount will be deducted from the initial payment due by Sinopharm-HLST to the

Subsidiary. The no-shop fee is presented as an advance on account of the license agreement among current liabilities, and is not to be carried to income prior to the recognition of such additional future payments from entering the license agreement. The Company will evaluate the accounting treatment of the agreement once the agreement is signed and agreed by the parties. See also note 14 as to the amendment to the LoI signed in October 2015.

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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):**

**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.

Successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the U.S. Food and Drug Administration 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, 2015 and 2014, 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.

**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):

**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.

**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.

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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):**

**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.

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 Office of Chief Scientist ("OCS") and from the Bio-Jerusalem fund ("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 8(i) and 8(j).

**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):**

**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, warrants and restricted stock units excluded from the calculation of diluted net loss was 2,953,962 for the year ended August 31, 2015 (1,924,491 and 2,343,972 for the years ended August 31, 2014 and 2013, respectively).

**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.

**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):

**k. 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, 2015, the assets or liabilities measured at fair value are comprised of available for sale equity 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.

As of August 31, 2015, the carrying amount of cash and cash equivalents, short term deposits, prepaid expenses and other current assets and accounts payable and accrued expenses approximate their fair values due to the short-term maturities of these instruments.

As of August 31, 2015, the carrying amount of long term deposits approximates their fair values due to the stated interest rates which approximate market rates.

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

## **I. Marketable securities**

### **1) Available-for-sale securities**

Available-for-sale equity 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.

**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) Held to maturity securities**

All debt securities are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity.

On a continuous basis, management assesses whether there are any indicators that the value of the Company's marketable securities may be impaired, which includes reviewing the underlying cause of any decline in value and the estimated recovery period, as well as the severity and duration of the decline. In the Company's evaluation, the Company considers its ability and intent to hold these investments for a reasonable period of time sufficient for the Company to recover its cost basis. A marketable security is impaired if the fair value of the security is less than the carrying value of the security and such difference is deemed to be other-than temporary. To the extent impairment has occurred, the loss shall be measured as the excess of the carrying amount of the security over the estimated fair value in the security.

**m. Concentration of credit risks**

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents, short and long term deposits 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.

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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 2 - SHORT TERM DEPOSITS:**

**Composition:**

	August 31 2015		2014	
	Annual interest rate	Amount	Annual interest rate	Amount
Dollar deposits	0.3-1.52%	\$ 11,928	0.12-0.6%	\$ 18,481

During the year ended August 31, 2015, the Group purchased short term deposits of \$13,123 and received proceeds from the sale of short term deposits of \$19,701. During the year ended August 31, 2014, the Group purchased short term deposits of \$55,750 and received proceeds from the sale of short term deposits of \$42,539.

**NOTE 3 - MARKETABLE SECURITIES:**

**a. Composition:**

The Group's marketable securities include investments in equity securities of D.N.A Biomedical Solutions Ltd (“D.N.A”) and in held to maturity bonds.

Composition:

August 31

	2015	2014
Short term:		
D.N.A (see b below)	\$1,153	\$1,047
Held to maturity bonds (see c below)	935	-
	\$2,088	\$1,047
Long term:		
Held to maturity bonds (see c below)	\$940	\$-

**b.D.N.A**

The investment in D.N.A. is 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.

The 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. During the year ended August 31, 2015, the Group did not sell any of the D.N.A ordinary shares.

As of August 31, 2015, the Group owns approximately 9.6% of D.N.A's outstanding ordinary shares.

The cost of the securities as of August 31, 2015 and 2014 is \$590.

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.



**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 3 - MARKETABLE SECURITIES (continued):**

As of August 31, 2015 and 2014, the available for sale equity securities are classified as Level 1.

**c. Held to maturity bonds**

The amortized cost and estimated fair value of held-to-maturity securities at August 31, 2015, are as follows:

	August 31, 2015		
	Amortized cost	Gross unrealized losses	<b>Estimated fair value</b>
Short term:			
Commercial bonds	\$914	\$ 1	\$ 913
Accrued interest	21	-	21
Long term	940	3	937
	\$1,875	\$ 4	\$ 1,871

As of August 31, 2015, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$940, and the yield to maturity rates vary between 0.57% to 1.31%.

**ORAMED PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

U.S. Dollars in thousands (except share and per share data)

**NOTE 4 - LONG TERM DEPOSITS:**

Composition:

	August 31	
	2015	2014
Bank deposits (1)	\$8,017	\$ -
Lease car deposits	4	2
Investment	1	1
	\$8,022	\$ 3

Represents U.S. dollar bank deposits which carry fixed annual interest rates between 1.28% to 1.64%, with (1) maturities of more than one year from August 31, 2015. The latest maturity date is during the year ending August 31, 2017.

**NOTE 5 - PROPERTY AND EQUIPMENT, NET:**

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

	August 31	
	2015	2014
Cost:		
Leasehold improvements	\$78	\$78
Office furniture and equipment	29	28
Computers and peripheral equipment	38	38
	145	144
Less - accumulated depreciation and amortization	134	130
	\$11	\$14

b. Depreciation expenses totaled \$4, \$6 and \$5 in the years ended August 31, 2015, 2014 and 2013.

## NOTE 6 - 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 9a (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 9c, 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.

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 6 – WARRANTS** (continued):

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.

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 year ended August 31, 2013. There were no Level 3 items for the years ended August 31, 2015 and 2014.

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

See note 9i with respect to outstanding warrants.

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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 - 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, 2015, 2014 and 2013, the Subsidiary deposited \$2 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, \$26 and \$23 for the years ended August 31, 2015, 2014 and 2013, respectively. In the years ended August 31, 2015, 2014 and 2013, the Group paid \$24, \$26 and \$13, respectively, in respect of a Contribution Plan.

The Subsidiary expects to contribute approximately \$26 in the year ending August 31, 2016 to insurance companies in connection with its severance liabilities for its operations for that year.

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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 - COMMITMENTS:**

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

**a.** 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, 2015, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary.

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

**b.** services. According to the Hadasit Agreement, Hadasit will be entitled to consideration of \$200 to be paid by the Company in accordance with the actual progress of the studies, \$111 of which were recognized through August 31, 2015. See also note 1a(1).

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

**c.** 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 fair value of the option as of August 31, 2015 was \$113, using the following assumptions: dividend yield of 0%; expected term of 5.46 years; expected volatility of 81.06%; and risk-free interest rate of 1.94%. 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 April 28, 2013, the Subsidiary entered into a new lease agreement for its office facilities in Israel. 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, 2015, the future annual lease payments under the new agreement will



be \$23, based on the exchange rate as of August 31, 2015).

The lease expenses for the years ended August 31, 2015, 2014 and 2013 were \$23, \$27 and \$13, respectively.

The future lease payments under the lease agreement are \$23 and \$2, respectively, in the years ending August 31, 2016 and 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, 2015, 2014 and 2013 were \$16, \$28 and \$30, respectively.

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 8 - COMMITMENTS** (continued):

The future lease payments under the lease agreement are \$15 and \$9 for the years ending August 31, 2016 and 2017, respectively.

As security for its obligation under the lease agreements the Subsidiary deposited \$4, which are classified as long term deposits.

On April 15, 2013, the Company entered into a consulting agreement with a third party advisor for a period of twelve months, pursuant to which such advisor provided investor relations services and received a monthly cash fee **f.** 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 provided investor relations services and was entitled to receive a monthly cash fee and 15,000 shares of the Company's common stock that were issued in four equal installments, on or about each of August 1, 2014, November 1, 2014, February 1, 2015 and May 1, 2015. As of August 31, 2015, the Company issued to such advisor all 15,000 shares. The fair value of the shares at the grant dates was \$107.

On July 1, 2015, 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, 2015, November 1, 2015, February 1, 2016 and May 1, 2016. As of August 31, 2015, the Company had issued to such advisor 3,750 shares. The fair value of the shares at the grant dates was \$24.

On February 6, 2014, 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 clinical trial for an oral insulin capsule for type **g.** 2 diabetes patients. As consideration for its services, the Subsidiary paid the CRO a total amount of approximately \$280, all of which was recognized through August 31, 2015.

On July 22, 2014, the Subsidiary entered into an additional agreement with the same CRO, for its Phase 2b clinical trial for an oral insulin capsule for type 2 diabetes patients, which began in the second quarter of calendar year 2015. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$3,290 during the term of the engagement and based on achievement of certain milestones, \$1,318 of which were recognized through August 31, 2015.



**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 8 - COMMITMENTS** (continued):

On July 23, 2013, the Subsidiary entered into a Master Service Agreement with a vendor for the process **h.** 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 a Master Service Agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of \$311, \$40 of which was recognized through August 31, 2015, 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, 2015.

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, all of which was recognized through August 31, 2015.

On December 12, 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 \$550, \$430 of which was recognized through August 31, 2015.

**i.** Grants from Bio-Jerusalem

The Subsidiary is committed to pay royalties to Bio-Jerusalem 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, 2015, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

During the years ended August 31, 2015 and 2014, the Company received no grants from Bio-Jerusalem. 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.

**j.** Grants from the 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, 2015, 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, 2015 was \$2,194.

k. For the years ended August 31, 2015, 2014 and 2013, the research and development expenses are presented net of OCS and Bio-Jerusalem fund grants, in the total amount of \$49, \$428 and \$297, respectively.

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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 - STOCKHOLDERS' EQUITY:**

The following are the significant capital stock transactions that took place during the years ended August 31, 2015, 2014 and 2013:

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

**a.** 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 6.

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 6.

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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 - STOCKHOLDERS' EQUITY (continued):**

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.

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.

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.

On November 3, 2014, the Company entered into a Stock Purchase Agreement with Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd. (the "Investor"), pursuant to which the Company issued to the Investor an aggregate of 696,378 shares of common stock, at a price of \$7.18 per share, which was equal to the closing price of the Company's common stock on the Nasdaq Capital Market on October 31, 2014, for aggregate gross proceeds of approximately \$5,000. The net proceeds to the Company from the offering were approximately \$4,833, after deducting a finder's fee of \$150 and other offering expenses of the Company. The offering closed on November 28, 2014.

On April 2, 2015, the Company entered into an at the market issuance sales agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$25,000 from time to time, at its option, through MLV as its sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3. The Company will pay MLV a commission of 3.0% of the gross proceeds of the sale of



any shares sold through MLV. To date, no shares have been sold under the Sales Agreement.

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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 - STOCKHOLDERS' EQUITY (continued):**

On June 4, 2015, the Company entered into a letter of agreement (the "Engagement Letter") with H.C. Wainwright & Co., LLC ("HCW"), pursuant to which HCW agreed to serve as exclusive agent, advisor or underwriter in any offering of the Company occurring between June 4, 2015 and July 4, 2015. On June 5, 2015, the Company entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell, in a registered direct offering (the "June 2015 Offering"): (1) an aggregate of 714,286 shares (the "Shares") of the Company's common stock at a price of \$7.50 per Share to six investors (the "Purchasers") and (2) at the option of each Purchaser (the "Overallotment Right"), additional shares of the Company's common stock (the "Overallotment Shares") up to the number equal to the number of Shares purchased by such Purchaser and at a price of \$10.00 per Overallotment Share. The closing of the sale of the Shares occurred on June 10, 2015. The Overallotment Right shall be exercisable beginning December 10, 2015, and shall remain exercisable until December 10, 2016. Pursuant to the Engagement Letter, HCW received, for its services in the June 2015 Offering, a fee equal to 7% of the gross proceeds raised in the June 2015 Offering and an expense allowance of 1% of the gross proceeds raised in the June 2015 Offering, and affiliates of HCW received warrants to purchase 28,571 shares of common stock of the Company, exercisable immediately and expires after a period of three years and with an exercise price of \$10.00 per share. The net proceeds to the Company from the June 2015 Offering were approximately \$4,880, after deducting HCW's expenses and other offering expenses of the Company totaling \$478.

As of August 31, 2015, the Company had outstanding warrants exercisable for 981,940 shares of common stock at exercise prices ranging from \$3.7656 to \$10.00 expiring at various dates between November 11, 2015 and June 10, 2018.

The following table presents the warrant activity for the years ended August 31, 2015, 2014 and 2013:

	2015		2014		2013	
	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price*
Warrants outstanding as of September 1	953,369	\$ 5.15	1,215,034	\$ 5.33	883,191	\$ 5.56
Issued	28,571	\$ 10.00	-	-	353,285	\$ 4.79
Exercised	-	-	(261,665 )	\$ 6.00	(21,442 )	\$ 6.00
Warrants outstanding as of August 31	981,940	\$ 5.29	953,369	\$ 5.15	1,215,034	\$ 5.33

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Warrants exercisable as of August 31	981,496	\$ 5.29	952,258	\$ 5.15	1,213,478	\$ 5.33
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\*See note 6 with regards to the amendment of price of certain warrants during the year ended August 31, 2013.

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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 - STOCK BASED COMPENSATION:**

As of August 31, 2015, 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 executives and board members made during the years ended August 31, 2015, 2014 and 2013:

- a. 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.
- b. 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 vested 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.

On April 9, 2014, options to purchase an aggregate of 52,376 shares of the Company were granted to four members of the Company's Board of Directors at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vested 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 5.21 years.

**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

U.S. Dollars in thousands (except share and per share data)

**NOTE 10 - STOCK BASED COMPENSATION (continued):**

d. On April 9, 2014, options to purchase an aggregate of 2,556 shares of the Company were granted to an employee of the Subsidiary at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vested in four equal quarterly installments commencing on May 1, 2014, and expire on April 9, 2024. The fair value of these options on the date of grant was \$21, 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.

e. On November 13, 2014, the Company granted a total of 19,576 restricted stock units (“RSUs”) representing a right to receive shares of the Company’s common stock to the CEO, and the Company’s CTO, both related parties. The RSUs vested in two equal installments, each of 9,788 shares, on November 30 and December 31, 2014. The total fair value of these RSUs on the date of grant was \$135, using the quoted closing market share price of \$6.90 on the Nasdaq Capital Market on the date of grant. The shares of common stock underlying the RSUs will be issued upon request of the grantee. As of August 31, 2015, a total of 19,576 RSUs were vested and outstanding.

f. On November 13, 2014, the Company granted a total of 10,872 RSUs representing a right to receive shares of the Company’s common stock to four members of the Company's Board of Directors. The RSUs vested on January 1, 2015. The total fair value of these RSUs on the date of grant was \$75, using the quoted closing market share price of \$6.90 on the Nasdaq Capital Market on the date of grant.

g. On February 23, 2015, the Company granted a total of 159,696 RSUs representing a right to receive shares of the Company’s common stock to the Company’s CEO and the CTO, both related parties. The RSUs vest in 23 installments consisting of one installment of 13,308 shares on February 28, 2015 and 22 equal monthly installments of 6,654 shares each, commencing March 31, 2015. The total fair value of these RSUs on the date of grant was \$728, using the quoted closing market share price of \$4.56 on the Nasdaq Capital Market on the date of grant. The shares of common stock underlying the RSUs will be issued upon request of the grantee. As of August 31, 2015, a total of 53,232 RSUs were vested and outstanding.

h. On February 23, 2015, the Company granted a total of 88,712 RSUs representing a right to receive shares of the Company’s common stock to four members of the Company's Board of Directors (22,178 RSUs to each director). The RSUs vest in two equal installments, each of 44,356 shares, on December 31, 2015 and December 31, 2016. The total fair value of these RSUs on the date of grant was \$405, using the quoted closing market share price of \$4.56 on the Nasdaq Capital Market on the date of grant.

i. On February 23, 2015, the Company granted a total of 63,216 RSUs to three employees of the Subsidiary. The RSUs vest in 23 installments, consisting of one installment of 5,268 shares on February 28, 2015 and 22 equal monthly installments of 2,634 shares each, commencing March 31, 2015. The total fair value of these RSUs on the

date of grant was \$288, using the quoted closing market share price of \$4.56 on the Nasdaq Capital Market on the date of grant.

On April 1, 2015, the Company granted a total of 4,632 RSUs to an employee of the Subsidiary. The RSUs vest in 21 installments, consisting of one installment of 772 shares on April 30, 2015 and 20 equal monthly installments of 193 shares each, commencing May 31, 2015. The total fair value of these RSUs on the date of grant was \$30, using the quoted closing market share price of \$6.39 on the Nasdaq Capital Market on the date of grant.

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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 - STOCK BASED COMPENSATION** (continued):

**k. Options to employees, directors and non-employees.**

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:

	<b>For options granted in the year ended</b>	
	<b>August 31</b>	
	2014	2013
Expected option life (years)	5.21	5.75-6
Expected stock price volatility (%)	82.06	64.35-75.46
Risk free interest rate (%)	1.65	0.92-1.01
Expected dividend yield (%)	0.0	0.0

No options were granted in 2015.

A summary of the status of the stock options granted to employees and directors as of August 31, 2015, 2014 and 2013, and changes during the years ended on those dates, is presented below:

	Year ended August 31,			2013	
	2015	2014		2013	
	Number of options	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	908,901	1,049,249	6.75	932,116	3.72
Changes during the year:					



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Granted - at market price	-	-	149,200	12.45	100,800	7.88
Granted - above market price	-	-	-	-	24,667	6.00
Forfeited	(3,297 )	6.00	-	-	-	-
Exercised	(1,370 )	6.00	(289,548 )	0.18	(8,334 )	5.04
Options outstanding at end of year	904,234	6.75	908,901	6.75	1,049,249	4.13
Options exercisable at end of year	883,234		786,328		870,883	
Weighted average fair value of options granted during the year	-		\$8.31		\$4.55	

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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 - STOCK BASED COMPENSATION (continued):**

Costs incurred in respect of stock based compensation for employees and directors, for the years ended August 31, 2015, 2014 and 2013 were \$278, \$1,422 and \$563, respectively.

The total intrinsic value of employees options exercised during the year ended August 31, 2014 was \$2,847. The options exercised during the year ended August 31, 2015, were at a price equal to the market price at the exercise date.

The following table presents summary information concerning the options granted to employees and directors outstanding as of August 31, 2015:

<b>Range of exercise prices</b>	<b>Number outstanding</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted average exercise price</b>	<b>Aggregate intrinsic value</b>
		Years	\$	
4.08 to 6.00	510,234	5.68	4.94	394,440
6.48 to 7.88	244,800	4.72	7.06	-
12.45	149,200	8.61	12.45	-
	904,234	5.90	6.75	394,440

The following table presents summary information concerning the options granted to employees and directors exercisable as of August 31, 2015:

<b>Range of exercise prices</b>	<b>Number exercisable</b>	<b>Weighted Average Remaining</b>	<b>Weighted average exercise</b>	<b>Aggregate intrinsic value</b>
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		<b>Contractual</b>	<b>price</b>	
		<b>Life</b>		
\$		Years	\$	
4.08 to 6.00	510,234	5.68	4.94	394,440
6.48 to 7.88	223,800	4.45	6.98	-
12.45	149,200	8.61	12.45	-
	883,234	5.86	6.73	394,440

As of August 31, 2015, there were \$14 of unrecognized compensation costs related to non-vested options previously granted to employees and directors, to be recorded over the next 8 months.

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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 - STOCK BASED COMPENSATION** (continued):

A summary of the status of the stock options granted to non-employees outstanding as of August 31, 2015, 2014 and 2013, and changes during the years ended on this date, is presented below:

	Year ended August 31					
	2015		2014		2013	
	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	62,221	7.13	\$ 79,689	7.21	\$ 79,689	\$ 7.21
Changes during the year:						
Exercised	-	-	(17,468)	7.49	-	-
Expired	(21,935)	6.82	-	-	-	-
Options outstanding at end of year	40,286	7.29	62,221	7.13	79,689	7.21
Options exercisable at end of year	36,119		53,888		47,469	

The Company recorded stock based compensation of \$3, \$46 and \$156 during the years ended August 31, 2015, 2014 and 2013, 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, 2015 and 2013.

The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2015:

<b>Range of exercise prices</b>	<b>Number outstanding</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Aggregate intrinsic value</b>
\$		Years	\$	
6.00	23,618	4.90	6.00	-
9.12	16,668	3.36	9.12	-
	40,286	4.26	7.29	-

The following table presents summary information concerning the options granted to non-employee exercisable as of August 31, 2015:

<b>Range of exercise prices</b>	<b>Number exercisable</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted average exercise price</b>	<b>Aggregate intrinsic value</b>
\$		Years	\$	
4.08 to 6.00	19,451	4.78	6.00	-
9.12	16,668	3.36	9.12	-
	36,119	4.13	7.44	-

As of August 31, 2015 there were approximately \$7 of unrecognized compensation costs related to non-vested non-employee options, to be recorded over the next 6 months.

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 10 - STOCK BASED COMPENSATION** (continued):

**I. Restricted stock units**

The following table summarizes the activities for unvested RSUs granted to employees and directors for the year ended August 31, 2015:

	Number
Unvested at the beginning of period	-
Granted	346,704
Vested and issued	(33,488 )
Outstanding at the end of the period	313,216
Includes vested and unissued (see note 10g)	53,232

The Company recorded stock based compensation of \$1,066 during the year ended August 31, 2015 related to RSU awards.

As of August 31, 2015 there were \$594 of unrecognized compensation costs related to RSUs, to be recorded over the next 16 months.

**NOTE 11 - FINANCIAL INCOME AND EXPENSES**

**a. Financial income**

	Year ended August		
	31		
	2015	2014	2013

Gain on sale of marketable securities (note 3b)	\$-	\$80	\$90
Changes in fair value of warrants	-	-	44
Income from interest on deposits	160	138	19
Exchange rate differences	-	7	-
Income from interest on corporate bonds	8	-	-
Other	-	-	27
	\$168	\$225	\$180

**b. Financial expenses**

	Year ended		
	August 31		
	2015	2014	2013
Exchange of warrants	\$-	\$ -	\$297
Exchange rate differences	3	-	3
Bank commissions	9	11	13
Other	6	-	-
	\$18	\$ 11	\$313

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 12 - 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, 2015, the Company has an accumulated tax loss carryforward of approximately \$7,569 (as of August 31, 2014, approximately \$6,791). 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 2015 and 2014 is 26.5%.

As of August 31, 2015, the Subsidiary has an accumulated tax loss carryforward of approximately \$11,701 (as of August 31, 2014, approximately \$9,487).

**Deferred income taxes:**



August 31  
2015      2014      2013

In respect of:

Net operating loss carryforward	\$5,750	\$4,890	\$3,993
Research and development expenses	906	688	339
Less - valuation allowance	(6,656)	(5,578)	(4,332)
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:**

	Year ended August 31		
	2015	2014	2013
Loss before taxes on income:			
U.S.	\$1,226	\$893	\$1,186
Outside U.S.	6,006	4,799	3,251
	\$7,232	\$5,692	\$4,437
Income tax expenses (benefit):			
Current:			
U.S.	-	-	(13 )
Outside U.S.	(1 )	4	(192 )
	\$(1 )	\$4	\$(205 )

**ORAMED PHARMACEUTICALS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

U.S. Dollars in thousands (except share and per share data)

**NOTE 12 - 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:

	Year ended		
	August 31		
	2015	2014	2013
Loss before income taxes as reported in the consolidated statement of comprehensive income (loss)	\$(7,232)	\$(5,692)	\$(4,437)
Statutory tax benefit	(2,531)	(1,992)	(1,552)
Increase (decrease) in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax	1,599	1,104	902
Disallowable deductions	422	480	374
	510	408	276
Influence of different tax rates applicable to the Subsidiary			
Uncertain tax position	(1 )	4	(205 )
Taxes on income for the reported year	\$(1 )	\$4	\$(205 )

**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, 2015, 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		
	2015	2014	2013
Balance at Beginning of Year	\$27	\$ 23	228
Increase (decrease) in uncertain tax positions for the current year	(1 )	4	(205)
Balance at End of Year	\$26	\$ 27	\$23

The decrease in uncertain tax positions for the year ended August 31, 2015, is a result of decreased 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 2010 through 2015.

The Subsidiary is subject to Israeli income tax examinations for the tax years of 2011 through 2015.

**ORAMED PHARMACEUTICALS INC.**

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 12 - TAXES ON INCOME** (continued):**f. Valuation Allowance Rollforward**

	Year ended August 31		
	Balance at beginning of period	Additions	Balance at end of period
Allowance in respect of carryforward tax losses:			
Year ended August 31, 2015	\$5,578	\$ 1,078	\$ 6,656
Year ended August 31, 2014	\$4,332	\$ 1,246	\$ 5,578
Year ended August 31, 2013	\$3,208	\$ 1,124	\$ 4,332

**NOTE 13 - RELATED PARTIES - TRANSACTIONS:**

- a. During each of the fiscal years of 2015, 2014 and 2013 the Company paid to directors \$47, \$40 and \$39, respectively, as directors fees.

- b. On July 1, 2008, the Subsidiary entered into two consulting agreements with KNR Y Ltd. (“KNRY”), an Israeli company owned by the CEO, whereby the CEO and the CTO, through KNR Y, provide services to the Group (the “Consulting Agreements”). The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNR Y (i) will be paid a gross amount of NIS 50,400 per month for each of the CEO and CTO (\$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 KNR Y, according to which, the CEO's and CTO's annual payment was set at \$250 and \$200, respectively, calculated at an exchange rate of NIS 3.6 per U.S. dollar, and in addition to such payment they were granted the use of a company car and certain cash bonus payments, 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.

On November 13, 2014, the Subsidiary entered into an amendment to the Consulting Agreements (the "Amendment Agreement"), according to which, the CEO and the CTO made some representations with regards to their relationship with KNRY and agreed to indemnify the Subsidiary in certain circumstances as defined in the amendment, among other revisions.

On July 1, 2015, the compensation committee of the Company's Board of Directors approved an increase of six percent to the annual payment of the CEO and the CTO effective July 1, 2015.

On July 16, 2015, the compensation committee of the Company's Board of Directors approved payment of cash bonuses to the CEO and the CTO in the amounts three monthly consulting fee.

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

U.S. Dollars in thousands (except share and per share data)

**NOTE 13 - RELATED PARTIES - TRANSACTIONS** (continued):

**c.** Balances with related parties:

	August 31	
	2015	2014
Receivable	\$-	\$330
Accounts payable and accrued expenses - KNRY	\$36	\$47

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		
	2015	2014	2013
KNRY	\$586	\$671	\$448

**NOTE 14 - SUBSEQUENT EVENT**

On October 22, 2015, the Company, the Subsidiary and HLST amended the LoI, dated July 3, 2015 (as described in note 1a1) by revising the schedule of payments and extending the no-shop period until December 22, 2015. The total payments to be made by HLST remains \$50,000, as initially agreed. According to the revised schedule of payments under the license, \$11,000 would be paid up front and \$26,500 would be payable upon achievement of certain milestones and conditions.

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 (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).
- 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 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 (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).

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 (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).



- 10.4+\* Amendment, dated July 21, 2015, to Consulting Agreements by and between Oramed Ltd. and KNRV, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron.
- 10.5+\* Amendment, dated July 21, 2015, to Consulting Agreements by and between Oramed Ltd. and KNRV, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron.
- 10.6+ Consulting Agreement by and between Oramed Ltd. and KNRV, 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 July 2, 2008).
- 10.7+ 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 Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).
- 10.8+ Oramed Pharmaceuticals Inc. Amended and Restated 2008 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed June 17, 2014).
- 10.9+ Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).
- 10.10+ Form of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our current report on Form 8-K filed July 2, 2008).
- 10.11+ 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 April 22, 2009).
- 10.12+\* Amendment to Employment Agreement, dated as of July 17, 2013, by and between Oramed Ltd. and Yifat Zommer.
- 10.13+\* Amendment to Employment Agreement, dated as of July 21, 2015, by and between Oramed Ltd. and Yifat Zommer.
- 10.14+ 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).
- 10.15+ 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).
- 10.16 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).
- 10.17 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).

- 10.18 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).

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- 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 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 (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).
- 10.22+\* Agreement and Amendment No. 2, dated April 1, 2015, with Dr. Michael Berelowitz.
- 10.23 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).
- 10.24+ 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).
- 10.25+\* Amendment to Employment Agreement, dated July 21, 2015, between Oramed Ltd. and Joshua Hexter.
- 10.26 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).
- 10.27 Clinical Research Organization Services Agreement, dated July 22, 2014, between Oramed Ltd. and Integrium, LLC. (Confidential treatment has been granted for portions of this document.)
- 10.28 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).
- 10.29 Securities Purchase Agreement, dated June 5, 2015, between Oramed Pharmaceuticals Inc. and the purchasers party thereto (incorporated by reference from our current report on Form 8-K filed June 5, 2015).
- 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.

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The following financial statements from the Company's annual report on Form 10-K for the year ended August 31, 2015, 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.

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## 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 25, 2015

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 25, 2015

/s/ YIFAT ZOMMER  
Yifat Zommer,  
Chief Financial Officer  
(principal financial and accounting officer) November 25, 2015

/s/ MIRIAM KIDRON  
Miriam Kidron,  
Chief Medical and Technology Officer and Director November 25, 2015

/s/ LEONARD SANK  
Leonard Sank,  
Director November 25, 2015

/s/ HAROLD JACOB  
Harold Jacob,  
Director November 25, 2015

/s/ MICHAEL BERELOWITZ  
Michael Berelowitz, November 25, 2015

Director

November 25, 2015

Gerald Ostrov,  
Director

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