ORAMED PHARMACEUTICALS INC.
Form 10-K
November 29, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended August 31, 2017

or

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

Commission file number 000-50298

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

Delaware	**98-0376008**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
Hi-Tech Park 2/4 **Givat-Ram** **P.O. Box 39098**	**91390**

Jerusalem, Israel
(Address of Principal Executive Offices) (Zip Code)

+972-2-566-0001
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.012 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 Date 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, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
(Do not check if a smaller reporting company)	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 $56,748,843, based on a price of $6.05, 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: 14,306,100 shares of common stock issued and outstanding as of November 28, 2017.

ORAMED PHARMACEUTICALS INC.

FORM 10-K
(FOR THE FISCAL YEAR ENDED AUGUST 31, 2017)

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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, 2017, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.596 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.

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 additional license agreements, or other partnerships or forms of cooperation with other companies or medical institutions;
- future milestones, conditions and royalties under the license agreement with Hefei Tianhui Incubator of Technologies Co., Ltd., or HTIT;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials, including without limitation, our expectation that we will initiate two six-month Phase III clinical trials if our Phase IIb three-month dosing clinical trial is successful, and our expectation to file a New Drug Application thereafter;
- 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, or ORMD-0801. In August 2017, we had a call with the U.S. Food and Drug Administration, or FDA, regarding ORMD-0801. During the call, the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a Biologics License Application, or BLA. Such a pathway would grant us 12 years of marketing exclusivity for ORMD-0801, if approved, and an additional six months of exclusivity may be granted to us if the product also receives approval for use in pediatric patients. We plan to initiate in the first quarter of calendar year 2018, a clamp study on six type 1 diabetic patients and a three-month dose-ranging clinical trial on approximately 240 type 2 diabetic patients to assess the safety and evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint. In February 2017, we completed a Phase IIa dose finding clinical trial which was initiated in October 2016 in order to better define the optimal dosing of ORMD-0801. In April 2016, we completed a Phase IIb clinical trial on 180 type 2 adult diabetic patients that was initiated in June 2015 and conducted in 33 sites in the United States. This double-blind, randomized, 28-day dosing clinical trial was conducted under an Investigational New Drug application, or IND, with the FDA. The clinical trial, designed to assess the safety and efficacy of ORMD-0801, investigated ORMD-0801 over a 28 day treatment period and had statistical power to give us greater insight into the drug's efficacy. The trial indicated a statistically significant lowering of blood glucose levels versus placebo across several endpoints, with no serious or severe adverse issues related to the drug. The trial successfully met all of its primary and most of its secondary and exploratory endpoints for both safety and efficacy. Prior to that trial, we completed Phase IIa clinical trials in patients with both type 1 and type 2 diabetes. 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 (a hormone involved in the 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 ORMD-0801 insulin capsule, we are using our technology for an orally ingestible GLP-1 capsule, or ORMD-0901. In August 2015, we began a non-FDA clinical trial outside of the United States for our oral exenatide capsule on type 2 diabetic patients. The trial was completed during the second quarter of calendar year 2016 and indicated positive results as it showed ORMD-0901 to be safe and well tolerated and also demonstrated encouraging efficacy data. We completed a three-month pre-clinical toxicology study in March 2017, anticipate receiving the final report during the fourth quarter of calendar year 2017 and expect to file an IND and move directly into a pharmacokinetics study, followed by a large Phase II trial in the United States under an FDA IND.

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 415 million adults worldwide suffered from diabetes in 2015 and the IDF projects this number will increase to 642 million by 2040. Also, according to the IDF, in 2015, an estimated 5.3 million people died from diabetes. According to the American Diabetes Association, or ADA, in the United States there were approximately 30.3 million people with diabetes, or 9.4% of the United States population in 2015. 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 Scientific 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. Roy Eldor, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Harold Jacob and Dr. Harvey L. Katzeff.

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. in 2006, and which is granted 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 have successfully developed an oral dosage form that will withstand the harsh 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 excipients 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 our oral insulin capsule, ORMD-0801, in order to evaluate the safety, tolerability and efficacy in 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 study. Following the FDA's clearance to proceed in May 2013, we began the Phase IIa study in July 2013. As we announced in January 2014, the Phase IIa 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 180 type 2 adult diabetic patients which was completed in April 2016. This double-blind, randomized, 28-day dosing clinical trial was designed to assess the safety and efficacy of ORMD-0801, and was conducted in 33 sites in the United States. The trial indicated a statistically significant lowering of blood glucose levels versus placebo across several endpoints, with no serious or severe adverse issues related to the drug. The trial successfully met all of its primary and most of its secondary and exploratory endpoints. The trial primarily evaluated the nighttime glucose lowering effect and safety of ORMD-0801 compared to a placebo. The results of the mean nighttime glucose showed a significant difference in mean change from run-in versus placebo. ORMD-0801 oral insulin was safe and well-tolerated for the dosing regimen in this trial. The trial further evaluated the effect of ORMD-0801 on mean 24-hour glucose, fasting glucose, and daytime glucose and the results showed a statistically significant difference in mean change from run-in versus placebo. Two examples of the data gleaned from this study are shown below:

* Indicates Statistically Significant Difference from Placebo (p-Value<0.05)

No significant difference was shown in change in morning fasting serum insulin, C-Peptide, or triglycerides.

Following the significant results of the Phase IIb trial, we initiated in October 2016 an additional Phase IIa dose finding clinical trial which was completed in February 2017. This randomized, double-blind trial was conducted on 32 type 2 adult diabetic patients in order to better define the optimal dosing of ORMD-0801 moving forward. The results of the trial indicated a positive safety profile and potentially meaningful efficacy of ORMD-0801, as the efficacy data suggest ORMD-0801 improves glucose control.

In March 2017, we initiated a six-month toxicology study to allow for the use of our oral insulin capsule for a longer period than previously performed, in preparation for our proposed upcoming three-month clinical trial for type 2. We anticipate receiving the final report of this study in the first quarter of calendar year 2018.

In August 2017, we had a call with the FDA regarding ORMD-0801. During the call, the FDA advised that the regulatory pathway for submission of ORMD-0801 would be a BLA. Such a pathway would grant a full 12 years of marketing exclusivity for ORMD-0801, if approved. On top of this, an additional six months of exclusivity may be granted if the product also receives approval for use in pediatric patients. The FDA confirmed that the approach to nonclinical toxicology, chemistry manufacturing controls and qualification of excipients would be driven by their published guidance documents. We plan to initiate in the first quarter of calendar year 2018 a three-month dose-ranging clinical trial on approximately 240 type 2 diabetes patients to assess the safety and evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint. In addition, the FDA confirmed our ability to use insulin from different suppliers in a Phase III study.

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 treatment 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 bolus 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, demonstrating the efficacy of ORMD-0801.

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We also plan to conduct a glucose clamp study of our oral insulin capsule on six type 1 diabetic patients in the first quarter of calendar year 2018. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose.

Should our Phase IIb three-month dosing clinical trial successfully meet its primary endpoints, we anticipate initiating two six-month Phase III clinical trials on both type 1 and type 2 diabetic patients, following which we expect to file a New Drug Application with a potential approval by the third quarter of calendar year 2023.

In September 2013, we submitted a pre-IND package to the FDA for ORMD-0901. In August 2015, we began a non-FDA clinical trial outside of the United States on type 2 diabetic patients. The trial was completed during the second quarter of calendar year 2016 and indicated positive results as it showed ORMD-0901 to be safe and well tolerated and demonstrated encouraging efficacy data. We completed a three-month pre-clinical toxicology study in March 2017 and anticipate receiving the final report during the fourth quarter of calendar year 2017. We expect to file an IND during the first quarter of calendar year 2018 and move directly into a small pharmacokinetics study followed by a large Phase II trial in the United States under an FDA IND.

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 primary product pipeline (calendar quarters):

		Phase I	Phase II	Phase III	Timeline
ORMD-0801 **oral insulin**	Type 2 diabetes				Q1 ’14: Phase IIa completed Q2 ’16: Phase IIb multi-center study completed Q1 ’17: Phase IIa - dose finding study completed Q1 ’18: Phase IIb 90-day multi-center study projected initiation (projected completion Q2 ’19) Q4 ’19: Phase III study projected initiation (projected completion Q2 ’21)

	Type 1 diabetes	Q3 ’14: Phase IIa study completed Q1 ’18: Clamp study projected initiation (projected completion Q3 ’18) Q4 ’19: Phase III projected initiation (projected completion Q2 ’21)
ORMD-0901 **oral GLP-1**	Type 2 diabetes	Q2 ’16: Phase Ib non-US study completed Q1 ’18: Pharmacokinetics clinical study projected initiation (projected completion Q3 ’18) H2 ’18: Phase II projected initiation (projected completion Q4 ’19)

Another component of our business strategy is to partner with other companies or medical institutions in order to further develop our technology and commence pre-commercialization activities. On November 30, 2015, we, our Israeli subsidiary and HTIT entered into a Technology License Agreement, which was further amended, according to which we granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong, or the Territory, related to our oral insulin capsule, ORMD-0801. Pursuant to this license agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to our technology related to the ORMD-0801 capsule, and will pay certain royalties and an aggregate of approximately $37.5 million (see “Out-Licensed Technology” below). We plan to seek additional partnerships or forms of cooperation with other companies or medical institutions. While our strategy is to partner with an appropriate party, no assurance can be given that we will in fact be able to reach an agreeable partnership with any third party. Under certain circumstances, we may determine to develop one or more of our oral dosage forms on our own, either world-wide or in select territories.

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, marketing and support 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 forms for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that we will in fact be able to reach an agreeable partnership with any third party. Under certain circumstances, we may determine to develop one or more of our oral dosage forms 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 the fiscal year ended August 31, 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 the fiscal year ended August 31, 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 the fiscal year ended August 31, 2009, or 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 successfully 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.

We began FDA-approved clinical trials of ORMD-0801 in July 2013, with the Phase IIa study, which evaluated the pharmacodynamic effects of ORMD-0801 on mean nighttime glucose (determined using a continuous glucose monitor) on 30 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 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 bolus 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, demonstrating the efficacy of ORMD-0801.

In June 2015, we initiated a Phase IIb clinical trial on 180 type 2 adult diabetic patients, which was completed in April 2016. This double-blind, randomized, 28-day dosing clinical trial was designed to assess the safety and efficacy of ORMD-0801 and was conducted in 33 sites in the United States. The trial indicated a statistically significant lowering of blood glucose levels versus placebo across several endpoints, with no serious or severe adverse issues related to the drug. The trial successfully met all of its primary and most of its secondary and exploratory endpoints for both safety and efficacy.

In October 2016, we initiated an additional Phase IIa, dose finding clinical trial which was completed in February 2017. This randomized, double-blind trial was conducted on 32 type 2 adult diabetic patients in order to better define the optimal dosing of ORMD-0801 moving forward. The results of the trial indicated a positive safety profile and potentially meaningful efficacy of ORMD-0801, as the efficacy data suggest ORMD-0801 improves glucose control.

In March 2017, we initiated a six-month toxicology study to allow for the use of our oral insulin capsule for a longer period than previously performed, in preparation for our proposed upcoming three-month clinical trial for type 2 diabetes. We anticipate receiving the final report of this study in the first quarter of calendar year 2018.

In August 2017, we had a call with the FDA regarding ORMD-0801. During the call, the FDA advised that the regulatory pathway for submission of ORMD-0801 would be a BLA. Such a pathway would grant a full 12 years of marketing exclusivity for ORMD-0801, if approved, and an additional six months of exclusivity may be granted to us if the product also receives approval for use in pediatric patients. We plan to initiate in the first quarter of calendar year 2018 a three-month dose-ranging clinical trial on approximately 240 type 2 diabetes patients to assess the safety and evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint.

We utilize Clinical Research Organizations, or CROs, to conduct our clinical studies.

GLP-1 Analog

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

In December 2009, we completed non-FDA approved clinical trial in healthy, male volunteers conducted at Hadassah University Medical Center in Jerusalem. This study evaluated the safety and efficacy of ORMD-0901. 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 pre-toxicology studies on the new capsules.

In September 2013, we submitted a pre-IND package to the FDA for ORMD-0901.

In August 2015, we began a non-FDA clinical trial outside of the United States for ORMD-0901 on type 2 diabetic patients. The trial was completed during the second quarter of calendar year 2016 and indicated positive results as it showed ORMD-0901 to be safe and well tolerated and also demonstrated encouraging efficacy data.

We completed a three-month toxicology study in March 2017 and anticipate receiving the final report during the fourth quarter of calendar year 2017 and expect to file an IND and move directly into a pharmacokinetics study followed by a large Phase II trial in the United States under an FDA IND.

Combination Therapy

In June 2012, we presented an abstract, which reported the impact of our oral insulin capsule, ORMD-0801, delivered in combination with our oral exenatide capsule ORMD-0901. The work 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 the near term, we are focusing our efforts on the development of our flagship products, oral insulin and oral exenatide. Once these two products have progressed further in clinical trials, we intend to conduct additional 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 conducted a feasibility study, using one of the Pharma Company's propriety injectable compounds. The study used our proprietary technology in order to deliver the compound orally. Following the successful completion of the first stage of the study in July 2016, we continued to the second step of the study. The study will provide data required for decision making on whether to enter into a license agreement between the parties.

Other products

During the first quarter of calendar 2017, we began developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule, and in April 2017, Israel’s Ministry of Health approved our commencement of a proof of concept single dose study for our oral leptin drug candidate to evaluate its pharmacokinetic and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients. The study is projected to initiate in calendar year 2018 and be completed during calendar year 2019.

In November 2017, Israel’s Ministry of Health approved us to initiate an exploratory clinical study of our oral insulin capsule, ORMD-0801, in patients with nonalcoholic steatohepatitis (NASH). The proposed three-month treatment study will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. We expect to initiate the study during the end of calendar year 2017 and complete it during calendar year 2019.

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.

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 26 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 64 patents, seventeen of which were issued in fiscal 2017, fifteen of which were issued in September 2017 and two of which were allowed in Europe and Canada, including patents issued by the United States, Swiss, German, French, U.K., Italian, Dutch, Spanish, Australian, Israeli, Japanese, New Zealand, South African, Russian, Canadian, Hong Kong, Chinese, European and Indian patent offices that cover a part of our technology, which allows for the oral delivery of proteins; patents issued by the Australian, European, Austrian, Belgian, French, German, Irish, Italian, Luxembourg , Monaco, Dutch, Norwegian, Spanish, Swedish, Swiss, U.K., Israeli, New Zealand, South African and Russian patent offices that cover part of our technology for the oral delivery of exenatide; and patents issued by the European, Austrian, Belgian, Danish, French, German, Irish, Italian, Luxembourg , Monaco, Netherland, Norway, Spanish, Swedish, Swiss, U.K. and Japanese patent offices for treating diabetes.

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 Ltd. 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. In March 2011, we entered into a patent transfer agreement to replace the original license agreement upon closing pursuant to which Oramed Ltd. 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, we also 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, retaining a 3% interest as of March 2011. In consideration for the shares sold to D.N.A, the Company received, among other payments, 4,202,334 ordinary shares of D.N.A

The D.N.A ordinary shares are traded on the Tel Aviv Stock Exchange and have a quoted price, which is subject to market fluctuations, and may, at times, have a price below the value on the date we acquired such shares. 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. During the years ended August 31, 2017, 2016 and 2015, we did not sell any of the D.N.A ordinary shares. As of August 31, 2017, we held approximately 7.9% of D.N.A's outstanding ordinary shares.

In November 2017, Entera filed with the SEC a draft registration statement on Form F-1 for the initial public offering by Entera, a listing of its shares on the Nasdaq and for potential resale by certain selling stockholders of Entera's ordinary shares previously issued.

In June 2016, Entera announced that it had obtained orphan status from the European Medicines Agency, or EMA, for its oral treatment for hypoparathyroidism. EMA approval is in addition to the orphan status it obtained from the FDA for the same oral treatment in April 2014.

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

On November 30, 2015, we, our Israeli subsidiary and HTIT entered into a Technology License Agreement, and on December 21, 2015 these parties entered into an Amended and Restated Technology License Agreement that was further amended by the parties on June 3, 2016 and July 24, 2016, or the License Agreement. According to the License Agreement, we granted HTIT an exclusive commercialization license in the Territory, related to our oral insulin capsule, ORMD-0801, or the Product. Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to our technology and ORMD-0801 capsule, and will pay (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory, or Royalties, and (ii) an aggregate of $37.5 million, of which $3 million is payable immediately, $8 million will be paid subject to our entry into certain agreements with certain third parties, and $26.5 million will be payable upon achievement of certain milestones and conditions. In the event that we will not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of our patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

The royalty payment obligation shall apply during the period of time beginning upon the first commercial sale of the Product in the Territory, and ending upon the later of (i) the expiration of the last-to-expire licensed patents in the Territory; and (ii) 15 years after the first commercial sale of the Product in the Territory, or the Royalty Term.

The License Agreement shall remain in effect until the expiration of the Royalty Term. The License Agreement contains customary termination provisions.

The initial payment of $3 million was received in January 2016. Following the achievement of certain milestones, the second and third milestone payments of $6.5 million and $4 million, respectively, were received in July 2016 and the fourth milestone payment of $4 million was received in October 2016.

We also entered into a separate securities purchase agreement with HTIT, or the SPA, pursuant to which HTIT invested $12 million in us in December 2015 (see – “Liquidity and capital resources” below). In connection with the License Agreement and the SPA, we received a non-refundable payment of $500,000 as a no-shop fee.

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 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 patient 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.

Biological License Application. The results of the clinical trials for a biological product are submitted to the FDA as part of a BLA. 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 a BLA 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. Approval of a BLA provides 12 years of exclusivity in the U.S. market.

Phase IV. The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV 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 IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring

the new drug to gain broader market value for an approved drug.

Similar to the U.S., a European sponsor of a biological product may submit a Marketing Approval Application to the EMA for the registration of the product. The approval process in Europe consists of several stages, which together are summed up to 210 days from the time of submission of the application (net, without periods in which the sponsor provides answers to questions raised by the agency) following which, a Marketing Approval may be granted. During the approval process, the sponsor's manufacturing facilities will be audited in order to assess Good Manufacturing Practice compliance.

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: Diabetology (UK), 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: Dr. Roy Eldor, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Harold Jacob and Dr. Harvey L. Katzeff.

Dr. Roy Eldor, MD, joined the Oramed Scientific Advisory Board in July 2016. He is an endocrinologist, internist and researcher with over twenty years of clinical and scientific experience. He is currently Director of the Diabetes Unit at the Institute of Endocrinology, Metabolism & Hypertension, Tel-Aviv Sourasky Medical Center. Prior to that, Dr. Eldor served as Principal Scientist at Merck Research Laboratories, Clinical Research - Diabetes & Endocrinology, Rahway, New Jersey. He has previously served as a senior physician in internal medicine at the Diabetes Unit in Hadassah Hebrew University Hospital, Jerusalem, Israel; and the Diabetes Division at the University of Texas Health Science Center in San Antonio, Texas (under the guidance of Dr. R.A. DeFronzo). Dr. Eldor is a recognized expert, with over 35 peer reviewed papers and book chapters, and has been a guest speaker at numerous international forums.

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 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).

Dr. Harold Jacob, MD, joined the Oramed Scientific Advisory Board in November 2016. 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.

Dr. Harvey L. Katzeff, MD, joined the Oramed Scientific Advisory Board in November 2016. Dr. Katzeff is an internationally recognized authority on diabetes with over 30 years' experience in academic medicine and clinical and basic research. He currently serves as Senior Director in the Cardiovascular, Metabolic, Endocrinology and Renal Division of Covance Inc. He previously was Executive Director and Global Director for Scientific Affairs for Diabetes at Merck, and former Chief of Endocrinology and Metabolism at LIJ/North Shore Health System. He was on the faculties of Cornell Medical College and Rockefeller University, was President of the Eastern region of the American Diabetes Association and has received numerous honors including a National Institutes of Health new investigator award. Dr. Katzeff has published over 40 original reports, book chapters and reviews.

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, 2017, we have contracted with fourteen individuals for employment or consulting arrangements. Of our staff, six are senior management, three are engaged in research and development work, and the remaining five are involved in administration work.

Additional Information

Additional information about us is contained on our Internet website at 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 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. The following Corporate Governance documents are also posted on our website: Code of Ethics, Whistleblowing Policy and the Charters for each of the Audit Committee, Compensation Committee and Nominating Committee of our Board.

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 in the future expect, to incur losses.

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. 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 and 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 do not have sufficient revenues from our research and development activities to fully support our operations. Consequently, we have incurred net losses and negative cash flows since inception. We currently have only licensing revenues and no product revenues, and may not succeed in developing or commercializing any products which could generate product 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, 2017, August 31, 2016 and August 31, 2015, we had working capital of $15,132,000, $27,609,000 and $15,883,000, respectively, and stockholders' equity of $19,238,000, $26,190,000 and $24,828,000, respectively. During the 12 month periods ended August 31, 2017, or fiscal 2017, and 2016, or fiscal 2016, we generated revenues of $2,456,000 and $641,000, respectively. No revenues were generated in prior periods. For the period from our inception on April 12, 2002 through August 31, 2017, fiscal 2017, fiscal 2016,

and the year ended August 31, 2015, or fiscal 2015, we incurred net losses of $56,496,000, $10,480,000, $10,964,000 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, Canada, Brazil, Europe, India, Hong Kong, Japan and China for our technologies covering oral administration of insulin and other proteins and oral administration of exenatide and proteins, two allowed patents in Europe and Canada and 62 patents issued by the United States, Australian, Canadian, Chinese, Israeli, Japanese, New Zealand, South African, Russian, European, Hong Kong, Swiss, German, Spanish, French, United Kingdom, Italian, Indian, Austrian, Belgian, Irish, Swedish, Danish, Luxembourg , Monaco, Norway and Dutch patent offices for our technologies covering oral administration of insulin and other proteins, or for our technologies covering oral administration of exenatide, or for methods and compositions for treating diabetes. 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 or against companies to which we have licensed our technology, 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. Further, we may need to indemnify companies to which we licensed our technology in the event that such technology is found to infringe upon the rights of others.

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 clinical development stage 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 LLC 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 a Phase IIb clinical trial in patients with type 2 diabetes under an IND with the FDA and we have completed Phase IIa clinical trials of ORMD-0801 in patients with type 1 diabetes under an IND with the FDA. 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 and GLP-1 capsules and do not currently have any long-term agreements in place for the supply of oral insulin or GLP-1 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.

Our future revenues from HTIT are dependent upon third party suppliers and Chinese regulatory approvals.

Our future revenues from HTIT are dependent upon the achievement of certain milestones and conditions, and the success of HTIT to implement our technology and to manufacture the oral insulin capsule. Our future revenues from HTIT are also dependent upon the ability of third parties to scale-up one of our oral capsule ingredients and to scale-up the manufacturing process of our capsules. Our future revenues from royalties from HTIT are further dependent upon the granting of regulatory approvals in the Territory. Accordingly, if any of the foregoing does not occur, we may not be successful in receiving future revenues from HTIT and may not succeed with our business plans in China.

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 Scientific 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 2010, the federal government enacted 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, these and other initiatives in the United States may 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. 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.

In September 2017, members of the U.S. Congress introduced legislation with the announced intention to repeal and replace major provisions of the Patient Protection and Affordable Care Act, or the ACA. Although it is unclear whether such legislation will ultimately become law, attempts to repeal or to repeal and replace the ACA will likely continue. In addition, various other healthcare reform proposals have also emerged at the federal and 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.

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 the fiscal years ended August 31, 2013, 2014 and 2017, 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 fiscals 2015 and 2016, 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 on the Tel Aviv Stock Exchange 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.

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 28, 2017, we had outstanding 14,306,100 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 15,722,651 shares of common stock.

Our issuance of warrants, options and RSUs 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 28, 2017, we had outstanding warrants and options exercisable for 1,221,855 shares of common stock at a weighted average exercise price of $7.11. We also had outstanding RSUs exercisable for 164,636 shares of common stock at a total exercise price of $900. 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 28, 2017, our directors, executive officers and principal affiliated stockholders beneficially own approximately 33.6% 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 Israel Innovation Authority we are subject to ongoing restrictions.

We received royalty-bearing grants from the Israel Innovation Authority, or IIA, of the Israeli Ministry of Economy & Industry, Trade and Labor, for research and development programs that meet specified criteria. We did not recognize any grants in fiscals 2017 and 2016, and recognized a grant in the amount of $49,000 in fiscal 2015. We do not expect to receive further grants from the IIA in the future. The terms of the IIA 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 October 1, 2016 until September 30, 2021. The aggregate annual base rent for this space is currently $33,000, linked to the increase in the Israeli consumer price index, and will be increased to $37,000 in October 2018. 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 provided a bank guarantee in an amount equal to three monthly lease payments, valid until December 31, 2021.

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

Our common stock is traded on Nasdaq and on the Tel Aviv Stock Exchange, in each case under the symbol "ORMP." The quarterly high and low sales price on Nasdaq for the periods indicated are as follows:

	High	Low
Year Ended August 31, 2016		
Three Months Ended November 30, 2015	$10.74	$5.40
Three Months Ended February 29, 2016	$9.95	$5.60
Three Months Ended May 31, 2016	$10.51	$6.06
Three Months Ended August 31, 2016	$8.82	$7.10
Year Ended August 31, 2017		
Three Months Ended November 30, 2016	$8.01	$5.70
Three Months Ended February 28, 2017	$6.97	$5.82
Three Months Ended May 31, 2017	$8.94	$5.85
Three Months Ended August 31, 2017	$9.17	$7.08

The last reported sale price per share of common stock as quoted on Nasdaq was $9.46 on November 28, 2017.

Holders

As of November 28, 2017, there were 14,306,100 shares of our common stock issued and outstanding held of record by approximately 50 registered stockholders. We believe that a significant number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories and are therefore not included in the number of stockholders of record.

Dividend Policy

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

Unregistered Sales of Equity Securities and Use of Proceeds

On August 1, 2017, we issued 2,500 shares of our common stock, valued at $20,000, 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 a Letter Agreements, dated May 3, 2017, between us and Corporate Profile.

On August 8, 2017, we issued 5,631 shares of our common stock to an investor resulting from his exercise of warrants purchased in connection with our 2012 private placement for a total exercise price of $33,786.

These issuances and sales were exempt under Section 4(a)(2) of the Securities Act of 1933, as amended.

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, 2012 through August 31, 2017. 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 Comprehensive Loss 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, 2017, 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 comprehensive loss data for fiscals 2017, 2016 and 2015 and the selected consolidated balance sheet data as of August 31, 2017 and 2016, 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, 2014 and 2013 and the balance sheet data as of August 31, 2015, 2014 and 2013 are derived from audited financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	2017	**2016**	**2015**	**2014**	**2013**
	(in thousands of dollars except share and per share data)				
Statements of Comprehensive Loss:					
Revenues	$2,456	$641	$-	$-	$-
Cost of revenues	187	490	-	-	-
Research and development expenses, net	10,281	7,709	4,781	3,277	2,272
General and administrative expenses	2,759	2,452	2,602	2,629	2,032
Financial income	792	474	168	225	180
Financial expenses	101	93	18	11	313
Loss before taxes on income	10,080	9,629	7,233	5,692	4,437
Taxes on income (Tax benefit)	400	1,335	(1)	4	(205)
Net loss for the year	$10,480	$10,964	$7,232	$5,696	$4,232
Loss per common share – basic and diluted	$0.79	$0.87	$0.67	$0.62	$0.59

Weighted average common shares outstanding	13,296,633	12,624,356	10,820,465	9,244,059	7,209,283

	As of August 31,				
	2017	2016	2015	2014	2013
	in thousands of dollars except share and per share data				
Balance Sheet Data:					
Cash, cash equivalents, short-term deposits, restricted cash and marketable securities	$20,138	$31,032	$17,245	$21,306	$8,491
Other current assets	159	198	127	472	153
Long-term deposits and other assets	16,264	11,070	8,042	24	16
Long-term marketable securities	2,151	530	940	-	-
Total assets	38,712	42,830	26,354	21,802	8,660
Current liabilities	5,165	3,621	1,489	973	498
Long-term liabilities	14,309	13,019	37	36	31
Stockholders’ equity	19,238	26,190	24,828	20,793	8,131

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 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, ORMD-0801, an orally ingestible insulin capsule. We completed a Phase IIb clinical trial in patients with type 2 diabetes under an IND with the FDA, following which we conducted a Phase IIa, dose finding clinical trial to better define the optimal dosing of ORMD-0801 moving forward. We also completed Phase IIa clinical trials in patients with both type 1 and type 2 diabetes. During a call with the FDA regarding ORMD-0801, we were advised that the regulatory pathway for submission of ORMD-0801 would be a BLA, and we plan to initiate a three-month trial in patients with type 2 diabetes to evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint.

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 pre-clinical studies on the new capsules. In September 2013, we submitted a pre-IND package to the FDA for ORMD-0901, our oral exenatide capsule. We completed during the second quarter of calendar year 2016 a Phase Ib trial outside of the United States, which began in August 2015. We also completed a pre-clinical toxicology study in March 2017, anticipate receiving the final report during the fourth quarter of calendar year 2017 and expect to file an IND and move directly into a pharmacokinetics

study followed by a large Phase II trial in the United States under an FDA IND.

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 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 to employees and directors in accordance with the guidance that requires awards classified as equity awards to 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 or Monte Carlo model when appropriate, and is recognized as an expense over the requisite service period.

We elected to recognize compensation cost for awards to employees and directors that have 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 each reporting date, and the gains (losses) are recorded to earnings over the related service period using the straight-line method.

Revenue recognition: Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title and risks and rewards for the products are transferred to the customer and collection is reasonably assured.

Given our continuing involvement through the expected product submission (June 2023), revenue from the License Agreement is recognized over the periods from which the Company is entitled to the respective payments (including milestones), and through the expected product submission date.

Comparison of Fiscal 2017 to Fiscal 2016 and Fiscal 2016 to Fiscal 2015

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2017, 2016 and 2015:

	Year ended August 31,		
Operating Data:	2017	2016	2015
	(dollar amounts in thousands)		

Revenues	$2,456	$641	$-
Cost of revenues	187	490	-
Research and development expenses, net	10,281	7,709	4,781
General and administrative expenses	2,759	2,452	2,602
Financial income, net	691	381	150
Loss before taxes on income	10,080	9,629	7,233
Taxes on income (Tax benefit)	400	1,335	(1)
Net loss for the year	10,480	10,964	7,232
Loss per common share – basic and diluted	$0.79	$0.87	$0.67
Weighted average common shares outstanding	13,296,633	12,624,356	10,820,465

Revenues

Revenues consist of proceeds related to the License Agreement that are recognized over the term of the License Agreement through June 2023.

Revenues for fiscal 2017 increased by 283% to $2,456,000 from $641,000 for fiscal 2016. The increase is attributed to additional milestone payments received in connection with the License Agreement. No revenues were recorded for fiscal 2015.

Cost of revenues

Cost of revenues consists of royalties related to the License Agreement with HTIT that will be paid over the term of the License Agreement in accordance with the revenue recognition and the Law for the Encouragement of Industrial Research, Development and Technological Innovation, 1984, as amended, including any regulations or tracks promulgated thereunder, or the R&D Law.

Cost of revenues for fiscal 2017 decreased by 62% to $187,000 from $490,000 for fiscal 2016. The decrease reflects a decrease in the total proceeds related to the License Agreement received during the year. No cost of revenues was recorded for fiscal 2015.

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, employee benefits, costs of materials, 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 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. 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 and exenatide capsules, payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

From August 2009 to March 2014, Oramed Ltd. was awarded five government grants amounting to a total net amount of NIS 8 million (approximately $2,194,000) from the IIA. We used the funds to support further research and development and clinical studies of our oral insulin capsule and oral GLP-1 analog during the period from February 2009 to December 2014. The five grants are subject to repayment according to the terms determined by the IIA and applicable law. See "—Government grants" below.

Research and development expenses, net, for fiscal 2017 increased by 33% to $10,281,000 from $7,709,000 for fiscal 2016. The increase is mainly attributed to expenses related to process development and production of our capsules and the required ingredients, progress in toxicology studies and increase in stock-based compensation costs, partially offset by a decrease in clinical trials due to completion of our Phase IIb clinical trial. During fiscal 2017, stock-based compensation costs totaled $1,134,000, as compared to $304,000 during fiscal 2016.

Research and development expenses, net, for fiscal 2016 increased by 61% to $7,709,000 from $4,781,000 for fiscal 2015. The increase is attributed to expenses related to clinical trials and mainly our Phase IIb clinical trial. This increase was partially offset by a decrease in stock based compensation costs. During fiscal 2016, stock based compensation costs totaled $304,000, as compared to $616,000 during fiscal 2015.

Government grants

The Government of Israel encourages research and development projects through the IIA, pursuant to 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 IIA.

In fiscals 2017 and 2016, we did not recognize any research and development grants and in fiscal 2015, we recognized a research and development grant in an amount of $49,000. As of August 31, 2017, we incurred a liability to pay royalties to the IIA of $533,000.

Under the terms of the grants we received from the IIA, we are obligated to pay royalties of 3.5% on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licensed ancillary services. Royalties are generally payable up to a maximum amount equaling 100% of the grants received (dollar linked) with the addition of interest at an annual rate based on the LIBOR rate.

The R&D Law generally requires that a product developed under a program be manufactured in Israel. However, when applying for a grant, the applicant may declare that part of the manufacturing will be performed outside of Israel or by non-Israeli residents and if the IIA is convinced that performing some of the manufacturing abroad is essential for the execution of the program, it may still approve the grant. This declaration will be a significant factor in the determination of the IIA as to whether to approve a program and the amount and other terms of the benefits to be granted. If a company wants to increase the volume of manufacturing outside of Israel after the grant has been approved, it may transfer up to 10% of the company’s approved Israeli manufacturing volume, measured on an aggregate basis, outside of Israel after first notifying the IIA thereof (provided that the IIA does not object to such transfer within 30 days). In addition, upon the approval of the IIA, a portion greater than 10% of the manufacturing volume may be performed outside of Israel. In any case of transfer of manufacturing out of Israel, the grant recipient is required to pay royalties at an increased rate, which may be substantial, and the aggregate repayment amount is increased up to 120%, 150% or 300% of the grant, depending on the portion of the total manufacturing volume that is performed outside of Israel. The approval we received from the IIA for the License Agreement was subject to payment of increased royalties and an increased ceiling, all in accordance with the provisions of the R&D Law. The R&D Law further permits the IIA, among other things, to approve the transfer of manufacturing rights outside of Israel in exchange for the import of different manufacturing into Israel as a substitute, in lieu of the increased royalties.

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred or licensed 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 or licensed to any third parties outside Israel absent IIA approval which may be granted in certain circumstances as follows: (a) the grant recipient pays to the IIA a portion of the sale or license price paid in consideration for the purchase or license of such IIA-funded know-how or the price paid in consideration for the sale of the grant recipient itself, as the case may be, in accordance with certain formulas included in the R&D Law; (b) the grant recipient receives know-how from a third party in exchange for its IIA-funded know-how; or (c) such transfer of IIA-funded know-how is made in the context of IIA approved research and development cooperation projects or consortia.

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 to notify the IIA 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 entity becoming an interested party in the recipient, and requires the new non-Israeli interested party to undertake to the IIA to comply with the R&D Law. In addition, the rules of the IIA may require the provision of 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 holds 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 IIA 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. We received no grants from the Bio-Jerusalem fund since the fiscal year ended August 31, 2013. As of August 31, 2017, we incurred a liability to pay royalties to the Bio-Jerusalem fund of $47,000.

General and administrative expenses

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

General and administrative expenses increased by 12.5% from $2,452,000 for fiscal 2016 to $2,759,000 for fiscal 2017. The increase in costs incurred related to general and administrative activities during fiscal 2017, reflects an increase in stock-based compensation costs and salaries and consulting expenses. During fiscal 2017, as part of our general and administrative expenses, we incurred $440,000 related to stock-based compensation costs, as compared to $329,000 during fiscal 2016.

General and administrative expenses decreased by 5.8% from $2,602,000 for fiscal 2015 to $2,452,000 for fiscal 2016. The decrease in costs incurred related to general and administrative activities during fiscal 2016, reflects a decrease in stock-based compensation costs that was partially offset by an increase in salaries and consulting expenses resulting from cash bonuses to employees and consultants paid in 2016. During fiscal 2016, as part of our general and administrative expenses, we incurred $329,000 related to stock-based compensation costs, as compared to $731,000 during fiscal 2015.

Financial income, net

Net financial income was $691,000 for fiscal 2017 as compared to net financial income of $381,000 for fiscal 2016. The increase is mainly due to an increase in income from bank deposits and held to maturity bonds as a result of the proceeds related to the License Agreement and due to an increase in yield rates on investments.

Net financial income was $381,000 for fiscal 2016 as compared to net financial income of $150,000 for fiscal 2015. The increase is mainly due to an increase in income from bank deposits and held to maturity bonds as a result of the increase in cash and investment balances.

Taxes on income / Tax benefit

We had taxes on income of $400,000 for fiscal 2017 as compared to $1,335,000 for fiscal 2016. The decrease is due to a decrease in withholding tax deducted from proceeds received related to the License Agreement, that resulted from a decrease in such proceeds. The Company estimates that withholding tax will not be utilized in the next five years, and therefore was deducted.

We had taxes on income of $1,335,000 for fiscal 2016 as compared to a tax benefit of $1,000 for fiscal 2015. The increase is due to withholding tax of $1,350,000 deducted from revenues received from the License Agreement, since according to the Company’s estimations, the withholding tax is not expected to be utilized in the next five years. This deduction is partially offset by a decrease in the accrual for an uncertain tax position in fiscal 2016.

Other comprehensive income

Unrealized gain on available for sale securities for fiscal 2017 of $295,000 resulted from the increase in fair value of our D.N.A ordinary shares.

Unrealized loss on available for sale securities for fiscal 2016 of $452,000 resulted from the decrease in fair value of our D.N.A ordinary shares.

Liquidity and Capital Resources

From our inception through August 31, 2017, we have incurred losses in an aggregate amount of $56,496,000. 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, raising a total of $56,079,000, net of transaction costs. During that period we also received cash consideration of $4,880,000 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, 2017, we had $3,969,000 of available cash, $29,525,000 of short term and long term deposits and investment and $5,011,000 of marketable securities.

Management continues to evaluate various financing alternatives for funding future research and development activities and general and administrative expenses through fundraising 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 future third party investments. 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.

As of August 31, 2017, our total current assets were $20,297,000 and our total current liabilities were $5,165,000. On August 31, 2017, we had a working capital surplus of $15,132,000 and an accumulated loss of $56,496,000. As of August 31, 2016, our total current assets were $31,230,000 and our total current liabilities were $3,621,000. On August 31, 2016, we had a working capital surplus of $27,609,000 and an accumulated loss of $46,016,000. The decrease in working capital surplus from August 31, 2016 to August 31, 2017 was primarily due to the purchase of long-term bank deposits and due to the cash used in operating activities.

During fiscal 2017, cash and cash equivalents increased to $3,969,000 from $3,907,000 as of August 31, 2016, which is due to the reasons described below.

Operating activities used cash of $5,831,000 in fiscal 2017 compared to $4,655,000 provided in fiscal 2016. Cash used in operating activities in fiscal 2017 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by changes in stock-based compensation expenses and deferred revenues, while cash provided by operating activities in fiscal 2016 primarily consisted of changes in deferred revenues due to the License Agreement partially offset by net loss resulting from research and development and general and administrative expenses.

Investing activities provided cash of $4,302,000 in fiscal 2017, as compared to $16,010,000 used in fiscal 2016. Cash provided by investing activities in fiscal 2017 consisted primarily of the proceeds from sale of short-term deposits and maturity of marketable securities, partially offset by the purchase of bank deposits and marketable securities, while cash used for investing activities in fiscal 2016 consisted primarily of the purchase of short-term and long-term bank deposits as well as the purchase of marketable securities.

Financing activities provided cash of $1,586,000 in fiscal 2017 and $12,043,000 in fiscal 2016. Cash provided by financing activities during both periods consisted of proceeds from our issuance of common stock and proceeds from exercise of warrants and options. Our primary financing activities in fiscal 2017 and fiscal 2016 were as follows:

During fiscal 2017, 248,882 warrants were exercised for cash and resulted in the issuance of 248,882 shares of common stock and 63,900 options were exercised for cash and resulted in the issuance of 63,900 shares of common stock. The cash consideration received for exercise of warrants was $1,242,000 and the cash consideration received for exercise of options was $319,000. During fiscal 2016, 331,054 warrants were exercised for cash and resulted in the issuance of 331,054 shares of common stock and 18,718 options were exercised for cash and resulted in the issuance of 18,718 shares of common stock. The cash consideration received for exercise of warrants was $1,337,000 and the cash consideration received for exercise of options was $112,000. During fiscal 2017 and fiscal 2016, we issued a total of 23,750 shares of common stock to a third party vendor for services rendered. The aggregate value of those shares was approximately $173,000.

In November 2016 and February, May and August 2017, we issued a total of 10,000 shares of our common stock, valued at $72,000, in the aggregate, to a certain service provider as remuneration for services rendered.

On November 30, 2015, we entered into the SPA with HTIT, pursuant to which HTIT agreed to buy and we agreed to sell 1,155,367 shares of our common stock at a price of approximately $10.39 per share, for the aggregate amount of $12 million. The transaction closed on December 28, 2015.

On April 2, 2015, we entered into an At The Market Issuance Sales Agreement and on April 5, 2017 into an amendment to such agreement, or the Sales Agreement, pursuant to which we may, from time to time and at our option, issue and sell shares of our common stock having an aggregate offering price of up to $25,000,000, 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 including a prospectus dated February 2, 2017, as supplemented by a prospectus supplement dated April 5, 2017. 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. As of August 31, 2017 and November 28, 2017, 2,970 and 456,889 shares, respectively, were sold under the Sales Agreement.

Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments at August 31, 2017, 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	$2,166	$2,166	$ -	$ -	$ -
Purchase and technology transfer obligations	4,153	3,442	711	-	-
Operating lease obligations	168	47	81	40	-
Royalty payment obligations	579	137	154	154	134
Accrued severance pay, net	18	-	-	-	18
Total	$7,084	$5,792	$946	$194	$152

Off-Balance Sheet Arrangements

As of August 31, 2017, 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

We invest heavily in research and development, and we expect that in the upcoming years our research and development expenses, net, will continue to be our major operating expense.

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, 2017, we had $4 million in cash and cash equivalents, $29.5 million in short and long term bank deposits and restricted deposits and $5 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 10,208,144 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, 2017, we own net balances in NIS of approximately $1,150,000. 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. dollar, we would experience an exchange rate loss of approximately $105,000.

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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,		
	2017	2016	2015
Average rate for period	3.697	3.864	3.851
Rate at period-end	3.596	3.786	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, 2017. 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, 2017 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, 2017 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, 2017 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.

Name	Age	Position
Nadav Kidron	43	President, Chief Executive Officer and Director
Miriam Kidron	77	Chief Scientific Officer and Director
Hilla Eisenberg	33	Chief Financial Officer, Treasurer and Secretary
Joshua Hexter	47	Chief Operating Officer and VP Business Development
Ronald Law	65	Chief Strategy Officer
Aviad Friedman	46	Director
Xiaopeng Li	33	Director
Kevin Rakin	57	Director
Leonard Sank	52	Director
David Slager	45	Director

Dr. Miriam Kidron is Mr. Nadav Kidron’s mother. There are no other directors or officers of the 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 executive officers who are not also directors, 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 a ***director*** in March 2006. He is also a director of Israel Advanced Technology Industries organization, and until 2016 was a director of Entera Bio Ltd. In 2009, he was a fellow at the Merage Foundation for U.S.-Israel Trade Programs for executives in the life sciences field. From 2003 to 2006, he was the managing director of the Institute of Advanced Jewish Studies at Bar Ilan University. From 2001 to 2003, he was a legal intern at Wine, Mishaiker & Ernstoff Law Offices in Jerusalem, Israel. Mr. Kidron holds an LL.B. and an International MBA from Bar Ilan University, Israel, and is a member of the Israel Bar Association.

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

Dr. Miriam Kidron was appointed ***Chief Scientific Officer*** and a ***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.

Ms. Hilla Eisenberg was appointed ***Chief Financial Officer, Treasurer and Secretary*** effective August 2017. Prior to her appointment, Ms. Eisenberg served as the Company's Finance Manager from March 2016 until July 2017. Before joining the Company, Ms. Eisenberg provided audit and other accounting services at a certified public accounting firm in Israel. Prior to that, Ms. Eisenberg served as an auditor at PricewaterhouseCoopers in Israel, including a short secondment to PricewaterhouseCoopers in New York. Ms. Eisenberg holds a bachelor's degree in accounting and economics from Tel-Aviv University and 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 Tel-Aviv Stock Exchange-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.

Dr. Ronald Law was appointed ***Chief Strategy Officer*** in March 2017. From 2004 to 2016, Dr. Law served in several leadership and strategic roles in Takeda Pharmaceuticals Company Limited and its business divisions, where his latest role was Vice President, New Frontier Science, Chief Medical and Scientific Officer in Takeda Pharmaceuticals International/Takeda Development Center, Americas. Dr. Law also served as the Consulting Head of Business Development in PharmaIN Corporation in 2016 and currently serves as a consultant for other medical companies. Prior to joining Takeda Pharmaceuticals Company Limited, Dr. Law was an Associate Professor of Medicine in the Endocrinology Division, University of California Los Angeles School of Medicine. Dr. Law received a Ph.D. in molecular biology from the University of California Los Angeles and a JD from the Whittier College School of Law. He is a member of the American Diabetes Association and the American Heart Association.

Mr. Aviad Friedman became a ***director*** in August 2016. Mr. Friedman is an international businessman. Since 2007, he has been Chief Executive Officer of Most Properties 1998 Ltd. and the Chairman of the Israel Association of Community Centers since 2013. Mr. Friedman was the first Director General of Israel's Ministry of Diaspora Affairs and served as personal advisor to Prime Minister Ariel Sharon from 1996 to 1999. Mr. Friedman served as Chief Operating Officer of one of Israel's premier newspapers, Ma'ariv from 2003 to 2007, and has more than 15 years of experience serving on boards of public and private companies including Maayan Ventures, Capital Point and Rosetta Green Ltd. Mr. Friedman additionally served as an investor and consultant at Rhythmia Medical Inc. from 2007, and was actively involved in the sale of the company to Boston Scientific in 2012. Mr. Friedman holds a bachelor's degree and master's degree with honors in Public Administration from Bar-Ilan University.

We believe that Mr. Friedman's qualifications to serve on our Board include his experience in serving as a director of public and private companies as well as his knowledge and familiarity with corporate finance.

Ms. Xiaopeng Li became a ***director*** in January 2016. Ms. Li currently serves on the board of directors in the Chairman's Office in Hefei Tianmai Biotechnology Development Co. Ltd, or HTBT, where she has served as the head of financing and investment activities since 2013. Ms. Li also has served as Chief Financial Officer of Hi-Tech Brain Investment Company Limited, an affiliated company of HTBT, since 2015. Prior to that, she was a senior auditor in the Shanghai Branch of Ernst & Young Hua Ming LLP, where she served for four years. Ms. Li holds a bachelor's degree from the College of Economics, Anhui University, a Master of Accounting degree from Monash University, Australia, and a Master of Management degree from Central Queensland University, Australia.

We believe that Ms. Li's qualifications to serve on our Board include her experience and relevant education in the fields of finance, economics, capital markets and management, as well as her familiarity with the Eastern market.

Mr. Kevin Rakin became a ***director*** in August 2016 and Chairman of the Board in July 2017. Mr. Rakin is a co-founder and partner at HighCape Partners, a growth equity life sciences fund where he has served since 2013. From June 2011 to November 2012, Mr. Rakin was the President of Regenerative Medicine at Shire plc, or Shire, a leading specialty biopharmaceutical company. Prior to joining Shire, Mr. Rakin served as the Chairman and Chief Executive Officer of Advanced BioHealing, Inc. from 2007 until its acquisition by Shire for $750 million in June 2011. Mr. Rakin currently serves on the board of Histogenics Corporation. Mr. Rakin holds an MBA from Columbia University and received his graduate and undergraduate degrees in Commerce from the University of Cape Town, South Africa.

We believe that Mr. Rakin’s qualifications to serve on our Board include his extensive experience as an executive in the biotechnology industry, as well as his service in positions in various companies as a chief executive officer, chief financial officer and president and his involvement in public and private financings and mergers and acquisitions in the biotechnology industry.

Mr. Leonard Sank became 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 seventeen years, Mr. Sank has served on the boards of a few 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.

Mr. David Slager became a ***director*** in August 2016. Mr. Slager is the founder and Chairman of Regals Capital, a New York based private investment firm, and the Portfolio Manager of the fund. Prior to founding Regals Capital in 2012, Mr. Slager was the Chairman and the Portfolio Manager of Attara Capital. Prior to Attara Capital in 2009, Mr. Slager was the Vice Chairman of Atticus Capital LP, a global investment management firm he joined in 1998. Mr. Slager’s previous professional experience also includes having been in the Proprietary Equity Arbitrage Group at Goldman, Sachs & Co. in London and a financial analyst at Goldman, Sachs & Co. in New York and London. Mr. Slager holds a master’s degree in Legal Philosophy (Jurisprudence) from Oxford University.

We believe that Mr. Slager’s qualifications to serve on our Board include his years of experience in the capital markets as well as his management skills, his knowledge and familiarity with corporate finance and his familiarity with the Company given his history as a leading shareholder in the Company.

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 Leonard Sank, David Slager, Kevin Rakin, Aviad Friedman and Xiaopeng Li are independent as defined under the rules promulgated by the Nasdaq. Other than Mr. Slager, Ms. Li and Mr. Friedman, none of the independent directors has any relationship with us besides serving on our Board. In connection with a private placement of our common stock in 2013, we have entered into a letter agreement with Mr. Slager pursuant to which we agreed not to issue stock options with an exercise price below $6.00 per share and not to grant more than 125,000 stock options in any calendar year without the consent of certain stockholders. Ms. Li was appointed to serve on our Board pursuant to the terms of the SPA dated November 30, 2015, but does not otherwise have any relationship with us. We had entered into a consulting agreement with Shikma A.M.R. Ltd., or Shikma, of which Mr. Friedman is the sole owner, pursuant to which Shikma was granted an option exercisable into shares of common stock of the Company as compensation for certain consulting services provided by Shikma to the Company. This consulting agreement was terminated in August 2016. The Board considered these relationships and determined that they would not interfere with Mr. Slager’s, Ms. Li’s or Mr. Friedman’s exercise of independent judgment in carrying out the responsibilities of a director.

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 fiscal 2017, our Board held 13 meetings and took actions by written consent on two occasions. Ms. Xiaopeng Li 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 Aviad Friedman, David Slager and Kevin Rakin. Our Board has determined that Aviad Friedman 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. The primary responsibilities of our Audit Committee include:

Overseeing the accounting and financial reporting processes of the Company and the audits of the financial statements of the Company;

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, Kevin Rakin and Aviad Friedman. 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. The primary responsibilities of our Compensation Committee include:

Reviewing, negotiating and approving, or recommending for approval by our Board 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

Making recommendations to our Board with respect to director compensation.

Nominating Committee

The members of our Nominating Committee are Leonard Sank and Aviad Friedman. The Board has determined that all of the members of the Nominating Committee are "independent" as defined by the rules of the SEC and Nasdaq rules and regulations. The Nominating Committee operates under a written charter that is posted on the "Investors" section of our website, www.oramed.com. The primary responsibilities of our Nominating Committee include:

Overseeing the composition and size of the Board, developing qualification criteria for Board members and actively seeking, interviewing and screening individuals qualified to become Board members for recommendation to the Board;

Recommending the composition of the Board for each annual meeting of shareholders; and

Reviewing periodically with the Chairman of the Board and the CEO the succession plans relating to positions held by directors, and making recommendations to the Board with respect to the selection and development of individuals to occupy those positions.

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 2017, we believe that during fiscal 2017, our executive officers, directors and all persons who own more than ten percent of a registered class of our equity securities complied with all Section 16(a) filing requirements, except: (a) Mr. Josh Hexter, our Chief Operating Officer, failed to timely file a Form 4 reporting his November 1, 2016 acquisition of 70,000 shares of our common stock. Mr. Hexter filed a Form 4 reporting this transaction on November 22, 2016, (b) Mr. Kevin Rakin, one of our directors, failed to timely file a Form 4 reporting his February 9, 2017 acquisition of options to purchase 5,697 shares of our common stock. Mr. Rakin filed a Form 4 reporting this transaction on February 16, 2017, (c) Mr. David Slager, one of our directors, failed to timely file a Form 4 reporting his February 9, 2017 acquisition of options to purchase 5,697 shares of our common stock. Mr. Slager filed a Form 4 reporting this transaction on February 16, 2017, (d) Mr. Aviad Friedman, one of our directors, failed to timely file a Form 4 reporting his February 9, 2017 acquisition of options to purchase 4,084 shares of our common stock. Mr. Friedman filed a Form 4 reporting this transaction on March 2, 2017 and (e) Ms. Xiaopeng Li, one of our directors, failed to timely file a Form 4 reporting her February 9, 2017 acquisition of options to purchase 12,253 shares of our common stock. Ms. Li filed a Form 4 reporting this transaction on March 2, 2017.

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. We intend to satisfy the disclosure requirement regarding any amendment to, or a waiver from, a provision of the Code of Ethics that applies to our Chief Executive Officer, or CEO, Chief Financial Officer, or CFO, or controller, or persons performing similar functions and that relates to the Code of Ethics by posting such information on our website, 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 2017 are those three 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 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;

ensure fairness among the executive management team via recognizing the contributions of each executive 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 Second 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 2017, 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 each 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 the scope of the NEOs' responsibilities and 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 2017, for example, the Compensation Committee received consulting services from Aon Consulting, Inc., or Aon, through its Radford subdivision (part of Aon Hewitt), or Radford, with regard to management and Board compensation. The Compensation Committee engaged the consultant solely to collect and analyze data regarding management and Board compensation at other companies comparable to the Company. The consultant collected data regarding U.S. and Israeli practices, reviewed executive compensation against a market composite of peer proxy data and Radford survey data, determined the U.S. to Israeli discount and applied the discount to position specific U.S. data to arrive at Israeli market data.

The Israeli peer group consisted of the following companies: Alcobra Ltd., BioLine Rx Ltd., Can-Fite BioPharma Ltd., Foamix Pharmaceuticals Ltd., Galmed Pharmaceuticals Ltd., Intec Pharma Ltd., Kamada Ltd., MediWound Ltd., Pluristem Therapeutics Inc., Protalix BioTherapeutics Inc., RedHill Biopharma Ltd. and Vascular Biogenics Ltd. The U.S. peer group consisted of the following companies: Actinium Pharmaceuticals Inc., Athersys Inc., Capricor Therapeutics Inc., Cara Therapeutics Inc., Catabasis Pharmaceuticals Inc., Cymabay Therapeutics Inc., Eiger BioPharmaceuticals Inc., Eleven Biotherapeutics Inc., Endocyte Inc., Genocea Biosciences Inc., GlycoMimetics Inc., GTx Inc., Kura Oncology Inc., Ocera Therapeutics Inc., Stemline Therapeutics Inc., Tracon Pharmaceuticals Inc. and vTv Therapeutics Inc.

The Compensation Committee did not receive any executive compensation consulting services in fiscal 2016 and 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. Generally, we believe that executives' base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities, experience and performance at comparable companies. 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 2017, our Compensation Committee increased the base salaries of our NEOs by ten to thirty three percent based on the report from Aon, as it determined salaries were not in line with market, and in fiscal 2016, our Compensation Committee increased the base salaries of our NEOs by ten to twenty percent, as it deemed this to be a reasonable rate in the biotechnology industry.

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 Compensation 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 the recommendation of management. For any given year, the compensation objectives vary, but relate generally to strategic factors such as developments in our clinical path, the execution of a license agreement for the commercialization of product candidates, the establishment of key strategic collaborations, the build-up of our pipeline and financial factors such as capital raising. Bonuses are awarded generally based on corporate performance, with adjustments made within a range for individual performance, at the discretion of the Compensation Committee. The Compensation Committee determines, on a discretionary basis, the size of the entire bonus pool and the amount of the actual award to each NEO. 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. Equity incentive awards are generally made at the commencement of employment and following a significant change in job responsibilities, or to meet other special retention or performance objectives. 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. 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 was based on monthly installments for periods of no longer than three years through the beginning of fiscal 2017; however, following consultation with Aon during fiscal 2017, the vesting schedule for NEOs was moved to annual installments for new grants. 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 and in November 2016. 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. In June 2017, following consultation with Aon, the Compensation Committee chose to grant options instead of RSUs and in addition granted to the CEO options with a market condition of our share price reaching a certain target, in order to further strengthen the alignment of our NEOs' interests with those of our stockholders, as part of our efforts to increase the Company's market value. The Compensation Committee believes that time-based vesting encourages recipients to build stockholder value over a long period of time.

Benefits and Perquisites

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

During fiscal 2017, the Compensation Committee approved the payment to Mr. Kidron of approximately $7,600 per month for a period beginning in August 2017, during which Mr. Kidron is in the United States. This payment replaced per diem payments for such business travel. The Compensation Committee determined that this amount reflects the difference in the cost of living between Israel and the United States.

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

Say-on-Pay Vote

Our stockholders approved, on an advisory basis, our executive compensation program at our 2016 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 2017.

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:

Aviad Friedman

Kevin Rakin

Leonard Sank

SUMMARY COMPENSATION TABLE

The following table sets forth the compensation earned by our NEOs for fiscals 2017, 2016 and 2015.

Name and Principal Position	Year (1)	Salary ($) (2)	Bonus ($) (2)(3)	Stock Awards ($) (4)	**Option Awards ($) (5)**	All Other Compensation ($) (2)(6)	Total ($)
Nadav Kidron	2017	399,804	123,000	-	585,150	45,579	1,153,533
President and CEO and	2016	273,086	195,729	-	-	17,366	486,181
director (7)	2015	254,318	63,045	431,645	-	16,217	765,225
Miriam Kidron	2017	254,765	50,000	581,932	359,224	12,775	1,258,696
Chief Scientific Officer	2016	203,378	136,583	-	-	13,191	353,152
and director (8)	2015	188,466	50,436	431,645	-	13,592	684,139
Joshua Hexter	2017	148,499	33,000	463,400	-	46,408	691,307
COO and VP Business	2016	132,306	86,974	-	-	42,014	261,294
Development	2015	124,108	32,363	-	-	39,547	196,018

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

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

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

(4) 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 8 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our NEOs will not realize the value of these awards in cash unless and until the awards vest and the underlying shares are issued and subsequently sold.

(5) 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 8 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our NEOs 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 KNRY, Ltd., an Israeli entity owned by Mr. Kidron, or KNRY. See “—Employment and Consulting Agreements” below.

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

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	2017	28,098	-	-	17,481	45,579
	2016	17,366	-	-	-	17,366
	2015	16,217	-	-	-	16,217
Miriam Kidron	2017	12,775	-	-	-	12,775
	2016	13,191	-	-	-	13,191
	2015	13,592	-	-	-	13,592
Joshua Hexter	2017	12,910	22,513	10,985	-	46,408
	2016	12,660	19,585	9,769	-	42,014
	2015	12,451	18,030	9,066	-	39,547

* 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 in fiscal 2017, for the period during which Mr. Kidron was in the United States.

Employment and Consulting Agreements

On July 1, 2008, Oramed Ltd. entered into a consulting agreement with KNRY, whereby Mr. Nadav Kidron, through KNRY, provides services as President and Chief Executive Officer of both the Company and Oramed Ltd., or the Nadav Kidron Consulting Agreement. Additionally, on July 1, 2008, Oramed Ltd. entered into a consulting agreement with KNRY whereby Dr. Miriam Kidron, through KNRY, provides services as Chief Scientific 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, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements and that Nadav Kidron receives a monthly consulting fee of NIS 127,570 and Miriam Kidron receives a monthly consulting fee of NIS 80,454. Pursuant to the Consulting Agreements, KNRY, Nadav Kidron and Miriam Kidron each agree that during the term of the Consulting Agreements and for a 12 month period thereafter, none of them will compete with Oramed Ltd. nor solicit employees of Oramed Ltd.

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 44,891. In addition, Mr. Hexter is provided with a cellular phone and a company car pursuant to the terms of his agreement.

We, through Oramed Ltd., have entered into a consulting agreement with Ronald Law as of March 1, 2017, pursuant to which Dr. Law was appointed as Chief Strategy Officer of the Company and Oramed Ltd., effective March 20, 2017. In accordance with the consulting agreement, Dr. Law's current monthly consulting fee is $10,000. In addition, Dr. Law is entitled to a reimbursement of his communication expenses.

We, through Oramed Ltd., have entered into an employment agreement with Hilla Eisenberg as of July 20, 2017, pursuant to which Ms. Eisenberg was appointed as Chief Financial Officer, Treasurer and Secretary of the Company and Oramed Ltd., effective August 1, 2017. In accordance with the employment agreement, Ms. Eisenberg's current gross monthly salary is NIS 34,000. In addition, Ms. Eisenberg is provided with a cellular phone and travel reimbursement pursuant to the terms of her 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.

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GRANTS OF PLAN-BASED AWARDS

The following table shows grants of plan-based equity awards made to our NEOs during fiscal 2017:

Name	Grant Date	**Options Awards: Number of Securities Underlying Options**	**All Other Stock Awards: Number of Securities Underlying RSUs**	**Grant Date Fair Value of Stock Awards**
		(#)	**(#)**	**($)**
Nadav Kidron[(1)]	6/30/17	147,000	-	585,150
Miriam Kidron[(2)]	6/30/17	69,999	-	359,224
Miriam Kidron[(3)]	6/30/17	-	75,000	581,932
Joshua Hexter[(4)]	11/1/2017	-	70,000	463,400

(1) These options were granted under our 2008 Plan and vest in 3 equal installments of 49,000 on each of December 31, 2017, December 31, 2018 and December 31, 2019, subject to the Company share price reaching the target of $8.00, $9.50 and $12.50 per share, respectively.

(2) These options were granted under our 2008 Plan and vest in 3 equal installments of 23,333 on each of December 31, 2017, December 31, 2018 and December 31, 2019.

(3) These RSUs were granted under our 2008 Plan, vested immediately and are issuable upon request.

(4) These RSUs were granted under our 2008 Plan and vest as follows: 9,000 shares vested immediately; 1,500 shares will vest in 18 consecutive installments on the last day of each month commencing November 30, 2016; and 17,000 will vest in each of April 30, 2017 and April 30, 2018.

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, 2017.

	Option Awards				Stock Awards	
Name	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 (1)	-	6.48	5/7/18		
	72,000 (2)	-	5.88	4/20/20		
	72,000 (3)	-	4.08	8/8/22		
	47,134 (4)	-	12.45	4/9/24		
	-	147,000 (5)	7.77	6/30/27		
					- (8)(9)	-
Miriam Kidron	72,000 (1)	-	6.48	5/7/18		
	72,000 (2)	-	5.88	4/20/20		
	72,000 (3)	-	4.08	8/8/22		
	47,134 (4)	-	12.45	4/9/24		
		69,999 (6)	7.77	6/30/27		
					- (10)	-
Joshua Hexter	100,800 (7)	-	7.88	3/14/23		
					29,000 (11)	250,850

(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 30, 2017, 147,000 options were granted to Nadav Kidron under the 2008 Plan at an exercise price of $7.77 per share; Such options vest in 3 equal installments of 49,000 on each of December 31, 2017, December 31, 2018 and December 31, 2019, subject to the Company share price reaching the target of $8.0, $9.5 and $12.5 per share, respectively. The options have an expiration date of June 30, 2027.

(6) On June 30, 2017, 147,000 options were granted to Miriam Kidron under the 2008 Plan at an exercise price of $7.77 per share; the options vest in 3 equal installments of 23,333 on each of December 31, 2017, December 31, 2018 and December 31, 2019. The options have an expiration date of June 30, 2027.

(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 vested in 35 consecutive equal installments during a 3-year period commencing on May 31, 2013, and two installments of 1,400 each, that were vested 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 Nadav 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 Nadav Kidron. The RSUs vested 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 June 30, 2016, 75,000 RSUs, representing a right to receive shares of the Company's common stock, were granted to Miriam Kidron. The RSUs vested immediately and according to a further resolution of the compensation committee dated September 26, 2017, have an exercise price of $0.012 per share of common stock and expire on June 30, 2017.

(11) On November 1, 2016, 70,000 RSUs, representing a right to receive shares of the Company's common stock, were granted to Joshua Hexter. The RSUs vest in 19 installments, consisting of one installment of 9,000 shares on November 1, 2016, 18 equal monthly installments of 1,500 shares each, commencing November 30, 2016, and 17,000 shares on each of April 30, 2017 and 2018.

OPTIONS EXERCISED AND STOCK VESTED

The following table sets forth information with respect to the NEOs concerning the vesting of RSUs during fiscal 2017. No options were exercised by the NEOs in fiscal 2017.

	Stock Awards	
Name	Number of Shares	Value Realized on

	Acquired on Vesting (#)	Vesting ($)
Joshua Hexter	41,000	298,430
Nadav Kidron	13,308 (1)	87,034 (2)
Miriam Kidron	88,308 (1)	668,966 (2)

(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 2017, Mr. Aviad Friedman, Mr. Kevin Rakin and Mr. Leonard Sank 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 2017:

Name of Director	Fees Earned or Paid in Cash ($)	Stock Awards (2) ($)	**Option Awards (3) ($)**	All Other Compensation ($)	Total ($)
Nadav Kidron [(1)]	-	-	-	-	-
Miriam Kidron [(1)]	-	-	-	-	-
Leonard Sank	20,000	-	86,076	-	106,076
Xiaopeng Li	20,000	-	153,909	-	173,909
Aviad Friedman	20,000	-	108,685	-	128,685
Kevin Rakin	20,000	-	316,406	-	336,406
David Slager	20,000	-	108,460	-	128,460

(1) Please refer to the Summary Compensation Table for executive compensation with respect to the named individual.

(2) As of August 31, 2017, our non-employee directors then in office held options and unvested RSUs to purchase shares of our common stock as follows:

Name of Director	Aggregate Number

	of Shares Underlying Stock Awards
Leonard Sank	74,867
David Slager	22,470
Aviad Friedman	20,857
Kevin Rakin	62,470
Xiaopeng Li	29,026

(3) 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 8 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our directors will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.

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, 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 2017.

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

Stock Option Plans

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, RSUs, 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, 2,400,000 shares were reserved for the grant of awards, which may be issued at the discretion of our Board from time to time. The 2008 Plan permits 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, 2017, options with respect to 1,870,848 shares have been granted, of which 12,297 have been forfeited, 119,224 have been exercised and 475,292 have expired. As of August 31, 2017, 525,824 RSUs have been granted, of which 294,300 have vested and the shares of common stock underlying RSUs were issued, 164,636 have vested and the shares of common stock underlying those RSUs will be issued upon request of the grantee and 33,248 have been forfeited.

The following table sets forth additional information with respect to our equity compensation plans (consisting solely of the 2008 Plan) as of August 31, 2017:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weight-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))

			(c)
Equity compensation plans approved by security holders	1,001,041	$ 5.47	524,165
Equity compensation plans not approved by security holders	-	-	-
Total	1,001,041	$ 5.47	524,165

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 28, 2017 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 NEOs listed above under “Summary Compensation Table”; and (4) all of our directors and executive officers as a group. On such date, we had 14,306,100 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 28, 2017. 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 152 West 57th Street, 9th Floor New York, NY 10019	1,316,328 (1)	8.6	%
HTIT No. 199 Fanhua Road Economic and Technological Development Zone Heifei, Anhui Province, P.R. China, Zip Code: 230601	1,155,367 (2)	7.5	%
Nadav Kidron #+	2,631,999 (3)	17.3	%
Miriam Kidron #+	361,467 (4)	2.4	%
Joshua Hexter +	147,800 (5)	1	%
Aviad Friedman #	29,366 (6)	*	
Xiaopeng Li #	224,194 (7)	*	
Kevin Rakin #	36,349 (8)	*	
Leonard Sank #	574,861 (9)	3.8	%
David Slager #	1,327,616 (10)	8.7	%
All current executive officers and directors, as a group (ten persons)	5,151,949 (11)	33.6	%

* Less than 1%
# Director
+NEO

(1) Regals Capital Management LP, or Regals Management, is the investment manager of Regals Fund LP, the owner of record of these shares of common stock. Mr. David Slager is the managing member of the general partner of Regals Management. 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 Management.

(2) Based solely on a Schedule 13D filed by HTIT on January 6, 2016. On November 30, 2015, we entered into a securities purchase agreement with HTIT pursuant to which, among other things, Nadav Kidron will serve as proxy and attorney in fact of HTIT, with full power of substitution, to cast on behalf of HTIT all votes that HTIT is entitled to cast with respect to 1,155,367 shares of common stock, or the Purchased Shares, at any and all meetings of our shareholders, to consent or dissent to any action taken without a meeting and to vote all the Purchased Shares held by HTIT in any manner Mr. Kidron deems appropriate except for matters related to our activities in the People's Republic of China, on which Mr. Kidron will consult with HTIT before taking any action as proxy.

(3) Includes 312,134 shares of common stock issuable upon the exercise of outstanding stock options and 89,636 shares of Common Stock underlying vested Restricted Stock Units that are issuable upon request. Also includes 1,155,367 shares of common stock held by HTIT, as further described in footnote (2) above, and 206,350 shares of

common stock held by Xiaopeng Li, as further discussed in footnote (7) below.

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(4) Includes 286,467 shares of common stock issuable upon the exercise of outstanding stock options and 75,000 shares of Common Stock underlying vested RSUs that are issuable upon request.

(5) Includes 100,800 shares of common stock issuable upon the exercise of outstanding stock options and 3,000 shares of common stock issuable upon the settlement of RSUs.

(6) Includes 9,675 shares of common stock issuable upon the exercise of outstanding stock options and 9,691 shares of common stock owned by Shikma, of which Mr. Friedman is the sole owner and chief executive officer. All investment decisions are made by Mr. Friedman, 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. Friedman through Shikma.

(7) Includes 17,844 shares of common stock issuable upon the exercise of outstanding stock options. The voting of these shares is subject to a revocable proxy granted to Nadav Kidron. On November 21, 2016, following her purchase of such shares, Ms. Li appointed Nadav Kidron as proxy and attorney in fact of Ms. Li, with full power of substitution, to cast on behalf of Ms. Li all votes that Ms. Li is entitled to cast with respect to the shares purchased at any and all meeting of the shareholders of the Company, to consent or dissent to any action taken without a meeting and to vote all the shares held by Ms. Li in any manner Mr. Kidron deems appropriate except for matters related to the Company's activities in the Territory and when obvious that specific votes violate Ms. Li's rights and interests, on which Mr. Kidron and Ms. Li will consult with each other in advance of the vote, and subsequently Mr. Kidron will vote according to Ms. Li's instructions. The proxy will also apply to shares of the Company purchased by Ms. Li through open market transactions. Ms. Li may revoke the proxy in writing at any time.

(8) Includes 21,288 shares of common stock issuable upon the exercise of outstanding stock options.

(9) Includes: (a) 294,162 shares of common stock held by Mr. Sank; (b) 78,125 shares of common stock held by Mr. Sank's wife; (c) 63,685 shares of common stock issuable to Mr. Sank upon the exercise of outstanding stock options; and (d) 138,889 shares of common stock owned by a company wholly owned by a trust of which Mr. Sank is a trustee. Mr. Sank disclaims beneficial ownership of the securities referenced in (b) and (d) above.

(10) See footnote (1) above. Also Includes 11,288 shares of common stock issuable upon the exercise of outstanding stock options.

(11) Includes 846,828 shares of common stock issuable upon the exercise of options beneficially owned by the referenced persons, 164,636 shares of Common Stock underlying vested RSUs that are issuable upon request and 3,000 shares of common stock issuable upon the settlement of RSUs.

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

During fiscal 2017 and 2016, except for compensation arrangements described elsewhere herein, 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 for the last two completed fiscal years, 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.

On November 30, 2015, we, our Israeli subsidiary and HTIT entered into a Technology License Agreement, which was further amended, according to which we granted HTIT an exclusive commercialization license in the Territory related to our oral insulin capsule, ORMD-0801. Pursuant to this license agreement, HTIT will conduct certain pre-commercialization and regulatory activities with respect to our technology related to the ORMD-0801 capsule, and will pay certain royalties and an aggregate of approximately $37.5 million. On November 30, 2015, we also entered into a securities purchase agreement with HTIT, pursuant to which, among other things, Mr. Kidron will serve as proxy and attorney in fact of HTIT, with full power of substitution, to cast on behalf of HTIT all votes that HTIT is entitled to cast with respect to the Purchased Shares at any and all meetings of our shareholders to consent or dissent to any action taken without a meeting and to vote all the Purchased Shares held by HTIT in any manner Mr. Kidron deems appropriate except for matters related to our activities in the People's Republic of China, on which Mr. Kidron will consult with HTIT before taking any action as proxy.

The Board has determined that Leonard Sank, David Slager, Kevin Rakin, Aviad Friedman and Xiaopeng Li 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 fiscals 2017 and 2016:

	2017	2016
Audit Fees[1]	$109,000	$116,000
Audit-Related Fees	-	-
Tax Fees[2]	4,000	32,000
All Other Fees	-	-
Total Fees	$113,000	$148,000

(1) Amount represents fees paid for professional services for the audit of our consolidated annual financial statements, review of our interim condensed consolidated financial statements included in quarterly reports and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings or engagements.

(2) Represents fees paid for tax consulting services.

SEC rules require that before the independent registered public accounting firm 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 registered public accounting firm. 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 consolidated financial statements are filed as part of this Annual Report on Form 10-K:

_____

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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 as of August 31, 2017 and 2016, 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, 2017. 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 Oramed Pharmaceuticals Inc. and its subsidiary as of August 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended August 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Tel Aviv, Israel
November 29, 2017

/s/ Kesselman & Kesselman
Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers
International Limited

P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

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ORAMED PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS

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

	August 31, 2017	2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$3,969	$3,907
Short-term deposits (note 2)	13,293	24,254
Marketable securities (note 3)	2,860	2,855
Restricted cash	16	16
Prepaid expenses and other current assets	159	198
Total current assets	20,297	31,230
LONG-TERM ASSETS:		
Long-term deposits and investment (note 4)	16,232	11,043
Marketable securities (note 3c)	2,151	530
Amounts funded in respect of employee rights upon retirement	14	11
Property and equipment, net	18	16
Total long-term assets	18,415	11,600
Total assets	$38,712	$42,830
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$2,716	$1,411
Deferred revenues	2,449	2,162
Related parties (note 11c)	-	48
Total current liabilities	5,165	3,621
LONG-TERM LIABILITIES:		
Deferred revenues	13,837	12,604
Employee rights upon retirement	18	14
Provision for uncertain tax position (note 10e)	11	11
Other liabilities	443	390
Total long-term liabilities	14,309	13,019
COMMITMENTS (note 6)		
STOCKHOLDERS’ EQUITY:		
Common stock, $ 0.012 par value (30,000,000 authorized shares as of August 31, 2017 and 2016; 13,668,530 and 13,183,425 shares issued and outstanding as of August 31, 2017 and 2016, respectively)	163	157
Additional paid-in capital	75,170	71,943
Accumulated other comprehensive income	401	106

Accumulated loss	(56,496)	(46,016)
Total stockholders' equity	19,238	26,190
Total liabilities and stockholders' equity	$38,712	$42,830

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

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended August 31,		
	2017	2016	2015
REVENUES	$2,456	$641	$-
COST OF REVENUES (notes 6j, 6k)	187	490	-
RESEARCH AND DEVELOPMENT EXPENSES, NET	10,281	7,709	4,781
GENERAL AND ADMINISTRATIVE EXPENSES	2,759	2,452	2,602
OPERATING LOSS	10,771	10,010	7,383
FINANCIAL INCOME (note 9a)	792	474	168
FINANCIAL EXPENSES (note 9b)	101	93	18
LOSS BEFORE TAXES ON INCOME	10,080	9,629	7,233
TAXES ON INCOME (TAX BENEFIT) (note 10c)	400	1,335	(1)
NET LOSS FOR THE YEAR	$10,480	$10,964	$7,232
UNREALIZED LOSS (GAIN) ON AVAILABLE FOR SALE SECURITIES	(295)	452	(106)
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	(295)	452	(106)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	$10,185	$11,416	$7,126
LOSS PER SHARE OF COMMON STOCK:			
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$0.79	$0.87	$0.67
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	13,309,372	12,624,356	10,820,465

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 data)

	Common Shares	Stock $	Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
	In thousands					
BALANCE AS OF AUGUST 31, 2014	10,103	$ 121	$ 48,040	$ 452	$ (27,820)	$ 20,793
SHARES, OPTIONS AND WARRANTS ISSUED FOR CASH, NET	1,411	17	9,696	-	-	9,713
SHARES ISSUED FOR SERVICES	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
ISSUANCE OF COMMON STOCK, NET	1,155	14	10,580	-	-	10,594
SHARES ISSUED FOR SERVICES	14	*	101	-	-	101
EXERCISE OF WARRANTS AND OPTIONS	350	4	1,445	-	-	1,449
STOCK-BASED COMPENSATION	101	1	633	-	-	634
OTHER COMPREHENSIVE LOSS	-	-	-	(452)	-	(452)
NET LOSS	-	-	-	-	(10,964)	(10,964)
BALANCE AS OF AUGUST 31, 2016	13,183	157	71,943	106	(46,016)	26,190
SHARES ISSUED FOR SERVICES	10	*	72	-	-	72
ISSUANCE OF COMMON STOCK, NET	3	*	25	-	-	25
EXERCISE OF WARRANTS AND OPTIONS	313	4	1,557	-	-	1,561
STOCK-BASED COMPENSATION	159	2	1,573	-	-	1,575
OTHER COMPREHENSIVE INCOME	-	-	-	295	-	295
NET LOSS	-	-	-	-	(10,480)	(10,480)
BALANCE AS OF AUGUST 31, 2017	13,668	$ 163	$ 75,170	$ 401	$ (56,496)	$ 19,238

* Represents an amount of less than $1.

The accompanying notes are an integral part of the financial statements

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. Dollars in thousands

	Year ended August 31,		
	2017	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(10,480)	$(10,964)	$(7,232)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	5	4	4
Exchange differences and interest on deposits and held to maturity bonds	124	(163)	(20)
Stock-based compensation	1,575	634	1,347
Shares issued for services	72	101	93
Changes in operating assets and liabilities:			
Prepaid expenses, other current assets and related parties	39	(71)	345
Accounts payable, accrued expenses and related parties	1,257	470	16
Deferred revenue	1,520	14,266	500
Liability for employee rights upon retirement	4	3	2
Provision for uncertain tax position	-	(15)	(1)
Other liabilities	53	390	-
Total net cash provided by (used in) operating activities	(5,831)	4,655	(4,946)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(7)	(9)	(1)
Purchase of short-term deposits	(3,557)	(7,010)	(3,673)
Purchase of long-term deposits	(17,230)	(22,274)	(17,452)
Purchase of held to maturity securities	(3,869)	(1,775)	(1,885)
Proceeds from sale of short-term deposits	26,551	14,160	19,701
Proceeds from maturity of held to maturity securities	2,417	900	-
Funds in respect of employee rights upon retirement	(3)	(2)	(2)
Total net cash provided by (used in) investing activities	4,302	(16,010)	(3,312)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock, options and warrants - net of issuance costs	25	10,594	9,713
Proceeds from exercise of warrants and options	1,561	1,449	8
Total net cash provided by financing activities	1,586	12,043	9,721
EFFECT OF EXCHANGE RATE CHANGES ON CASH	5	6	(12)
INCREASE IN CASH AND CASH EQUIVALENTS	62	694	1,451
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,907	3,213	1,762
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$3,969	$3,907	$3,213

SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -			
Interest received	$833	$256	$115

The accompanying notes are an integral part of the financial statements

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. (collectively with its subsidiary, the “Company”, unless the context indicates otherwise) 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. (the “Subsidiary”), which is engaged in research and development.

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

On November 30, 2015, the Company entered into a Technology License Agreement with Hefei Tianhui Incubation of Technologies Co. Ltd. (“HTIT”) and on December 21, 2015, the parties entered into an Amended and Restated Technology License Agreement, that was further amended by the parties on June 3, 2016 and July 24, 2016 (the “License Agreement”). According to the License Agreement, the Company granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong (the “Territory”), related to the Company’s oral insulin capsule, ORMD-0801 (the "Product"). Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to the Subsidiary’s technology and ORMD-0801 capsule, and will pay to the Subsidiary (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory (“Royalties”), and (ii) an aggregate of $37,500, of which $3,000 was payable immediately, $8,000 will be paid subject to the Company entering into certain agreements with certain third parties, and $26,500 will be paid upon achievement of certain milestones and conditions. In the event that the Company does not meet certain conditions, the Royalties rate may be reduced to a minimum of

8%. Following the final expiration of the Company's patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

The royalty payment obligation shall apply during the period of time beginning upon the first commercial sale of the Product in the Territory, and will end upon the later of (i) the expiration of the last-to-expire licensed patents in the Territory; and (ii) 15 years after the first commercial sale of the Product in the Territory (the "Royalty Term").

The License Agreement shall remain in effect until the expiration of the Royalty Term. The License Agreement contains customary termination provisions.

Among others, the Company's involvement through the product submission date will include consultancy for the pre-commercialization activities in the Territory, as well as advisory services to HTIT on an ongoing basis.

ORAMED PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The initial payment of $3,000 was received in January 2016. Following the achievement of certain milestones, the second and third payments of $6,500 and $4,000, respectively, were received in July 2016 and the fourth milestone payment of $4,000 was received in October 2016.

In addition, on November 30, 2015, the Company entered into a Stock Purchase Agreement with HTIT (the “SPA”). According to the SPA, the Company issued 1,155,367 shares of common stock to HTIT for $12,000. The transaction closed on December 28, 2015.

The License Agreement and the SPA were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $49,500 between the License Agreement and the SPA according to their fair value, as follows: $10,617 was allocated to the issuance of common stock (less issuance expenses of $23), based on the quoted price of the Company's shares on the closing date of the SPA on December 28, 2015, and $38,883 was allocated to the License Agreement. Given the Company's continuing involvement through the expected product submission (June 2023), amounts received relating to the License Agreement are recognized over the period from which the Company is entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees are earned.

In July 2015, according to the letter of intent signed between the parties or their affiliates, HTIT's affiliate paid the Subsidiary a non-refundable amount of $500 as a no-shop fee. The no-shop fee was deferred and the related revenue is recognized over the estimated term of the License Agreement.

Amounts that were allocated to the License Agreement as of August 31, 2017 aggregated $19,383, all of which were received through the balance sheet date. Through August 31, 2017, the Company recognized revenue in the amount of $3,097, and deferred the remaining amount of $16,286.

The following table summarizes the activities for deferred revenues for the years ended August 31, 2017 and 2016:

	August 31,	
	2017	2016
Deferred revenue at the beginning of period	$14,766	$-
Amounts received	4,000	15,383
Amounts the Company was entitled to	(24)	24
Revenue recognized	(2,456)	(641)
Deferred revenue at the end of period	16,286	14,766
Less – current deferred revenue portion	(2,449)	(2,162)
Non-current deferred revenue portion	$13,837	$12,604

2) Development and liquidity risks

The Company 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 significant 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, obtaining foreign regulatory approvals to sell its products internationally, or entering into licensing agreements with third parties. 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.

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. Basis of presentation

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 and to the expected product submission date for revenue recognition purposes.

d. Functional currency

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

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions - exchange rates at transaction dates or average rates and (2) for

other items (derived from non-monetary balance sheet items such as depreciation) - historical exchange rates. The resulting transaction gains or losses are carried to financial income or expenses, as appropriate.

e. Principles of consolidation

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

f. 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.

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):

g. Fair value measurement:

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. 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, 2017, 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, 2017, the carrying amount of cash and cash equivalents, short-term deposits, other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term maturities of these instruments.

As of August 31, 2017, the carrying amount of long-term deposits approximates their fair values due to the stated interest rates which approximate market rates.

The fair value of held to maturity bonds as presented in note 3 was based on a level 1 measurement.

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

There were no Level 3 items for the years ended August 31, 2017, 2016 and 2015.

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. 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 accumulated other comprehensive income (loss) 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. Cost of the securities sold and amount reclassified out of accumulated other comprehensive income into financial income are determined by specific identification.

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.

i. 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.

As of the date of issuing these financial statements, all amounts due from HTIT have been received, as described in note 1 above.

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

j. 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. See note 10.

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.

k. Revenue recognition

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title and risks and rewards for the products are transferred to the customer and collection is reasonably assured.

Given the Company's continuing involvement through the expected product submission (June 2023), revenue from the License Agreement is recognized over the periods from which the Company is entitled to the respective payments, and through the expected product submission date.

l. Cost of revenues

Cost of revenues consists of royalties related to the License Agreement with HTIT. The royalties are recognized when proceeds related to the License Agreement are received.

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):

m. 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 IIA 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 6(j) and 6(k).

n. Stock-based compensation

Equity awards granted to employees are accounted for using the grant date fair value method. The grant date fair value is determined as follows: for stock options and restricted stock units ("RSUs") with an exercise price using the Black Scholes pricing model, for stock options with market conditions using a Monte Carlo model and for RSUs with service conditions based on the grant date share price. The fair value of share based payment awards is recognized as an expense over the requisite service period. The expected term is the length of time until the expected dates of exercising the award and is estimated using the simplified method due to insufficient specific historical information of

employees' exercise behavior, unless the award includes a market condition, in which case the contractual term is used. The volatility is based on a historical volatility, by statistical analysis of the weekly share price for past periods. The Company elected to recognize compensation cost for awards granted to employees that have a graded vesting schedule using the accelerated method based on the multiple-option award approach. For awards with only market conditions, compensation expense is not reversed if the market conditions are not satisfied.

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 to consultants and other non-employees is measured on a final basis at the end of the related service period using the Black Scholes pricing model and is recognized over the related service period using the straight-line method.

The Company elects to account for forfeitures as they occur.

o. 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 for each period. Outstanding stock options, warrants and RSUs 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 RSUs excluded from the calculation of diluted net loss was 1,827,719, 2,676,573 and 2,249,164 for the years ended August 31, 2017, 2016 and 2015, respectively.

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):

p. Newly issued and recently adopted Accounting Pronouncements

1) In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update ("ASU") No. 2014-09 (Topic 606) “Revenue from Contracts with Customers” that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle of this ASU is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity’s contracts with customers. The guidance is effective in annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company will implement the guidance for annual period ending on August 31, 2019 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

2) In January 2016, the FASB issued guidance on recognition and measurement of financial assets and financial liabilities (ASU No. 2016-01) that will supersede most current guidance. Changes to the U.S. GAAP model primarily affect the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities, is largely unchanged. The guidance is effective in annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company will implement the guidance for annual period ending on August 31, 2019 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

3) In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)" (“ASU 2016-02”), which supersedes the existing guidance for lease accounting, "Leases (Topic 840)". ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in ASU 2016-02 are

effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

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):

4) In June 2016, the FASB issued ASU 2016-13, “Financial Instruments-Credit Losses (Topic 326)” ("ASU 2016-13"). ASU 2016-13 requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis. The income statement reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

5) In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flow - Classification of Certain Cash Receipts and Cash Payments (Topic 230)” ("ASU 2016-15"), which addresses a few specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact of this new pronouncement on its consolidated financial statements.

6) In May 2017, the FASB issued ASU 2017-09, “Compensation - Stock Compensation (Topic 718) - Scope of Modification Accounting” ("ASU 2017-09"), which gives direction on which changes to the terms or conditions of share-based payment awards require an entity to apply modification accounting in ASC Topic 718. In general, entities will apply the modification accounting guidance if the value, vesting conditions or classification of the award changes. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company does not expect the implementation of this new pronouncement to have a material impact on its consolidated financial statements.

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, 2017		2016	
	Annual interest rate	Amount	Annual interest rate	Amount
Dollar deposits	1.84-5.95%	$13,293	0.85-2%	$24,254

NOTE 3 - MARKETABLE SECURITIES:

a. Composition:

The Company'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,	
	2017	2016
Short-term:		
D.N.A (see b below)	$996	$701
Held to maturity bonds (see c below)	1,864	2,154
	$2,860	$2,855
Long-term:		
Held to maturity bonds (see c below)	$2,151	$530

b. D.N.A

The D.N.A ordinary shares are traded on the Tel Aviv Stock Exchange. 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, 2017, 2016 and 2015, the Company did not sell any of the D.N.A ordinary shares. As of August 31, 2017, the Company owns approximately 7.9% of D.N.A's outstanding ordinary shares.

The cost of the securities as of August 31, 2017 and 2016 and 2015 is $595.

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):

c. Held to maturity bonds

The amortized cost and estimated fair value of held-to-maturity securities at August 31, 2017, are as follows:

	August 31, 2017		
	Amortized cost	Gross unrealized losses	**Estimated fair value**
Short-term:			
Commercial bonds	$1,823	$ (1)	$ 1,822
Accrued interest	41	-	41
Long-term	2,151	-	2,151
	$4,015	$ (1)	$ 4,014

As of August 31, 2017, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $2,151 and the yield to maturity rates vary between 1.30% to 1.87%.

The amortized cost and estimated fair value of held-to-maturity securities at August 31, 2016, are as follows:

	August 31, 2016		
	Amortized cost	Gross unrealized gains	**Estimated fair value**
Short-term:			
Commercial bonds	$2,118	$ -	$ 2,118
Accrued interest	36	-	36

Long-term	530	1	531
	$2,684	$ 1	$ 2,685

As of August 31, 2016, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $530, and the yield to maturity rates vary between 0.96% to 1.8%.

NOTE 4 - LONG-TERM DEPOSITS:

Composition:

	August 31,	
	2017	2016
Bank deposits (see (1) below)	$16,230	$11,038
Lease car deposits	1	4
Investment	1	1
	$16,232	$11,043

(1) Represents U.S. dollar bank deposits which carry fixed annual interest rates between 2.06% to 2.56%, with maturities of more than one year from balance sheet date. The latest maturity date is during the year ending August 31, 2019.

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

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

NOTE 5 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

Composition:

	August 31,	
	2017	2016
Accounts payable	$571	$365
Payroll and related accruals	97	66
Institutions	228	-
Accrued liabilities	1,593	980
Other	227	-
	$2,716	$1,411

NOTE 6 - COMMITMENTS:

a. In March 2011, the Subsidiary sold shares of its investee company, Entera Bio Ltd. (“Entera”) to D.N.A, retaining a 3% interest as of March 2011, which is accounted for as a cost method investment (amounting to $1). In consideration for the shares sold to D.N.A, the Company received, among other payments, 4,202,334 ordinary shares of D.N.A (see also note 3).

As part of this agreement, the Subsidiary entered into a patent transfer agreement, according to which the Subsidiary assigned to Entera all of its right, title and interest in and to the patent application that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera’s net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. As of August 31, 2017, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary.

In addition, as part of a consulting agreement with a third party, dated February 15, 2011, the Subsidiary is obliged to pay this third party royalties of 8% of the net royalties received in respect of the patent that was sold to Entera in March 2011.

b. On January 3, 2017, the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement is for a period of 60 months commencing October 1, 2016.

The annual lease payment will be New Israeli Shekel ("NIS") 119,000 ($33) from October 2016 through September 2018 and NIS 132,000 ($37) from October 2018 through September 2021, and will be linked to the increase in the Israeli consumer price index ("CPI") (as of August 31, 2017, the future lease payments until the expiration of the lease agreement will be $143, based on the exchange rate as of August 31, 2017).

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

The lease expenses for the years ended August 31, 2017, 2016 and 2015 were $32, $23 and $23, respectively.

c. On March 3, 2016, the Subsidiary entered into an agreement with a vendor for process development and production of its capsules and on November 24, 2016, April 3, 2017 and July 10, 2017 into amendments to such agreement in an amount of up to Swiss Franc ("CHF") 1,000,000 ($1,027), CHF 605,000 ($615) of which was recognized through August 31, 2017.

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

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

NOTE 6 - COMMITMENTS (continued):

d. On May 11, 2016, the Subsidiary entered into a Master Service Agreement with a vendor to retain its services for a pre-clinical toxicology trial for an oral GLP-1 analog capsule for type 2 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total amount of $1,283 during the term of the engagement and based on achievement of certain milestones, of which $1,163 was recognized through August 31, 2017.

e. On June 13, 2016, the Subsidiary entered into a four-year service agreement with a third party and on December 19, 2016, this agreement and all of the third party rights and obligations thereunder were assigned to another third party. This agreement is required by the License Agreement as described in note 1 and will support the Company's research and development. The Subsidiary is obligated to pay the third party a total amount of up to €2,360,000 ($2,726), of which €800,000 ($878) is a non-refundable fee to be paid within 12 months from the effective date, all of which was recognized in research and development through August 31, 2017. The remaining fee will be paid over the term of the engagement and will be based on achievement of certain milestones.

f. 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, $175 of which was recognized through August 31, 2017, 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, 2017.

On July 24, 2016, the Subsidiary entered into a General Technical Agreement with the same vendor, for the scale-up process development and production of the same capsule ingredients in the amount of $4,300 that will be paid over the term of the engagement and based on the achievement of certain development milestones, $3,327 of which were recognized in research and development through August 31, 2017. This agreement is part of the requirements of the License Agreement as described in note 1.

g. On February 21, 2017, the Subsidiary entered into an agreement with a vendor to retain its services for a pre-clinical toxicology trial for an oral insulin capsule for type 2 and type 1 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total of up to $952 during the term of the engagement and based on achievement of certain milestones, of which $594 was recognized through August 31, 2017.

h.

On May 3, 2017, the Company entered into a consulting agreement with a third party advisor for a period of one year, pursuant to which such advisor will provide investor relations services and will be entitled to receive a monthly cash fee and 10,000 shares of the Company's common stock that will be issued in four equal quarterly installments commencing August 1, 2017. As of August 31, 2017, the Company had issued to such advisor 2,500 shares. The fair value of the shares at the grant date was $20.

i. On June 5, 2017, the Subsidiary entered into a clinical research agreement with a vendor, for the conduct of its clamp clinical trial for an oral insulin capsule for type 1 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total amount of $958 during the term of the engagement and based on achievement of certain milestones, $160 of which was recognized through August 31, 2017.

j. Grants from the Bio-Jerusalem Fund ("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 (Israeli CPI linked) at the total amount of $65. The Company received no grants from Bio-Jerusalem since fiscal year 2013.

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

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

NOTE 6 - COMMITMENTS (continued):

Royalty expenses for the year ended August 31, 2017 of $47 are included in cost of revenues. As of August 31, 2017, the Subsidiary had realized revenues from its related project in the amount of $2,653.

k. Grants from the IIA

Under the terms of the Company's funding from the IIA, royalties of 3.5% are payable on sales of products developed from a project so funded, up to a maximum amount equaling 100%-150% of the grants received (dollar linked) with the addition of interest at an annual rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured.

The total amount that was received through August 31, 2017 was $2,194.

Royalty expenses for the year ended August 31, 2017 of $140 are included in cost of revenues and will be paid over the term of the License Agreement in accordance with the revenue recognized from the related project. As of August 31, 2017, the Subsidiary had realized revenues from its project in the amount of $2,653.

l. For the years ended August 31, 2017 and 2016, no grants from the IIA were recognized. For the year ended August 31, 2015, the research and development expenses are presented net of IIA grants in the total amount of $49.

NOTE 7 - STOCKHOLDERS' EQUITY:

The following are the significant capital stock transactions that took place during the years ended August 31, 2017, 2016 and 2015:

a. On November 3, 2014, the Company entered into a Stock Purchase Agreement with Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd., pursuant to which the Company issued to such 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.

b. On April 2, 2015, the Company entered into an At The Market Issuance Sales Agreement and on April 5, 2017 into an amendment to such agreement (as amended, the "Sales Agreement") with FBR Capital Markets & Co. ("FBR") pursuant to which the Company may, from time to time and at its option, issue and sell shares of its common stock having an aggregate offering price of up to $25,000 through FBR 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 including a prospectus dated February 2, 2017, as supplemented by a prospectus supplement dated April 5, 2017. The Company will pay FBR a commission of 3.0% of the gross proceeds of the sale of any shares sold through FBR. As of August 31, 2017, 2,970 shares were sold under the Sales Agreement and an additional 453,919 shares were subsequently sold during September and October 2017.

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

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

NOTE 7 - STOCKHOLDERS' EQUITY (continued):

c. 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 the 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.

d. On December 28, 2015, the Company completed a private placement of 1,155,367 shares of the Company's common stock to HTIT. See also note 1.

e. As of August 31, 2017, the Company had outstanding warrants exercisable for 166,642 shares of common stock at exercise prices ranging from $3.7656 to $10.00 per share and expiring at various dates between November 2, 2017 and June 10, 2018.

The following table presents the warrant activity for the years ended August 31, 2017, 2016 and 2015:

	2017		2016		2015	
	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price		Weighted-Average Exercise Price

					Warrants	
Warrants outstanding as of September 1	615,338	$ 5.92	981,940	$ 5.29	953,369	$ 5.15
Issued	-	$ -	-	$ -	28,571	$ 10.00
Exercised	(248,882)	$ 4.99	(331,054)	$ 4.04	-	$ -
Expired	(199,814)	$ 6.82	(35,548)	$ 6.00	-	$ -
Warrants outstanding as of August 31	166,642	$ 6.46	615,338	$ 5.92	981,940	$ 5.29
Warrants exercisable as of August 31	166,642	$ 6.46	615,338	$ 5.92	981,496	$ 5.29

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

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

NOTE 8 - STOCK-BASED COMPENSATION:

As of August 31, 2017, the Company has one stock option plan, the Second Amended and Restated 2008 Stock Incentive Plan, under which, the Company had reserved a pool of 2,400,000 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 following are the significant stock options transactions with employees, board members and non-employees made during the years ended August 31, 2017, 2016 and 2015:

a. On November 13, 2014, the Company granted a total of 19,576 RSUs representing a right to receive shares of the Company's common stock to the Company's Chief Executive Officer (the "CEO"), and the Company's Chief Scientific Officer (the "CSO"), both related parties. The RSUs vested in two equal installments, each of 9,788 shares, on November 30, 2014 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 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, 2017, 9,788 RSUs were vested and outstanding and the remaining 9,788 were exercised.

b. 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.

c. 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 CSO, 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, 2017, 79,848 RSUs were vested and outstanding and the remaining 79,848 were exercised.

d. 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 vested in two equal installments of 44,356 shares on each of 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.

On August 24, 2016 the Company determined, with respect to three of these members of the Company's Board of Directors, to accelerate the second installment of their RSUs, such that 22,179 RSUs were vested on August 29, 2016 and their remaining 11,088 RSUs were forfeited.

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

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

NOTE 8 - STOCK-BASED COMPENSATION (continued):

e. 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.

f. On November 19, 2015, options to purchase an aggregate of 22,000 of the Company's shares of common stock were granted to two consultants at an exercise price of $7.36 per share (equivalent to the traded market price on the date of grant) and expiration date of November 19, 2025. 10,000 of the options vested in one installment on December 1, 2015, and the remaining 12,000 options vest in twelve equal quarterly installments, commencing January 1, 2016.

On August 3, 2016 the consulting agreement with one of these consultants, to whom 12,000 options were granted, was terminated. As a result, only 3,000 options were vested, and the remaining 9,000 unvested options were forfeited. In addition, the expiration date of the 3,000 vested options was updated to November 3, 2016 (3 months following the termination date of the agreement).

g. On November 1, 2016, the Company granted a total of 70,000 RSUs representing a right to receive 70,000 shares of the Company's common stock to an employee of the Subsidiary. The RSUs vest in 19 installments, consisting of one installment of 9,000 shares on November 1, 2016, 18 equal monthly installments of 1,500 shares each, commencing November 30, 2016 and 17,000 shares on each of April 30, 2017 and 2018. The total fair value of these RSUs on the date of grant was $463, using the quoted closing market share price of $6.62 on the Nasdaq Capital Market on the date of grant.

h. On February 9, 2017, options to purchase an aggregate of 27,731 shares of the Company were granted to four members of the Company's Board of Directors as follows: (a) 16,337 options at an exercise price of $1 per share (lower than the traded market price of $6.23 on the date of grant). The fair value of these options on the date of grant was $90, using the Black Scholes option-pricing model and was based on the following assumptions: Stock price of $6.23; dividend yield of 0% for all years; expected volatility of 77.29%; risk-free interest rates of 1.88%; and expected term of 5 years; (b) 11,394 options at an exercise price of $6.23 per share (equivalent to the traded market price on the date of grant). The fair value of these options on the date of grant was $45, using the Black Scholes option-pricing model and was based on the following assumptions: Stock price of $6.23; dividend yield of

0% for all years; expected volatility of 77.29%; risk-free interest rates of 1.88%; and expected term of 5 years. All the options vested immediately and expire on February 9, 2027.

i. On March 20, 2017, options to purchase an aggregate of 37,152 of the Company's shares of common stock were granted to a consultant at an exercise price of $6.00 per share (higher than the traded market price of $5.96 on the date of grant). The options expire on March 20, 2027. The options vest in 24 consecutive equal installments of 1,548 shares of common stock each, commencing March 31, 2017. The fair value of these options on the date of grant was $177. The fair value of these options as of August 31, 2017 was $261, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 73.62%; risk-free interest rates of 2.12%; and expected term of 9.6 years.

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

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

NOTE 8 - STOCK-BASED COMPENSATION (continued):

j. On June 30, 2017, the Company granted options to purchase shares of the Company and RSUs as follows:

(1) To the CEO, options to purchase an aggregate of 147,000 shares of the Company, at an exercise price of $7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments of 49,000, on each of December 31, 2017, 2018 and 2019, subject to the Company share price reaching the target of $8.00 per share, $9.50 per share and $12.50 per share, respectively. These options expire on June 30, 2027. The fair value of the options at the date of grant was $585 using the Monte Carlo model, which utilizes multiple input variables to estimate the probability that market conditions will be achieved, and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 75.00%; risk-free interest rates of 2.34%; and expected term of 10 years.

(2) To the CSO: (a) 75,000 RSUs representing a right to receive shares of the Company's common stock which vested immediately, have an exercise price of $0.012 per share of common stock and expire on June 30, 2027. The total fair value of these RSUs on the date of grant was $582, using the quoted closing market share price of $7.77 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, 2017, none of these RSUs were exercised. (b) options to purchase an aggregate of 69,999 shares of the Company, at an exercise price of $7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments of 23,333, on each of December 31, 2017, 2018 and 2019. These options expire on June 30, 2027. The fair value of all these options on the date of grant was $359, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $7.77; dividend yield of 0% for all years; expected volatility of 74.77%; risk-free interest rates of 1.89%; and expected term of 6 years.

(3) To four members of the Company's Board of Directors, options to purchase an aggregate of 67,092 shares of the Company (16,773 options to each director), at an exercise price of $7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments, on each of December 31, 2017, 2018 and 2019. These options expire on June 30, 2027. The fair value of all these options on the date of grant was $344, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $7.77; dividend yield of 0% for all years; expected volatility of 74.77%; risk-free interest rates of 1.89%; and expected term of 6 years.

(4)

To a member of the Company's Board of Directors, options to purchase an aggregate of 56,773 shares of the Company at an exercise price of $7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in four annual installments, 15,591 of which shall vest on each of December 31, 2017, 2018 and 2019, and 10,000 of which shall vest on December 31, 2020. These options expire on June 30, 2027. The fair value of all these options on the date of grant was $294, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $7.77; dividend yield of 0% for all years; expected volatility of 74.15%; risk-free interest rates of 2.14%; and expected term of 6.18 years.

(5) To employees of the Subsidiary, options to purchase an aggregate of 38,901 shares of the Company, at an exercise price of $7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments, on each of December 31, 2017, 2018 and 2019. These options expire on June 30, 2027. The fair value of all these options on the date of grant was $200, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $7.77; dividend yield of 0% for all years; expected volatility of 74.77%; risk-free interest rates of 1.89%; and expected term of 6 years.

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

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

NOTE 8 - STOCK-BASED COMPENSATION (continued):

k. On July 19, 2017, options to purchase an aggregate of 20,001 shares of the Company were granted to an employee of the Subsidiary. The fair value of all these options on the date of grant was $113, using the Black Scholes option-pricing model and was based on the following assumptions: Stock price of $8.57; dividend yield of 0% for all years; expected volatility of 74.65%; risk-free interest rates of 1.83%; and expected term of 6 years.

l. 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 or Monte Carlo model with the following assumptions:

	For options granted in the year ended	
	August 31,	
	2017	2016
Expected option life (years)	5.00-10.00	10.00
Expected stock price volatility (%)	74.15-77.29	80.46
Risk free interest rate (%)	1.83-2.47	2.24
Expected dividend yield (%)	0.0	0.0

No options were granted in fiscal year 2015.

A summary of the status of the stock options granted to employees and directors as of August 31, 2017, 2016 and 2015, and changes during the years ended on those dates, is presented below:

	Year ended August 31, 2017		2016		2015	
	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	904,234	6.75	904,234	6.75	908,901	6.75
Changes during the year:						
Granted	427,497	7.51	-	-	-	-
Forfeited	-	-	-	-	(3,297)	6.00
Expired	(59,282)	10.27				
Exercised	63,900	5	-	-	(1,370)	6.00
Options outstanding at end of year	1,208,549	6.94	904,234	6.75	904,234	6.75
Options exercisable at end of year	808,783		904,234		883,234	
Weighted average fair value of options granted during the year	$4.75		$-		$-	

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

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

NOTE 8 - STOCK-BASED COMPENSATION (continued):

Costs incurred in respect of stock options granted to employees and directors, for the years ended August 31, 2017, 2016 and 2015 were $451, $14 and $278, respectively.

The total intrinsic value of employees' options exercised during the year ended August 31, 2017 was $85. None of the options were exercised by employees during the year ended August 31, 2016. 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, 2017:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted average exercise price	Aggregate intrinsic value
$		Years	$	$
1.00 to 6.00	442,671	3.92	4.74	1,730,803
6.48 to 7.88	635,959	7.09	7.47	751,863
8.57 to 12.45	129,919	7.12	11.85	1,600
	1,208,549	5.93	6.94	2,484,266

808,783 of options granted to employees and directors that were outstanding as of August 31, 2017, were also exercisable as of August 31, 2017.

As of August 31, 2017, there were $1,579 of unrecognized compensation costs related to non-vested options previously granted to employees and directors. The unrecognized compensation costs are expected to be recognized over a weighted average period of 2.5 years.

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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 - STOCK-BASED COMPENSATION (continued):

A summary of the status of the stock options granted to non-employees outstanding as of August 31, 2017, 2016 and 2015, and changes during the years ended on this date, is presented below:

	Year ended August 31,					
	2017		2016		2015	
	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	29,668	8.35	40,286	7.29	62,221	7.13
Changes during the year:						
Granted	37,152	6.00	22,000	7.36		
Exercised	-	-	(18,718)	6.00	-	-
Forfeited	-	-	(9,000)	7.36		
Expired	(11,334)	8.65	(4,900)	6.00	(21,935)	6.82
Options outstanding at end of year	55,486	6.71	29,668	8.35	40,286	7.29
Options exercisable at end of year	27,622		29,668		36,119	

The Company recorded stock-based compensation of $59, $102 and $3 during the years ended August 31, 2017, 2016 and 2015, respectively, related to non-employees' awards.

The total intrinsic value of non-employees' options exercised during the year ended August 31, 2016, was $37. None of the options were exercised by non-employees during the years ended August 31, 2017 and 2015.

The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2017:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate intrinsic value
$		Years	$	$
6.00	37,152	9.56	6.00	98,453
7.36	10,000	8.22	7.36	12,900
9.12	8,334	1.36	9.12	-
	55,486	8.09	6.71	111,353

27,622 options granted to non-employees and directors that were outstanding as of August 31, 2017, were also exercisable as of August 31, 2017.

As of August 31, 2017, there were $196 of unrecognized compensation costs related to non-vested non-employee options. The unrecognized compensation costs are expected to be recognized over a weighted average period of 1.5 years.

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

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

NOTE 8 - STOCK-BASED COMPENSATION (continued):

m. Restricted stock units

The following table summarizes the activities for unvested RSUs granted to employees and directors for the years ended August 31, 2017, 2016 and 2015:

	Year ended August 31,		
	2017	2016	2015
	Number of RSUs		
Unvested at the beginning of period	201,669	313,216	-
Granted	178,120	1,000	346,704
Vested and issued	(159,353)	(101,459)	(33,488)
Forfeited	(22,160)	(11,088)	-
Outstanding at the end of the period	198,276	201, 669	313,216
Vested and unissued (see notes 8a, 8c and 8j(2))	164,636	152,656	72,808

The Company recorded compensation costs related to RSUs of $1,064, $518 and $1,066, during the years ended August 31, 2017, 2016 and 2015, respectively, related to RSU awards.

As of August 31, 2017, there were $88 unrecognized compensation costs related to RSUs, to be recorded over the next 12 months.

NOTE 9 - FINANCIAL INCOME AND EXPENSES

a. Financial income

	Year ended August 31,		
	2017	2016	2015
Income from interest on deposits	$657	$378	$160
Exchange rate differences	7	-	-
Income from interest on corporate bonds	128	96	8
	$792	$474	$168

b. **Financial expenses**

	Year ended August 31,		
	2017	2016	2015
Exchange rate differences	$17	$ 17	$ 3
Bank commissions	6	11	9
Other	78	65	6
	$101	$ 93	$ 18

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

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

NOTE 10 - 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, 2017, the Company has an accumulated tax loss carryforward of approximately $10,060 (as of August 31, 2016, approximately $8,945). 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 2037.

b. Corporate taxation in Israel:

The Subsidiary is taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2017, 2016 and 2015 are 24%, 25% and 26.5%, respectively.

As of August 31, 2017, the Subsidiary has an accumulated tax loss carryforward of approximately $26,881 (as of August 31, 2016, approximately $18,580). Under the Israeli tax laws, carryforward tax losses have no expiration date.

Deferred income taxes:

	August 31,		
	2017	2016	2015
In respect of:			
Net operating loss carryforward	$9,253	$9,219	$5,750
Research and development expenses	2,046	-	906
Less - valuation allowance	(11,299)	(9,219)	(6,656)
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,		
	2017	2016	2015
Loss before taxes on income:			
U.S.	$1,115	$959	$1,226
Outside U.S.	8,965	8,670	6,007
	$10,080	$9,629	$7,233
Taxes on income (tax benefit):			
Current:			
U.S.	-	(15)	-
Outside U.S.	400	1,350	(1)
	$400	$1,335	$(1)

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

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

NOTE 10 - TAXES ON INCOME (continued):

Taxes on income of $400 is derived from withholding tax deducted from HTIT milestones payments, which were received during the year ended August 31, 2017, according to the License Agreement. As of August 31, 2017, the Company did not expect to reach taxable income in the 5 years following the balance sheet date, and therefore recognized this amount as taxes on income.

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,		
	2017	2016	2015
Loss before income taxes as reported in the consolidated statement of comprehensive loss	$(10,080)	$(9,629)	$(7,233)
Statutory tax benefit	(3,528)	(3,370)	(2,531)
Increase (decrease) in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax	2,080	2,563	1,599
Disallowable deductions	327	167	422
Influence of different tax rates and changes in tax rates applicable to the Subsidiary	1,121	640	510
Withholding tax, see note 10c above	400	1,350	-
Uncertain tax position	-	(15)	(1)
Taxes on income (tax benefit) for the reported year	$400	$1,335	$(1)

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.

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

	Year ended August 31,		
	2017	2016	2015
Balance at Beginning of Year	$11	$26	27
Decrease in uncertain tax positions for the current year	-	(15)	(1)
Balance at End of Year	$11	$11	$ 26

The CoThe 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 2013 through 2017.

The Subsidiary is subject to Israeli income tax examinations for the tax years of 2013 through 2017.

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

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

NOTE 10 - 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, 2017	$9,219	$ 2,080	$11,299
Year ended August 31, 2016	$6,656	2,563	9,219
Year ended August 31, 2015	$5,578	$ 1,078	$6,656

NOTE 11 - RELATED PARTIES - TRANSACTIONS:

a. During each of the fiscal years of 2017, 2016 and 2015 the Company paid to directors $100, $92 and $47, respectively, as directors' fees.

b. On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. (“KNRY”), an Israeli company owned by the CEO, whereby the CEO and the CSO, through KNRY, provide services to the Company (the “Consulting Agreements”). The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements and that the monthly consulting fee paid to the CEO and the CSO is NIS 127,570 ($35) and NIS 80,454 ($22), respectively.

c. Balances with related parties:

	August 31,

	2017	2016
Accounts payable and accrued expenses - KNRY	$-	$ 48

d. Expenses to related parties:

	Year ended August 31,		
	2017	2016	2015
KNRY	$868	$839	$586

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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, further amended July 25, 2014 and corrected September 5, 2017.
3.2	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	Form of Common Stock Purchase Warrant between Oramed Pharmaceuticals Inc. and the purchasers party thereto (incorporated by reference from our quarterly report on Form 10-Q filed July 1, 2015).
10.1+	Consulting Agreement by and between Oramed Ltd. and KNRY, 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, File No. 000-50298).
10.2+	Amendment, dated July 13, 2013, to Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008 for the services of 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 KNRY, 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 KNRY, 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 25, 2015).
10.5+	Amendment, dated June 27, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, 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 25, 2016).
10.6+	Amendment, dated November 28, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron (incorporated by reference from our quarterly report on Form 10-Q filed January 11, 2017).
10.7+	Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our current report on Form 8-K filed July 2, 2008, File No. 000-50298).

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10.8+	Amendment, dated July 13, 2013, to Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008 for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).
10.9+	Amendment, dated July 21, 2015, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2015).
10.10+	Amendment, dated June 27, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.11+*	Amendment, dated June 30, 2017, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron.
10.12+	Oramed Pharmaceuticals Inc. Second Amended and Restated 2008 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed August 4, 2016).
10.13+	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).
10.14+*	Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement between the Company and the CSO or CEO.
10.15+	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, File No. 000-50298).
10.16+	Amended and Restated Employment Agreement, dated as of July 20, 2017, by and between Oramed Ltd. and Hilla Eisenberg (incorporated by reference from our current report on Form 8-K filed July 21, 2017).
10.17+	Consulting Agreement, dated as of March 1, 2017, by and between Oramed Ltd. and Ronald Law (incorporated by reference from our current report on Form 8-K filed March 21, 2017).
10.18+	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).
10.19+	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, File No. 000-50298).
10.20	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, File No. 000-50298).
10.21	Manufacturing and Clinical 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, File No. 000-50298).
10.22	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 25, 2011, File No. 333-173058).
10.23+*	Representative Form of Indemnification Agreements between Oramed Pharmaceuticals Inc. and each of our directors and officers.

10.24+	Letter Agreement, dated as of February 5, 2013, between Oramed Pharmaceuticals Inc. and Regals Capital LP (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.25+	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).
10.26+	Amendment to Employment Agreement, dated July 21, 2015, between Oramed Ltd. and Joshua Hexter (incorporated by reference from our annual report on Form 10-K filed November 25, 2015).
10.27+	Amendment to Employment Agreement, dated June 27, 2016, between Oramed Ltd. and Joshua Hexter (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.28	Securities Purchase Agreement, dated November 3, 2014, between Oramed Pharmaceuticals Inc. and Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd. (incorporated by reference from our current report on Form 8-K filed November 4, 2014).
10.29	Securities Purchase Agreement, dated November 30, 2015, between Oramed Pharmaceuticals, Inc. and Hefei Tianhui Incubator of Technologies Co., Ltd. (incorporated by reference from Schedule 13D/A filed by Nadav Kidron on December 29, 2015).
10.30	Amended and Restated Technology License Agreement, dated December 21, 2015, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been granted for portions of this document. Incorporated by reference from our quarterly report on Form 10-Q filed January 13, 2016).
10.31	Amendment to the Amended and Restated Technology License Agreement, dated June 3, 2016, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.32	Amendment to the Amended and Restated Technology License Agreement, dated July 24, 2016, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.33	Service Agreement, dated as of June 3, 2016, between Oramed Ltd. and XERTECS GmbH (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.34	General Technical Agreement between Oramed Ltd. and Premas Biotech Pvt. Ltd., dated July 24, 2016 (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).

10.35	At the Market Issuance Sales Agreement, dated April 2, 2015, by and between Oramed Pharmaceuticals Inc. and MLV & CO. LLC. (incorporated by referenced from our quarterly report on Form 10-Q filed April 3, 2015).
10.36	Amendment No. 1 to At-The-Market Issuance Sales Agreement, dated April 5, 2017, among FBR Capital Markets & Co., MLV & Co. LLC and Oramed Pharmaceuticals Inc. (incorporated by reference from our quarterly report on Form 10-Q filed April 5, 2017).

21.1	Subsidiary (incorporated by reference from our annual report on Form 10-K filed November 27, 2013).
23.1*	Consent of Kesselman & Kesselman, Independent Registered Public Accounting Firm.
31.1*	Certification Statement of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification Statement of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certification Statement of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification Statement of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.1*	The following financial statements from the Company's annual report on Form 10-K for the year ended August 31, 2017, 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.

ITEM 16. FORM 10-K SUMMARY.

None.

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 29, 2017

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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 29, 2017
/s/ HILLA EISENBERG Hilla Eisenberg, Chief Financial Officer (principal financial and accounting officer)	November 29, 2017
Aviad Friedman, Director	
/s/ MIRIAM KIDRON Miriam Kidron, Director	November 29, 2017
Xiaopeng Li, Director	
/s/ KEVIN RAKIN Kevin Rakin, Director	November 29, 2017
/s/ LEONARD SANK Leonard Sank, Director	November 29, 2017
/s/ DAVID SLAGER David Slager, Director	November 29, 2017