ORAMED PHARMACEUTICALS INC.
Form 10-K
November 28, 2018

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, 2018

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.)
142 W. 57th Street	
New York, New York	**10019**

(Address of Principal Executive Offices) (Zip Code)

844-967-2633
(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 every Interactive Date File required to be submitted 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 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
	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 $74,402,451, based on a price of $7.25, 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: 17,378,359 shares of common stock issued and outstanding as of November 26, 2018.

ORAMED PHARMACEUTICALS INC.

FORM 10-K
(FOR THE FISCAL YEAR ENDED AUGUST 31, 2018)

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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, 2018, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.604 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 dose-ranging 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 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 known by us at the time of such statements. 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. 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.

In April 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801. This placebo controlled, randomized, 90 day treatment clinical trial is being conducted on approximately 285 type 2 diabetic patients in multiple centers throughout the United States pursuant to an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA. The primary endpoints of the trial are to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90 day treatment period. Secondary endpoints of the trial include measurements of fasting plasma glucose, or FPG, post-prandial glucose, or PPG levels, during a mixed-meal tolerance test, or MMTT, and weight.

We had a call with the FDA in August 2017 regarding ORMD-0801 after the completion of a Phase IIb clinical trial on 180 diabetic patients, which indicated a statistically significant blood glucose lowering effect of ORMD-0801 versus placebo across several endpoints. During the call, the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a Biologics License Application, or BLA. If approved, the BLA pathway would grant us 12 years of marketing exclusivity for ORMD-0801, from the approval date, and an additional six months of exclusivity may be granted to us 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.

In June 2018, we initiated a glucose clamp study which will quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. This exploratory, randomized, double-blind glucose clamp study is evaluating exposure-response profiles of type 1 diabetic patients treated with ORMD-0801. Six patients with HbA1c levels of 10% or below, aged 18-50, are enrolled in the study.

In June 2018, we also initiated a food effect trial in the United States for ORMD-0801. This single-blind, five period, randomized, placebo-controlled crossover trial is evaluating the pharmacokinetics and pharmacodynamics of ORMD-0801 taken at different times in relation to meals in healthy volunteers and patients with type 1 diabetes. Up to 48 patients will be enrolled, including up to 24 healthy volunteers and 24 patients with type 1 diabetes.

In October 2018, we initiated an exploratory clinical study of ORMD-0801, in patients with nonalcoholic steatohepatitis, or NASH. The three-month treatment study, which was approved by the Israel's Ministry of Health, will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH.

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 September 2018, the FDA cleared our IND application for human trials of ORMD-0901. We expect to initiate in the first quarter of calendar year 2019 a Phase I pharmacokinetic, or PK, trial which will evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. This study will be conducted pursuant to the IND and will be followed by a large Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

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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 425 million adults worldwide suffered from diabetes in 2017 and the IDF projects this number will increase to 629 million by 2045. Also, according to the IDF, in 2017, an estimated 4 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, Dr. Robert R. Henry, Professor Avram Hershko, Dr. Harold Jacob and Dr. Jane E. B. Reusch.

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.

As noted above, in April 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801 and in August 2017, we had a call with the FDA regarding ORMD-0801, during which the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a BLA.

In April 2016 we completed a smaller Phase IIb clinical trial on 180 type 2 adult diabetic patients. 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.

Should our Phase IIb three-month dose-ranging 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 NDA with potential FDA approval by the second half of calendar year 2023.

As noted above, in September 2018, the FDA cleared our IND application for human trials of our oral GLP-1 analog capsule ORMD-0901 and we expect to initiate in the first quarter of calendar year 2019 a Phase I PK trial which will evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo.

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
	Type 2 diabetes				Q2 ’18: Phase IIb 90-day multi-center study initiated (projected completion Q4 ’19) Q3 ’20: Phase III study projected initiation (projected completion Q3 ’22)
ORMD-0801 **oral insulin**	Type 1 diabetes				Q2 ’18: Clamp study initiated (projected completion Q1 ’19) Q2 ’18: Food effect study initiated (projected completion Q2 ’19) Q3 ’20: Phase III projected initiation (projected completion Q3 ’22)
ORMD-0901 **oral GLP-1**	Type 2 diabetes				Q1 ’19: Pharmacokinetics clinical study projected initiation (projected completion Q2 ’19) Q4 ’19: Phase II projected initiation (projected completion Q1 ’21)

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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 subsidiary's technology related to the ORMD-0801 capsule, and will pay, upon the meeting of certain conditions, 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.

Oral 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 PK 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, 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 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.

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. The Phase IIa study met all primary and secondary endpoints. 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 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 then-existing IND to include both type 1 and type 2 diabetes indications. In March 2014, we began a seven-day treatment in a double-blind, randomized, placebo controlled, FDA-approved Phase IIa trial of ORMD-0801 on 25 volunteers with type 1 diabetes. 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 treatment period 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. We anticipate receiving the final report of this study in the first quarter of calendar year 2019.

In August 2017, we had a call with the FDA regarding ORMD-0801. During the call, the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a BLA. If approved, the BLA pathway would grant us 12 years of marketing exclusivity for ORMD-0801, from the approval date, and 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.

In April 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801. This placebo controlled, randomized, 90 day treatment clinical trial is being conducted on approximately 285 type 2 diabetic patients in multiple centers throughout the U.S. pursuant to an IND. The primary endpoints of the trial are to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90 day treatment period. Secondary endpoints of the trial include measurements of FPG, PPG levels during a MMTT and weight.

As noted above, in June 2018, we initiated a glucose clamp study which will quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801.

As noted above, in June 2018, we also initiated a food effect trial in the United States for ORMD-0801.

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

Oral GLP-1 Analog

During the fiscal year ended August 31, 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 our capsule technology, is absorbed through the gastrointestinal tract and retains its biological activity.

In December 2009, we completed a 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 began 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 demonstrated encouraging efficacy data.

We completed a three-month pre-clinical toxicology study in March 2017 and submitted the report relating to this study to the FDA with our IND.

In September 2018, the FDA cleared our IND application for human trials of ORMD-0901. We expect to initiate in the first quarter of calendar year 2019 a Phase I PK trial which will evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. This fully-randomized, single-blind, placebo-controlled four-way crossover study will be conducted on up to 15 healthy patients pursuant to the IND and will be followed by a large Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

Combination Therapy

In June 2012, we presented an abstract, which reported the impact of ORMD-0801 delivered in combination with 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.

Other products

During the first quarter of calendar year 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 be initiated in calendar year 2019 and be completed during calendar year 2019.

As noted above, in October 2018, we initiated an exploratory clinical study of our oral insulin capsule, ORMD-0801, in patients with NASH, and we expect to complete the study in the first quarter of calendar year 2020.

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 25 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 74 patents, 27 of which were issued during the fiscal year ended August 31, 2018, or fiscal 2018, including patents issued by the United States, Swiss, German, French, U.K., Italian, Netherlands, Swedish, 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, Canadian, European, Austrian, Belgian, French, German, Irish, Italian, Luxembourg, Monaco, Netherlands, Norwegian, Spanish, Swedish, Swiss, U.K., Israeli, New Zealand, South African, Russian and Japanese patent offices that cover part of our technology for the oral delivery of exenatide; and patents issued by the European, Austrian, Belgian, Denmark, French, German, Irish, Italian, Luxembourg, Monaco, Netherlands, 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 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, we received, among other payments, ordinary shares of D.N.A. The D.N.A ordinary shares are traded on the Tel Aviv Stock Exchange and its quoted price 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, 2018, 2017 and 2016, we did not sell any of the D.N.A ordinary shares. As of August 31, 2018, we held approximately 6.9% of D.N.A's outstanding ordinary shares.

As of August 31, 2018, Entera had not yet realized any revenues. In July 2018, Entera completed an initial public offering and became listed on The Nasdaq Capital Market, or Nasdaq. In August 2018, Entera announced that it completed the treatment of patients in the first part of the PK/pharmacodynamic study in hypoparathyroidism patients with its oral parathyroid hormone drug, EB612.

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 subsidiary's 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 was 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. Through August 31, 2018, we received aggregate milestone payments of $17.5 million.

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 Ltd. (UK) and Biocon Limited (India).

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, Dr. Robert R. Henry, Professor Avram Hershko, Dr. Harold Jacob and Dr. Jane E. B. Reusch.

Dr. Roy Eldor, MD, PhD, 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.

Dr. Robert R. Henry, MD, joined the Oramed Scientific Advisory Board in February 2018 and is a leader in diabetes research. As a past President of the ADA and recipient of its Banting Medal for Scientific Achievement, among other international recognitions, his basic and clinical research funded by the National Institutes of Health, or NIH, has resulted in more than 400 journal articles, chapters and books. Dr. Henry is currently Chief of the Section of Endocrinology, Metabolism & Diabetes, Veterans Affairs Healthcare System in San Diego, California, Professor of Medicine at the University of California, San Diego and Chief of the Center for Metabolic Research in San Diego, California. In addition to studying the metabolic and cardiovascular effects of human skeletal muscle and adipose tissue signaling and interactions, his current clinical research interests involve the study and development of new therapies for type 1 and type 2 diabetes and obesity.

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. Jane E. B. Reusch, MD, joined the Oramed Scientific Advisory Board in February 2018. She is a distinguished academic physician-scientist-diabetologist committed to understanding and treating the vascular complications of diabetes. She is currently Professor of Medicine and Associate Director, Center for Women's Health, at the University of Colorado at Denver and Director of the Diabetes Care Team at the Veteran's Administration Medical Center in Denver, Colorado. Dr. Reusch has been awarded numerous NIH Research Project Grant (R01) and VA Merit grants for both basic and clinical research, leading to more than 100 peer-reviewed publications on diabetes and diabetic vascular complications. In a continuation of her life-long service to the diabetes community, Dr. Reusch is the current ADA President for Medicine and Science.

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, 2018, we have contracted with thirteen individuals for employment or consulting arrangements. Of our staff, five are senior management, four are engaged in research and development work, and the remaining four 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. Reports filed with the SEC are 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, 2018, August 31, 2017 and August 31, 2016, we had working capital of $26,484,000, $15,132,000 and $27,609,000, respectively, and stockholders' equity of $31,112,000, $19,238,000 and $26,190,000, respectively. During fiscal 2018 and the fiscal years ended August 31, 2017, or fiscal 2017, and 2016, or fiscal 2016, we generated revenues of $2,449,000, $2,456,000 and $641,000, respectively. For the period from our inception on April 12, 2002 through August 31, 2018, fiscal 2018, fiscal 2017 and fiscal 2016, we incurred net losses of $69,223,000, $12,727,000, $10,480,000 and $10,964,000, 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 and 74 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, Denmark, Luxembourg, Monaco, Norway and Netherlands 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 our 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. In addition to those efforts, on October 12, 2017, President Trump signed an executive order that modified certain aspects of the ACA. 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.

Changes to tax laws could have a negative effect on us or our stockholders.

At any time, the U.S. federal or state income tax laws, or the administrative interpretations of those laws, may be amended. Federal and state tax laws are constantly under review by persons involved in the legislative process, the U.S. Internal Revenue Service, the U.S. Department of the Treasury and state taxing authorities. Changes to the tax laws, regulations and administrative interpretations, which may have retroactive application, could adversely affect us.

Tax reform legislation in December 2017 made substantial changes to the Internal Revenue Code of 1986, as amended, or the Code, particularly as it relates to the taxation of both corporate income and international income. Among those changes are a significant permanent reduction in the generally applicable corporate income tax rate and the modification of tax policies, credits and deductions for businesses and individuals. This legislation also imposes additional limitations on the deduction of net operating losses, which could negatively impact our ability to utilize our net operating losses to offset our taxable income in future taxable years. The effect of these and other changes made in this legislation is still uncertain in many respects, both in terms of their direct effect on the taxation of an investment in our securities and their indirect effect on the value of assets owned by us. Furthermore, many of the provisions of the new law will require additional guidance in order to assess their effect. It is also possible that there will be technical corrections legislation proposed with respect to the tax reform legislation, the effect of which cannot be predicted and may be adverse to us or our stockholders. Our stockholders are encouraged to consult with their tax advisors about the potential effects that changes in law may have on them and their ownership of our securities.

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, 2014, 2017 and 2018, 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 the fiscal years ended August 31, 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 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 26, 2018, we had outstanding 17,378,359 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 21,814,795 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 26, 2018, we had outstanding warrants and options exercisable for 4,271,800 shares of common stock at a weighted average exercise price of $7.26. 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.

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 26, 2018, our directors, executive officers and principal affiliated stockholders beneficially own approximately 23.6% 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 having operations in Israel.

We have operations 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 of the Israeli Ministry of Economy & Industry we are subject to ongoing restrictions.

We received royalty-bearing grants from the Israel Innovation Authority of the Israeli Ministry of Economy & Industry, or IIA, for research and development programs that meet specified criteria. We did not recognize any grants in fiscals 2018, 2017 and 2016. 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 its 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 located at 142 W. 57th Street New York, New York. The current lease term is for 12 months starting September 1, 2018 and can be terminated at any time upon one month’s notice. The aggregate annual base rent for this space is currently $14,000.

Our Israeli subsidiary's principal executive offices are located in Givat-Ram, Jerusalem, Israel. The current lease term is scheduled to end on September 30, 2021. The aggregate annual base rent for this space is currently $37,000, linked to the increase in the Israeli consumer price index. 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.

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.

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."

Holders

As of November 26, 2018, there were 17,378,359 shares of our common stock issued and outstanding held of record by approximately 40 registered stockholders. We believe that a significant number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories and are therefore not included in the number of stockholders of record.

Unregistered Sales of Equity Securities and Use of Proceeds

On August 1, 2018, we issued 2,500 shares of our common stock, valued at $13,250, 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 Agreement, dated April 8, 2018, between us and Corporate Profile.

On July 26, 2018, we issued 4,180 shares of our common stock, valued at $25,000, in the aggregate, to Acorn Management Partners, L.L.C., or Acorn, in payment of a portion of the consulting fee for investor relations services owed to Acorn pursuant to a Consulting Agreement, dated July 15, 2018, between us and Acorn.

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

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, 2018, 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 2018, 2017 and 2016 and the selected consolidated balance sheet data as of August 31, 2018 and 2017, 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, 2015 and 2014 and the balance sheet data as of August 31, 2016, 2015 and 2014 are derived from audited financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	2018	2017	2016	2015	2014
	(in thousands of dollars except share and per share data)				
Statements of Comprehensive Loss:					
Revenues	$2,449	$2,456	$641	$-	$-
Cost of revenues (income)	(86)	187	490	-	-
Research and development expenses	11,979	10,281	7,709	4,781	3,277
General and administrative expenses	4,083	2,759	2,452	2,602	2,629
Financial income	903	792	474	168	225
Financial expenses	103	101	93	18	11
Loss before taxes on income	12,727	10,080	9,629	7,233	5,692
Taxes on income (Tax benefit)	-	400	1,335	(1)	4
Net loss for the year	$12,727	$10,480	$10,964	$7,232	$5,696
Loss per common share – basic and diluted	$0.86	$0.79	$0.87	$0.67	$0.62
Weighted average common shares outstanding	14,882,356	13,309,372	12,624,356	10,820,465	9,244,059

	As of August 31,				
	2018	2017	2016	2015	2014
	in thousands of dollars except share and per share data				
Balance Sheet Data:					
Cash, cash equivalents, short-term deposits, restricted cash and marketable securities	$30,463	$20,138	$31,032	$17,245	$21,306
Other current assets	574	159	198	127	472
Long-term deposits and other assets	13,575	16,262	11,070	8,042	24
Long-term marketable securities	2,785	2,151	530	940	-
Total assets	47,397	38,712	42,830	26,354	21,802
Current liabilities	4,553	5,165	3,621	1,489	973
Long-term liabilities	11,732	14,309	13,019	37	36
Stockholders' equity	31,112	19,238	26,190	24,828	20,793

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 initiated a three-month dose-ranging Phase IIb clinical trial on

approximately 285 type 2 diabetic patients in multiple centers throughout the United States pursuant to an IND to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90 day treatment period. We also initiated a glucose clamp study to quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801. In addition we initiated a food effect trial to evaluate the pharmacokinetics and pharmacodynamics of ORMD-0801 taken at different times in relation to meals in healthy volunteers and patients with type 1 diabetes. We completed a Phase IIb clinical trial in patients with type 2 diabetes under an IND, 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.

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 September 2018, the FDA cleared our IND application for human trials of ORMD-0901. We expect to initiate in the first quarter of calendar year 2019 a Phase I PK trial to evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo.

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.

Other products: We initiated an exploratory clinical study of ORMD-0801 in patients with NASH to assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. In addition, we have begun developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule, and plan to initiate in calendar year 2019 a proof of concept study for our oral leptin drug candidate.

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 2018 to Fiscal 2017 and Fiscal 2017 to Fiscal 2016

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2018, 2017 and 2016:

Operating Data:	Year ended August 31, 2018	2017	2016
	(dollar amounts in thousands)		
Revenues	$2,449	$2,456	$641
Cost of revenues (income)	(86)	187	490
Research and development expenses	11,979	10,281	7,709
General and administrative expenses	4,083	2,759	2,452
Financial income, net	800	691	381
Loss before taxes on income	12,727	10,080	9,629
Taxes on income	-	400	1,335
Net loss for the year	12,727	10,480	10,964
Loss per common share – basic and diluted	$0.86	$0.79	$0.87
Weighted average common shares outstanding	14,882,356	13,309,372	12,624,356

Revenues

Revenues consist of proceeds related to the License Agreement that are recognized over the period from which the Company is entitled to the respective payments and through June 2023.

Revenues for fiscal 2018 totaled $2,449,000, consistent with $2,456,000 for fiscal 2017.

Revenues for fiscal 2017 increased by 283% to $2,456,000 from $641,000 for fiscal 2016. The increase is attributed to milestone payments received during fiscal 2016 in connection with the License Agreement which are recognized

through the expected product submission date using a time-based model approach.

Cost of revenues (income)

Cost of revenues consists of royalties related to the License Agreement that will be paid over the term of the License Agreement in accordance with revenue recognition accounting 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 2018 decreased to income of $86,000 compared to cost of $187,000 for fiscal 2017. The decrease is attributed to a decrease in the royalties we are obligated to pay to the IIA from 3.5% to 3% due to the amendment of the applicable regulations, as well as due to no additional milestone payments having been received during fiscal 2018.

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 milestone payments received during the year.

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 drugs 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 for fiscal 2018 increased by 16.5% to $11,979,000 from $10,281,000 for fiscal 2017. The increase is mainly attributed to expenses related to our Phase IIb three-month dose-ranging clinical trial, our clamp study and our oral leptin development and is partially offset by a decrease in expenses related to toxicology studies and scale-up process development and production of our oral capsule ingredients. During fiscal 2018, stock-based compensation costs totaled $575,000, as compared to $1,134,000 during fiscal 2017. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods and is partially offset by an increase due to awards granted to employees and a consultant during fiscals 2018 and 2017.

Research and development expenses 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 previous Phase IIb clinical trial. During fiscal 2017, stock-based compensation costs totaled $1,134,000, as compared to $304,000 during fiscal 2016.

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 generally 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 2018, 2017 and 2016, we did not recognize any research and development grants. As of August 31, 2018, we incurred a liability to pay royalties to the IIA of $390,000.

Under the terms of the grants we received from the IIA, we are obligated to pay royalties of 3% 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 were committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grants received by the Company (Israeli CPI linked) in the total aggregate amount of $65,000. As of August 31, 2018, we had no liability to the Bio-Jerusalem fund, as all royalties were paid.

General and administrative expenses

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

General and administrative expenses increased by 48% from $2,759,000 for fiscal 2017 to $4,083,000 for fiscal 2018. The increase in costs incurred related to general and administrative activities during fiscal 2018, is mainly attributable to an increase in stock-based compensation costs and expenses related to the relocation of our Chief Executive Officer to New York, where the Company leases an office and has its principal executive office. During fiscal 2018, as part of our general and administrative expenses, we incurred $972,000 related to stock-based compensation costs, as compared to $440,000 during fiscal 2017. The increase is mainly attributable to awards granted to employees and directors during fiscals 2018 and 2017.

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.

Financial income, net

Net financial income was $800,000 for fiscal 2018 as compared to net financial income of $691,000 for fiscal 2017. The increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates.

Net financial income 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.

Taxes on income

No taxes on income were recognized for fiscal 2018 as compared to $400,000 for fiscal 2017. The decrease is due to the absence of withholding taxes during the more recent period as compared to the prior period, as withholding taxes were recorded during fiscal 2017 in connection with the receipt of a milestone payment pursuant to the License Agreement.

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 taxes during fiscal 2017 as compared to fiscal 2016, attributable to the decrease in milestone

payments received in connection with the License Agreement.

Other comprehensive income

Unrealized gain on available for sale securities for fiscal 2018 of $301,000 resulted from an increase attributable to the measurement of our Entera ordinary shares at fair value from the date they began trading on Nasdaq instead of measurement at cost method in prior periods, partially offset by a decrease in fair value of our D.N.A ordinary shares.

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.

Liquidity and Capital Resources

From our inception through August 31, 2018, we have incurred losses in an aggregate amount of $69,223,000. 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 $77,736,000, net of transaction costs. During that period we also received cash consideration of $5,877,000 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, 2018, we had $4,996,000 of available cash, $34,417,000 of short term and long term deposits and $7,377,000 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, 2018, our total current assets were $31,037,000 and our total current liabilities were $4,553,000. On August 31, 2018, we had a working capital surplus of $26,484,000 and an accumulated loss of $69,223,000. 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. The increase in working capital surplus from August 31, 2017 to August 31, 2018 was primarily due to the proceeds from a registered direct offering, or the Offering, completed in July 2018.

During fiscal 2018, cash and cash equivalents increased to $4,996,000 from $3,969,000 as of August 31, 2017, which is due to the reasons described below.

Operating activities used cash of $14,657,000 in fiscal 2018 compared to $5,831,000 used in fiscal 2017. Cash used in operating activities in fiscal 2018 primarily consisted of net loss resulting from research and development and general and administrative expenses and changes in deferred revenues, while cash used by 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.

Investing activities used cash of $7,004,000 in fiscal 2018, as compared to $4,302,000 provided in fiscal 2017. Cash used in investing activities in fiscal 2018 consisted primarily of the purchase of bank deposits and marketable securities, partially offset by the sale of short-term deposits and maturity of marketable securities, while 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.

Financing activities provided cash of $22,654,000 in fiscal 2018 and $1,586,000 in fiscal 2017. Cash provided by financing activities during both periods consisted of proceeds from our issuance of common stock and warrants and proceeds from exercise of warrants and options. Our primary financing activities in fiscal 2018 and fiscal 2017 were as follows:

On July 2, 2018, we entered into a Securities Purchase Agreement with each of three investors, or the Purchasers, pursuant to which we agreed to sell, in the Offering, an aggregate of 2,892,000 units, or the Units, each Unit consisting of one share of our common stock and a warrant to purchase one share of common stock at an exercise price of $7.25 per share, or the Warrants, to the Purchasers for an offering price of $6.25 per Unit. The Warrants will be exercisable commencing six months following their issuance for a period of three and one-half years from the date of issuance. The closing of the sale of the Units occurred on July 6, 2018. The net proceeds to us from the Offering, after deducting the placement agent’s fees and expenses and our Offering expenses were approximately $16,484,000.

On July 2, 2018, we entered into a letter agreement with H.C. Wainwright & Co., LLC, or HCW, pursuant to which HCW agreed to serve as exclusive placement agent in any offering by us occurring between July 2, 2018 and August 1, 2018. For its services in the Offering, HCW received a fee equal to 7% of the gross proceeds raised in the Offering and a management fee of 1% of the gross proceeds raised in the Offering, up to $50,000 for non-accountable expenses as well as warrants to purchase up to 115,680 shares of our common stock, exercisable for a period of three and one-half years from the date of issuance and with an exercise price of $7.8125 per share. Upon the exercise of the Warrants, HCW will receive a fee equal to 7% of the gross proceeds raised as a result of such exercise.

During fiscal 2018, 138,071 warrants were exercised for cash and resulted in the issuance of 138,071 shares of common stock and 50,750 options were exercised for cash and resulted in the issuance of 50,750 shares of common stock. The cash consideration received for the exercise of warrants was $790,000 and the cash consideration received for the exercise of options was $207,000. 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 the exercise of warrants was $1,242,000 and the cash consideration received for the exercise of options was $319,000. During fiscal 2018 and fiscal 2017, we issued a total of 24,180 shares of common stock to third party vendors for services rendered. The aggregate value of those shares was approximately $170,000.

In November 2017 and February, May, July and August 2018, we issued a total of 14,180 shares of our common stock, valued approximately $99,000, in the aggregate, to certain service providers 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, 2018, 576,834 shares were sold under the Sales Agreement for aggregate net proceeds of $5,198,000.

Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments at August 31, 2018, 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	$8,044	$8,044	$ -	$ -	$ -
Purchase and technology transfer obligations	5,742	5,742	-	-	-
Operating lease obligations	120	44	73	3	-
Royalty payment obligations	390	77	132	181	-
Accrued severance pay, net	20	-	-	-	20
Total	$14,316	$13,907	$205	$184	$ 20

Off-Balance Sheet Arrangements

As of August 31, 2018, 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, 2018, we had $5 million in cash and cash equivalents, $34.4 million in short and long term bank deposits and $7.4 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 and 117,000 ordinary shares of Entera, 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. Entera shares are traded on Nasdaq in U.S. dollars, while D.N.A shares are traded on the Tel Aviv Stock Exchange and the D.N.A shares' price is denominated in NIS. We are also exposed to changes in the market price of the Entera and D.N.A shares, as well as to exchange rates fluctuations in the NIS currency compared to the U.S. dollar with respect to the D.N.A shares.

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, 2018, we own net balances in NIS of approximately $789,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate gain of approximately $72,000, while assuming a 10% devaluation of the NIS against the U.S. dollar, we would experience an exchange rate loss of approximately $88,000.

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

	Year Ended August 31,		
	2018	2017	2016
Average rate for period	3.544	3.697	3.864
Rate at period-end	3.604	3.596	3.786

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, 2018. 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, 2018 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, 2018 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, 2018 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	44	President, Chief Executive Officer and Director
Miriam Kidron	78	Chief Scientific Officer and Director
Hilla Eisenberg	34	Chief Financial Officer, Treasurer and Secretary
Mark Hasleton	46	VP Business Development
Aviad Friedman	47	Director
Xiaopeng Li	34	Director
Kevin Rakin	58	Director
Leonard Sank	53	Director
David Slager	46	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.

Dr. Mark Hasleton was appointed ***VP Business Development*** effective November 15, 2018. Prior to his appointment, Dr. Hasleton, served in several leadership and pharmaceutical development roles. From 2010 to 2018, he served in Business Development and later as Senior Director of Portfolio - Global New Therapeutic Entities at Teva Pharmaceutical Industries Ltd. Prior to joining Teva, from 2007 to 2010, Dr. Hasleton was at Bristol Myers Squibb Co., in the UK and then in the European business as EMEA Business Operations Manager - Field Medical. Dr. Hasleton holds a PhD in molecular biology and cancer research from the Imperial College London, UK, a MRes in molecular biology from the University of Manchester, UK and an MBA from Tanaka Business School, Imperial College London, UK.

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 HTIT, an affiliated company of HTBT, since 2016. 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. Ms. Li has also been a member of the Association of Chartered Certified Accountants since 2017.

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 and a number of private companies. 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 Management LP, or Regals Management, and the Portfolio Manager of the fund. Prior to founding Regals Management 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 stockholder 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 and Ms. Li, 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 is the chief financial officer of HTIT, a stockholder holding more than 5% of our common stock and was initially 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. The Board considered these relationships and determined that they would not interfere with Mr. Slager's or Ms. Li'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 2018, our Board held 7 meetings and took actions by written consent on one occasion. 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 stockholders; and

Reviewing periodically with the Chairman of the Board and the Chief Executive Officer 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 2018, we believe that during fiscal 2018, our executive officers, directors and all persons who own more than ten percent of a registered class of our equity securities complied with all Section 16(a) filing requirements.

Code of Ethics

We have adopted a Code of Ethics and Business Conduct for our senior officers, directors and employees. A copy of the Code of Ethics and Business Conduct is located at our website at www.oramed.com. 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 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 2018 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 2018, 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 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.

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 2018, our Compensation Committee increased the base salary of one of our NEOs by fifteen percent, as it deemed this to be a reasonable rate based on, among other factors, such NEO's increased responsibilities, and 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.

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 changed to generally provide for annual installments for new grants, though the Compensation Committee also utilizes quarterly vesting from time to time. As part of its fiscal 2017 engagement described above, Aon provided consulting services to the Compensation Committee in fiscal 2018 in

connection with grants of stock options to our executive officers. Aon reviewed annual long-term incentive grants at peer companies, as well as such grants made by companies in the broader market, based on a blend of Black-Scholes valuations and grants as a percentage of the applicable company's capitalization. Aon provided recommendations at various percentiles as well as for both the U.S. and Israeli local markets for the Compensation Committee's consideration. Aon used both a U.S. and an Israeli peer group. 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 Israeli peer group consisted of the following companies: Alcobra Ltd. (now Arcturus Therapeutics 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. Following such consultation, we granted stock options that vest over a period of four years to certain of our executive officers. 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 prior years the Compensation Committee 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. No RSUs were granted in fiscal 2018.

Benefits and Perquisites

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

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

In fiscal 2018, the Company retained ORI - Organizational Resources International Ltd., or ORI, to prepare a cost analysis on the difference between the cost of living in Israel and New York. Based on the relocation cost analysis prepared by ORI, the Company pays for certain direct costs, related taxes and expenses incurred in connection with the relocation of our CEO to New York. During fiscal 2018, such relocation expenses totaled approximately $430,000, and included mainly payments intended to reflect the difference in the cost of living between Israel and the United States, relocation expenses, accommodation allowances, education allowances, health insurance and related taxes.

Say-on-Pay Vote

Our stockholders approved, on an advisory basis, our executive compensation program at our 2018 annual meeting of stockholders held on August 28, 2018. 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 2018.

REPORT OF THE COMPENSATION COMMITTEE

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

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SUMMARY COMPENSATION TABLE

The following table sets forth the compensation earned by our NEOs for fiscals 2018, 2017 and 2016.

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	2018	436,310	148,795	-	522,569	442,326	1,550,000
President and CEO and	2017	399,804	123,000	-	585,150	45,579	1,153,533
director (7)	2016	273,086	195,729	-	-	17,366	486,181
Miriam Kidron	2018	273,595	46,614	-	253,204	13,643	587,056
Chief Scientific Officer	2017	254,765	50,000	581,932	359,224	12,775	1,258,696
and director (8)	2016	203,378	136,583	-	-	13,191	353,152
Joshua Hexter	2018	161,002	26,895	-	269,196	50,505	507,598
COO and VP Business	2017	148,499	33,000	463,400	-	46,408	691,307
Development (9)	2016	132,306	86,974	-	-	42,014	261,294

(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 certain compensation from Oramed Ltd. through KNRY, Ltd., an Israeli entity owned by Dr. Miriam 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.

(9) Mr. Hexter resigned from his positions with us, effective November 15, 2018.

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* ($)	**Relocation Expenses** ($)**	Total ($)
Nadav Kidron	2018	12,596	--	--	429,730	442,326
	2017	28,098	--	--	17,481	45,579
	2016	17,366	--	--	--	17,366
Miriam Kidron	2018	13,643	--	--	--	13,643
	2017	12,775	--	--	--	12,775
	2016	13,191	--	--	--	13,191
Joshua Hexter	2018	13,909	24,623	11,973	--	50,505
	2017	12,910	22,513	10,985	--	46,408
	2016	12,660	19,585	9,769	--	42,014

* 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.

** Relocation expenses represents additional compensation in fiscal 2018 and fiscal 2017, for the period during which Mr. Kidron was in the United States. These expenses mainly include relocation expenses, supplemental living expenses, accommodation allowances, education allowances, health insurance and related costs.

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 140 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., had 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 gross monthly salary was NIS 51,625. In addition, Mr. Hexter was provided with a cellular phone and a company car pursuant to the terms of his agreement. Effective November 15, 2018, Mr. Hexter resigned as our COO and VP Business Development.

We, through Oramed Ltd., have entered into an employment agreement with Mark Hasleton as of November 6, 2018, pursuant to which Dr. Hasleton was appointed as VP Business Development of the Company and Oramed Ltd., effective November 15, 2018. In accordance with the employment agreement, Dr. Hasleton's current gross monthly salary is NIS 38,000. In addition, Dr. Hasleton is provided with a cellular phone and a company car pursuant to the terms of his agreement.

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, as amended, Ms. Eisenberg's current gross monthly salary is NIS 35,700. 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.

GRANTS OF PLAN-BASED AWARDS

The following table shows grants of plan-based equity awards made to our NEOs during fiscal 2018:

Name	Grant Date	**Options Awards: Number of Securities Underlying Options**	**Grant Date Fair Value of Stock Awards**
		(#)	**($)**
Nadav Kidron[(1)]	1/31/2018	97,000	522,569
Miriam Kidron[(2)]	1/31/2018	47,000	253,204
Joshua Hexter[(3)]	4/8/2018	30,000	137,933
Joshua Hexter[(3)]	5/3/2018	30,000	131,262

(1) These options were granted under our 2008 Plan and vest in 4 equal installments of 24,250 on each of January 1, 2019, January 1, 2020, January 1, 2021 and January 1, 2022.

(2) These options were granted under our 2008 Plan and vest in 4 equal installments of 11,750 on each of January 1, 2019, January 1, 2020, January 1, 2021 and January 1, 2022.

(3) These options were granted under our 2008 Plan and vest in 16 equal installments of 1,875 on the last day of each quarter commencing June 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, 2018.

	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)	-		5.88	4/20/20		
	72,000 (2)	-		4.08	8/8/22		
	47,134 (3)	-		12.45	4/9/24		
	49,000 (4)	98,000	(4)	7.77	6/30/27		
		97,000	(5)				
						0 (8)(9)	0
Miriam Kidron	72,000 (1)	-		5.88	4/20/20		
	72,000 (2)	-		4.08	8/8/22		
	47,134 (3)	-		12.45	4/9/24		
	23,333 (6)	46,666	(6)	7.77	6/30/27		
		47,000	(7)				
						0 (10)	0
Joshua Hexter	100,800 (11)	-		7.88	4/14/23		
	1,875 (12)	28,125	(12)	7.05	4/8/28		
	1,875 (13)	28,125	(13)	6.70	5/3/28		
						0 (14)	0

(1) 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.

(2) 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.

(3) 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.

(4) 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; 49,000 of such options vested on December 31, 2017 and the remainder vest in two equal installments of 49,000 on each of December 31, 2018 and December 31, 2019, subject to the Company share price reaching the target of $9.5 and $12.5 per share, respectively. The options expire on June 30, 2027.

(5) On January 31, 2018, 97,000 options were granted to Nadav Kidron under the 2008 Plan at an exercise price of $8.14 per share; Such options vest in 4 equal installments of 24,250 on each of January 1, 2019, January 1, 2020, January 1, 2021 and January 1, 2022. The options expire on January 31, 2028.

(6) On June 30, 2017, 69,000 options were granted to Miriam Kidron under the 2008 Plan at an exercise price of $7.77 per share; 23,000 of such options vested on December 31, 2017 and the remainder vest in two equal installments of 23,333 on each of December 31, 2018 and December 31, 2019. The options have an expiration date of June 30, 2027.

(7) On January 31, 2018, 47,000 options were granted to Miriam Kidron under the 2008 Plan at an exercise price of $8.14 per share; Such options vest in 4 equal installments of 11,750 on each of January 1, 2019, January 1, 2020, January 1, 2021 and January 1, 2022. The options expire on January 31, 2028.

(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, 2017, 75,000 RSUs, representing a right to receive shares of the Company’s common stock, were granted to Miriam Kidron. The RSUs vested immediately, have an exercise price of $0.012 per share of common stock and expire on June 30, 2027.

(11) 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.

(12) On April 8, 2018, 30,000 options were granted to Joshua Hexter under the 2008 Plan at an exercise price of $7.05 per share; 3,750 of the options vested in two installments of 1,875 on each of June 30, 2018 and September 30, 2018 and expire on April 8, 2028. The remainder of the options were forfeited by the grantee as of November 15, 2018.

(13) On May 3, 2018, 30,000 options were granted to Joshua Hexter under the 2008 Plan at an exercise price of $6.70 per share; 3,750 of the options vested in two installments of 1,875 on each of June 30, 2018 and September 30, 2018 and expire on May 3, 2028. The remainder of the options were forfeited by the grantee as of November 15,

2018.

(14) 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 vested 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 2018. No options were exercised by the NEOs in fiscal 2018.

	Stock Awards	
Name	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
Joshua Hexter	29,000	214,710

Compensation Committee Interlocks and Insider Participation

During fiscal 2018, 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 2018:

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	-	-	-	20,000
Xiaopeng Li	20,000	-	-	-	20,000
Aviad Friedman	20,000	-	-	-	20,000
Kevin Rakin	20,000	-	-	-	20,000
David Slager	20,000	-	-	-	20,000

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

(2) As of August 31, 2018, our non-employee directors then in office held options 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 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 2018.

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 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, 2018, options with respect to 2,089,848 shares have been granted, of which 35,074 have been forfeited, 169,974 have been exercised and 620,680 have expired. As of August 31, 2018, 525,824 RSUs have been granted, of which 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. Other than in the case of certain options, the shares underlying an award granted under the 2008 Plan may become available for future grant under the 2008 Plan if the award is forfeited, canceled or expired.

The following table sets forth additional information with respect to our equity compensation plans (consisting solely of the 2008 Plan) as of August 31, 2018: