# 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, 2019

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	(I.R.S. Employer
Incorporation or Organization)	Identification No.)
1185 Avenue of the Americas, Suite 228, New Yor	rk, NY 10036
(Address of Principal Executive Offices)	(Zip Code)
	844-967-2633
(Registrar	nt's Telephone Number, Including Area Code)
Securities registere	d 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	own seasoned issuer, as defined in Rule 405 of the Securities Act. Yes □ No ⊠
Indicate by check mark if the registrant is not require	ed to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
	as filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of iod that the registrant was required to file such reports), and (2) has been subject to such filing
	abmitted electronically every Interactive Date File required to be submitted pursuant to Rule 405 eding 12 months (or for such shorter period that the registrant was required to submit such files).
	arge accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or ccelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth
Large accelerated filer $\square$	Accelerated filer □
Non-accelerated filer ⊠	Smaller reporting company ⊠
	Emerging growth company □
If an emerging growth company, indicate by check renew or revised financial accounting standards provided pursuance.	mark if the registrant has elected not to use the extended transition period for complying with any lant to Section 13(a) of the Exchange Act. $\Box$
Indicate by check mark whether the registrant is a sh	nell company (as defined in Rule 12b-2 of the Act). Yes □ No ⊠
	oting common equity held by non-affiliates as of the last business day of the registrant's most used on a price of \$3.20, being the last price at which the shares of the registrant's common stock he most recently completed second fiscal quarter.
Indicate the number of shares outstanding of each of common stock issued and outstanding as of November 26, 20	f the registrant's classes of common stock, as of the latest practicable date: 17,398,112 shares of 019.

# ORAMED PHARMACEUTICALS INC.

# FORM 10-K (FOR THE FISCAL YEAR ENDED AUGUST 31, 2019)

# TABLE OF CONTENTS

PART I		1
	ITEM 1. BUSINESS.	1
	ITEM 1A, RISK FACTORS.	11
	ITEM IB. UNRESOLVED STAFF COMMENTS.	21
	ITEM 2. PROPERTIES.	21
	ITEM 3. LEGAL PROCEEDINGS.	21
	ITEM 4. MINE SAFETY DISCLOSURES.	21
PART II		22
	ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER	
	PURCHASES OF EQUITY SECURITIES.	22
	ITEM 6. SELECTED FINANCIAL DATA.	22
	ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.	23
	ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.	29
	ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.	30
	ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL	
	<u>DISCLOSURE.</u>	30
	ITEM 9A. CONTROLS AND PROCEDURES.	30
	ITEM 9B. OTHER INFORMATION.	31
PART III		31
	ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.	31
	ITEM 11. EXECUTIVE COMPENSATION.	35
	ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED	
	STOCKHOLDER MATTERS.	46
	ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.	48
	ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.	49
PART IV		50
	ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.	50
	ITEM 16. FORM 10-K SUMMARY.	54

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, 2019, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.535 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 similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements. 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, 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. We utilize Clinical Research Organizations, or CROs, to conduct our clinical studies.

*Oral insulin*: We are seeking to transform 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 the 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.

FDA Guidance: In August 2017, during a call with the U.S. Food and Drug Administration, or FDA, we were 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.

Phase IIb Study: In May 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801. This placebo controlled, randomized, 90-day treatment clinical trial was conducted on 269 type 2 diabetic patients in multiple centers throughout the United States pursuant to an Investigational New Drug application, or IND, with the FDA. The primary endpoints of the trial were 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 included measurements of fasting plasma glucose, or FPG, post-prandial glucose, or PPG levels, during a mixed-meal tolerance test, or MMTT, and weight. In May 2019 we began an extension of this protocol for approximately 75 type 2 diabetic patients, who were dosed using a lower dosage.

In November 2019, we announced positive results from the initial cohort of the Phase IIb trial. Patients randomized in the trial to once-daily ORMD-0801 achieved a reduction in mean HbA1c of 0.60% from baseline, or a reduction of 0.54% adjusted for placebo (p value = 0.036). This 0.54% reduction in HbA1c is considered clinically meaningful, reflecting an improved glucose control that would result in reduced risk of developing diabetes-related complications. Treatment with ORMD-0801 demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes. In addition, during this 90-day trial, no weight gain was observed. In the initial cohort, 269 U.S.-based patients were enrolled and treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32 mg per day), twice-daily (64 mg per day), thrice daily (96 mg per day). There was a corresponding placebo for each treatment arm. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis as they showed results opposite from the rest of the statistically significant results. We are still investigating the cause of this discrepancy. The once-daily and twice-daily arms achieved statistically significant (p-value 0.036 and 0.042, respectively) reductions from baseline in A1C of 0.60% (0.54% with placebo adjustment) and 0.59% (0.53% with placebo adjustment), respectively. The thrice-daily arm did not meet statistical significance (p-value 0.093). ORMD-0801 demonstrated an excellent safety profile with no serious drug-related adverse events.

As our Phase IIb three-month dose-ranging clinical trial successfully met 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 BLA with potential FDA approval by the end of calendar year 2024

Clamp Study: 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. We expect to receive the results of this study in the first quarter of calendar year 2020.

Food Effect 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, or PK, and pharmacodynamics of ORMD-0801 taken at different times in relation to meals in healthy volunteers and patients with type 1 diabetes. Forty-eight (48) patients are enrolled, including 24 healthy volunteers and 24 patients with type 1 diabetes. We expect to receive the results of this study in the first quarter of calendar year 2020.

*NASH Study:* 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 Israel's Ministry of Health, will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in 30 patients with NASH. As requested by Israel's Ministry of Health, the first part of the study will be conducted on 10 participants and is expected to be completed during first quarter of calendar year 2020.

Toxicology Study (6 Months): In March 2019, we completed a six-month dosing toxicology study of ORMD-0801, which was initiated in September 2018 following the FDA's request. We expect to receive the results of this study in the first quarter of calendar year 2020.

*Type 1 Study:* In November 2019 we initiated a crossover study of type 1 diabetic patients to compare the effects of ORMD-0801 given once daily versus the effects of ORMD-0801 given three times daily. The study is anticipated to include 26 subjects and is expected to be completed in the second quarter of calendar year 2020.

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 February 2019, we completed a Phase I PK trial to evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. We expect to receive the results of this study in the first quarter of calendar year 2020. This study was conducted pursuant to an IND, which we expect to be followed by a Phase II trial on type 2 diabetic patients which will likely be conducted in the United States under an IND.

**Diabetes**: Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life. The cause of diabetes is attributed both to genetics (type 1 diabetes) and, most often, to environmental factors such as obesity and lack of exercise (type 2 diabetes). According to the International Diabetes Federation, or IDF, an estimated 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 an experienced management team knowledgeable in the treatment of diabetes. Our Chief Scientific Officer, Miriam Kidron, PhD, is a 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*".

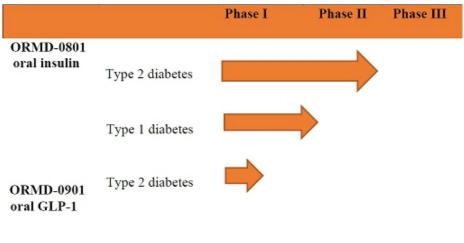
Through our research and development efforts, we have successfully developed an oral dosage form that is intended to withstand the harsh environment of the stomach and intestines and effectively deliver active insulin or other proteins, such as exenatide, for the treatment of diabetes. The excipients that are added to the proteins in the formulation process are not intended to modify the proteins chemically or biologically, and the dosage form is designed to be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology.

As our oral insulin (ORMD-0801) Phase IIb three-month dose-ranging clinical trial successfully met 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 BLA with potential FDA approval by the end of calendar year 2024.

In September 2018, the FDA cleared our IND application for human trials of our oral GLP-1 analog capsule ORMD-0901 and we initiated a Phase I PK trial which will evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. We expect to get the results of this study in the first calendar quarter of 2020.

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:



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

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 products 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**

## **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. We anticipate initiating 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 in the fourth quarter of calendar year 2019. We anticipate receiving the final report of this study in the first quarter of calendar year 2020.

#### Raw Materials

Our oral insulin capsule is currently manufactured by Swiss Caps AG, a member of Aenova Group GmbH.

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 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 21 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 77 patents, 3 of which were issued during the fiscal year ended August 31, 2019, or fiscal 2019, 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, or the 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, 2019, 2018 and 2017, we did not sell any of the D.N.A ordinary shares. As of August 31, 2019, we held approximately 6.9% of D.N.A's outstanding ordinary shares

As of August 31, 2019, 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 December 11, 2018, Entera announced that it had entered into a research collaboration and license agreement, or the Amgen License, with Amgen Inc. related to research of inflammatory disease and other serious illnesses. As reported by Entera, under the terms of the Amgen License, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to \$270,000,000 in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs. To the extent the Amgen License results in net revenues as defined in the Patent Transfer Agreement, our Subsidiary will be entitled to the aforementioned royalties.

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, 2019, we received aggregate milestone payments of \$20.5 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 substudies. 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 some of the 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.

# 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 a previous 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, 2019, we have contracted with thirteen individuals for employment or consulting arrangements. Of our staff, four are senior management, five 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, 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, 2019, August 31, 2018 and August 31, 2017, we had working capital of \$28,016,000, \$26,484,000 and \$15,132,000, respectively, and stockholders' equity of \$19,393,000, \$31,112,000 and \$19,238,000, respectively. During fiscal 2019 and the fiscal years ended August 31, 2018, or fiscal 2018, and 2017, we generated revenues of \$2,703,000, \$2,449,000 and \$2,456,000, respectively. For the period from our inception on April 12, 2002 through August 31, 2019, and for fiscal 2019, fiscal 2018 and fiscal 2017, we incurred net losses of \$83,578,000, \$14,355,000, \$12,727,000 and \$10,480,000, 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 77 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; similarly, we may encounter discrepancies due to evidence of treatment-by-center interaction which could cause us to exclude certain results, as happened with the results of two sites in the initial cohort of our Phase IIb trial,
- 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.

# Clinical trials of our products conducted by third parties may encounter delays, suspensions or other problems and are outside of our control.

Third parties who conduct clinical trials of our products may encounter problems that may cause delays, suspensions or other problems at any phase. These problems could include the possibility that they may not be able to conduct clinical trials at their preferred sites, enroll a sufficient number of patients for their clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. In addition, these third parties are not controlled by us and may conduct these trials in a manner in which we disagree or which may prove to be unsuccessful. Furthermore, domestic or foreign regulatory agencies may suspend clinical trials at any time if they believe the subjects participating in the trials are being exposed to unacceptable health risks or if they find deficiencies in the clinical trial process or conduct of the investigation. If such clinical trials conducted by third parties fail, it 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. Even within a clinical trial there might be discrepancies from statistically significant data, as occurred at two of the sites in the initial cohort of our Phase IIb trial, which we excluded while we investigate such discrepancies. Further, 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 and Euro. 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, 2016, 2017 and 2019, 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 2018, 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, 2019, we had outstanding 17,398,112 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 21,882,225 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, 2019, we had outstanding warrants and options exercisable for 3,007,680 shares of common stock at a weighted average exercise price of \$7.27. 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 in the foreseeable future, 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, 2019, our directors, executive officers and principal affiliated stockholders beneficially own approximately 16.9% 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 or in the future may be 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 2019, 2018 and 2017. 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.

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, 2019, there were 17,398,112 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

No unregistered sales of equity securities were made during the three months ended August 31, 2019.

# 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, 2019, 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 2019, 2018 and 2017 and the selected consolidated balance sheet data as of August 31, 2019 and 2018, 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, 2016 and 2015 and the balance sheet data as of August 31, 2017, 2016 and 2015 are derived from audited financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	2019			2018 2017				2016		2015
			(in tl	nousands of do	llars	except share a	ınd p	per share data)		
Statements of Comprehensive Loss:										
Revenues	\$	2,703	\$	2,449	\$	2,456	\$	641	\$	-
Cost of revenues (income)		90		(86)		187		490		-
Research and development expenses		13,522		11,979		10,281		7,709		4,781
General and administrative expenses		3,722		4,083		2,759		2,452		2,602
Financial income		1,061		903		792		474		168
Financial expenses		485		103		101		93		18
Loss before taxes on income		14,055		12,727		10,080		9,629		7,233
Taxes on income (Tax benefit)		300		-		400		1,335		(1)
Net loss for the year	\$	14,355	\$	12,727	\$	10,480	\$	10,964	\$	7,232
Loss per common share – basic and diluted	\$	0.82	\$	0.86	\$	0.79	\$	0.87	\$	0.67
						_				_
Weighted average common shares outstanding	_	17,454,489	_	14,882,356	_	13,309,372	_	12,624,356	_	10,820,465

				As o	f August 31,			
	2019		2018		2017		2016	2015
		in t	housands of do	llars	except share a	ınd p	er share data	
<b>Balance Sheet Data:</b>								
Cash, cash equivalents, short-term deposits, restricted cash and								
marketable securities	\$ 32,282	\$	30,463	\$	20,138	\$	31,032	\$ 17,245
Other current assets	1,042		574		159		198	127
Long-term deposits and other assets	1		13,575		16,262		11,070	8,042
Long-term marketable securities	1,295		2,785		2,151		530	940
Total assets	34,663		47,397		38,712		42,830	26,354
Current liabilities	5,308		4,553		5,165		3,621	1,489
Long-term liabilities	9 962		11 732		14 309		13.019	37

24,828

26,190

# 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."

19,393

31,112

19,238

# **Overview of Operations**

Stockholders' equity

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. An overview of our current clinical studies can be found in "Item 1. Business." of this Annual Report on Form 10-K.

## **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.

**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.

Under Accounting Standards Codification, or ASC, 605 (which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018) given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which we were entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees were earned.

However, under ASC 606, we are required to recognize the total transaction price (which includes consideration related to milestones once the criteria for recognition have been satisfied) using the input method over the period the performance obligation is fulfilled. Accordingly, once the consideration associated with a milestone is included in the transaction price, incremental revenue is recognized immediately based on the period of time that has elapsed towards complete satisfaction of the performance obligation.

Since the customer benefits from the services as the entity performs, revenue is recognized over time through the expected product submission date in June 2023, using the input method. The Company used the input method to measure the process for the purpose of recognizing revenue, which approximates the straight line attribution. The Company used significant judgment when it determined the product submission date.

Under ASC 606, the consideration that the Company would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events, are a form of variable consideration. When assessing the portion, if any, of such milestones-related consideration to be included in the transaction price, the Company first assesses the most likely outcome for each milestone and excludes the consideration related to milestones of which the occurrence is not considered the most likely outcome.

The Company then evaluates if any of the variable consideration determined in the first step is constrained by including in the transaction price variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company used significant judgment when it determined the first step of variable consideration.

## Comparison of Fiscal 2019 to Fiscal 2018

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2019 and 2018:

	Year ended	l August 31,	
Operating Data:	2019	2018	
	(dollar amount	ts in thousands)	
Revenues	\$ 2,703	\$ 2,449	
Cost of revenues (income)	90	(86)	
Research and development expenses	13,522	11,979	
General and administrative expenses	3,722	4,083	
Financial income, net	576	800	
Loss before taxes on income	14,055	12,727	
Taxes on income	300	-	
Net loss for the year	14,355	12,727	
Loss per common share – basic and diluted	\$ 0.82	\$ 0.86	
Weighted average common shares outstanding	17,454,489	14,882,356	

#### 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 2019 increased by 10% to \$2,703,000 from \$2,449,000 for fiscal 2018. The increase is mainly attributed to milestone payments received during fiscal 2019 in connection with the License Agreement which are recognized through the expected product submission date using a cost-to-cost 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 2019 increased to expense of \$90,000 compared to income of \$86,000 for fiscal 2018. The increase is attributed to an adjustment that was made during fiscal 2018 and related to a decrease in the royalties rate we are obligated to pay to the IIA from 3.5% to 3% due to the amendment of the applicable regulations. As a result, during fiscal 2018 we recorded income which effected our cost of revenues.

# 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 2019 increased by 13% to \$13,522,000 from \$11,979,000 for fiscal 2018. The increase is mainly attributed to expenses related to our Phase IIb three-month dose-ranging clinical trial 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 2019, stock-based compensation costs totaled \$231,000, as compared to \$575,000 during fiscal 2018. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods.

#### 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 2019 and 2018, we did not recognize any research and development grants. As of August 31, 2019, we incurred a liability to pay royalties to the IIA of \$390,810.

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.

#### 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 decreased by 9% from \$4,083,000 for fiscal 2018 to \$3,722,000 for fiscal 2019. The decrease in costs incurred related to general and administrative activities during fiscal 2019, is primarily attributable to a decrease in stock-based compensation costs and is partially offset by an increase in salaries and related expenses. During fiscal 2019, as part of our general and administrative expenses, we incurred expenses of \$591,000 related to stock-based compensation costs, as compared to \$972,000 during fiscal 2018. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods and to option forfeitures during the period.

## Financial income, net

Net financial income, net was \$576,000 for fiscal 2019 as compared to net financial income of \$800,000 for fiscal 2018. The decrease is mainly attributable to a decrease in fair market value of some investments and to the change in accounting method which classifies such losses under profit and loss rather than other comprehensive income.

## Taxes on income

Taxes on income were \$300,000 recognized for fiscal 2019 as compared to no tax expenses in fiscal 2018. The increase is due to the withholding taxes during 2019 in connection with the receipt of a milestone payment pursuant to the License Agreement, while no withholding taxes applied in fiscal 2018.

# Comparison of Fiscal 2018 to Fiscal 2017

For a discussion of fiscal 2018 compared to fiscal 2017, see Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended August 31, 2018.

## **Liquidity and Capital Resources**

From our inception through August 31, 2019, we have incurred losses in an aggregate amount of \$81,103,000. 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 \$77,790,000, net of transaction costs. During that period we also received cash consideration of \$5,879,000 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, 2019, we had \$3,329,000 of available cash, \$25,253,000 of short term and long term deposits and \$4,996,000 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.

As of August 31, 2019, our total current assets were \$33,324,000 and our total current liabilities were \$5,308,000. On August 31, 2019, we had a working capital surplus of \$28,016,000 and an accumulated loss of \$81,103,000. 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. The increase in working capital surplus from August 31, 2018 to August 31, 2019 was primarily due to an increase in short term deposits.

During fiscal 2019, cash and cash equivalents decreased to \$3,329,000 from \$4,996,000 as of August 31, 2019, which is due to the reasons described below

Operating activities used cash of \$12,940,000 in fiscal 2019 compared to \$14,657,000 used in fiscal 2018. Cash used in operating activities in fiscal 2019 primarily consisted of net loss resulting from research and development and general and administrative expenses and changes in stock based compensation, while cash used by 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.

Investing activities used cash of \$11,259,000 in fiscal 2019, as compared to \$7,004,000 provided in fiscal 2018. Cash used in investing activities in fiscal 2019 consisted primarily of the proceeds from short term deposits, partially offset by the acquisition of short and long term marketable securities, while cash provided by 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.

There were no financing activities in 2019 compared to cash provided by financing activities of \$22,654,000 in fiscal 2018. Cash provided by financing activities during fiscal 2018 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 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, 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, or the Offering. The Warrants became 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 2019, no warrants or options were exercised. 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.
- In October and November 2018 and February and May 2019, we issued a total of 13,194 shares of our common stock, valued approximately \$54,000, in the aggregate, to certain service providers as remuneration for services rendered.
- On September 5, 2019, we entered into an Equity Distribution 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 \$15,000,000, 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 September 5, 2019. We will pay the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Sales Agreement. As of August 31, 2019, no shares were sold under the Sales Agreement.

# **Contractual Obligations**

The following table summarizes our significant contractual obligations and commercial commitments at August 31, 2019, and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

		]	Less than					
Contractual Obligations	 Total		1 year	 1-3 years	3-	-5 years	Over	5 years
Clinical research study obligations	\$ 3,400	\$	3,400	\$ 	\$	-	\$	
Purchase and technology transfer obligations	2,639		2,639	-		-		-
Operating lease obligations	120		45	75		3		-
Royalty payment obligations	391		81	162		148		-
Accrued severance pay, net	19		-	-		-		19
Total	\$ 6,569	\$	6,156	\$ 237	\$	148	\$	19

## **Off-Balance Sheet Arrangements**

As of August 31, 2019, 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, 2019, we had \$3.3 million in cash and cash equivalents, \$25.2 million in short and long term bank deposits and \$5.0 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, 2019, we own net balances in NIS of approximately \$717,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate gain of approximately \$80,000, while assuming a 10% devaluation of the NIS against the U.S. dollar, we would experience an exchange rate loss of approximately \$65,000.

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	Year Ended August 31,		
	2019	2018	2017	
Average rate for period	3.623	3.544	3.697	
Rate at period-end	3.535	3.604	3.596	

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, 2019. 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, 2019 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, 2019 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, 2019 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
Naday Kidron	45	President, Chief Executive Officer and Director
ivadav Kidioli	73	Testaent, Chief Executive Officer and Director
Miriam Kidron	79	Chief Scientific Officer and Director
Avraham Gabay	34	Chief Financial Officer, Treasurer and Secretary
Avranam Gabay	J <del>4</del>	Chief Philancial Officer, Treasurer and Secretary
Joshua Hexter	49	Chief Operating & Business Officer
Aviad Friedman	48	Director
Avida i irodinan	10	Bilector
Kevin Rakin	59	Director
Leonard Sank	54	Director
Zeomara Same	υ.	
Gao Xiaoming	57	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.

Mr. Avraham Gabay was appointed Chief Financial Officer, Treasurer and Secretary effective June 2019. Prior to his appointment, from March 2015 until May 2019, Mr. Gabay served as a corporate controller at Orcam Technologies Ltd., a company which develops, manufactures and sells a wearable assistive technology device for people who are blind, visually impaired or have reading or other disabilities. From 2014 to 2015, Mr. Gabay provided economic services in the advisory department of KPMG Israel, a certified public accounting firm. From 2013 until 2014, Mr. Gabay worked in the tax department of the law firm, Gornitzky & Co. Mr. Gabay holds a bachelor's degree in law and accounting from Tel-Aviv University and is a certified public accountant in Israel and a member of the Israeli Bar Association.

Mr. Joshua Hexter was appointed Chief Operating & Business Officer, effective September 2019. Prior to his appointment, Mr. Hexter served as Chief Business Officer at BrainsWay Ltd. (Nasdaq/TASE: BWAY) from 2018 to 2019, a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products. From 2013 to 2018, Mr. Hexter served as Chief Operating Officer and VP Business Development of the Company and from 2007 to 2013, Mr. Hexter was a Director or Executive Director of BioLineRx Ltd. (Nasdaq/TASE: BLRX), a biopharmaceutical development company dedicated to identifying, in-licensing and developing innovative therapeutic candidates. Prior to his employment with BioLineRx, Mr. Hexter was a member of the board of directors and Chief Executive Officer of Biosensor Systems Design, Inc., a company developing market-driven biosensors. Mr. Hexter holds a bachelor's degree from the University of Wisconsin and a master's degree in management from Boston University.

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.

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. Gao Xiaoming* became a *director* in July 2019. Mr. Gao has more than 25 years' experience in the bio-pharmaceutical field. Mr. Gao has experience in the registration, license-in, sales and promotion of pharmaceuticals and was involved in the introduction of Novo Nordisk (Denmark)'s insulin into China. Mr. Gao is proficient in the insulin industry. From 2005 to 2009, Mr. Gao led a team for the registration of imported Insulin-SciLin in China and obtained an Imported Drug License. Since 2007, Mr. Gao founded Hefei Tianmai Biotechnology Development Co., Ltd. and HTIT, which are committed to the research, development and commercialization of high-tech bio-pharmaceutical products. Mr. Gao is the Chairman and chief executive officer of HTIT.

We believe that Mr. Gao's qualifications to serve on our Board include his years of experience in the bio-pharmaceutical industry as well as his experience and familiarity with the Eastern market.

#### **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 Aviad Friedman, Kevin Rakin, Leonard Sank and Xiaoming Gao are independent as defined under the rules promulgated by the Nasdaq. Other than Mr. Gao, none of the independent directors has any relationship with us besides serving on our Board. Mr. Gao is the chairman chief executive officer of HTIT, a stockholder holding more than 5% of our common stock, but does not otherwise have any relationship with us. The Board considered this relationship and determined that they would not interfere with Mr. Gao'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 2019, our Board held 5 meetings and took actions by written consent on 5 occasions. All of our directors attended at least 75% of the aggregate number of meetings of the Board and the committees that were held during the period such director served on the Board. 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, Kevin Rakin and Leonard Sank. 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.

# **Delinquent Section 16(a) Reports**

Based solely upon a review of Forms 3, 4 and 5, and amendments thereto, furnished to us during fiscal 2019, we believe that during fiscal 2019, our executive officers, directors and all persons who own more than ten percent of a registered class of our equity securities complied with all Section 16(a) filing requirements, except: (a) Mr. Avraham Gabay, our Chief Financial Officer, Treasurer and Secretary, failed to timely file a Form 4 reporting his June 17, 2019 acquisition of 33,146 shares of our common stock. Mr. Gabay filed a Form 4 reporting this transaction on June 27, 2019, and (b) Mr. Xiaoming Gao, a member of our board of directors, failed to timely file a Form 3 reporting his status as a reporting person effective July 1, 2019. Mr. Gao filed a Form 3 reporting his status on July 19, 2019.

# **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 2019 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 made awards during fiscal 2019 to executives under our Second Amended and Restated 2008 Stock Incentive Plan, or 2008 Plan. Beginning September 11, 2019, the Compensation Committee began making awards to executives under our 2019 Stock Incentive Plan, or 2019 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 grants; and (iv) benefits and perquisites.

In establishing overall executive compensation levels and making specific compensation decisions for our NEOs in fiscal 2019, 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.

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 2019, our Compensation Committee did not increase the base salaries of our NEOs.

# 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 generally provides for annual installments for new grants, though the Compensation Committee also utilizes quarterly vesting from time to time. The Compensation Committee believes that time-based vesting encourages recipients to build stockholder value over a long period of time.

# Benefits and Perquisites

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

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

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 2019, such relocation expenses totaled approximately \$486,000, 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 2019.

# 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

# SUMMARY COMPENSATION TABLE

The following table sets forth the compensation earned by our NEOs for fiscals 2019, 2018 and 2017.

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	2019	419,460	224,975		398,910	507,750	1,551,095
President and CEO and director	2018	436,310	148,795	_	522,569	442,326	1,550,000
(7)	2017	399,804	123,000	-	585,150	45,579	1,153,533
Miriam Kidron	2019	267,386	123,149	-	211,128	14,503	616,166
Chief Scientific Officer and	2018	273,595	46,614	-	253,204	13,643	587,056
director (8)	2017	254,765	50,000	581,932	359,224	12,775	1,258,696
Hilla Eisenberg	2019	80,145	23,859	-	75,113	11,669	190,786
Chief Financial Officer (9)	2018	140,518	9,985	-	80,810	26,099	257,412
	2017	87,045	-	-	112,978	16,133	200,023
Avraham Gabay	2019	32,122	-	-	73,928	9,441	115,491
Chief Financial Officer (10)							
Mark Hasleton VP Business	2019	114,118	-	-	45,677	18,949	178,745
Development (11)							

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

- (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) Ms. Eisenberg resigned from her positions with us, effective May 25, 2019.
- (10) Mr. Gabay was appointed as Chief Financial Officer, Treasurer and Secretary effective June 1, 2019.
- (11) Mr. Hasleton was appointed as VP Business Development effective November 15, 2018 and terminated his employment effective August 27, 2019.

<sup>(2)</sup> 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.

<sup>(3)</sup> Bonuses were granted at the discretion of the Compensation Committee.

<sup>(4)</sup> 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.

<sup>(5)</sup> 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.

# **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	2019	21,090			486,660	507,750
	2018	12,596			429,730	442,326
	2017	28,098			17,481	45,579
Miriam Kidron	2019	14,503				14,503
	2018	13,643				13,643
	2017	12,775				12,775
Hilla Eisenberg	2019		7,750	3,919		11,669
	2018		17,333	8,766		26,099
	2017		10,691	5,442		16,133
Avraham Gabay	2019	2,808	4,405	2,228		9,441
Mark Hasleton	2019	10,186	5,505	3,258		18,949

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.

# **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.

<sup>\*\*</sup> Relocation expenses represents additional compensation 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.

We, through Oramed Ltd., 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 gross monthly salary was NIS 35,700. In addition, Ms. Eisenberg was provided with a cellular phone and travel reimbursement pursuant to the terms of her agreement. Ms. Eisenberg resigned from her positions with us, effective May 25, 2019.

We, through Oramed Ltd., have entered into an employment agreement with Avi Gabay as of May 16, 2019, pursuant to which Mr. Gabay was appointed as Chief Financial Officer, Treasurer and Secretary of the Company and Oramed Ltd., effective June 1, 2019. In accordance with the employment agreement, as amended, Mr. Gabay's current gross monthly salary is NIS 35,000. In addition, Mr. Gabay is provided with a cellular phone and a company car pursuant to the terms of his agreement.

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

Potential Payments upon Termination or Change-in-Control

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

Pension, Retirement or Similar Benefit Plans

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

# GRANTS OF PLAN-BASED AWARDS

The following table shows grants of plan-based equity awards made to our NEOs during fiscal 2019:

		Options Awards: Number of Securities Underlying Options	Grant Date Fair Value of Stock Awards
Name	Grant Date	(#)	(\$)
Nadav Kidron <sup>(1)</sup> *	2/26/2019	196,500	398,810
Miriam Kidron <sup>(2)</sup> *	2/26/2019	104,000	211,128
Hilla Eisenberg <sup>(3)</sup>	2/26/2019	37,000	75,113
Avraham Gabay (4)*	6/17/2019	33,146	73,928
Mark Hasleton (5)	2/26/2019	22,500	45,677

<sup>(1)</sup> These options were granted under our 2008 Plan and vest in 4 equal installments of 49,125 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022.

<sup>(2)</sup> These options were granted under our 2008 Plan and vest in 4 equal installments of 26,000 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022.

These options were granted under our 2008 Plan and vest in 4 equal installments of 9,250 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022.

<sup>(4)</sup> These options were granted under our 2008 Plan. 5,396 of the options shall vest on December 31, 2019 and the remining options shall vest in 3 equal installments of 9,250 on each of December 31, 2020, December 31, 2021 and December 31, 2022.

<sup>(5)</sup> These options were granted under our 2008 Plan and vest in 4 equal installments of 5,625 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022.

<sup>(\*)</sup> On September 11, 2019, the options in this table were canceled and re-granted under the 2019 Plan in the same amounts and under the same terms as the original grants.

# **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, 2019.

		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)	<del></del>	5.88	4/20/20				
	$72,000^{(2)}$	-	4.08	8/8/22				
	47,134 <sup>(3)</sup>	-	12.45	4/9/24				
	49,000 <sup>(4)</sup>	98,000(4) 97,000(5)	7.77 8.14	6/30/27 1/31/28				
					0(8)(9)	0		
		196,500(11)(14)	3.16	2/26/29				
Miriam Kidron	72,000 <sup>(1)</sup>	-	5.88	4/20/20				
	$72,000^{(2)}$	-	4.08	8/8/22				
	47,134 <sup>(3)</sup>	-	12.45	4/9/24				
	23,333 <sup>(6)</sup>	46,666(6)	7.77	6/30/27				
		47,000(7)	8.14	1/31/28				
		104,000(12)(14)	3.16	2/26/29	0(10)	0		
Avraham Gabay	_	33,146(13)(14)	3.55	6/17/29				

<sup>(1)</sup> 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.

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.

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.

- 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, 49,000 of such options were forfeited on December 31, 2018 as a result of the Company's share price not reaching the target and the remaining 49,000 vest on December 31, 2019, subject to the Company share price reaching the target of \$12.50 per share. The options expire on June 30, 2027.
- 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; 24,250 of such options vested on January 1, 2019 and the remaining options vest in 3 equal installments of 24,250 on each of January 1, 2020, January 1, 2021 and January 1, 2022. The options expire on January 31, 2028.
- 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, 23,000 of such options vested on December 31, 2018 and the remaining 23,000 of such options vest on 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; 11,750 of such options vested on January 1, 2019 and the remaining options vest in 3 equal installments of 11,750 on each of 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.
- On February 26, 2019, 196,500 options were granted to Nadav Kidron under the 2008 Plan at an exercise price of \$3.16 per share; the options vest in four installments of 49,125 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022.
- On February 26, 2019, 104,000 options were granted to Miriam Kidron under the 2008 Plan at an exercise price of \$3.16 per share; the options vest in four installments of 26,000 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022.
- On June 17, 2019, 33,146 options were granted to Avraham Gabay under the 2008 Plan at an exercise price of \$3.55 per share; 5,396 of the options shall vest on December 31 and the remining options shall vest in 3 equal installments of 9,250 on each of December 31, 2020, December 31, 2021 and December 31, 2022.
- On September 11, 2019, the options were canceled and re-granted under the 2019 Plan in the same amounts and under the same terms as the original grants.

# **Compensation Committee Interlocks and Insider Participation**

During fiscal 2019, 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 2019:

Name of Director	Fees Earned or Paid in Cash (\$)	Stock Awards (2) (\$)	Option Awards (3) (\$)	All Other Compensation (\$)	Total (\$)
Nadav Kidron <sup>(1)</sup>	-	-	-	-	_
Miriam Kidron (1)	-	-	-	-	-
Aviad Friedman	20,000	-	-	-	20,000
Xiaoming Gao <sup>(4)</sup>	3,333	-	-	-	3,333
Xiaopeng Li <sup>(4)</sup>	16,667	-	-	-	16,667
Kevin Rakin <sup>(5)</sup>	20,000	-	24,648	-	44,648
Leonard Sank	20,000	-	-	-	20,000
David Slager <sup>(6)</sup>	20,000	-	40,554	-	60,554

- (1) Please refer to the Summary Compensation Table for executive compensation with respect to the named individual.
- (2) As of August 31, 2019, our non-employee directors then in office held options to purchase shares of our common stock as follows:

	Aggregate
	Number
	of Shares
	Underlying
	Stock
Name of Director	Awards
Aviad Friedman	32,857
Kevin Rakin	72,470
Leonard Sank	74,867
Xiaoming Gao	_

- (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.
- (4) Ms. Li resigned from the board as of June 25, 2019. Mr. Gao joined the board as of July 1, 2019.

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 2019.

- (5) On September 11, 2019, 10,000 of the options were canceled and re-granted under the 2019 Plan in the same amounts and under the same terms as the original grants.
- (6) Mr. Slager ceased to be a director as of August 29, 2019.

# 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, 2019, options with respect to 2,512,994 shares have been granted, of which 148,658 have been forfeited, 182,227 have been exercised and 860,065 have expired. As of August 31, 2019, 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.

In August 2019, the Company became aware of a shareholder derivative claim and putative class action alleging, among other things, that the 2008 Plan may have terminated in 2018. However, the Company disputes these claims and believes that the 2008 Plan does not terminate until 2026 and any suggestion to the contrary is not well-founded. For the sake of clarity and out of an abundance of caution, the Company adopted the 2019 Plan, which was approved at the Company's 2019 shareholders meeting. The 2019 Plan allows the Company to grant up to 1,000,000 options. Since the Company had granted options during the time after the old plan allegedly terminated, and out of an abundance of caution, the Company canceled these grants and re-granted certain of the options under 2019 Plan in the same amounts and under the same terms as the original grants.

The following table sets forth additional information with respect to our equity compensation plans as of August 31, 2019:

Plan category	Number of securities to be issued upon exercise of outstanding options, RSUs and rights (a)	Weight averag exercis price o outstand options, R and righ (b)	e compensation e plans f (excluding ing securities SUs reflected in
Equity compensation plans approved by security holders	1,498,933		5.26 404,023
Equity compensation plans not approved by security holders			
Total	1,498,933	\$	5.26 404,023

# Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our common stock as of November 26, 2019 by: (1) each person who is known by us to own beneficially more than 5% of our common stock; (2) each director; (3) each of our NEOs listed above under "Summary Compensation Table"; and (4) all of our directors and current executive officers as a group. On such date, we had 17,383,359 shares of common stock outstanding.

As used in the table below and elsewhere in this form, the term "beneficial ownership" with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following November 26, 2019. Inclusion of shares in the table does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares. Unless otherwise indicated, (1) each person or entity named in the table has sole voting power and investment power (or shares that power with that person's spouse) with respect to all shares of common stock listed as owned by that person or entity and (2) the address of each of the individuals named below is: c/o Oramed Pharmaceuticals Inc., 1185 Avenue of the Americas, Suite 228, New York, NY 10036.

	Number of	Percentage of Shares Beneficially
Name and Address of Beneficial Owner	Shares	Owned
Regals Fund LP		
152 West 57th Street, 9th Floor		
New York, NY 10019	1,316,328(1)	7.6%
HTIT		
No. 199 Fanhua Road		
Economic and Technological Development Zone		
Heifei, Anhui Province, P.R. China, Zip Code: 230601	1,155,367(2)	6.6%
Sabby Volatility Warrant Master Fund, Ltd.		
c/o Ogier Fiduciary Services (Cayman) Limited		
89 Nexus Way, Camana Bay		
Grand Cayman KY1-9007		
Cayman Islands	933,050(3)	5.4%
Nadav Kidron #+	2,669,938(4)	15.4%
Miriam Kidron #+	385,633(5)	2.2%
Hilla Eisenberg+	1,000	*
Aviad Friedman #	43,048(6)	*
Avraham Gabay+		
Xiaoming Gao #	1,155,367(7)	6.6%
Kevin Rakin #	77,531(8)	*
Leonard Sank #	666,880(9)	3.8%
Mark Hasleton+		
All current executive officers and directors, as a group (eight persons)	3,936,465(10)	22.4%

Less than 1%

<sup>#</sup> Director

<sup>+</sup> NEO

<sup>(1)</sup> Regals Management is the investment manager of Regals Fund LP, the owner of record of these shares of common stock. Mr. David Slager, a former director of the Company, is the managing member of the general partner of Regals Management. All investment decisions are made by Mr. Slager, and thus the power to vote or direct the votes of these shares of common stock, as well as the power to dispose or direct the disposition of such shares of common stock is held by Mr. Slager through Regals Management.

- Based solely on a Schedule 13D filed by HTIT on January 6, 2016. On November 30, 2015, we entered into a securities purchase agreement with HTIT pursuant to which, among other things, Nadav Kidron will serve as proxy and attorney in fact of HTIT, with full power of substitution, to cast on behalf of HTIT all votes that HTIT is entitled to cast with respect to 1,155,367 shares of common stock, or the Purchased Shares, at any and all meetings of our stockholders, to consent or dissent to any action taken without a meeting and to vote all the Purchased Shares held by HTIT in any manner Mr. Kidron deems appropriate except for matters related to our activities in the People's Republic of China, on which Mr. Kidron will consult with HTIT before taking any action as proxy.
- (3) Includes 933,050 shares of common stock owned by Sabby Volatility Warrant Master Fund, Ltd., or Sabby Volatility. Sabby Management, LLC, or Sabby Management, is the investment manager of Sabby Volatility, and Hal Mintz, or Mr. Mintz is the manager of Sabby Management. The foregoing is based solely on a Schedule 13G filed jointly by Sabby Volatility, Sabby Management and Mr. Mintz on January 7, 2019.
- (4) Includes 337,759 shares of common stock issuable upon the exercise of outstanding stock options and 89,636 shares of Common Stock underlying vested RSUs that are issuable upon request. Also includes 1,155,367 shares of common stock held by HTIT, as further described in footnote (2) above, and 218,603 shares of common stock held by Xiaopeng Li, former director of the Company.
- (5) Includes 310,633 shares of common stock issuable upon the exercise of outstanding stock options and 75,000 shares of Common Stock underlying vested RSUs that are issuable upon request.
- (6) Includes 20,857 shares of common stock issuable upon the exercise of outstanding stock options and 12,191 shares of common stock owned by Shikma, of which Mr. Friedman is the sole owner and chief executive officer. All investment decisions are made by Mr. Friedman, and thus the power to vote or direct the votes of these shares of common stock, as well as the power to dispose or direct the disposition of such shares of common stock is held by Mr. Friedman through Shikma.
- (7) Includes 1,155,367 shares of common stock held by HTIT. Mr. Gao is the chairman of HTIT.
- (8) Includes 62,470 shares of common stock issuable upon the exercise of outstanding stock options.
- (9) Includes: (a) 374,999 shares of common stock held by Mr. Sank; (b) 78,125 shares of common stock held by Mr. Sank's wife; (c) 74,867 shares of common stock issuable to Mr. Sank upon the exercise of outstanding stock options; and (d) 138,889 shares of common stock owned by a company wholly owned by a trust of which Mr. Sank is a trustee. Mr. Sank disclaims beneficial ownership of the securities referenced in (b) and (d) above.
- (10) Includes 830,021 shares of common stock issuable upon the exercise of options beneficially owned by the referenced persons and 164,636 shares of common stock underlying vested RSUs that are issuable upon request.

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

During fiscals 2019 and 2018, except for compensation arrangements described elsewhere herein, we did not participate in any transaction, and we are not currently participating in any proposed transaction, or series of transactions, in which the amount involved exceeded the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which, to our knowledge, any of our directors, officers, five percent beneficial security holders, or any member of the immediate family of the foregoing persons had, or will have, a direct or indirect material interest.

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

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

The Board has determined that Leonard Sank, Kevin Rakin, Aviad Friedman and Xiaoming Gao are independent as defined under the rules promulgated by Nasdaq.

# ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The aggregate fees billed by Kesselman & Kesselman, independent registered public accounting firm, and member firm of PricewaterhouseCoopers International Limited, for services rendered to us during fiscals 2019 and 2018:

	201	19	 2018
Audit Fees <sup>(1)</sup>	\$	97,000	\$ 111,000
Audit-Related Fees		-	-
Tax Fees <sup>(2)</sup>		8,000	9,000
All Other Fees		-	-
Total Fees	\$ 1	105,000	\$ 120,000

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

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

The Audit Committee pre-approves all services provided by our independent registered public accounting firm. All of the above services and fees were reviewed and approved by the Audit Committee before the services were rendered.

# PART IV

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

# (a) Index to Financial Statements

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

		 Page
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOU	NTING FIRM	F - 1
CONSOLIDATED FINANCIAL STATEMENTS:		
Balance sheets		F - 2
Statements of comprehensive loss		F - 3
Statements of changes in stockholders' equity		F - 4
Statements of cash flows		F - 5
Notes to financial statements		F - 6 - F - 34
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	30	



# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Oramed Pharmaceuticals Inc.

# **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Oramed Pharmaceuticals Inc. and its subsidiaries (the "Company") as of August 31, 2019 and 2018, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended August 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of August 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended August 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 1(k) to the consolidated financial statements, the Company changed the manner in which it accounts for revenues from contracts with customers during the year ended August 31, 2019.

# Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

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

Tel Aviv, Israel November 27, 2019

We have served as the Company's auditor since 2008.

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel, P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

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

	Aug		ıst 31,	
		2019		2018
ASSETS				
CURRENT ASSETS:	¢.	2 220	Ф	4.006
Cash and cash equivalents	\$	3,329	\$	4,996
Short-term deposits (note 2)		25,252		20,875
Marketable securities (note 3) Prepaid expenses and other current assets		3,701		4,592
• •		1,042		574
Total current assets		33,324		31,037
LONG-TERM ASSETS:				
Long-term deposits and investment (note 4)		1		13,542
Marketable securities (note 3)		1,295		2,785
Amounts funded in respect of employee rights upon retirement		19		16
Property and equipment, net		24		17
Total long-term assets		1,339		16,360
Total assets	\$	34,663	\$	47,397
	_			
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued expenses (note 5)	\$	2,541	\$	2,058
Deferred revenues		2,703		2,449
Payable to related parties (note 11c)		64		46
Total current liabilities		5,308		4,553
LONG-TERM LIABILITIES:				
Deferred revenues		9.658		11,388
Employee rights upon retirement		22		20
Provision for uncertain tax position (note 10f)		11		11
Other liabilities		271		313
Total long-term liabilities		9,962		11,732
COMMITMENTS (note 6)				
CTOCKHOLDERG FOLLTV				
STOCKHOLDERS' EQUITY:				
Common stock, \$ 0.012 par value (30,000,000 authorized shares as of August 31, 2019 and 2018; 17,383,359 and		200		207
17,369,875 shares issued and outstanding as of August 31, 2019 and 2018, respectively) Additional paid-in capital		208 100,288		207 99,426
Accumulated other comprehensive income		100,288		702
Accumulated other comprehensive income Accumulated deficit		(91 102)		
		(81,103)		(69,223)
Total stockholders' equity		19,393	-	31,112
Total liabilities and stockholders' equity	\$	34,663	\$	47,397

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

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

	Year ended August 31,					
		2019		2018		2017
REVENUES	\$	2,703	\$	2,449	\$	2,456
COST OF REVENUES (INCOME) (note 6g)		90		(86)		187
RESEARCH AND DEVELOPMENT EXPENSES		13,522		11,979		10,281
GENERAL AND ADMINISTRATIVE EXPENSES		3,722		4,083		2,759
OPERATING LOSS		14,631		13,527		10,771
FINANCIAL INCOME (note 9a)		1,061		903		792
FINANCIAL EXPENSES (note 9b)		485		103		101
LOSS BEFORE TAXES ON INCOME		14,055		12,727		10,080
TAXES ON INCOME (note 10d)		300		-		400
NET LOSS FOR THE YEAR	\$	14,355	\$	12,727	\$	10,480
UNREALIZED INCOME ON AVAILABLE FOR SALE SECURITIES				(301)		(295)
TOTAL OTHER COMPREHENSIVE INCOME	_		_		_	
			_	(301)	_	(295)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$	14,355	\$	12,426	\$	10,185
LOSS PER SHARE OF COMMON STOCK:						
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	¢	0.82	\$	0.86	\$	0.79
	Φ	0.82	Ф	0.80	Þ	0.79
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN						
COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK		17,454,489		14,882,356		13,309,372

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

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY U.S. Dollars in thousands (except share data)

		on Stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	\$		capital	income	deficit	equity
	In thousands						
BALANCE AS OF AUGUST 31, 2016	13,183		157	71,943	106	(46,016)	26,190
ISSUANCE OF COMMON STOCK, NET	3		*	25	-	-	25
SHARES ISSUED FOR SERVICES	10		*	72	-	-	72
EXERCISE OF WARRANTS AND OPTIONS	313		4	1,557	-	-	1,561
STOCK-BASED COMPENSATION	159		2	1,573	-	-	1,575
OTHER COMPREHENSIVE INCOME	-		-	-	295	-	295
NET LOSS						(10,480)	(10,480)
BALANCE AS OF AUGUST 31, 2017	13,668		163	75,170	401	(56,496)	19,238
ISSUANCE OF COMMON STOCK AND							
WARRANTS, NET	3,466		42	21,615	-	-	21,657
SHARES ISSUED FOR SERVICES	14		*	99	-	-	99
EXERCISE OF WARRANTS AND OPTIONS	189		2	995	-	-	997
STOCK-BASED COMPENSATION	32		*	1,547	-	-	1,547
OTHER COMPREHENSIVE INCOME	-		-	-	301	-	301
NET LOSS						(12,727)	(12,727)
BALANCE AS OF AUGUST 31, 2018	17,369	\$	207	\$ 99,426	\$ 702	\$ (69,223)	\$ 31,112
INITIAL ADOPTION OF ASU 2016-01					(702)	702	0
INITIAL ADOPTION OF ASC 606						1,773	1,773
SHARES ISSUED FOR SERVICES	14		1	54			55
STOCK-BASED COMPENSATION				808			808
NET LOSS						(14,355)	(14,355)
BALANCE AS OF AUGUST 31, 2019	17,383		208	100,288	0	(81,103)	19,393

<sup>\*</sup> Represents an amount of less than \$1.

The accompanying notes are an integral part of the financial statements

# CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. Dollars in thousands

	Year ended August 31,			
		2019	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$	(14,355) \$	(12,727)	\$ (10,480)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Depreciation		8	6	5
Exchange differences and interest on deposits and held to maturity bonds		(183)	22	124
Stock-based compensation		808	1,547	1,575
Change in fair value of investments		437	-	-
Shares issued for services		55	99	72
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(468)	(415)	39
Accounts payable, accrued expenses and payable to related parties		501	(612)	1,257
Deferred revenue		297	(2,449)	1,520
Liability for employee rights upon retirement		2	2	4
Provision for uncertain tax position			-	-
Other liabilities		(42)	(130)	53
Total net cash used in operating activities		(12,940)	(14,657)	(5,831)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment		(15)	(5)	(7)
Purchase of short-term deposits		(24,990)	(7,101)	(3,557)
Purchase of long-term deposits		(4,237)	(15,040)	(17,230)
Purchase of held to maturity securities		(1,357)	(4,429)	(3,869)
Proceeds from maturity of short-term deposits		38,611	17,316	26,551
Proceeds from maturity of held to maturity securities		3,250	2,257	2,417
Funds in respect of employee rights upon retirement		(3)	(2)	(3)
Total net cash provided by (used in) investing activities		11,259	(7,004)	4,302
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of common stock and warrants, net of issuance costs		-	21,657	25
Proceeds from exercise of warrants and options		-	997	1,561
Total net cash provided by financing activities			22,654	1,586
EFFECT OF EXCHANGE RATE CHANGES ON CASH		14	34	5
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(1,667)	1,027	62
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		4,996	3,969	3,907
	_			
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$	3,329 \$	4,996	\$ 3,969
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -				
Interest received	\$	929 \$	826	\$ 833
Taxes paid	\$	300 \$	-	\$ 400

The accompanying notes are an integral part of the financial statements

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

# **NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:**

#### a. General

# 1) Incorporation and operations

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

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd. (the "Subsidiary"), which is engaged in research and development.

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

On July 30, 2019, the Company's subsidiary incorporated a wholly-owned subsidiary in Hong Kong, Oramed HK Limited. As of August 31, 2019, Oramed HK Limited has no operation.

On November 30, 2015, the Company entered into a Technology License Agreement with Hefei Tianhui Incubation of Technologies Co. Ltd. ("HTIT") and on December 21, 2015, the parties entered into an Amended and Restated Technology License Agreement that was further amended by the parties on June 3, 2016 and July 24, 2016 (the "License Agreement"). According to the License Agreement, the Company granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong (the "Territory"), related to the Company's oral insulin capsule, ORMD-0801 (the "Product"). Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to the Subsidiary's technology and ORMD-0801 capsule, and will pay to the Subsidiary (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory ("Royalties"), and (ii) an aggregate of \$37,500, of which \$3,000 was payable immediately, \$8,000 will be paid subject to the Company entering into certain agreements with certain third parties, and \$26,500 will be paid upon achievement of certain milestones and conditions. In the event that the Company does not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of the Company's patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

The royalty payment obligation shall apply during the period of time beginning upon the first commercial sale of the Product in the Territory, and 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 (the "Royalty Term").

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

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

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

As of August 31, 2019 the Company has received milestone payments in an aggregate amount of \$20,500 as follows: the initial payment of \$3,000 was received in January 2016. Following the achievement of certain milestones, the second and third payments of \$6,500 and \$4,000, respectively, were received in July 2016, the fourth milestone payment of \$4,000 was received in October 2016 and the fifth milestone payment of \$3,000 was received in January 2019.

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

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

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

Amounts that were allocated to the License Agreement as of August 31, 2019 aggregated \$22,382, all of which were received through the balance sheet date. Through August 31, 2019, the Company recognized revenue in the amount of \$10,021, and deferred the remaining amount of \$12,361.

The following table sets forth the transactions in deferred revenues balances for the years ended August 31, 2019 and 2018:

		August 31,			
	_	2019		2018	
Deferred revenue at the beginning of period	\$	13,837	\$	16,286	
Amounts received		3,000		-	
Initial adoption of ASC 606 (note 1k)		(1,773)		-	
Revenue recognized		(2,703)		(2,449)	
Deferred revenue at the end of period		12,361		13,837	
Less – current deferred revenue portion		(2,703)		(2,449)	
Non-current deferred revenue portion	\$	9,658	\$	11,388	

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

# 2) Development and liquidity risks

The Company is engaged in research and development in the biotechnology field for innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules for delivery of other polypeptides, and has not generated significant revenues from its operations. 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. 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, 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.

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

# b. Basis of presentation

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

# c. Use of estimates in the preparation of financial statements

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

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to stock-based compensation, expectation of milestone payments and to the expected product submission date for revenue recognition purposes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

# d. Functional currency

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

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

# e. Principles of consolidation

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

# f. Cash equivalents

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

# g. Fair value measurement:

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

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Observable prices that are based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of August 31, 2019, the assets measured at fair value are comprised of equity securities (Level 1). The fair value of held to maturity bonds as presented in note 3 was based on a Level 2 measurement.

As of August 31, 2019, the carrying amounts of cash equivalents, short-term deposits and accounts payable approximate their fair values due to the short-term maturities of these instruments.

As of August 31, 2019, the carrying amounts of long-term deposits approximate their fair values due to the stated interest rates which approximate market rates.

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

There were no Level 3 items for the years ended August 31, 2019, 2018 and 2017.

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

#### h. Marketable securities

# 1) Available-for-sale securities

In January 2016, the Financial Accounting Standards Board ("FASB") issued guidance which updates certain aspects of recognition, measurement, presentation and disclosure of financial assets and financial liabilities ("ASU 2016-01"). The guidance requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. The Company adopted the provisions of this update in the first quarter of fiscal year 2019. Following the adoption, as of September 1, 2018, the Company classified the available for sale securities (investments in equity securities of D.N.A Biomedical Solutions Ltd. ("D.N.A") and Entera Bio Ltd. ("Entera")) to financial assets measured at fair value through profit or loss. The Company adopted the standard using the modified retrospective method and, accordingly, reclassified the cumulative unrealized gain from accumulated other comprehensive income to a reduction of its accumulated deficit in an amount of \$702.

# 2) Held to maturity securities

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

# i. Concentration of credit risks

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

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

As of August 31, 2019, amounts due from HTIT with regard to expense reimbursements owed to the Company totaled \$805 and are included in the balance of prepaid expenses and other current assets. HTIT had paid \$390 of these reimbursements as of the date of issuing these financial statements.

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

# j. Income taxes

# 1. Deferred taxes

Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has provided a full valuation allowance with respect to its deferred tax assets. See note 10.

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

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

# 2. Uncertainty in income tax

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

# k. Revenue recognition

The License Agreement and the SPA were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of \$49,500 between the License Agreement and the SPA according to their fair value, as follows: \$10,617 was allocated to the issuance of common stock (less issuance expenses of \$23), based on the quoted price of the Company's shares on the closing date of the SPA on December 28, 2015, and \$38,883 was allocated to the License Agreement.

Under Accounting Standards Codification ("ASC") 605 (which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018) given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which the Company was entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees were earned.

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

On September 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2014-09 "Revenue from Contracts with Customers (Topic 606)" ("ASC 606"), using the modified retrospective method of adoption. Under this method, the Company applied ASC 606 to the License Agreement at the adoption date and was required to make an adjustment to the September 1, 2018 opening accumulated deficit balance. All prior periods continue to be presented under ASC 605. The most significant impact from adopting ASC 606 was the impact of the timing of recognition of revenue associated with the milestone payment. Under ASC 605, which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018, given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which the Company was entitled to the respective payment and the expected product submission date using a time-based model approach over the periods that the fees were earned. However, under ASC 606, the Company is required to recognize the total transaction price (which includes consideration related to milestones once the criteria for recognition have been satisfied) using the input method over the period the performance obligation is fulfilled. Accordingly, once the consideration associated with a milestone is included in the transaction price, incremental revenue is recognized immediately based on the period of time that has elapsed towards complete satisfaction of the performance obligation. This method results in the recognition of revenue earlier than under ASC 605, and the resulting impact was recorded as a reduction of the opening balance of accumulated deficit at September 1, 2018, as further described below.

Under ASC 606, the Company identified a single performance obligation in the agreement and determined that the license and services are not distinct as the license and services are highly dependent on each other. In other words, HTIT cannot benefit from the license without the related services, and vice versa.

Since the customer benefits from the services as the entity performs, revenue is recognized over time through the expected product submission date in June 2023, using the input method. The Company used the input method to measure the process for the purpose of recognizing revenue, which approximates the straight line attribution. The Company used significant judgment when it determined the product submission date.

Under ASC 606, the consideration that the Company would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events, are a form of variable consideration. When assessing the portion, if any, of such milestones-related consideration to be included in the transaction price, the Company first assesses the most likely outcome for each milestone and excludes the consideration related to milestones of which the occurrence is not considered the most likely outcome.

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The Company then evaluates if any of the variable consideration determined in the first step is constrained by including in the transaction price variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company used significant judgment when it determined the first step of variable consideration.

The potential future royalty consideration is also considered a form of variable consideration under ASC 606 as it is based on a percentage of potential future sales of the Company's products. However, the Company applies the sales-based royalty exception and accordingly will recognize the sales-based royalty amounts when the related sale has occurred. To date, the Company has not recognized any royalty-related revenue.

As of the adoption date, the Company adjusted its accumulated deficit by \$1,773 against contract liabilities due to the effect of variable consideration.

Amounts that were allocated to the License Agreement as of August 31, 2019 aggregated \$22,383, all of which was received through the balance sheet date. Through August 31, 2019, the Company recognized revenue associated with this agreement in the aggregate amount of \$10,022 (of which \$2,703 was recognized in the twelve-months period ended August 31, 2019 and \$1,773 was recognized as an increase to the September 1, 2018 opening balance of stockholders' equity associated with the impact of the adoption of ASC 606 under the modified retrospective method of adoption), and deferred the remaining amount of \$12,361, which is presented as a contract liability on the condensed consolidated balance sheet.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

In accordance with ASC 606, the disclosure of the impact of adoption to the Company's consolidated balance sheet as of August 31, 2019 was as follows:

	Au	reported gust 31, 2018	pdated otember 1, 2018	Effect of Change
Deferred revenue (short-term)	\$	2,449	\$ 1,230	\$ (1,219)
Deferred revenue (long-term)		11,388	10,834	(554)
Accumulated deficit		69,223	67,450	(1,773)

The impact of adoption of ASC 606 on the consolidated balance sheet as of August 31, 2019 and on the consolidated statement of operations for the twelve months ended August 31, 2019 was as follows:

	reported ugust 31, 2019	Balances without Adoption of ASC 606	fect of hange
Revenues	\$ 2,703	\$ 2,910	\$ (207)
Cost of revenues	90	90	-
Deferred revenue (short term)	2,703	3,112	(409)
Deferred revenue (long term)	9,658	10,815	(1,157)
Accumulated deficit	81,103	82,669	(1,566)

# l. Cost of revenues

Cost of revenues consists of royalties to the Israel Innovation Authority ("IIA") related to the License Agreement with HTIT. The royalties are recognized when proceeds related to the License Agreement are received.

# m. Research and development

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

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Clinical trial expenses are charged to research and development expense as incurred. The Company accrues for expenses resulting from obligations under contracts with clinical research organizations (CROs). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments are recorded as other assets, which will be recognized as expenses as services are rendered.

# n. Stock-based compensation

Equity awards granted to employees are accounted for using the grant date fair value method. The grant date fair value is determined as follows: for stock options and restricted stock units ("RSUs") with an exercise price using the Black Scholes pricing model, for stock options with market conditions using a Monte Carlo model and for RSUs with service conditions based on the grant date share price. The fair value of share based payment awards is recognized as an expense over the requisite service period. The expected term is the length of time until the expected dates of exercising the award and is estimated using the simplified method due to insufficient specific historical information of employees' exercise behavior, unless the award includes a market condition, in which case the contractual term is used. The volatility is based on a historical volatility, by statistical analysis of the weekly share price for past periods. The Company elected to recognize compensation cost for awards granted to employees that have a graded vesting schedule using the accelerated method based on the multiple-option award approach. For awards with only market conditions, compensation expense is not reversed if the market conditions are not satisfied.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable. The fair value of the options granted to consultants and other non-employees is measured on a final basis at the end of the related service period using the Black Scholes pricing model and is recognized over the related service period using the straight-line method.

On September 1, 2018, the Company adopted ASU 2017-09, "Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which gives direction on which changes to the terms or conditions of share-based payment awards require an entity to apply modification accounting in ASC Topic 718, see note 7b.

The Company elects to account for forfeitures as they occur.

# o. Loss per common share

Basic and diluted net loss per common share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding for each period. Outstanding stock options, warrants and RSUs have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The weighted average number of stock options, warrants and RSUs excluded from the calculation of diluted net loss was 4,423,325, 1,873,098 and 1,827,719 for the years ended August 31, 2019, 2018 and 2017, respectively.

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

# NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

# p. Newly issued Accounting Pronouncements

- 1) In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)" ("ASU 2016-02"), which supersedes the existing guidance for lease accounting, "Leases (Topic 840)". ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in ASU 2016-02 are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company adopted ASU 2016-02 on September 1, 2019 and expects the impact of this new standard on the consolidated financial statements to be approximately \$116 on right of use assets and lease liabilities and does not expect a material impact on its expenses.
- 2) In June 2016, the FASB issued ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326)" ("ASU 2016-13"). ASU 2016-13 requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis. The income statement reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

# **NOTE 2 - SHORT-TERM DEPOSITS:**

# Composition:

	August 31,					
	2019		2018	3		
	Annual		Annual			
	interest		interest			
	rate	Amount	rate	Amount		
Dollar deposits	1.80-3.44%	\$ 25,252	2.06-3.01%	\$ 20,875		

# **NOTE 3 - MARKETABLE SECURITIES:**

# a. Composition:

The Company's marketable securities include investments in equity securities of D.N.A, Entera and in held to maturity bonds.

# Composition:

		August 31,				
	- :	2019		2019		2018
Short-term:						
D.N.A (see b below)	\$	557	\$	666		
Entera (see c below)		304		632		
Held to maturity bonds (see d below)		2,840		3,294		
	\$	3,701	\$	4,592		
Long-term:						
Held to maturity bonds (see d below)	\$	1,295	\$	2,785		
	\$	4,996	\$	2,785		

# b. D.N.A

The D.N.A ordinary shares are traded on the Tel Aviv Stock Exchange. The fair value of those securities is measured at the quoted prices of the securities on the measurement date.

During the years ended August 31, 2019, 2018 and 2017, the Company did not sell any of the D.N.A ordinary shares. As of August 31, 2019, the Company owns approximately 6.9% of D.N.A's outstanding ordinary shares.

The cost of the securities as of August 31, 2019, 2018 and 2017 is \$595.

# c. Entera

Entera ordinary shares have been traded on Nasdaq since June 28, 2018. The Company measures the investment at fair value from such date, since it has a readily determinable fair value (prior to such date the investment was accounted for as a cost method investment (amounting to \$1)).

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

# NOTE 3 - MARKETABLE SECURITIES (continued):

# d. Held to maturity bonds

The amortized cost and estimated fair value of held-to-maturity securities at August 31, 2019, are as follows:

	August 31, 2019										
Amortized unrea		Gross ed unrealized gains		unrealized		d unrealized		Amortized unrealized			imated r value
\$	2,808	\$	6	\$	2,814						
	32		-		32						
	1,295		4		1,299						
\$	4,135	\$	10	\$	4,145						
		### Amortized cost  \$ 2,808	Amortized cost   G unre green	Amortized cost         Gross unrealized gains           \$ 2,808         \$ 6           32         -           1,295         4	Amortized cost unrealized gains Est fair  \$ 2,808 \$ 6 \$ 32 - 1,295 4						

As of August 31, 2019, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$1,295 and the yield to maturity rates vary between 2.55% to 3.20%.

The amortized cost and estimated fair value of held-to-maturity securities at August 31, 2018, are as follows:

	August 31, 2018					
			Amortized cost		Estimated fair value	
\$	3,259	\$ (17)	\$ 3,242			
	35	-	35			
	2,785	(17)	2,768			
\$	6,079	\$ (34)	\$ 6,045			
		* 3,259 35 2,785	Amortized cost         Gross unrealized losses           \$ 3,259         \$ (17)           35         -           2,785         (17)			

As of August 31, 2018, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$2,785 and the yield to maturity rates vary between 1.45% to 3.13%.

Held to maturity securities which will mature during the 12 months from the balance sheet date are included in short-term marketable securities. Held to maturity securities with maturity dates of more than one year are considered long-term marketable securities.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

# **NOTE 4 - LONG-TERM DEPOSITS AND INVESTMENT:**

# **Composition:**

		August 31,			
	2019		2	2018	
Bank deposits (see (1) below)	\$	-	\$	13,541	
Lease car deposits		1		1	
	\$	1	\$	13,542	

(1) Represents U.S. dollar bank deposits which carry fixed annual interest rates between 1.80% to 3.44%, with maturities of more than one year from the balance sheet date. The latest maturity date is during the fiscal year ending August 31, 2020.

# NOTE 5 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

# **Composition:**

	 August 31,			
	2019		2018	
Accounts payable	\$ 1,337	\$	1,135	
Payroll and related accruals	25		80	
Institutions	33		29	
Other accrued liabilities	 1,146		814	
	\$ 2,541	\$	2,058	

# **NOTE 6 - COMMITMENTS:**

In March 2011, the Subsidiary sold shares of its investee company, Entera, to D.N.A, retaining 117,000 ordinary shares after a stock split which was performed by Entera in July 2018. In consideration for the shares sold to D.N.A, the Company received, among other payments, ordinary shares of D.N.A (see also note 3).

As part of this agreement, the Subsidiary entered into a patent transfer agreement (the "Patent Transfer Agreement") according to which the Subsidiary assigned to Entera all of its right, title and interest in and to a certain patent application related to the oral administration of proteins that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. On December 11, 2018, Entera announced that it had entered into a research collaboration and license agreement (the "Amgen License") with Amgen related to research of inflammatory disease and other serious illnesses. As reported by Entera, under the terms of the Amgen License, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to \$270,000 in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs. To the extent the Amgen License results in net revenues as defined in the Patent Transfer Agreement, the Subsidiary will be entitled to the aforementioned royalties.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

#### NOTE 6 - COMMITMENTS (continued):

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

The annual lease payment was New Israeli Shekel ("NIS") 119,000 (\$33) from October 2016 through September 2018 and NIS 132,000 (\$37) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index ("CPI") (as of August 31, 2019, the future lease payments until the expiration of the lease agreement will be \$77, based on the exchange rate as of August 31, 2019).

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

The lease expenses related to the Israeli offices for the years ended August 31, 2019, 2018 and 2017 were \$37, \$32 and \$32, respectively.

- c. On December 18, 2017, the Subsidiary entered into an agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of \$2,905 that will be paid over the term of the engagement and based on the achievement of certain development milestones, \$1,542 of which was recognized in research and development expenses through August 31, 2019.
- d. On February 14, 2018, the Subsidiary entered into a Clinical Research Organization Services Agreement with a third party, effective as of November 1, 2017, to retain it as a clinical research organization ("CRO") for the Subsidiary's three-month dose-ranging clinical trial for its oral insulin capsule for type 2 diabetes patients and, on May 20, 2019, the Subsidiary entered into amendments to such agreement. As consideration for its services, the Subsidiary will pay the CRO a total amount of \$10,206 during the term of the engagement and based on achievement of certain milestones, of which \$6,408 was recognized in research and development expenses through August 31, 2019.
- e. On May 21, 2018, the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's food effect clinical trial for its oral insulin capsule. As consideration for its services, the Subsidiary will pay the CRO a total amount of \$1,166 during the term of the engagement and based on achievement of certain milestones, \$1,141 of which was recognized in research and development expenses through August 31, 2019.
- f. On July 29, 2019, the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's doseranging clinical trial for its oral insulin. As consideration for its services, the Subsidiary will pay the CRO a total amount of \$658 during the term of the engagement and based on achievement of certain milestones, of which no cost was recognized through August 31, 2019.

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

#### NOTE 6 - COMMITMENTS (continued):

g. Grants from the Israel Innovation Authority ("IIA")

Under the terms of the Company's funding from the IIA, royalties of 3% are payable on sales of products developed from a project so funded, up to a maximum amount equaling 100%-150% of the grants received (dollar linked) with the addition of interest at an annual rate based on LIBOR.

Following an amendment to applicable regulations that was published by the IIA, the royalties rate that the Company is obligated to pay to the IIA was reduced from 3.5% to 3%, and the difference in the amount of \$86 was recognized as a reduction in cost of revenue in fiscal 2018.

At the time the grants were received, successful development of the related projects was not assured. The total amount that was received through August 31, 2019 was \$2,207. As of August 31, 2019, the Company has recorded expenses of \$615 and paid \$224.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the year ended August 31, 2019 and in prior periods.

For the years ended August 31, 2019, 2018 and 2017, no grants from the IIA were recognized.

## NOTE 7 - STOCKHOLDERS' EQUITY:

The following are the significant capital stock transactions that took place during the years ended August 31, 2019, 2018 and 2017:

- a. On July 2, 2018, the Company entered into a Securities Purchase Agreement with each of three investors (the "Purchasers"), pursuant to which the Company agreed to sell, in a registered direct offering (the "Offering") an aggregate of 2,892,000 units (the "Units"), each Unit consisting of one share of the Company's common stock, par value \$0.012 per share, and a warrant to purchase one share of common stock at an exercise price of \$7.25 per share (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. For accounting purposes, the warrants were classified as equity considering the warrant conditions. The closing of the sale of the Units occurred on July 6, 2018. The net proceeds to the Company from the Offering, after deducting the placement agent's fees and expenses and the Company's Offering expenses were approximately \$16,484.
- b. On July 2, 2018, the Company entered into a letter agreement with H.C. Wainwright & Co., LLC ("HCW"), pursuant to which HCW agreed to serve as exclusive placement agent for the Company in any offering of the Company 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 common stock of the Company, exercisable commencing six months following their issuance for a period of three and one-half years from the date of issuance and with an exercise price of \$7.8125 per share. The Company recognized the fair value of the warrants as a share based payment which was included as part of the offering costs. 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. The agreement with HCW was terminated on July 19, 2019.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

#### NOTE 7 - STOCKHOLDERS' EQUITY (continued):

- c. On September 5, 2019, we entered into an Equity Distribution 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 \$15,000,000, 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 September 5, 2019. We will pay the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Sales Agreement. As of August 31, 2019, no shares were sold under the Sales Agreement.
- d. In August 2019, the Company became aware of a shareholder derivative claim and putative class action alleging, among other things, that the Company's Second Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan") may have terminated in 2018. However, the Company disputes these claims and believes that the 2008 Plan does not terminate until 2026 and any suggestion to the contrary is not well-founded. For the sake of clarity and out of an abundance of caution, the Company adopted its 2019 Stock Incentive Plan (the "2019 Plan") at its 2019 shareholders meeting. The 2019 Plan allows the Company to grant up to 1,000,000 options. Since the Company has granted options during the time after the 2008 Plan allegedly terminated, and out of an abundance of caution, the Company canceled these grants and re-granted certain of these options under the 2019 Plan in the same amounts and under the same terms as the original grants. The cancellation and reissuance was approved by the Company's board of directors on September 11, 2019. Out of the available 1,000,000 options under the 2019 Plan, the Company has granted 563,646 to replace the options under dispute as mentioned above. The cancellation of the award accompanied by the concurrent grant of a replacement award was accounted for as modification of the terms of the cancelled award. Since the replacement award was given under the same terms as the cancelled award, no incremental compensation cost was recognized.
- e. As of August 31, 2019, the Company had outstanding warrants exercisable commencing January 6, 2019 for 3,007,680 shares of common stock at exercise prices ranging from \$7.25 to \$7.8125 per share and expiring on January 6, 2022.

The following table presents the warrant activity for the years ended August 31, 2019, 2018 and 2017:

				Year ended A	Aug	gust 31,				
	20	19		20	18		2017			
	Warrants		Veighted- Average Exercise Price	Warrants		Veighted- Average Exercise Price	Warrants	1	Veighted- Average Exercise Price	
Warrants outstanding at beginning of year	3,007,680	\$	7.27	166,642	\$	6.46	615,338	\$	5.92	
Issued	-	\$	-	3,007,680	\$	7.27	-	\$	-	
Exercised	-	\$	-	(138,071)	\$	5.73	(248,882)	\$	4.99	
Expired	-	\$	-	(28,571)	\$	10.00	(199,814)	\$	6.82	
Warrants outstanding at end of year	3,007,680	\$	7.27	3,007,680	\$	7.27	166,642	\$	6.46	
Warrants exercisable at end of year	3,007,680	\$	7.27	-	\$	-	166,642	\$	6.46	

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

#### NOTE 8 - STOCK-BASED COMPENSATION:

During the year ended August 31, 2019, the Company made awards under the 2008 Plan. Beginning September 11, 2019, the Company began making awards under the 2019 Plan, under which, the Company has reserved a pool of 1,000,000 shares of the Company's common stock which may be issued at the discretion of the Company's Board of Directors from time to time. Under the 2019 Plan, each option is exercisable into one share of common stock of the Company. The options may be exercised after vesting and in accordance with vesting schedules which will be determined by the Board of Directors for each grant. The maximum term of the options is 10 years.

The following are the significant stock options transactions with employees, board members and non-employees made during the years ended August 31, 2019, 2018 and 2017:

- a. On February 9, 2017, options to purchase an aggregate of 27,731 shares of the Company were granted to four members of the Company's Board of Directors as follows: (a) 16,337 options at an exercise price of \$1 per share (lower than the traded market price of \$6.23 on the date of grant). The fair value of these options on the date of grant was \$90, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$6.23; dividend yield of 0% for all years; expected volatility of 77.29%; risk-free interest rates of 1.88%; and expected term of 5 years; (b) 11,394 options at an exercise price of \$6.23 per share (equivalent to the traded market price on the date of grant). The fair value of these options on the date of grant was \$45, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$6.23; dividend yield of 0% for all years; expected volatility of 77.29%; risk-free interest rates of 1.88%; and expected term of 5 years. All the options vested immediately and expire on February 9, 2027.
- **b.** On March 20, 2017, options to purchase an aggregate of 37,152 of the Company's shares of common stock were granted to a consultant at an exercise price of \$6.00 per share (higher than the traded market price of \$5.96 on the date of grant). The options expire on March 20, 2027. The options vest in 24 consecutive equal monthly installments of 1,548 shares of common stock each, commencing March 31, 2017. The fair value of these options on the date of grant was \$177.

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

#### NOTE 8 - STOCK-BASED COMPENSATION (continued):

On July 30, 2018, the vesting schedule of the options was amended and restated, effective July 1, 2018, as follows: the 12,384 of the options that remain unvested will vest in 24 consecutive equal monthly installments of 516 shares each, commencing July 31, 2018. The amendment did not have any impact on the Company's financial statements.

- c. On June 30, 2017, the Company granted options to purchase shares of the Company and RSUs as follows:
  - (1) To the Chief Executive Officer, options to purchase an aggregate of 147,000 shares of the Company, at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). 49,000 of such options vested on December 31, 2017, as the Company share price reached the target of \$8.00 per share, and the remainder will vest in two equal annual installments of 49,000, on each of December 31, 2018 and 2019, subject to the Company share price reaching the target of \$9.50 per share and \$12.50 per share, respectively. These options expire on June 30, 2027. The fair value of the options at the date of grant was \$585 using the Monte Carlo model, which utilizes multiple input variables to estimate the probability that market conditions will be achieved, and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 75.00%; risk-free interest rates of 2.34%; and expected term of 10 years.
  - (2) To the Chief Scientific Officer: (a) 75,000 RSUs representing a right to receive shares of the Company's common stock which vested immediately, have an exercise price of \$0.012 per share of common stock and expire on June 30, 2027. The total fair value of these RSUs on the date of grant was \$582, using the quoted closing market share price of \$7.77 on Nasdaq on the date of grant. The shares of common stock underlying the RSUs will be issued upon request of the grantee. As of August 31, 2018, none of these RSUs were exercised; and (b) options to purchase an aggregate of 69,999 shares of the Company, at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). 23,333 of such options vested on December 31, 2017 and the remainder will vest in two equal annual installments of 23,333, on each of December 31, 2018 and 2019. These options expire on June 30, 2027. The fair value of all these options on the date of grant was \$359, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$7.77; dividend yield of 0% for all years; expected volatility of 74.77%; risk-free interest rates of 1.89%; and expected term of 6 years.
  - (3) To four members of the Company's Board of Directors, options to purchase an aggregate of 67,092 shares of the Company (16,773 options to each director), at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). 22,364 of such options (5,591 options for each director) vested on December 31, 2017 and the remainder will vest in two equal annual installments, on each of December 31, 2018 and 2019. These options expire on June 30, 2027. The fair value of all these options on the date of grant was \$344, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$7.77; dividend yield of 0% for all years; expected volatility of 74.77%; risk-free interest rates of 1.89%; and expected term of 6 years.

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

#### NOTE 8 - STOCK-BASED COMPENSATION (continued):

- (4) To a member of the Company's Board of Directors, options to purchase an aggregate of 56,773 shares of the Company at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). 15,591 of such options vested on December 31, 2017 and the remainder will vest in three annual installments, 15,591 of which will vest on each of December 31, 2018 and 2019, and 10,000 of which will vest on December 31, 2020. These options expire on June 30, 2027. The fair value of these options on the date of grant was \$294, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$7.77; dividend yield of 0% for all years; expected volatility of 74.15%; risk-free interest rates of 2.14%; and expected term of 6.18 years.
- (5) To employees of the Subsidiary, options to purchase an aggregate of 38,901 shares of the Company, at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). 4,912 of such options vested on December 31, 2017, 22,777 of such options were forfeited through August 31, 2018, 1,388 options expired through August 31, 2018 and the remainder will vest in two equal annual installments, on each of December 31, 2018 and 2019. These options expire on June 30, 2027. The fair value of all these options on the date of grant was \$200, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$7.77; dividend yield of 0% for all years; expected volatility of 74.77%; risk-free interest rates of 1.89%; and expected term of 6 years.
- **d.** On July 19, 2017, options to purchase an aggregate of 20,001 shares of the Company were granted to an employee of the Subsidiary at an exercise price of \$8.57 per share (equivalent to the traded market price on the date of grant). 6,667 of such options vested on December 31, 2017 and the remainder will vest in two equal annual installments, on each of December 31, 2018 and 2019. These options expire on July 19, 2027. The fair value of these options on the date of grant was \$113, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$8.57; dividend yield of 0% for all years; expected volatility of 74.65%; risk-free interest rates of 1.83%; and expected term of 6 years.
- e. On January 31, 2018, the Company granted options to purchase an aggregate of 159,000 shares of the Company at an exercise price of \$8.14 per share (equivalent to the traded market price on the date of grant) as follows: 97,000 to the Chief Executive Officer; 47,000 to the Chief Scientific Officer; and 15,000 to an employee of the Subsidiary. The options will vest in four equal annual installments, on each of January 1, 2019, 2020, 2021 and 2022. These options expire on January 31, 2028. The fair value of all these options on the date of grant was \$857, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$8.14; dividend yield of 0% for all years; expected volatility of 71.96%; risk-free interest rates of 2.66%; and expected term of 6.25 years.
- f. On each of April 8, 2018 and May 3, 2018, the Company granted options to purchase 30,000 shares of the Company to an employee of the Subsidiary at exercise prices of \$7.05 and \$6.70 per share, respectively (equivalent to the traded market price on the date of grant). The options vest in sixteen consecutive equal installments on the last day of each quarter commencing June 30, 2018. 30,000 options expire on April 8, 2028 and 30,000 options expire on May 3, 2028. The fair value of all these options on the date of grant was \$269, using the Black Scholes option-pricing model and was based on the following assumptions: (a) for the options granted on April 8, 2018: stock price of \$7.05; dividend yield of 0% for all years; expected volatility of 71.54%; risk-free interest rates of 2.70%; and expected term of 6.07 years; and (b) for the options granted on May 3, 2018: stock price of \$6.70; dividend yield of 0% for all years; expected volatility of 71.62%; risk-free interest rates of 2.90%; and expected term of 6.02 years.

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

## NOTE 8 - STOCK-BASED COMPENSATION (continued):

- g. On February 26, 2019, the Company granted options to purchase an aggregate of 360,000 shares of common stock of the Company at an exercise price of \$3.16 per share (equivalent to the closing price of the Company's common stock on the date of grant) as follows: 196,500 to the Chief Executive Officer; 104,000 to the Chief Scientific Officer; and 59,500 to employees of the Subsidiary. The options will vest in four equal annual installments, on each of December 31, 2019, 2020, 2021 and 2022. These options expire on February 26, 2029. The fair value of all these options on the date of grant was \$731, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$3.16; dividend yield of 0% for all years; expected volatility of 69.05%; risk-free interest rates of 2.54%; and expected term of 6.25 years. On September 11, 2019, the options were canceled and re-granted at the same terms under the 2019 Plan.
- h. On April 10, 2019 and April 15, 2019, the Company granted options to its directors to purchase an aggregate of 30,000 shares of common stock of the Company at an exercise price of \$4.17 and \$4.13 per share, respectively (equivalent to the closing price of the Company's common stock on the date of grant). 20,000 of such options vested immediately and the remaining 10,000 options will vest on December 31, 2019. The fair value of all these options on the date of grant was \$64, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$4.13 and \$4.17, respectively; dividend yield of 0% for all years; expected volatility of 54.64% and 66.40%, respectively; risk-free interest rates of 2.37% and 2.28%, respectively; and expected term of 5 and 5.5 years, respectively. On September 11, 2019, the options were canceled and re-granted at the same terms under the 2019 Plan.
- i. On June 17, 2019, the Company granted options to its Chief Financial Officer to purchase an aggregate of 33,146 shares of common stock of the Company at an exercise price of \$3.55 per share (equivalent to the closing price of the Company's common stock on the date of grant). 5,396 of such options will vest on December 31, 2019 and the remaining 27,750 will vest in 3 equal installments on each of December 31, 2020, December 31, 2021 and December 31, 2022. The fair value of all these options on the date of grant was \$74, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of \$3.55; dividend yield of 0% for all years; expected volatility of 67.79%; risk-free interest rates of 2.03%; and expected term of 6.25 years. On September 11, 2019, the options were canceled and re-granted at the same terms under the 2019 Plan.

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

## NOTE 8 - STOCK-BASED COMPENSATION (continued):

## j. Options to employees, directors and non-employees

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

For options granted in the year ended August 31

		the year ended August 31,						
	2019	2018	2017					
Expected option life (years)	5-6.25	6.02-6.25	5.00-10.00					
Expected stock price volatility (%)	54.64-69.05	71.54-71.96	74.15-77.29					
Risk free interest rate (%)	2.03-2.54	2.66-2.90	1.83-2.47					
Expected dividend yield (%)	0.0	0.0	0.0					

A summary of the status of the stock options granted to employees and directors as of August 31, 2019, 2018 and 2017, and changes during the years ended on those dates, is presented below:

Year ended August 31, 2019 2018 2017 Weighted Weighted Weighted Number Number Number average average average of exercise  $\mathbf{of}$ exercise of exercise options price options price options price \$ \$ \$ Options outstanding at beginning of year 1,208,634 7.25 1,208,549 6.94 904,234 6.75 Changes during the year: Granted 423,146 3.26 219,000 7.79 427,497 7.51 Forfeited 5.79 (136,084)(22,777)7.77 Expired (231,051)7.07 (145,388)6.49 (59,282)10.27 Exercised 4.08 (50,750)(63,900)Options outstanding at end of year 6.11 7.25 6.94 1,264,645 1,208,634 1,208,549 Options exercisable at end of year 709,383 739,650 808,783 Weighted average fair value of options granted during the year 2.06 5.14 4.75

Expenses recognized in respect of stock options granted to employees and directors, for the years ended August 31, 2019, 2018 and 2017 were \$791, \$1,350 and \$451, respectively.

The total intrinsic value of employees' options exercised during the years ended August 31, 2018 and 2017 was \$248 and \$85, respectively. None of the options were exercised by employees during the year ended August 31, 2019.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

## NOTE 8 - STOCK-BASED COMPENSATION (continued):

The following table presents summary information concerning the options granted to employees and directors outstanding as of August 31, 2019:

Exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted average exercise price
<u> </u>		Years	\$
1.00 to 5.88	697,233	6.08	3.97
6.23 to 7.88	313,494	7.93	7.71
8.14 to 12.45	253,918	6.87	10.01
	1,264,645	6.70	6.11

As of August 31, 2019, there were \$832 of unrecognized compensation costs related to non-vested options previously granted to employees and directors. The unrecognized compensation costs are expected to be recognized over a weighted average period of 1.25 years.

A summary of the status of the stock options granted to non-employees outstanding as of August 31, 2019, 2018 and 2017, and changes during the years ended on those dates, is presented below:

			Year ended A	August 31,		
	201	9	201	18	201	7
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Options outstanding at beginning of year	55,486	6.71	55,486	6.71	29,668	8.35
Changes during the year:						
Granted			-	-	37,152	6.00
Exercised			-	-	-	-
Forfeited			-	-	-	-
Expired	(8,334)	9.12	-	-	(11,334)	8.65
Options outstanding at end of year	47,152	9.51	55,486	6.71	55,486	6.71
Options exercisable at end of year	41,992	6.32	44,134	6.90	27,622	7.43

The Company recorded stock-based compensation of \$22, \$111 and \$59 during the years ended August 31, 2019, 2018 and 2017, respectively, related to non-employees' awards.

None of the options were exercised by non-employees during the years ended August 31, 2019 and 2018.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

## NOTE 8 - STOCK-BASED COMPENSATION (continued):

The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2019:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$		Years	\$
6.00	37,152	7.66	6.00
7.36	10,000	1.23	7.36
	47,152	6.30	6.29

As of August 31, 2019, there were no unrecognized compensation costs related to non-vested non-employee options.

#### k. Restricted stock units

The following table summarizes the activities for unvested RSUs granted to employees and directors for the years ended August 31, 2019, 2018 and 2017:

	Year ended August 31,						
	2019	2018	2017				
	Number of RSUs						
Unvested at the beginning of period	165,796	198,276	201,669				
Granted	-	-	178,120				
Vested and issued	(290)	(32,480)	(159,353)				
Forfeited	(870)	<u> </u>	(22,160)				
Outstanding at the end of the period	164,636	165,796	198,276				
Vested and unissued	164,636	164,636	164,636				

The Company recorded compensation income related to RSUs of \$5 for the year ended August 31, 2019 and compensation expense of \$86 and \$1,064 during the years ended August 31, 2018 and 2017, respectively, related to RSU awards.

As of August 31, 2019, there were no unrecognized compensation costs related to RSUs.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

#### NOTE 9 - FINANCIAL INCOME AND EXPENSES

#### a. Financial income

	Year ended August 31,					
	2019	2	018		2017	
Income from interest on deposits	\$ 909	\$	741	\$	657	
Exchange rate differences			-		7	
Income from interest on corporate bonds	 152		162		128	
	\$ 1,061	\$	903	\$	792	

#### b. Financial expenses

	Year ended August 31,						
	2	019	2	2018		2017	
Exchange rate differences	\$	14	\$	30	\$	17	
Bank commissions		4		6		6	
Loss from securities		436		-		-	
Other		31		67		78	
	\$	485	\$	103	\$	101	

#### **NOTE 10 - TAXES ON INCOME:**

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

The applicable corporate tax rate for the Company is 21% following the U.S. Tax Cuts and Jobs Act (the "TCJA"), excluding state tax and local tax. On December 22, 2017, the TCJA was signed into law, which among other changes reduced the federal corporate income tax rate from 35% to 21%, effective January 1, 2018.

As of August 31, 2019, the Company has an accumulated tax loss carryforward of approximately \$14,336 (as of August 31, 2018, approximately \$12,053). Under U.S. tax laws, subject to certain limitations, carryforward tax losses expire 20 years after the year in which incurred. In the case of the Company, subject to potential limitations in accordance with the relevant law, the net loss carryforward will expire in the years 2026 through 2038.

### b. Corporate taxation in Israel:

The Subsidiary is taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2019, 2018 and 2017 are 23%, 23% and 24%, respectively.

As of August 31, 2019, the Subsidiary has an accumulated tax loss carryforward of approximately \$44,469 (as of August 31, 2018, approximately \$34,695). Under the Israeli tax laws, carryforward tax losses have no expiration date.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

## NOTE 10 - TAXES ON INCOME (continued):

#### c. Deferred income taxes:

	August 31,					
		2019		2018		2017
In respect of:						
Net operating loss carryforward	\$	13,239	\$	10,451	\$	9,253
Research and development expenses		2,999		2,431		2,046
Less - valuation allowance		(16,238)		(12,882)		(11,299)
Net deferred tax assets	\$	-	\$	-	\$	-

Deferred taxes are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

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

The reduction of the tax rate and TCJA had no impact on the net deferred taxes of the Company.

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

	Year ended August 31,						
20		2018			2017		
\$	2,283	\$	1,934	\$	1,115		
<u></u>	11,772		10,793		8,965		
\$	14,055	\$	12,727	\$	10,080		
	-		-		-		
	300		-		400		
\$	300	\$		\$	400		
		\$ 2,283 11,772 \$ 14,055	\$ 2,283 \$ 11,772 \$ 14,055 \$	2019 2018  \$ 2,283 \$ 1,934	2019 2018  \$ 2,283 \$ 1,934 \$ 11,772 10,793 \$ 14,055 \$ 12,727 \$		

Taxes on income of \$300 in the year ended August 31, 2019 resulted from withholding tax deducted from HTIT milestones payments, which were received during the year ended August 31, 2019, according to the License Agreement. As of August 31, 2019, the Company did not expect to reach taxable income in the 5 years following the balance sheet date, and therefore recognized this amount as taxes on income.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

## NOTE 10 - TAXES ON INCOME (continued):

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

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

	Year ended August 31,						
	2019			2018		2017	
Loss before income taxes as reported in the consolidated statement of comprehensive							
loss	\$	(14,056)	\$	(12,727)	\$	(10,080)	
Statutory tax benefit		(2,952)		(2,673)		(3,528)	
Increase in income taxes resulting from:							
Change in the balance of the valuation allowance for deferred tax		3,356		1,583		2,080	
Disallowable deductions		86		112		327	
Influence of different tax rate applicable to the Subsidiary and changes in tax rates							
from previous years		(490)		978		1,121	
Withholding tax, see note 10d above		300				400	
Taxes on income for the reported year	\$	300	\$		\$	400	

## f. Uncertainty in Income Taxes

ASC Topic 740, "Income Taxes" requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company. The Company recognizes interest and penalties related to its tax contingencies as income tax expense.

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

	Year ended August 31,					
	2019			2018	2017	
Balance at Beginning of Year	\$	11	\$	11		11
Decrease in uncertain tax positions for the current year		_		-		-
Balance at End of Year	\$	11	\$	11	\$	11

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

The Company is subject to U.S. Federal income tax examinations for the tax years of 2014 through 2018.

The Subsidiary is subject to Israeli income tax examinations for the tax years of 2013 through 2018.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

## NOTE 10 - TAXES ON INCOME (continued):

g. Valuation Allowance Rollforward

	Y	Year ended August 31,			
	Balance at beginning of period	A	dditions	e	ance at nd of eriod
Allowance in respect of carryforward tax losses:					
Year ended August 31, 2019	12,88	2	3,356		16,238
Year ended August 31, 2018	\$ 11,29	9 \$	1,583	\$	12,882
Year ended August 31, 2017	9,21	9	2,080		11,299

#### **NOTE 11 - RELATED PARTIES - TRANSACTIONS:**

- a. During each of the fiscal years of 2019, 2018 and 2017, the Company paid to directors \$100 as directors' fees.
- b. On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the CSO, whereby the CEO and the CSO, through KNRY, provide services to the Company (the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 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 the monthly consulting fee paid to the CEO and the CSO is NIS 127,570 (\$36) and NIS 80,454 (\$23), respectively.

In addition to the Consulting Agreements, based on a relocation cost analysis prepared by consulting company ORI - Organizational Resources International Ltd., the Company pays for certain direct costs, related taxes and expenses incurred in connection with the relocation of the CEO to New York. During fiscal 2019, such relocation expenses totaled \$486.

c. Balances with related parties:

	Au	August 31,	
	2019	2018	_
Accounts payable and accrued expenses - KNRY	\$ 4	6 \$ 46	6
Accounts payable and accrued expenses – CEO (relocation)	\$ 2	3 \$	-

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

## **NOTE 12 - SUBSEQUENT EVENTS**

- a. As mentioned in note 7d above on September 11, 2019, some of the options that were granted during 2019 were canceled and re-granted under the 2019 Plan in the same amounts and under the same terms as the original grants.
- b. On September 11, 2019, the Company granted options to its Chief Operating & Business Officer to purchase an aggregate of 100,000 shares of common stock of the Company at an exercise price of \$3.69 per share. 6,250 of such options vested on November 1, 2019 and the remaining 93,750 of such options vest in 15 consecutive equal installments of 6,250 options on the first day of every three month period thereafter. Such officer was granted additional options to purchase 100,000 shares of the Company's common stock at an exercise price of \$3.69 per share. Such options vest based on such officer's performance as determined by the Company's Board of Directors pursuant to the criteria set forth in the stock option award agreement between such officer and the Company. These options expire on September 11, 2029.

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

## **Exhibits (b)** 3.1 Composite Copy of Certificate of Incorporation, as amended as of January 22, 2013, corrected February 8, 2013, further amended July 25, 2014 and corrected September 5, 2017 (incorporated by reference from our annual report on Form 10-K filed November 29, 2017). 3.2 Amended and Restated By-laws (incorporated by reference from our current report on Form 8-K filed February 1, 2013). 4.1 Specimen Common Stock Certificate (incorporated by reference from our registration statement on Form S-1 filed February 1, 2013). 4.2 Form of Common Stock Purchase Warrant (incorporated by reference from our current report on Form 8-K filed July 5, 2018). 4.3\* Description of Securities. Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron 10.1 +(incorporated by reference from our current report on Form 8-K filed July 2, 2008). 10.2 +Amendment, dated July 13, 2013, to Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008 for the services of Nadav Kidron (incorporated by reference from our annual report on Form 10-K filed November 14, 2014). 10.3 +Amendment, dated November 13, 2014, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron and Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 14, 2014). 10.4 +Amendment, dated July 21, 2015, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2015). 10.5 +Amendment, dated June 27, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2016). 10.6 +Amendment, dated November 28, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron (incorporated by reference from our quarterly report on Form 10-Q filed January 11, 2017). 10.7 +Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our current report on Form 8-K filed July 2, 2008). 10.8 +Amendment, dated July 13, 2013, to Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008 for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 14, 2014). Amendment, dated July 21, 2015, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for 10.9 +the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2015).

the se	ndment, dated June 30, 2017, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for ervices of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 29, 2017).  ned Pharmaceuticals Inc. Second Amended and Restated 2008 Stock Incentive Plan (incorporated by reference from our definitive proxy ment on Schedule 14A filed August 4, 2016).
	Helit off Befreddie 1471 fried August 4, 2010).
	of Restricted Stock Unit Notice and Restricted Stock Unit Agreement (incorporated by reference from our annual report on Form 10-K November 14, 2014).
	of Restricted Stock Unit Notice and Restricted Stock Unit Agreement between the Company and the CSO or CEO (incorporated by ence from our annual report on Form 10-K filed November 29, 2017).
	of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our current report on Form 8-K July 2, 2008).
	ned Pharmaceuticals Inc. 2019 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed ast 6, 2019).
10.17+* <u>Form</u>	of Notice of Stock Option Award and Stock Option Award Agreement.
	nded and Restated Employment Agreement, dated July 20, 2017, by and between Oramed Ltd. and Hilla Eisenberg (incorporated by ence from our current report on Form 8-K filed July 21, 2017).
	ndment to Amended and Restated Employment Agreement, dated October 29, 2018, by and between Oramed Ltd. and Hilla Eisenberg reporated by reference from our annual report on Form 10-K filed November 28, 2018).
	oyment Agreement, dated November 6, 2018, by and between Oramed Ltd. and Mark Hasleton (incorporated by reference from our al report on Form 10-K filed November 28, 2018).
	oyment Agreement, dated May 16, 2019, by and between Oramed Ltd. and Avraham Gabay (incorporated by reference from our quarterly t on Form 10-Q filed July 10, 2019).
	cal Trial Agreement, dated September 11, 2011, between Oramed Ltd., Hadasit Medical Research Services and Development Ltd., Miriam on and Daniel Schurr (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
	cal Trial Agreement, dated July 8, 2009, between Oramed Ltd., Hadasit Medical Research Services and Development Ltd., Miriam Kidron tamar Raz (incorporated by reference from our current report on Form 8-K filed July 9, 2009).
	ement, dated January 7, 2009, between Oramed Pharmaceuticals Inc. and Hadasit Medical Research Services and Development Ltd. rporated by reference from our current report on Form 8-K filed January 7, 2009).
	tt Transfer Agreement, dated February 22, 2011, between Oramed Ltd. and Entera Bio Ltd. (incorporated by reference from our tration statement on Form S-1 filed March 25, 2011).

Amendment, dated June 27, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for

10.10+

10.26+*	Representative Form of Indemnification Agreements between Oramed Pharmaceuticals Inc. and each of our directors and officers.
10.27+*	Employment Agreement, dated August 18, 2019, between Oramed Ltd. and Joshua Hexter.
10.28+	Consulting Agreement, dated December 12, 2018, between Oramed Pharmaceuticals Inc. and Joshua Hexter (incorporated by reference from our quarterly report on Form 10-Q filed January 14, 2019).
10.29	Securities Purchase Agreement, dated November 30, 2015, between Oramed Pharmaceuticals, Inc. and Hefei Tianhui Incubator of Technologies Co., Ltd. (incorporated by reference from Schedule 13D/A filed by Nadav Kidron on December 29, 2015).
10.30	Amended and Restated Technology License Agreement, dated December 21, 2015, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been granted for portions of this document. Incorporated by reference from our quarterly report on Form 10-Q filed January 13, 2016).
10.31	Amendment to the Amended and Restated Technology License Agreement, dated June 3, 2016, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been granted for portions of this document. The confidential portions have been omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.32	Amendment to the Amended and Restated Technology License Agreement, dated July 24, 2016, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been granted for portions of this document. The confidential portions have been omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.33	Service Agreement, dated as of June 3, 2016, between Oramed Ltd. and XERTECS GmbH (Confidential treatment has been granted for portions of this document. The confidential portions have been omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.34	General Technical Agreement between Oramed Ltd. and Premas Biotech Pvt. Ltd., dated July 24, 2016 (Confidential treatment has been granted for portions of this document. The confidential portions have been omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.35	Equity Distribution Agreement, dated September 5, 2019, between Oramed Pharmaceuticals Inc. and Canaccord Genuity LLC (incorporated by reference from our current report on Form 8-K filed September 5, 2019).
10.36	Clinical Research Organization Services Agreement, dated February 14, 2018 and effective as of November 1, 2017, between Oramed Ltd. and Integrium, LLC (Confidential treatment has been granted for portions of this document. The confidential portions have been omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission.) (incorporated by reference from our quarterly report on Form 10-Q filed April 9, 2018).
10.37	Amendment #1 to Clinical Research Organization Services Agreement Protocol # ORA-D-015 between Oramed, Inc. and Integrium, LLC (incorporated by reference from our quarterly report on Form 10-Q filed July 10, 2019).

10.38	Amendment #2 to Clinical Research Organization Services Agreement Protocol # ORA-D-015 between Oramed, Inc. and Integrium, LLC (incorporated by reference from our quarterly report on Form 10-Q filed July 10, 2019).
21.1*	<u>Subsidiaries.</u>
23.1*	Consent of Kesselman & Kesselman, Independent Registered Public Accounting Firm.
31.1*	Certification Statement of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification Statement of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certification Statement of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification Statement of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.1*	The following financial statements from the Company's annual report on Form 10-K for the year ended August 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.

Filed herewith.

## ITEM 16. FORM 10-K SUMMARY.

None.

Furnished herewith.

Management contract or compensation plan.

## **SIGNATURES**

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

## ORAMED PHARMACEUTICALS INC.

/s/ NADAV KIDRON

Nadav Kidron,

President and Chief Executive Officer

Date: November 27, 2019

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

/s/ NADAV KIDRON	November 27, 2019
Nadav Kidron,	
President and Chief Executive Officer and Director	
(principal executive officer)	
/s/ AVRAHAM GABAY	November 27, 2019
Avraham Gabay,	
Chief Financial Officer	
(principal financial and accounting officer)	
/s/ AVIAD FRIEDMAN	November 27, 2019
Aviad Friedman,	
Director	
/s/ MIRIAM KIDRON	November 27, 2019
Miriam Kidron,	
Director	
/s/ XIAOMING GAO	November 27, 2019
Xiaoming Gao,	
Director	
/s/ KEVIN RAKIN	November 27, 2019
Kevin Rakin,	
Director	
/s/ LEONARD SANK	November 27, 2019
Leonard Sank,	
Director	

## DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the securities of Oramed Pharmaceuticals Inc. (the "Company") is a summary only. This summary is not complete and is subject to and qualified by the provisions of the Company's Certificate of Incorporation, as amended (the "Charter"), and Amended and Restated By-laws, as amended (the "By-laws"), which are filed as exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 2019 and are incorporated by reference herein.

#### Common Stock

Pursuant to the Company's Charter, the Company is authorized to issue up to thirty million (30,000,000) shares of common stock, par value \$0.012 per share (the "Common Stock").

The Common Stock is traded on The Nasdaq Capital Market and the Tel Aviv Stock Exchange, in each case under the symbol "ORMP".

The holders of shares of Common Stock vote together as one class on all matters as to which holders of Common Stock are entitled to vote. Except as otherwise required by applicable law, all voting rights are vested in and exercised by the holders of Common Stock with each share of Common Stock being entitled to one vote, including in all elections of directors. The Company does not have a classified board of directors (the "Board").

The holders of Common Stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Board out of legally available funds therefore. The Company has not declared any dividends on its Common Stock and does not anticipate paying any dividends on its Common Stock in the foreseeable future.

In the event of the Company's liquidation, dissolution or winding up, holders of the Common Stock are entitled to share ratably in all assets remaining after payment of liabilities. The Common Stock has no cumulative voting rights and no preemptive or other rights to subscribe for shares of the Company.

There are no redemption or sinking fund provisions applicable to the Common Stock. All shares of Common Stock currently outstanding are fully paid and non-assessable.

The Company is permitted to issue, and has from time to time, issued warrants and options to purchase shares of the Common Stock, as well as restricted stock units.

Anti-Takeover Effects of the Company's Charter and By-Laws

In addition to provisions under Delaware law, the Company's Charter and By-Laws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, the Charter and/or By-Laws, as applicable, among other things:

- · provide the Board with the exclusive authority to call special meetings of the stockholders;
- · provide the Board with the ability to alter the By-Laws without stockholder approval;
- provide the Board with the exclusive authority to fix the number of directors constituting the whole Board; and
- · provide that vacancies on the Board may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third-party from acquiring the Company, even if doing so would be beneficial to the Company's stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of the Board and in its policies, and to discourage some types of transactions that may involve an actual or threatened change in control of the Company. These provisions are designed to reduce the Company's vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. The Company believes that the benefits of increased protection of its potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms. However, these provisions could have the effect of discouraging others from making tender offers for shares of the Company's Common Stock and, as a consequence, they also may inhibit fluctuations in the market price of the shares of the Company's Common Stock that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in the Company's management.

## ORAMED PHARMACEUTICALS INC. 2019 STOCK INCENTIVE PLAN

## NOTICE OF STOCK OPTION AWARD

You have been granted an option to purchase shares of Common Stock, subject to the terms and conditions of this Notice of Stock Option Award (the "Notice"), the Oramed Pharmaceuticals Inc. 2019 Stock Incentive Plan, as amended from time to time (the "Plan"), and the Stock Option Award Agreement (the "Option Agreement") attached hereto, as follows. Unless otherwise defined herein or in the Option Agreement, capitalized terms used herein shall have the respective meaning ascribed to such terms in the Plan.

Iutai		
Total		
Installment	Number of Options	Vesting Date
Notice, the Plan a	and the Option Agreement, the Opti	ion may be exercised, in whole or in part, in accordance with the following vesting schedule:
_		umed Pharmaceuticals Inc., or one of its subsidiaries ("Oramed"), and other limitations set forth in thi
Vesting Schedule	:	
Expirati	on Date:	
Type of	Option:	102 Option/Non-qualified Option
Total Ex	gercise Price:	
Total Nu	umber of Shares Subject to the Option	on (the "Shares"):
Exercise	e Price per Share:	
Vesting	Commencement Date:	
Date of	Award:	
Grantee	's Name and Address:	

IN WITNESS WHEREOF, the Company and the Grantee	e have executed this Notice and	agree that the Option is to be	governed by the terms and
conditions of this Notice, the Plan and the Option Agreement.			

# ORAMED PHARMACEUTICALS INC. a Delaware corporation

		Nadav Kidron President and Chief Executive Officer
The Grantee acknowledges receipt of a copy of the provisions thereof, and hereby accepts the Option subject to and the Option Agreement in their entirety, has had an opportunity of this Notice, the Plan and the Option Agreement shall be resolved in accordance with change in the residence address indicated in this Notice.	o all of the terms and provisions hereof and thereof ortunity to obtain the advice of counsel prior to exe nt. The Grantee hereby agrees that all disputes aris	f. The Grantee has reviewed this Notice, the Plan ecuting this Notice, and fully understands all sing out of or relating to this Notice, the Plan and
Dated:	Signed:	
	2	

#### STOCK OPTION AWARD AGREEMENT

1. Grant of Option. Oramed Pharmaceuticals Inc., a Delaware corporation (the "Company"), hereby grants to the Grantee (the "Grantee") named in the Notice of Stock Option Award which is attached to this Stock Option Award Agreement (the "Notice"), an option (the "Option") to purchase the Total Number of Shares of Common Stock subject to the Option (the "Shares") set forth in the Notice, at the Exercise Price per Share set forth in the Notice (the "Exercise Price") subject to the terms and provisions of the Notice, this Stock Option Award Agreement (the "Option Agreement") and the Company's 2019 Stock Incentive Plan, as amended from time to time (the "Plan"), which are incorporated herein by reference. The Company, during the term of the Option, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Option. Unless otherwise defined herein, capitalized terms use herein shall have the respective meanings ascribed to such terms in the Plan. If so provided in the "Grant Type" shown in the Notice, this Option is intended to constitute for United States income tax purposes an Incentive Stock Option and to qualify for the special United States federal income tax treatment under Section 422 of the Code and upon exercise, the maximum number of shares that can be treated as Incentive Stock Options shall be so treated, and the remainder shall be treated as Non-qualified Stock Options.

#### 2. Exercise of Option.

(a) *Right to Exercise*. The vested portion of the Option shall be exercisable during its term in accordance with the Vesting Schedule set out in the Notice and with the applicable provisions of the Plan and this Option Agreement. The Grantee's employment, contractual or other service relationship with the Company or its affiliates ("Relationship") must be in effect on a given date in order for any scheduled increment in vesting to become effective. In the event the Relationship is terminated for any reason (whether voluntary or involuntary), (i) the Grantee's right to vest in the Option will, except as explicitly provided by the Board, terminate as of the date of termination of the Relationship (and such right shall not be extended by any notice period mandated under local law), (ii) the Grantee's continuing right (if any) to exercise the Option after termination of the Relationship will be measured from the date of termination of the Relationship (and such right will not be extended by any notice period mandated under local law) and (iii) the Board shall have the exclusive discretion to determine when the Relationship has terminated for purposes of this Option (including determining when the Grantee is no longer considered to be providing active service while on a leave of absence).

(b) Adjustments of Award Upon Change in Control. The Option shall be subject to the provisions of Section 13 of the Plan relating to the vesting and exercisability of the Option in the event of a Change in Control.

(c) Method of Exercise. The vested portion of the Option shall be exercisable by delivery of an exercise notice (a form of which is attached as Exhibit A) which shall state the election to exercise the Option, the whole number of Shares in respect of which the Option is being exercised, and such other provisions as set forth in Exhibit A. The exercise notice shall be delivered in person, by certified mail, or by such other reasonable method (including electronic transmission) accompanied by payment of the Exercise Price and all applicable income and employment taxes required to be withheld. The vested portion of the Option shall be deemed to be exercised upon receipt by the Company of such notice accompanied by the Exercise Price and all applicable withholding taxes, which, to the extent selected, shall be deemed to be satisfied by use of the broker-dealer sale and remittance procedure to pay the Exercise Price provided in Section 3(d) below to the extent such procedure is available to the Grantee at the time of exercise and such an exercise would not violate any applicable law.

As soon as practicable after its receipt of the notice and Exercise Price and all applicable withholding taxes, the Company shall (a) deliver to the Grantee (or other person entitled to exercise this Option), at the principal executive offices of the Company or such other place as shall be mutually acceptable, a stock certificate or certificates for such shares out of theretofore authorized but unissued shares or treasury shares of its Shares as the Company may elect or (b) issue shares of its Shares in book entry form. If the Grantee (or other person entitled to exercise this Option) fails to pay for and accept delivery of all of the shares specified in the notice upon tender of delivery thereof, his or her right to exercise this Option with respect to such shares not paid for may be terminated by the Company. In no event shall the Company issue fractional Shares.

- (d) *Taxes*. No Shares will be delivered to the Grantee or other person pursuant to the exercise of the Option until the Grantee or other person has made reasonable arrangements for the satisfaction of applicable income tax and employment tax withholding obligations, including, without limitation, such other tax obligations of the Grantee incident to the receipt of Shares. Upon exercise of the Option, the Company or the Grantee's employer may offset or withhold (from any amount owed by the Company or the Grantee's employer to the Grantee) or collect from the Grantee or other person an amount sufficient to satisfy such tax withholding obligations.
- 3. <u>Method of Payment</u>. Payment of the Exercise Price shall be made by any of the following, or a combination thereof, at the election of the Grantee; provided, however, that such exercise method does not then violate any applicable law:
  - (a) cash;
  - (b) check;
- (c) surrender of Shares or delivery of a properly executed form of attestation of ownership of Shares which have a Fair Market Value on the date of surrender or attestation equal to the aggregate Exercise Price of the Shares as to which the Option is being exercised;
- (d) payment through a broker-dealer sale and remittance procedure pursuant to which the Grantee (i) shall provide written instructions to a Company-designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (ii) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction;

- (e) with respect to a Non-qualified Stock Option, payment through a "net exercise" such that, without the payment of any funds, the Grantee may exercise the Option and receive the net number of Shares equal to (i) the number of Shares as to which the Option is being exercised, multiplied by (ii) a fraction, the numerator of which is the Fair Market Value per Share (on such date as is determined by the Administrator) less the Exercise Price, and the denominator of which is such Fair Market Value per Share (the number of net Shares to be received shall be rounded down to the nearest whole number of Shares) and, at the election of the Grantee, less (iii) such number of Shares as is equal to the withholding obligation provided in Section 2(d); or
  - (f) any combination of the foregoing methods of payment.
- 4. Expiration of Option. The Option must be exercised no later than the Expiration Date set forth in the Notice (the "Expiration Date"). After the Expiration Date, the Option shall be of no further force or effect and may not be exercised. The Option may not be exercised if the issuance of the Shares subject to the Option upon such exercise would constitute a violation of any Applicable Laws.

This Option may not be exercised after three (3) months following the date of termination of the Relationship, except that if the Relationship terminates by reason of the Grantee's death or total and permanent disability (as determined by the Board on the basis of medical advice satisfactory to it), the unexercised portion of the Option that is otherwise exercisable on the date of termination of the Relationship shall remain exercisable thereafter for twelve (12) months. It is the Grantee's responsibility to be aware of the date the Option expires.

- 5. <u>Transferability of Option</u>. The Option may not be transferred in any manner other than by will or by the laws of descent and distribution and may be exercised during the lifetime of the Grantee only by the Grantee; provided, however, that the Grantee may designate a beneficiary of the Grantee's Option in the event of the Grantee's death on a beneficiary designation form provided by the Administrator. No transfer permitted hereby shall be effective to bind the Company unless the Administrator has been furnished with written notice of such transfer and an authenticated copy of the will and/or such other evidence as the Administrator may deem necessary to establish the validity of the transfer and the acceptance by the transferee of the terms and conditions of such Award. The terms of the Option shall be binding upon the executors, administrators, heirs, successors and transferees of the Grantee.
- 6. <u>Adjustment Upon Changes in Capitalization</u>. Subject to any required action by the stockholders of the Company, the number of Shares covered by this Option and the Exercise Price shall be proportionately adjusted as provided under Section 12 of the Plan.
- 7. <u>Tax Consequences</u>. The Grantee may incur tax liability as a result of the Grantee's purchase or disposition of the Shares. THE GRANTEE SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THE OPTION OR DISPOSING OF THE SHARES.

- 8. Entire Agreement: Governing Law. This Option Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Grantee with respect to the subject matter hereof, and may not be modified adversely to the Grantee's interest except by means of a writing signed by the Company and the Grantee. Nothing in this Award Agreement (except as expressly provided therein) is intended to confer any rights or remedies on any persons other than the parties. This Award Agreement is to be construed in accordance with and governed by the laws of the State of Delaware without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of Delaware to the rights and duties of the parties. Should any provision of this Award Agreement be determined to be illegal or unenforceable, such provision shall be enforced to the fullest extent allowed by law and the other provisions shall nevertheless remain effective and shall remain enforceable.
- 9. <u>Construction</u>. The captions used in this Option Agreement are inserted for convenience and shall not be deemed a part of the Option for construction or interpretation. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise. This Option Agreement is to be construed in accordance with the terms of the Plan. In case of any conflict between the Plan and this Option Agreement, the Plan shall control. Capitalized terms not defined herein shall have the meanings given to them in the Plan.
- 10. <u>Venue and Waiver of Jury Trial</u>. The Company, the Grantee, and the Grantee's assignees (the "parties") agree that any suit, action, or proceeding arising out of or relating to this Award Agreement shall be brought in the United States District Court for the District of Delaware (or should such court lack jurisdiction to hear such action, suit or proceeding, in a Delaware Court of Chancery) and that the parties shall submit to the jurisdiction of such court. The parties irrevocably waive, to the fullest extent permitted by law, any objection the party may have to the laying of venue for any such suit, action or proceeding brought in such court. THE PARTIES ALSO EXPRESSLY WAIVE ANY RIGHT THEY HAVE OR MAY HAVE TO A JURY TRIAL OF ANY SUCH SUIT, ACTION OR PROCEEDING. If any one or more provisions of this Section 10 shall for any reason be held invalid or unenforceable, it is the specific intent of the parties that such provisions shall be modified to the minimum extent necessary to make it or its application valid and enforceable.
- 11. <u>Notices</u>. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery, upon deposit for delivery by an internationally recognized express mail courier service or upon deposit in the United States mail by certified mail (if the parties are within the United States), with postage and fees prepaid, addressed to the other party at its address as shown in these instruments, or to such other address as such party may designate in writing from time to time to the other party.
- 12. <u>Rights as Shareholder</u>. The Grantee shall have no rights as a shareholder with respect to any shares covered by this Option until the date of issuance of a stock certificate(s) (or appropriate book entry(ies) is(are) made in the case of book entry form) to him or her for such shares. Except as otherwise provided pursuant to the Plan, no adjustment shall be made for dividends or other rights for which the record date is prior to the date such stock certificate is issued (or appropriate entry is made in the case of book entry form).

- 13. Notice of Disqualifying Disposition. If the "Grant Type" shown in the Customizing Information indicates that the Option is an Incentive Stock Option, the Grantee agrees to notify the Company promptly in the event that he or she sells, transfers, exchanges or otherwise disposes of any shares of Shares issued upon exercise of the Option before the later of (a) the second anniversary of the date of grant of the Option and (b) the first anniversary of the date the shares were issued upon his or her exercise of the Option.
- 14. <u>Amendment; Waivers</u>. This Option Agreement, including the Plan, contains the full and complete understanding and agreement of the parties hereto as to the subject matter hereof, and except as otherwise permitted by the express terms of the Plan, this Option Agreement and applicable law, it may not be modified or amended nor may any provision hereof be waived without a further written agreement duly signed by each of the parties; provided, however, that a modification or amendment that does not materially diminish the rights of the Grantee hereunder, as they may exist immediately before the effective date of the modification or amendment, shall be effective upon written notice of its provisions to the Grantee, to the extent permitted by applicable law. The waiver by either of the parties hereto of any provision hereof in any instance shall not operate as a waiver of any other provision hereof or in any other instance. The Grantee shall have the right to receive, upon request, a written confirmation from the Company of the Customizing Information.
- 15. <u>Data Privacy</u>. By entering into this Option Agreement and except as otherwise provided in any data transfer agreement entered into by the Company, the Grantee: (i) authorizes the Company, and any agent of the Company administering the Plan or providing Plan recordkeeping services, to disclose to the Company such information and data as the Company shall request in order to facilitate the grant of options and the administration of the Plan; (ii) waives any data privacy rights he or she may have with respect to such information; and (iii) authorizes the Company to store and transmit such information in electronic form. For purposes of this Section, the term "Company" refers to the Company and any affiliate.

#### EXHIBIT A

## ORAMED PHARMACEUTICALS, INC.

## EXERCISE NOTICE

Oramed Pharmaceuticals Inc.

1185 Avenue of the Americas, Suite 228 New York, NY 10036 USA

USA
Attention: Chief Executive Officer
1. Exercise of Option. Effective as of today,
2. <u>Representations of the Grantee</u> . The Grantee acknowledges that the Grantee has received, read and understood the Plan and Award Agreement and agrees to abide by and be bound by their terms and conditions.
3. <u>Rights as Stockholder</u> . Until the stock certificate evidencing such Shares is issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder shall exist with respect to the Shares, notwithstanding the exercise of the Option. The Company shall issue (or cause to be issued) such stock certificate promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the stock certificate is issued, except as provided in Section 12 of the Plan.
4. <u>Delivery of Payment</u> . The Grantee herewith delivers to the Company the full Exercise Price for the Shares, which, to the extent selected, shall be deemed to be satisfied by use of the broker-dealer sale and remittance procedure to pay the Exercise Price provided in Section 3(d) of the Option Agreement, if available.
5. <u>Tax Consultation</u> . The Grantee understands that the Grantee may suffer adverse tax consequences as a result of the Grantee's purchase or disposition of the Shares. The Grantee represents that the Grantee has consulted with any tax consultants the Grantee deems advisable in connection with the purchase or disposition of the Shares and that the Grantee is not relying on the Company for any tax advice.
6. <u>Taxes</u> . The Grantee agrees to satisfy all applicable foreign, federal, state and local income and employment tax withholding obligations and herewith

delivers to the Company the full amount of such obligations or has made arrangements acceptable to the Company to satisfy such obligations.

8

- 7. <u>Successors and Assigns</u>. The Company may assign any of its rights under this Exercise Notice to single or multiple assignees, and this agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Exercise Notice shall be binding upon the Grantee and his or her heirs, executors, administrators, successors and assigns.
- 8. <u>Construction</u>. The captions used in this Exercise Notice are inserted for convenience and shall not be deemed a part of this agreement for construction or interpretation. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.
- 9. Governing Law; Severability. This Exercise Notice is to be construed in accordance with and governed by the internal laws of the State of Delaware without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the laws of the State of Delaware to the rights and duties of the parties. Should any provision of this Exercise Notice be determined by a court of law to be illegal or unenforceable, such provision shall be enforced to the fullest extent allowed by law and the other provisions shall nevertheless remain effective and shall remain enforceable.
- 10. <u>Notices</u>. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery, upon deposit for delivery by an internationally recognized express mail courier service or upon deposit in the United States mail by certified mail (if the parties are within the United States), with postage and fees prepaid, addressed to the other party at its address as shown below beneath its signature, or to such other address as such party may designate in writing from time to time to the other party.
- 11. <u>Further Instruments</u>. The parties agree to execute such further instruments and to take such further action as may be reasonably necessary to carry out the purposes and intent of this agreement.
- 12. Entire Agreement. The Plan and the Award Agreement are incorporated herein by reference and together with this Exercise Notice constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Grantee with respect to the subject matter hereof, and may not be modified adversely to the Grantee's interest except by means of a writing signed by the Company and the Grantee. Nothing in the Plan, Option Agreement and this Exercise Notice (except as expressly provided therein) is intended to confer any rights or remedies on any persons other than the parties.

Submitted by:	Accepted by:
GRANTEE:	ORAMED PHARMACEUTICALS INC.
(Signature)	By: Name: Title:
Address:	Address:  1185 Avenue of the Americas, Suite 228 New York, NY 10036 USA
	9

#### INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT (the "Agreement") is made and entered into as of August 30, 2016 between Oramed Pharmaceuticals Inc., a Delaware corporation (the "Company"), and Kevin Rakin ("Indemnitee").

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors or officers unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the By-laws and/or the Certificate of Incorporation of the Company require indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware ("DGCL"). The By-laws and/or Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the Board of Directors of the Company (the "Board") officers and other persons with respect to indemnification;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the By-laws and/or Certificate of Incorporation of the Company and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

NOW, THEREFORE, in consideration of Indemnitee's agreement to serve as an officer and director from and after the date hereof, the parties hereto agree as follows:

1. <u>Indemnity of Indemnitee</u>. The Company hereby agrees to hold harmless and indemnify Indemnitee to the fullest extent permitted by law, as such may be amended from time to time. In furtherance of the foregoing indemnification, and without limiting the generality thereof:

(a) <u>Proceedings Other Than Proceedings by or in the Right of the Company.</u> Indemnitee shall be entitled to the rights of indemnification provided in this <u>Section I(a)</u> if, by reason of his Corporate Status (as hereinafter defined), the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding (as hereinafter defined) other than a Proceeding by or in the right of the Company. Pursuant to this <u>Section I(a)</u>, Indemnitee shall be indemnified against all Expenses (as hereinafter defined), judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him, or on his behalf, in connection with such Proceeding or any claim, issue or matter therein, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful.

(b) <u>Proceedings by or in the Right of the Company</u>. Indemnitee shall be entitled to the rights of indemnification provided in this <u>Section 1(b)</u> if, by reason of his Corporate Status, the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company. Pursuant to this <u>Section 1(b)</u>, Indemnitee shall be indemnified against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by the Indemnitee, or on the Indemnitee's behalf, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, if applicable law so provides, no indemnification against such Expenses shall be made in respect of any claim, issue or matter in such Proceeding as to which Indemnitee shall have been adjudged to be liable to the Company unless and to the extent that the Court of Chancery of the State of Delaware shall determine that such indemnification may be made.

(c) <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a party to and is successful, on the merits or otherwise, in any Proceeding, he shall be indemnified to the maximum extent permitted by law, as such may be amended from time to time, against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him or on his behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with each successfully resolved claim, issue or matter. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

2. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1 of this Agreement, the Company shall and hereby does indemnify and hold harmless Indemnitee against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him or on his behalf if, by reason of his Corporate Status, he is, or is threatened to be made, a party to or participant in any Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or active or passive wrongdoing of Indemnitee. The only limitation that shall exist upon the Company's obligations pursuant to this Agreement shall be that the Company shall not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, set forth in Sections 5 and 6 hereof) to be unlawful.

#### 3. Contribution.

(a) Whether or not the indemnification provided in Sections 1 and 2 hereof is available in respect of any threatened, pending or completed Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such Proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required by law to pay all or any portion of any judgment or settlement in any threatened, pending or completed Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such Proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such Expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary and the degree to which their conduct is active or passive.

(c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee.

(d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

- 3. <u>Indemnification for Expenses of a Witness</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.
- 4. Advancement of Expenses. Notwithstanding any other provision of this Agreement, the Company shall advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding by reason of Indemnitee's Corporate Status within thirty (30) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by Indemnitee and shall include or be preceded or accompanied by a written undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it shall ultimately be determined by a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee is not entitled to be indemnified against such Expenses. Any advances and undertakings to repay pursuant to this Section 4 shall be unsecured and interest free.
- 5. <u>Procedures and Presumptions for Determination of Entitlement to Indemnification</u>. It is the intent of this Agreement to secure for Indemnitee rights of indemnity that are as favorable as may be permitted under the DGCL and public policy of the State of Delaware. Accordingly, the parties agree that the following procedures and presumptions shall apply in the event of any question as to whether Indemnitee is entitled to indemnification under this Agreement:
- (a) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification, provided that Indemnitee shall not be required to provide any documentation or information which is privileged or otherwise protected from disclosure. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification. Notwithstanding the foregoing, any failure of Indemnitee to provide such a request to the Company, or to provide such a request in a timely fashion, shall not relieve the Company of any liability that it may have to Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company.
- (b) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 5(a) hereof, a determination with respect to Indemnitee's entitlement thereto shall be made in the specific case by one of the following four methods, which shall be at the election of Indemnitee, in his sole discretion: (1) by a majority vote of the disinterested directors, even though less than a quorum, (2) by a majority vote of a committee of disinterested directors designated by a majority vote of the disinterested directors, even though less than a quorum, (3) if there are no disinterested directors or if a Change of Control shall have occurred after the date hereof, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee, or (4) by a simple majority of the stockholders of the Company voting on the matter. For purposes hereof, disinterested directors are those members of the Board who are not parties to the Proceeding in respect of which indemnification is sought by Indemnitee.

- "Change of Control" shall mean the occurrence of any of the following:
- (a) any "person," as such term is currently used in Section 13(d) of the Securities Exchange Act of 1934, as amended (the "1934 Act") (a "person"), becomes a "beneficial owner" (as such term is currently used in Rule 13d-3 promulgated under the 1934 Act (a "Beneficial Owner") of 30% or more of the Voting Stock (as defined below) of the Company;
- (b) the Board of Directors of the Company adopts any plan of liquidation providing for the distribution of all or substantially all of the Company's assets;
- (c) all or substantially all of the assets or business of the Company are disposed of in any one or more transactions pursuant to a sale, merger, consolidation or other transaction (unless the shareholders of the Company immediately prior to such sale, merger, consolidation or other transaction beneficially own, directly or indirectly, in substantially the same proportion as they owned the Voting Stock of the Company, more than fifty percent (50%) of the Voting Stock or other ownership interests of the entity or entities, if any, that succeed to the business of the Company);
- (d) the Company combines with another company and is the surviving corporation but, immediately after the combination, the shareholders of the Company immediately prior to the combination hold, directly or indirectly, fifty percent (50%) or less of the Voting Stock of the combined company; or
- (e) Continuing Directors cease to constitute at least a majority of the Board of Directors of the Company.
- "Voting Stock" of any entity shall mean the issued and outstanding share capital or other securities of any class or classes having general voting power under ordinary circumstances, in the absence of contingencies, to elect the members of the board of directors (or members of a similar managerial body if such entity has no board of directors) of such entity.
- "Continuing Director" means a director who either was a director of the Company on the Commencement Date or who became a director of the Company subsequent thereto and whose election, or nomination for election by the Company's shareholders, was approved by a majority of the Continuing Directors then on the Board of Directors of the Company.

(c) If the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 5(b) hereof, the Independent Counsel shall be selected as provided in this Section 5(c). The Independent Counsel shall be selected by the Board. Indemnitee may, within 10 days after such written notice of selection shall have been given, deliver to the Company a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in this Agreement, and the objection shall set forth with reasonable particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If a written objection is made and substantiated, the Independent Counsel selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within 20 days after submission by Indemnitee of a written request for indemnification pursuant to Section 5(a) hereof, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Court of Chancery of the State of Delaware or other court of competent jurisdiction for resolution of any objection which shall have been made by the Indemnitee to the Company's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel in connection with acting pursuant to Section 5(b) hereof, and the Company shall pay any and all reasonable fees and expenses (including those incurred by Indemnitee) incident to the procedures of this Section 5(c), regardless of the manner in which such Independent Counsel was select

(d) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(e) Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise (as hereinafter defined), including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected by the Enterprise. In addition, the knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement. Whether or not the foregoing provisions of this Section 5(e) are satisfied, it shall in any event be presumed that Indemnitee has at all times acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(f) If the person, persons or entity empowered or selected under Section 5 to determine whether Indemnitee is entitled to indemnification shall not have made a determination within thirty (30) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall be deemed to have been made and Indemnitee shall be entitled to such indemnification absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 30-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making such determination with respect to entitlement to indemnification in good faith requires such additional time to obtain or evaluate documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 5(f) shall not apply if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 5(b) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination, the Board or the Disinterested Directors, if appropriate, resolve to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within sixty (60) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within forty (40) days after having been so called and such determination is made thereat.

(g) Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Independent Counsel, member of the Board or stockholder of the Company shall act reasonably and in good faith in making a determination regarding the Indemnitee's entitlement to indemnification under this Agreement. Any costs or expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(h) The Company acknowledges that a settlement or other disposition short of final judgment may be successful if it permits a party to avoid expense, delay, distraction, disruption and uncertainty. In the event that any Proceeding to which Indemnitee is a party is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such Proceeding with or without payment of money or other consideration) it shall be presumed that Indemnitee has been successful on the merits or otherwise in such Proceeding. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(i) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful.

#### 6. Remedies of Indemnitee.

(a) In the event that (i) a determination is made pursuant to Section 5 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 4 of this Agreement, (iii) no determination of entitlement to indemnification is made pursuant to Section 5(b) of this Agreement within 30 days after receipt by the Company of the request for indemnification (subject to extension, as provided in Section 5(f)), (iv) payment of indemnification is not made pursuant to this Agreement within ten (10) days after receipt by the Company of a written request therefor or (v) payment of indemnification is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or such determination is deemed to have been made pursuant to Section 5 of this Agreement, Indemnitee shall be entitled to an adjudication in an appropriate court of the State of Delaware, or in any other court of competent jurisdiction, of Indemnitee's entitlement to such indemnification. Indemnitee shall commence such proceeding seeking an adjudication within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 6(a). The Company shall not oppose Indemnitee's right to seek any such adjudication.

(b) In the event that a determination shall have been made pursuant to <u>Section 5(b)</u> of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this <u>Section 6</u> shall be conducted in all respects as a de novo trial on the merits, and Indemnitee shall not be prejudiced by reason of the adverse determination under <u>Section 5(b)</u>.

(c) If a determination shall have been made pursuant to <u>Section 5(b)</u> of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this <u>Section 6</u>, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's misstatement not materially misleading in connection with the application for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) In the event that Indemnitee, pursuant to this Section 6, seeks a judicial adjudication of his rights under, or to recover damages for breach of, this Agreement, or to recover under any directors' and officers' liability insurance policies maintained by the Company, the Company shall pay on his behalf, in advance within ten (10) days after the receipt by the Company of a statement from Indemnitee requesting such payment, any and all expenses (of the types described in the definition of Expenses in this Agreement) actually and reasonably incurred by him in such judicial adjudication, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of expenses or insurance recovery.

(e) The Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 6 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefore) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case may be.

(f) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

#### 7. Non-Exclusivity; Survival of Rights; Insurance; Primacy of Indemnification; Subrogation.

(a) The rights of indemnification as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the By-laws, any agreement, a vote of stockholders, a resolution of directors of the Company, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL, whether by statute or judicial decision, permits greater indemnification than would be afforded currently under the Certificate of Incorporation, By-laws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, employee, agent or fiduciary under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee (other than against the Outside Indemnitors), who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company hereby acknowledges that the Indemnitee may have other sources of indemnification or insurance, whether currently in force or established in the future (collectively, the "Outside Indemnitors"). The Company hereby agrees: (i) that it is the indemnitor of first resort (i.e., its obligations to the Indemnitee are primary and any obligation of the Outside Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by the Indemnitee are secondary); (ii) that it shall be required to advance the full amount of Expenses incurred by the Indemnitee and shall be liable in full for all indemnifiable amounts to the extent legally permitted and as required by the Company's Certificate of Incorporation and Bylaws or any agreement between the Company and the Indemnitee, without regard to any rights the Indemnitee may have against the Outside Indemnitors and (iii) that it irrevocably waives, relinquishes and releases the Outside Indemnitors from any and all claims against the Outside Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Outside Indemnitors on behalf of the Indemnitee with respect to any claim for which the Indemnitee have sought indemnification from the Company shall affect the foregoing and the Outside Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of the Indemnitee against the Company. The Company and the Indemnitee agree that the Outside Indemnitors are express third party beneficiaries of the terms hereof.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.

- 8. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:
- (a) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of state statutory law or common law; or
- (b) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law or (iii) such Proceeding is brought by Indemnitee to assert, interpret or enforce his rights under this Agreement.
- 9. <u>Duration of Agreement</u>. All agreements and obligations of the Company contained herein shall continue during the period Indemnitee is an officer or director of the Company (or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise) and shall continue thereafter so long as Indemnitee shall be subject to any Proceeding (or any proceeding commenced under <u>Section 6</u> hereof) by reason of his Corporate Status, whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors and personal and legal representatives.
- 10. Security. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time provide security to Indemnitee for the Company's obligations hereunder through an irrevocable bank line of credit, funded trust or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of the Indemnitee.

#### 11. Enforcement.

- (a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it hereby in order to induce Indemnitee to serve as an officer or director of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as an officer or director of the Company.
- (b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.
- (c) The Company shall not seek from a court, or agree to, a "bar order" which would have the effect of prohibiting or limiting the Indemnitee's rights to receive advancement of expenses under this Agreement.

#### 12. <u>Definitions</u>. For purposes of this Agreement:

- (a) "Corporate Status" describes the status of a person who is or was a director, officer, employee, agent or fiduciary of the Company or any subsidiary thereof or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person is or was serving at the express written request of the Company.
- (b) "**Disinterested Director**" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee and who is not subject to any other relationship that may reasonably prejudice such director's determination as to the Indemnitee's entitlement to indemnification hereunder.
- (c) "**Enterprise**" shall mean the Company and any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that Indemnitee is or was serving at the express written request of the Company as a director, officer, employee, agent or fiduciary.
- (d) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in any Proceeding. Expenses also shall include Expenses incurred in connection with any appeal resulting from any Proceeding and any federal, state, local or foreign taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, including without limitation the premium, security for, and other costs relating to any cost bond, supersede as bond, or other appeal bond or its equivalent.
- (e) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.
- (f) "Proceeding" includes any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative, in which Indemnitee was, is or will be involved as a party or otherwise, by reason of his or his Corporate Status, by reason of any action taken by him or of any inaction on his part while acting in his Corporate Status; in each case whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement; including one pending on or before the date of this Agreement, but excluding one initiated by an Indemnitee pursuant to Section 6 of this Agreement to enforce his rights under this Agreement.

- 13. <u>Severability</u>. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision. Without limiting the generality of the foregoing, this Agreement is intended to confer upon Indemnitee indemnification rights to the fullest extent permitted by applicable laws. In the event any provision hereof conflicts with any applicable law, such provision shall be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.
- 14. <u>Modification and Waiver</u>. No supplement, modification, termination or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.
- 15. Notice By Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification covered hereunder. The failure to so notify the Company shall not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise unless and only to the extent that such failure or delay materially prejudices the Company.
- 16. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to Indemnitee at the address set forth below Indemnitee signature hereto, and to the Company, at its principal executive offices to the attention of the President, or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.
- 17. <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Agreement. This Agreement may also be executed and delivered by facsimile signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

18. <u>Headings</u>. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

19. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties with respect to the subject matter of this Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement on and as of the day and year first above

written.

#### **COMPANY**

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron Name: Nadav Kidron

Title: Chief Executive Officer

### INDEMNITEE

/s/ Kevin Rakin

Name: Kevin Rakin

Address: 36 Church Lane, Westport, CT 06880, USA

#### Schedule to Exhibit 10.26

The following executive officers and directors are each party to an Indemnification Agreement or Amended and Restated Indemnification Agreement with the Company, each of which is substantially identical in all material respects to the representative Indemnification Agreement filed herewith and is dated as of the respective date listed below.

Name of Signatory	Date
Nadav Kidron President, Chief Executive Officer and Director	March 26, 2017
Miriam Kidron Chief Medical and Technology Officer and Director	March 26, 2017
Avraham Gabay Chief Financial Officer	May 19, 2019
Hilla Eisenberg Former Chief Financial Officer	July 20, 2017
Joshua Hexter Former Chief Operating Officer and VP Business Development	March 26, 2017
Mark Hasleton Former VP Business Development	November 15, 2018
Aviad Friedman Director	March 26, 2017
Xiaopeng Li Former Director	March 26, 2017
Leonard Sank Director	January 26, 2017
David Slager Former Director	January 19, 2017
Gao Xiaoming Director	June 28, 2019
Joshua Hexter Chief Operating & Business Officer	September 8, 2019
16	

#### **EMPLOYMENT AGREEMENT**

THIS AGREEMENT is made this 18<sup>th</sup> day of August, 2019 by and between **ORAMED Ltd.**, a company incorporated under the laws of the State of Israel, with an address at 2/4 High Tech Park, Givat Ram, Jerusalem, Israel 91390 (the "**Company**") and **Joshua Hexter** I.D. no. 317759470 an individual residing at, Alfasi 9, Jerusalem, Israel (the "**Executive**").

#### WHEREAS:

- A. The Company has agreed to engage the Executive to serve in the role of Chief Operating & Business Officer of the Company; and
- B. The Executive and the Company wish to formally record the terms and conditions upon which the Executive will be employed by the Company, and each of the Company and the Executive have agreed to the terms and conditions set forth in this Agreement, as evidenced by their execution hereof.

NOW THEREFORE THIS AGREEMENT WITNESSES that in consideration of the premises and the mutual covenants and agreements herein contained, the parties hereto covenant and agree as follows:

#### 1. ENGAGEMENT

- 1.1 Engagement of Executive. The Company hereby agrees to employ the Executive in accordance with the terms and provisions hereof.
- 1.2 <u>Term.</u> Unless terminated earlier in accordance with the provisions hereof, the term of employment under this Agreement shall commence on September 19<sup>th</sup>, 2019 (the "**Effective Date**") and shall continue until terminated by either party as provided herein (the "**Term**").

#### 1.3 Service.

- (a) As of September 19<sup>th</sup>, 2019, the Executive shall serve in the role of Chief Operating & Business Officer of the Company and ORAMED PHARMACEUTICALS INC. (the "**Parent**").
- (b) Scope of service from the Effective Date, the Executive shall perform his work on the basis of a full-time position.
- (c) Without derogating Article 2.1(b) below, it is hereby agreed that the working hours of the Executive shall be as required by the nature of the Executive's position in the Company, however no less than 9 hours per day. The Executive's regular weekly rest day is Saturday.
- (d) The Executive agrees to faithfully, honestly and diligently serve the Company. The Executive undertakes to devote all his working time, efforts and the best of his qualifications and skills to promoting the business and affairs of the Company, and further undertakes to comply with the policies and working arrangements of the Company, to loyally and fully comply with the decisions of the Company, its management, to follow the Company procedures as established from time to time. The Executive agrees and undertakes to inform the Company's Chief Executive Officer (the "CEO") immediately after becoming aware of any matter that may in any way raise a conflict of interest between the Executive and the Company.

- (e) The Executive undertakes to fulfill the responsibilities described in this Agreement and assist the Company, its affiliates, subsidiaries, related corporations and parent company now or hereafter existing (collectively, "Affiliates") and to make himself available to it, even after the termination of his employment relations with the Company, for any reason, in any matter which the Company may reasonably request his assistance, including for the purpose of providing any information relating to his work or actions taken by him and including in the framework of disputes (including legal or quasi-legal proceedings).
- 1.4 <u>Duties.</u> The Executive's services hereunder shall be provided on the basis of the following terms and conditions:
  - (a) reporting to the CEO and the Company's and Parent's Board of Directors (the "Board")
  - (b) the Executive shall be responsible for everyday operations in all aspects of the company, including: patent portfolio, production and supply, clinical trial, contracts and negotiations with different vendors, managing and overseeing the office, being part of the strategic and executive strategic planning and executing it, and being part of the PR and IR implementation, all subject to any applicable law and to instructions provided by the CEO from time to time;
  - (c) the Executive shall faithfully, honestly and diligently serve the Company and the Parent and cooperate with the Company and the Parent and utilize his professional skill and care to ensure that all services rendered hereunder are to the satisfaction of the Company and the Parent, acting reasonably, and the Executive shall provide any other services not specifically mentioned herein, but which by reason of the Executive's capability the Executive knows or ought to know to be necessary to ensure that the best interests of the Company and the Parent are maintained;
  - (d) the Executive shall assume, obey, implement and execute such duties, directions, responsibilities, procedures, policies and lawful orders as may be determined or given from time to time by the Board, and/or CEO; and
  - (e) the Executive shall report the results of his duties hereunder to the CEO and/or the Board as it may request from time to time.

#### 2. COMPENSATION

- 2.1 Salary. For services rendered by the Executive during the Term, the Executive shall be paid a monthly salary, as follows:
  - (a) the Executive shall be entitled to a gross monthly amount of NIS 56,000 (the "Salary").
  - (b) The Executive's assignment is included among the positions of management or those requiring a special degree of personal trust, and the Company is not able to supervise the number of working hours of the Executive; therefore the provisions of the Israeli Hours of Work and Rest Law 1951, will not apply to the Executive and he will not be entitled to any additional remuneration whatsoever for his work with the exception of that specifically set out in this Agreement.
  - (c) Executive's Salary and other benefits shall be annually reviewed by the Board based on his and the Company's performance, all at the Board's sole and absolute discretion.
- 2.2 Company Vehicle. The Executive shall be entitled to the use a company car, as shall be determined by the Company (the "Car"). The Company shall incur all reasonable expenses associated with use of the Car, including fuel expenses, maintenance, tolls, licensing, testing, registration, and insurance, however excluding personal traffic fines, payments to the tax authorities resulting from the use of the Car ("Shovi Shimush") and the like, and the Executive hereby authorizes the Company to deduct any such amount from any amount owing to him thereby, including from the Salary and the Salary minus any such deduction will be referred to as the Executive's Salary for all purpose (including social benefits and the parties' contributions). The use of the Car shall be in accordance with the provisions of the Company's car internal procedures, as may be amended from time to time by the Company and the Executive hereby authorizes the Company to deduct any amount needs to be deducted according to such internal procedures from any amount owing to him thereby, including from the Salary. The Employee shall bear any tax payments resulting from the aforesaid, to the extent applicable. The Car will be returned to the Company by the Employee immediately upon termination of Employee's employment by the Company, for any reason whatsoever.
- 2.3 Expenses. The Executive will be reimbursed by the Company for pre-approved business expenses incurred by the Executive in connection with his duties, and in accordance with Company's policy.
- 2.4 <u>Vacation; Sick Leave and Recreation Pay.</u> The Executive shall be entitled to 22 working days paid vacation (the "Annual Vacation"). It is hereby expressed that the Executive must make every effort to exercise his Annual Vacation; however, if the Executive is unable to utilize all the vacation days, he shall be entitled to accumulate the unused balance of the vacation days standing to his credit up to a ceiling of double the number of his Annual Vacation (the "Ceiling"), provided that he takes at least seven consecutive annual working days vacation. If the Executive accumulate vacation days exceeding the Ceiling, the balance shall be deleted at the beginning of each calendar year. The Company may instruct the Executive to use his Annual Vacation, in the event that Company employees are sent by the Company on an organized vacation. In addition, Executive shall be entitled to sick leave, recuperation, holidays, recreation pay and any other benefits as mandated by applicable law. Treatment of the accrual of unused vacation time and other leave time shall be as provided by applicable law.

- 2.5 Additional Benefits. The Employee shall be entitled to the use of a Company paid mobile phone for business purposes, according to the Company's policies and instructions, as amended from time to time. In addition, the Employee shall be entitled to the use of a Company owned laptop computer, according to the Company's policies and instructions, as amended from time to time. Without derogating from the aforesaid, the Executive hereby undertakes not to make improper use of computer, computer devices, internet and/or e-mails, including (but not limited to) use of illegal software or the receipt and/or transfer of pornographic material, and/or any other material that is not connected with his work and may be harmful to the Company, other employees or any other third party. It is hereby clarified that for purposes of protecting its employees and property, the Company is entitled to conduct examinations and inspections every now and then in order to verify the fulfillment of the Executive's undertakings set forth herein. The Employee shall bear any tax payments resulting from the aforesaid, to the extent applicable.
- 2.6 <u>Deductions.</u> The Executive acknowledges that all payments by the Company in respect of the services provided by the Executive are gross and shall be subject to the deduction of any amount which the Company as an employer is required to deduct or withhold from the Salary or other payments to an executive in accordance with statutory requirements (including, without limitation, health insurance, income tax, employee contributions and unemployment insurance contributions).
- 2.7 <u>Bonus.</u> The appropriate organ of the Company shall consider granting the Executive a bonus for each then-outgoing calendar year and salary and compensation increases for each then-incoming calendar year in amounts to be determined by the Board at least once every calendar year in line with other Executives.
- 2.8 <u>Stock based compensation.</u> Subject to the sole discretion and determination of the Board and/or its compensation committee as applicable and to the terms and provisions of Oramed's Second Amended and Restated 2008 Stock Incentive Plan, as may be amended, restated or otherwise modified from time to time ("**Plan**"), the Executive shall be granted the following:
  - (a) an option ("**Option**") exercisable into 100,000 shares of Common Stock of the Parent ("**Shares**"). The exercise or "strike" price of the Options shall be the market price as of the date of issuance of the Options, and the Options shall be qualified employee stock options under applicable law. The Options shall vest in 16 consecutive equal installments during the 4 year period following September 1, 2019, such that every three months beginning December 1, 2019, 6,250 Options shall vest. Subject to the approval by Oramed's board of directors or compensation committee, as applicable, in the case of a substantial change in the holdings of the Company, i.e. buyout or dilution of more than 35% of issued shares or the sale or licensing of the Company's lead candidate drug, all Options shall be deemed to have fully vested and the Executive, in his discretion, may immediately exercise all his 100,000 Options immediately upon such event.

- (b) Additional Options ("Additional Options") will vest upon the satisfaction (as determined by the Board of Directors of the Parent) of the following conditions:
  - (i) 40,000 Options upon the Company or Parent consummating an out-license arrangement in the aggregate amount of at least \$10,000,000;
  - (ii) 20,000 Options upon the Company or Parent consummating any follow-on licensing transaction with Hefei Tianhui Incubator of Technologies Co. Ltd. or Hefei Tianmai Biotechnology development Co., Ltd.;
  - (iii) 20,000 Options upon the Company or Parent entering into a collaboration agreement (including business or research and development) with a third-party pharmaceutical company having a market capitalization of at least \$500,000,000;
  - (iv) 20,000 Options upon the consummation of the merger, acquisition or sale of substantially all assets of Oramed HK Limited, the Company's subsidiary organized under the laws of Hong Kong, in an aggregate amount of at least \$100,000,000.
- (c) The Employee undertakes to take all actions and to sign all documents required, at the discretion of the Company, in order to give effect to and enforce the above terms and conditions. Any tax liability in connection with the Options (including with respect to the grant, exercise, sale of the Options or the shares receivable upon their exercise) shall be borne solely by the Employee.

#### 3. SOCIAL INSURANCE AND BENEFITS

3.1 The Executive shall be entitled to a pension arrangement, a Managers' Insurance Policy (the "Policy") and/or Pension Fund (the "Pension Fund") as follows:

The Company shall contribute 8.33% of the Salary for severance compensation (the "Severance Contribution").

In addition, the Company shall contribute 6.5% of the Salary for pension compensation (Tagmulim) towards Policy/Pension Fund.

In the event that the Executive chooses Policy arrangement, the pension compensation (Tagmulim) shall include the Company's payment for purchase of disability insurance coverage sufficient to secure 75% of the Salary; provided that the Company's contributions solely for pension compensation (Tagmulim) shall be not less than 5% and subject to the consent of the insurance company to insure the Executive. For the avoidance of any doubt, in the event that the cost to the Company shall be more than the required contributions rates towards pension compensation (6.5% as described above) due to the cost of the disability insurance, the total cost of the Company's contributions to pension compensation and disability insurance collectively shall not exceed 7.5% of the Salary.

The Company shall deduct from the Salary the Executive's contributions for pension compensation (Tagmulim) in an amount of 6% of the Salary towards Policy/Pension Fund.

Any tax liability in connection with pension arrangement shall be borne solely by the Executive.

The Executive agrees and acknowledges that the Company's Severance Contribution in accordance with the foregoing, shall be in lieu of 100% of the severance payment to which the Executive (or his beneficiaries) shall be entitled with respect to the Salary and the contributions were made and for the period in which they were made, pursuant to Section 14 of the Severance Pay Law, 1963 (the "Severance Law") in accordance with the instructions of "The General Approval Regarding Employers' Payments to Pension Fund and Insurance Fund Instead of Severance Pay" (the "General Approval", a copy of which is attached hereto as Exhibit A), as amended from time to time in case the Executive chooses a Policy and in the event that the Executive chooses Pension Fund arrangement in accordance with Sections 7 and 9 to the Extension Order General Insurance Pension In The Israeli Market.

The Company hereby waives any of its rights to refund monies from the payments it transfers to the Policy/Pension Fund in accordance with this Section, unless the Executive's right to severance pay is denied by virtue of a court order, under Sections 16 or 17 of the Severance Law, and in the same amount which was denied, or the Executive withdraws monies from the Policy and/or the Pension Fund not due to a Granting Event. The term "Granting Event" shall mean - death, disability or retirement at the age of sixty or more.

- 3.2 <u>Keren Hishtalmut</u>. The Company shall make monthly contributions on the Executive's behalf to a recognized advanced study fund (the "**Fund**" ("Keren Hishtalmut") in an amount equal to 7.5% of the Salary. In addition, the Company shall deduct 2.5% from the Salary and transfer those monies to the Study Fund. The Employee shall bear any and all taxes, which may apply with respect to such benefit.
- 3.3 Effect of Termination. Upon termination of this Agreement by either party, other than in circumstances constituting Cause (as defined below), the Company shall assign and transfer to the Executive, after Executive has met all of Executive's obligations hereunder in connection with such termination of employment, the ownership in the Keren Hishtalmut Fund. Notwithstanding the above, in the event that this Agreement is terminated in circumstances constituting Cause, the Company, in its absolute discretion, may retain its payments to such funds and release to the Executive only those sums contributed by Executive to such funds.

3.4 <u>Liability Insurance Indemnification</u>. The Company shall provide the Executive (including his heirs, executors and administrators) with coverage under a standard directors' and officers' liability insurance policy at the Company's expense.

#### 4. CONFIDENTIALITY, INTELLECTUAL PROPERTY, COPYRIGHTS, PATENT AND NON COMPETITION

4.1 Maintenance of Confidential Information. The Executive acknowledges that in the course of employment hereunder the Executive will, either directly or indirectly, have access to and be entrusted with proprietary, non-public information (whether oral, written or by inspection) relating to the Company and its parent company, or its associates or customers (collectively for this Article 4 the "Company") (the "Confidential Information"). For the purposes of this Agreement, "Confidential Information" includes, without limitation, any and all Developments (as defined herein), trade secrets, inventions, innovations, techniques, processes, formulas, drawings, designs, products, systems, creations, improvements, documentation, data, specifications, technical reports, customer lists, supplier lists, distributor lists, distribution channels and methods, retailer lists, reseller lists, employee information, financial information, sales or marketing plans, competitive analysis reports and any other thing or information whatsoever, whether copyrightable or uncopyrightable or unpatentable or unpatentable. The Executive acknowledges that the Confidential Information constitutes a proprietary right, which the Company is entitled to protect. Accordingly the Executive covenants and agrees that during the Term and thereafter until such time as Confidential Information becomes publicly known and made generally available through no action or inaction of the Executive, the Executive will keep in strict confidence the Confidential Information and shall not, without prior written consent of the Company, disclose, use or otherwise disseminate the Confidential Information, directly or indirectly, to any third party.

The Executive undertakes not to directly or indirectly give and/or transfer, directly or indirectly, to any person or entity, any material and/or raw material and/or product and/or part of a product and/or model and/or document and/or diskette and/or other information storage media and/or photocopied and/or printed and/or duplicated object containing any or all of the Confidential Information.

The Executive undertakes not to make any use, including duplication, production, sale, transfer, imitation and distribution, of all or any of the Confidential Information, without the prior written consent of the Company.

The Executive will not use or disclose any confidential information or trade secrets, if any, of any former employer or any third party or any information in respect of which the Executive has confidentiality obligations, and the Executive will not bring onto the premises of the Company any such information, unless express written consent was provided by such former employer or third party.

- 4.2 Exceptions. The general prohibition contained in Section 4.1 against the unauthorized disclosure, use or dissemination of the Confidential Information shall not apply in respect of any Confidential Information that:
- (a) is available to the public generally in the form disclosed;
- (b) becomes part of the public domain through no fault of the Executive;
- (c) is already in the lawful possession of the Executive at the time of receipt of the Confidential Information, as can be proven by written documentation; or
- (d) is compelled by applicable law to be disclosed, provided that the Executive gives the Company prompt written notice of such requirement prior to such disclosure and provides assistance in obtaining an order protecting the Confidential Information from public disclosure.

#### 4.3 Intellectual Property, Copyright and Patents

- 4.3.1 The Executive hereby acknowledges and agrees that the Company owns and shall own any and all Intellectual Property Rights created, made or discovered by the Executive or employee or personal that reports to Executive either: during the term of employment; and/or in connection therewith; and/or in connection with the Company, its business (actual and/or contemplated), products, technology and/or know how ("Company IPR"). Intellectual Property Rights means all worldwide (a) patents, patent applications and patent rights; (b) rights associated with works of authorship, including copyrights, copyrights applications, copyrights restrictions, mask work rights, mask work applications and mask work registrations; (c) rights relating to the protection of trade secrets and confidential information; (d) moral rights; (e) rights analogous to those set forth herein and any other proprietary rights relating to intangible property including ideas; and (f) divisions, continuations, renewals, reissues and extensions of the foregoing (as applicable) now existing or hereafter filed, issued, or acquired.
- 4.3.2 The Executive hereby assigns to the Company and/or its designee, all right, title and interest in and to Company IPR upon its creation. The Executive will assist the Company to obtain, and from time to time enforce, any Company IPR worldwide, including without limitation, executing, verifying and delivering such documents and performing such other acts as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Company IPR. Such obligation shall remain in effect beyond the termination of the Executive's relationship with the Company, all for no additional consideration provided that Executive shall not be required to bear any expenses as a result of such assignment. In the event the Company is unable for any reason, after reasonable effort, to secure Executive's signature on any document required, Executive hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as its agent and attorney in fact to act for and in its behalf to further the above purposes.

- 4.3.3 The Executive irrevocably confirms that the Salary is inclusive of any and all rights for compensation that may arise in connection with the Company IPR under applicable law, and the Executive hereby waives, releases and forever discharges any claims and/or demands whatsoever, whether in law, in equity or otherwise, in relation to the Company IPR, including without limitation any moral rights and rights to receive royalties in connection therewith and expressly waive any rights to receive royalties under the Israeli Patent Law- 1967 without limitation, Section 134 thereof or other applicable laws.
- 4.3.4 The Executive represents and warrants that upon execution hereof it has not created and does not have any right, title or interest in and to any Intellectual Property Rights related and/or similar to Company's business, products or Intellectual Property Rights, other than those set forth in Annex A1 hereto ("**Prior Inventions**"). The Executive undertakes not to incorporate any Prior Inventions in any Company IPR.
- 4.3.5 The Executive undertakes to immediately inform and deliver to the Company, written notice of any Company IPR conceived/ invented by him and/or personal of the Company and/or its successors who are subordinate to him, immediately upon the discovery thereof.
- 4.3.6 The Executive's obligations pursuant to this Section shall survive the termination of his employment with the Company and/or its successors and assigns with respect to inventions conceived by him during the term of his employment or as a result of his employment with the Company.

#### 4.4 Non-Competition/Non solicitation

- 4.4.1 Non-Competition. Executive agrees and undertakes that he will not, so long as he is employed by the Company and for a period of 6 months following the last date of actual service for whatever reason, directly or indirectly, as owner, partner, joint venture, stockholder, employee, broker, agent, principal, corporate officer, director, licensor or in any other capacity whatever engage in, become financially interested in, be employed by, or have any connection with any business or venture that directly competes with the Company's business, including any business which, when this Agreement terminates, the Company contemplates in good faith to be materially engaged in within six (6) months thereafter, provided that the Company has taken demonstrable actions to promote such engagement or that the Company's Board of Directors has adopted a resolution authorizing such actions prior to the date of termination; provided, however, that Executive may own securities of any corporation which is engaged in such business and is publicly owned and traded but in an amount not to exceed at any one time 5% of any class of stock or securities of such company, so long as he has no active role in the publicly owned and traded company as director, employee, consultant or otherwise.
- 4.4.2 No Solicitation. Executive agrees and undertakes that during the period of his employment and for a period of 6 months following termination for any reason whatsoever, he will not, directly or indirectly, including personally or in any business in which he is an officer, director or shareholder, for any purpose or in any place, approach and/or solicit and/or recruit any employee, consultant, customer and/or supplier of the Company to leave his employ/disconnect his engagement with the Company.
- 4.5 <u>Fiduciary Obligation.</u> The Executive declares that the Executive's relationship to the Company is that of fiduciary, and the Executive agrees to act towards the Company and otherwise behave as a fiduciary of the Company.
- 4.6 Remedies. The parties to this Agreement recognize that any violation or threatened violation by the Executive of any of the provisions contained in this Article 4 may result in immediate and irreparable damage to the Company and that the Company could not adequately be compensated for such damage by monetary award alone. Accordingly, the Executive agrees that in the event of any such violation or threatened violation, the Company shall, in addition to any other remedies available to the Company at law or in equity, be entitled as a matter of right to apply to such relief by way of restraining order, temporary or permanent injunction and to such other relief as any court of competent jurisdiction may deem just and proper.

  Nothing contained herein shall be construed to be a concession as to the appropriateness of any such application under the particular circumstances.
- 4.7 <u>Reasonable Restrictions.</u> The Executive agrees that all restrictions in this Article 4 are reasonable, in view of his position and the nature of the business in which the Company is engaged, the Executive's knowledge of the Company's business and the compensation he receives.

#### 5. TERMINATION

- 5.1 <u>Termination For Cause or Disability.</u> This Agreement may be terminated at any time by the Company upon notice, for Cause or in the event of the Disability of Executive. For the purposes of this Agreement, "Cause" means that the Executive shall have:
- (a) committed an intentional act of fraud, embezzlement or theft in connection with the Executive's duties or in the course of the Executive's employment with the Company;
- (b) intentionally and wrongfully damaged property of the Company, or any of its respective affiliates, associates or customers;
- (c) intentionally or wrongfully disclosed any of the Confidential Information;
- (d) made material personal benefit at the expense of the Company without the prior written consent of the management of the Company;
- (e) accepted shares or options or any other gifts or benefits from a vendor without the prior written consent of the management of the Company;
- (f) fundamentally breached any of the Executive's material covenants contained in this Agreement, and did not cure the breach within a reasonable period (but in no event shall such period be less than 14 days) after being warned in writing by Company's CEO of possible termination for cause on account of such breach; or
- (g) willfully and persistently, without reasonable justification, failed or refused to follow the lawful and proper directives of the Company specifying in reasonable detail the alleged failure or refusal and did not cure the breach within a reasonable period (but in no event shall such period be less than 14 days) after being warned in writing by Company's CEO of possible termination on account of such insubordination.

For the purposes of this Agreement, an act or omission on the part of the Executive shall not be deemed "intentional," if it was due to an error in judgment or negligence, but shall be deemed "intentional" if done by the Executive not in good faith and without reasonable belief that the act or omission was in the best interests of the Company, or its respective affiliates, associates or customers.

For the purposes of this Agreement, "**Disability**" shall mean any physical or mental illness or injury as a result of which Executive remains absent from work for a period of six (6) successive months, or an aggregate of six (6) months in any twelve (12) month period. Disability shall occur upon the end of such six-month period. It is agreed that Disability will not be reason to exempt Company from Severance pay or any social benefits, or bonuses Executive is entitled to upon Termination.

Executive may terminate this employment without any prior notice and effective immediately in the event he was not paid his salary or his benefits, more than 45 days after such payment or benefit must be paid, or if his car or his mobile phone taken away from him without being replaced, for a period of more than 30 days, or if his responsibilities or title in the company were taken from him, for a period exceeding 60 days. Under such conditions Executive will be entitled to all social benefits related to termination including full Severance Pay and full release of funds under his Policy.

5.2 <u>Termination Without Cause</u>. Either the Executive or the Company may terminate the Executive's employment without Cause, for any reason whatsoever, with 30 days' prior written notice within the first 6 months of the Executive's engagement, and 60 days, prior written notice thereafter (said terms of 30 days and 60 days, respectively, shall be defined as the "Notice Period").

#### 5.3 The Notice Period.

(a) During the period following the notice of termination (the "Notice Period"), Executive shall cooperate with the Company and use his best efforts to assist the integration into the Company's organization of the person or persons who will assume Executive's responsibilities.

Nevertheless, the Company shall have the right not to take advantage of the full or part of the Notice Period. In the event of such termination, the Company shall pay the Executive his Salary his social benefits as described in Articles 3.1 and 3.2 as detailed in this Agreement for the remainder in lieu of the Notice Period.

It is hereby expressly stated that the Company reserves the right to terminate the Executive's employment at any time during the Notice Period, regardless of whether notice of termination of employment was delivered by the Company or whether such notice was delivered by the Executive. In the latter case such termination shall not constitute a dismissal of the Executive by the Company.

It is agreed that if Company needs Executive for any further assistance after the Notice Period it will pay Executive \$200 per hour of work plus VAT, beyond the first 20 hours of such work.

(b) Notwithstanding the foregoing, the Company may terminate the Executive's employment with a delivery of written notice, without waiting the Notice Period in the event of termination under circumstances which deprive the Executive of severance pay under Israeli law, and/or a breach of trust. In such case, Company must pay the Executive his salary and other benefits for the Notice Period, and the Company must file a claim to the competent Labor court within 30 days of delivery of written notice of termination to the Executive. In a case of a judgment that ruled that Executive is not entitled even to his salary and benefits during the Notice Period, Executive must return all money and value of benefits he received to Company within 60 days this judgment becomes final and non- appealable.

- (c) In the event that the Executive terminates his employment with the Company, for any reason, without the delivery of a written notice in accordance with Section 6.2 above, or without the completion of the Notice Period or any part thereof, the Company will be entitled to deduct from any debt which it may owe the Executive an amount equal to the salary that would have been paid to the Executive during the Notice Period, had he worked; this deduction shall be without derogation of any of the Executive's rights or the Company's obligations.
- 5.4 <u>Limitation of Damages.</u> It is agreed that in the event of termination of employment, neither the Company, nor the Executive shall be entitled to any notice, or payment in excess of that specified in this Article 5, unless a Labor court rules that the Termination or Termination Process was not lawful or was not effective.
- 5.5 <u>Return of Materials.</u> Within three days of any termination of employment hereunder, or upon any request by the Company at any time, the Executive will return or cause to be returned any and all Confidential Information and other assets of the Company (including all originals and copies thereof), which "assets" include, without limitation, car, cell phone, hardware, software, keys, security cards and backup tapes that were provided to the Executive either for the purpose of performing the employment services hereunder or for any other reason. The Executive acknowledges that the Confidential Information and the assets are proprietary to the Company, and the Executive agrees to return them to the Company in the same condition as the Executive received such Confidential Information and assets.
- 5.6 Effect of Termination. Articles 4 hereto and hereto shall remain in full force and effect after termination of this Agreement, for any reason whatsoever but without derogation of any rights of the Executive under applicable law, including without limitation, to unpaid salary, benefits, options, vacation time, etc., throughout the date of termination and the Notice Period.

#### 6. MUTUAL REPRESENTATIONS

- 6.1 Each party hereto represents and warrants to the other that the execution and delivery of this Agreement and the fulfillment of the terms hereof (i) will not constitute a default under or conflict with any agreement or other instrument to which he/it is a party or by which he/it is bound, and (ii) do not require the consent of any person or entity, or that to the extent such consent is required, it has been obtained.
- 6.2 The Company represents and warrants to Executive that this Agreement is subject to the approval of the compensation committee and all the applicable approvals according to applicable law.

6.3 Each party hereto warrants and represents to the other that this Agreement constitutes the valid and binding obligation of such party enforceable against such party in accordance with its terms subject to applicable bankruptcy, insolvency, moratorium and similar laws affecting creditors' rights generally, and subject, as to enforceability, to general principles of equity (regardless if enforcement is sought in proceeding in equity or at law).

#### 7. NOTICES

- 7.1 Notices. All notices required or allowed to be given under this Agreement shall be made either personally by delivery to or by facsimile transmission to the address as hereinafter set forth or to such other address as may be designated from time to time by such party in writing:
- (a) in the case of the Company, to:

#### Oramed Ltd.

2/4 High Tech Park PO Box 39098 Givat Ram, Jerusalem Israel 91390 Fax: 972 2 5660004

- (b) and in the case of the Executive, to the Executive's last residence address known to the Company.
- 7.2 <u>Change of Address.</u> Any party may, from time to time, change its address for service hereunder by written notice to the other party in the manner aforesaid.

#### 8. **GENERAL**

- 8.1 Entire Agreement. As of from the date hereof, any and all previous agreements, written or oral between the parties hereto or on their behalf relating to the employment of the Executive by the Company are null and void. The parties hereto agree that they have expressed herein their entire understanding and agreement concerning the subject matter of this Agreement and it is expressly agreed that no implied covenant, condition, term or reservation or prior representation or warranty shall be read into this Agreement relating to or concerning the subject matter hereof or any matter or operation provided for herein.
- 8.2 <u>Personal Agreement</u>. The provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law).
- 8.3 <u>Further Assurances.</u> Each party hereto will promptly and duly execute and deliver to the other party such further documents and assurances and take such further action as such other party may from time to time reasonably request in order to more effectively carry out the intent and purpose of this Agreement and to establish and protect the rights and remedies created or intended to be created hereby.

- 8.4 <u>Waiver.</u> No provision hereof shall be deemed waived and no breach excused, unless such waiver or consent excusing the breach is made in writing and signed by the party to be charged with such waiver or consent. A waiver by a party of any provision of this Agreement shall not be construed as a waiver of a further breach of the same provision.
- 8.5 <u>Amendments in Writing.</u> No amendment, modification or rescission of this Agreement shall be effective unless set forth in writing and signed by the parties hereto.
- 8.6 <u>Severability.</u> In the event that any provision contained in this Agreement shall be declared invalid, illegal or unenforceable by a court or other lawful authority of competent jurisdiction, such provision shall be deemed not to affect or impair the validity or enforceability of any other provision of this Agreement, which shall continue to have full force and effect.
- 8.7 <u>Headings.</u> The headings in this Agreement are inserted for convenience of reference only and shall not affect the construction or interpretation of this Agreement.
- 8.8 Number and Gender. Wherever the singular or masculine or neuter is used in this Agreement, the same shall be construed as meaning the plural or feminine or a body politic or corporate and vice versa where the context so requires.
- 8.9 <u>Governing Law.</u> This Agreement shall be exclusively construed and interpreted in accordance with the laws of the state of Israel applicable therein, and each of the parties hereto expressly agrees to the jurisdiction of the courts of the state of Israel. The sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the applicable Jerusalem court.
- 8.10 Enurement. This Agreement is intended to bind and enure to the benefit of the Company, its successors and assigns, and the Executive and the personal legal representatives of the Executive.

This Agreement constitutes due notification in accordance with the Notice to Employee Law (Employment Terms), 2002 and the regulations promulgated thereunder.

ORAMED Ltd.		
Nadav Kidron: /s/ Nadav Kidron	Joshua Hexter:	/s/ Joshua Hexter
Title: Chief Executive Officer		
	-15-	

IN WITNESS WHEREOF the parties hereto have executed this Agreement effective as of the date and year first above written.

#### ANNEX "A"

#### Use of computer systems, internet browsing and company email

- 1. It is strictly forbidden to make use of company <sup>1</sup> computers, internet browsing or company email for any purposes which are illegal, inappropriate or unsuitable, including accessing inappropriate or unsuitable websites (such as pornographic websites). it is additionally forbidden to install any programs on company computer systems, or make use of any such system to transfer materials unrelated to work or detrimental to the company, its clients, employees, or any other third party. misuse of company computers, internet browsing or company emails may cause considerable harm to the company or other third parties, as well as the computer systems themselves and their users. if in doubt, please refer to the company it manager.
- 2. We would like to clarify that the company does not forbid private use of the computer made available to you for work purpose or the office internet connection, within reasonable bounds, and while always maintaining confidentiality (as set forth in your employment agreement), without derogating from work requirements and subject to section 1 above. nonetheless, it is important to clarify that due to the nature of the company computer systems, network operational maintenance requirements, as well as for the implementation of this section 2, the company may block certain websites from access, and the company it manager may access any computer on the company network, and accordingly, any information found on your computer may be exposed to the company it manager and his/her /her superiors.
- 3. The company provides you with an email account exclusively for professional use as required within the scope of your position in the company, therefore, the company shall be entitled to monitor and conduct surveillance of the communicated data in any such professional mailbox, you are aware, and hereby consent that the company shall be permitted to access the contents of such mailbox, should an urgent professional need arise or in case there is grave concern or reasonable grounds for concern regarding activity which is illegal or harmful to the company or any third party (including violation of the terms above), or in any other case in accordance with the law. such monitoring shall be conducted proportionally, in adherence to the goals as stated above, and the information, if aggregated, shall be stored solely for the period of time required for the purposes as stated above, the monitored information, if and any as such, shall not be transferred to any third party, excluding the security and support service provider of the company's computer systems, any security and support service provider which shall replace it in the future, or in accordance with the law, subject to the aforementioned, accordingly, any information found in the professional electronic mailbox may be accessible to the company, and as such it should be taken into account that any private use of the professional mailbox should be avoided, at the expiration of your position with the company, any private correspondence saved in the professional mailbox must be removed (if any such correspondence exists despite the above) and any information found in the professional mailbox (which should contain solely professional correspondence) shall be exposed to the relevant parties in the company. if you wish to do so, you may make private use of electronic mail correspondence using a private and external mail service (such as gmail), with which you may send and receive private correspondence which will not be exposed to the company, and so long as such
- 4. It is also clarified that the company may allow other employees and other third parties and use the personal laptop / laptop that is given to you for your work. since the computer, e-mail, corporate network and internet connection are provided for professional purposes only, the company has the right to disconnect you from such systems at its sole discretion at any time. without prejudice to the foregoing, it is prohibited to leave these tools and / or to give access to any of these tools without supervision and / or contrary to the company's policy. in any case where there is a concern that another party, other than you, has access to these tools (for example, in the event of password disclosure, theft and / or loss), contact the computer administrator immediately.

<sup>&</sup>lt;sup>1</sup> All terms not defined herein shall have the meaning ascribed to them in the Employment Agreement.

- 5. In addition, you are to avoid using the internet in general and social networks in particular in a manner that is likely to create the impression that your private use of the social networks is on behalf of the company and/or in its name. thus, for example, it is forbidden to upload pictures or other information connected to the company or the company's events or the company's employees, or make use of the company's name or any insignia in a manner that indicates that your publication is an official publication of the company, as opposed to your private publication, upon your own authority. in any event of doubt, you may contact the it manager with any questions.
- 6. For the avoidance of any doubt, the it manager, anyone acting on his/her behalf, and any other person who has access to the e-mail, computer and the various folders, are to refrain from any use at all of the information therein, including its publication or any other personal use, beyond the purposes delineated in this policy, and to keep this information in strictest confidence.
- 7. It is preferable, that during your absence from work, for whatever reason, you leave an orderly "out of office" email message with the date of your return and a referral to whomever is substituting for you during the period of your absence.
- 8. You undertake that, at the termination of your employment, you transfer the content of the computer and your email account, as is, to the it manager. if you wish to delete personal and private files or to remove them from the computer this shall be done only with the approval of and in coordination with the it manager.
- 9. After termination of your employment, the company, by means of the direct supervisor and it manager, shall be entitled to access your computer, email account and folders.
- 10. You are required to keep current regarding the company's policy of computer use as will be updated from time to time.

I hereby read and declare I read this annex A, understood its provisions and agree thereto.

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Joshua Hexter:	/s/ Joshua Hexter		Date:	18/8/19	
		A-2			

# Exhibit A To the Personal Employment Agreement by and between Oramed Ltd. and Joshua Hexter הסכם עפ"י סעיר 14 לחוק פיצויי פיטורים

אני הח"מ, מאשר/ת בזאת כי אני מסכים/מה לאמץ את התנאים המפורטים להלן בדבר תשלומים שוטפים בלבד של 30.6.98 מיום 4659 מיום 4659 מיום 4659 מיום 20.6.98 מיום 20.6.98 מיום 20.6.98 מיום 20.6.98 מיום 20.6.98 מיום 20.6.98 מיום 20.6.99 מ

"בתוקף סמכותי לפי סעיף 14 לחוק פיצויי פיטורים התשכ"ג – 1963 (להלן – החוק), אני מאשר כי תשלומים ששילם מעביד החל ביום פרסומו של אישור זה, בעד עובדו לפנסיה מקיפה בקופת גמל לקצבה שאינה קופת ביטוח כמשמעותה בתקנות מס הכנסה (כללים לאישור ולניהול קופת גמל) התשכ"ד – 1964 (להלן – קרן פנסיה), או לביטוח מנהלים הכולל אפשרות לקצבה או שילוב של תשלומים לתכנית קצבה ולתכנית שאינה לקצבה בקופת ביטוח כאמור (להלן – קופת ביטוח), לרבות תשלומים ששילם תוך שילוב של תשלומים לקרן פנסיה ולקופת ביטוח בין אם יש בקופת הביטוח תכנית לקצבה ובין אם לאו (להלן – תשלומי המעביד), יבואו במקום פיצויי הפיטורים המגיעים לעובד האמור בגין השכר שממנו שולמו התשלומים האמורים ולתקופה ששולמו (להלן – השכר המופטר), ובלבד שנתקיימו כל אלה:

#### תשלומי המעביד .1

- (א) לקרן פנסיה אינם פחותים מ- 14.33% מן השכר המופטר או 12% מן השכר המופטר אם משלם המעביד בעד עובדו בנוסף לכך גם תשלומים להשלמת פיצויי פיטורים לקופת גמל לפיצויים או לקופת ביטוח על שם העובד בשיעור של 2.33% מן השכר המופטר. לא שילם המעביד בנוסף ל- 12% גם 2.33% כאמור, יבואו תשלומיו במקום 75% מפיצויי הפיטורים של העובד, בלבד;
  - (ב) לקופת ביטוח אינם פחותים מאחד מאלה:
- (1) 13.33 מן השכר המופטר, אם משלם המעביד בעד עובדו בנוסף לכך גם תשלומים להבטחת הכנסה חודשית במקרה אובדן כושר עבודה, בתכנית שאישר הממונה על שוק ההון ביטוח וחיסכון במשרד האוצר, בשיעור הדרוש להבטחת 75% מן השכר המופטר לפחות או בשיעור לפי 2.5% מהשכר המופטר, לפי הנמוך מביניהם (להלן – תשלום לביטוח אובדן כושר עבודה):
- (2) מן השכר המופטר, אם שילם המעביד בנוסף גם תשלום לביטוח אובדן כושר עבודה, ובמקרה זה יבואו תשלומי המעביד במקום 77% מפיצויי הפיטורים של העובד, בלבד; שילם המעביד נוסף על אלה גם תשלומים להשלמת פיצויי פיטורים לקופת גמל לפיצויים או לקופת ביטוח על שם העובד בשיעור של 2.33% מן השכר המופטר, יבואו תשלומי המעביד במקום 100% פיצויי הפיטורים של העובד.
- 2. לא יאוחר משלושה חודשים מתחילת ביצוע תשלומי המעביד נערך הסכם בכתב בין המעביד לבין העובד ובו (א) הסכמת העובד להסדר לפי אישור זה בנוסח המפרט את תשלומי המעביד ואת קרן הפנסיה וקופת הביטוח, לפי העניין; בהסכם האמור ייכלל גם נוסחו של אישור זה; (ב) ויתור המעביד מראש על כל זכות שיכולה להיות לו להחזר כספים מתוך תשלומיו, אלא אם כן נשללה זכות העובד לפיצויי פיטורים בפסק דין מכוח סעיפים 16 או 17 לחוק ובמידה שנשללה או משך העובד כספים מקרן הפנסיה או מקופת הביטוח שלא בשל אירוע מזכה; לעניין זה, "אירוע מזכה" מוות, נכות או פרישה בגיל שישים ויותר.
  - 3. אין באישור זה כדי לגרוע מזכותו של עובד לפיצויי פיטורים לפי החוק, הסכם קיבוצי, צו הרחבה או חוזה עבודה, בגין שכר שמעבר לשכר המופטר.

/s/ Nadav Kidron	/s/ Joshua Hexter
החברה	העובד

#### **Exhibit A (English Translation)**

#### General Confirmation Regarding Employers' Payments to Pension Funds and Insurance Funds Instead of Severance Pay

By my power under section 14 of the Severance Pay Law, 5723-1963 (hereinafter - the **Law**), I hereby confirm that payments made by an employer from the date of publication of this confirmation, for an employee's comprehensive pension, to a provident fund for pension which is not an insurance fund, as defined in the Income Tax Regulations (Rules for Approval and Management of Provident Funds), 5724-1964 (hereinafter - **pension fund**), or for an executive insurance policy that includes the possibility of a pension or a combination of payments for a pension plan and for a non-pension plan in an insurance fund as stated (hereinafter - **insurance fund**), including payments which the employer made by a combination of payments to a pension fund and to an insurance fund, whether the insurance fund includes a pension plan or not (hereinafter - **employer payments**), will replace the severance pay to which the employee is entitled for the salary on which said payments were made and the period for which they were made (hereinafter - **exempt salary**), if the following conditions are satisfied:

- (1) Employer payments -
  - (A) To a pension fund are not less than 14 1/3% of the exempt salary, or 12% of the exempt salary if the employer makes additional payments on behalf of his employee for severance pay supplementation to a provident fund for pension or to an insurance fund at the rate of 2 1.3% of the exempt salary. If an employer does not pay beyond the 12% an additional 2 1/3% as stated, then his payments will come instead of only 72% of the employee's severance pay.
  - (B) To an insurance fund are not less than one of the following:
    - (1) 13 1/3% of the exempt salary, if the employer makes additional payments on behalf of the employee to assure his monthly income in case of work disability, in a plan approved by the Capital Market, Insurance and Savings Commissioner in the Finance Ministry, at the lower of the rate required to assure 75% of the exempt salary or 2 1/2% of the exempt salary (hereinafter work disability payment).
    - (2) 11% of the exempt salary, if the employer makes an additional work disability payment, and in such case the employer payments will come instead of only 72% of the employee's severance pay. If in addition to the above the employer pays 2 1/3% of the exempt salary for severance pay supplementation to a provident fund for pension or to an insurance fund in the name of the employee, the employer payments will come instead of 100% of the employee's severance pay.
- (2) A written agreement was made between the employer and the employee no later than three months after the commencement of the employer payments that includes -
  - (A) The agreement of the employee to the arrangement pursuant to this confirmation, which details the employer payments as well as the pension fund or the insurance fund, as the case may be. Said agreement must include the text of this confirmation.
  - (B) The employer's prior waiver of any right he could have to reimbursement of any amount of his payments, unless the employee's right to severance pay is denied by judgment under sections 16 or 17 of the Law, and to the extent it is so denied, and in case the employee withdrew monies from the pension fund or the insurance fund other than for an entitling event. In this regard, entitling event means death, disability or retirement at the age of 60 or over.
- (3) This confirmation does not derogate from the employee's right to severance pay under the Law, a collective agreement, an extension order or an employment contract, for any salary above the exempt salary.

/s/ Nadav Kidron	_	/s/ Joshua Hexter
The Company	_	The Employee
	A-4	

### **SUBSIDIARIES**

Oramed Ltd. – Incorporated in the State of Israel Oramed HK Limited – Incorporated in Hong Kong



### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-215525 and 333-190497) and Form S-8 (Nos. 333-234303, 333-213835, 333-199120, 333-190222 and 333-163919) of Oramed Pharmaceuticals Inc. of our report dated November 27, 2019 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel November 27, 2019 /s/ Kesselman & Kesselman Certified Public Accountants (lsr.) A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel, P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

## CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

- I, Nadav Kidron, certify that:
  - 1. I have reviewed this Annual Report on Form 10-K of Oramed Pharmaceuticals Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 27, 2019 By: /s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

## CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

- I, Avraham Gabay, certify that:
  - 1. I have reviewed this Annual Report on Form 10-K of Oramed Pharmaceuticals Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 27, 2019 By: /s/ Avraham Gabay

Avraham Gabay Chief Financial Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the annual report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-K for the period ended August 31, 2019, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Nadav Kidron, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

- 1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 27, 2019 /s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the annual report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-K for the period ended August 31, 2019, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Avraham Gabay, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

- 1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 27, 2019 /s/ Avraham Gabay

Avraham Gabay Chief Financial Officer