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, 2020

or

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

Commission file number 000-50298

ORAMED PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**98-0376008**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1185 Avenue of the Americas, Third Floor, New York, NY	**10036**
(Address of Principal Executive Offices)	(Zip Code)

844-967-2633
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

None.
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Date File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter was $60,800,854, based on a price of $4.08, being the last price at which the shares of the registrant's common stock were sold on The Nasdaq Capital Market prior to the end of the most recently completed second fiscal quarter.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 23,675,530 shares of common stock issued and outstanding as of November 24, 2020.

ORAMED PHARMACEUTICALS INC.

FORM 10-K
(FOR THE FISCAL YEAR ENDED AUGUST 31, 2020)

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As used in this Annual Report on Form 10-K, the terms "we," "us," "our," the "Company," and "Oramed" mean Oramed Pharmaceuticals Inc. and our wholly-owned subsidiaries, Oramed Ltd. an Israeli corporation, and Oramed HK Limited, a Hong Kong corporation, unless otherwise indicated. All dollar amounts refer to U.S. dollars unless otherwise indicated.

On August 31, 2020, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.362 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 Biologics License 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;

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

- our expectations regarding the impact of the coronavirus, or COVID-19, pandemic, including on our clinical trials and operations.

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.

Through our research and development efforts, we have successfully developed an oral dosage form intended to withstand the harsh environment of the stomach and intestines and effectively deliver active insulin or other proteins, such as Glucagon-like peptide-1, or GLP-1, leptin, and others. The excipients in the formulation 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.

Oral insulin: Our proprietary flagship product, an orally ingestible insulin capsule, or ORMD-0801, 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.

FDA Guidance: In August 2017, the U.S. Food and Drug Administration, or FDA, instructed us 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.

Phase IIb Study: In May 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801 (Cohort A). 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 initiated an extension of this protocol for approximately 75 type 2 diabetic patients, who were dosed using a lower dosage of insulin (Cohort B).

Cohort A: 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 statistically significant (p-value 0.036) reduction from baseline in HbA1c of 0.60% (0.54% with placebo adjustment). This 0.54% reduction in HbA1c is clinically meaningful. Treatment with ORMD-0801 demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes when compared to placebo. 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). The twice-daily arms achieved statistically significant (p-value 0.042) reductions from baseline in HbA1c of 0.59% (0.53% with placebo adjustment). The thrice-daily arm did not meet statistical significance (p-value 0.093). 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. Our internal investigation as well as an independent investigation did not find a cause for such discrepancy.

Cohort B: In February 2020, we announced positive topline data from the second and final cohort of the Phase IIb trial with a different regimen across three daily dose ranges (8 mg, 16 mg, 32 mg). Patients randomized in the trial treated with 8 mg of ORMD-0801 once-daily achieved a statistically significant (p-value 0.028) observed mean reduction of 1.29% from baseline and a least square mean reduction of 0.95% from baseline, or 0.81% adjusted for placebo. Patients who had HbA1c readings above 9% at baseline and received 8 mg of oral insulin once-daily experienced a 1.26% reduction in HbA1c by week 12. Treatment with ORMD-0801 at all doses demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes or weight gain compared to placebo. The primary efficacy endpoint was a reduction in HbA1c at week 12.

Phase III Study: Based on guidance received from the FDA as part of the end-of-phase II meeting process for our oral insulin candidate, ORMD-0801, we have submitted to the FDA the protocols for our upcoming pivotal Phase III studies. In line with the FDA's expectations and recommendations, we intend to conduct two Phase III studies concurrently in patients with type 2 diabetes. These studies involve about 1,125 patients to provide evidence of ORMD-0801's safety and efficacy in type 2 diabetic patients over a treatment period of 6 to 12 months. A geographically diverse patient population will be recruited from multiple sites throughout the United States, European, and Israel. Our phase III study will be composed from 2 protocols:

ORA-D-013-1: This study will treat type 2 diabetic patients with inadequate glycaemic control who are currently on 1, 2 or 3 oral glucose-lowering agents. This U.S. study will recruit 675 patients from 75 clinical sites located throughout the U.S. Patients will be randomized 1:1:1 in this double-dummy study into cohorts of: 8 mg ORMD-0801 once-daily at night and placebo 45 minutes before breakfast; 8 mg ORMD-0801 twice-daily, at night and 45 minutes before breakfast; and placebo twice-daily, at night and 45 minutes before breakfast. The primary endpoint of the study is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycaemic control as assessed by HbA1c, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. We expect to initiate this trial on the fourth quarter of 2020.

ORA-D-013-2: This study will include type 2 diabetic patients with inadequate glycaemic control who are managing their condition with either diet alone or with diet and metformin monotherapy. A total of 450 patients will be recruited through 36 sites in the U.S. and 25 sites in Western Europe and Israel. Patients will be randomized 1:1 into two cohorts dosed with: 8 mg ORMD-0801 at night; and placebo at night. The primary endpoint is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycaemic control as assessed by HbA1c over a 26-week treatment period, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. We expect to initiate this trial on the first half of 2021.

If we successfully complete the pivotal studies, we expect to conduct a pre-BLA meeting with the FDA to finalize the plans and data for the BLA submission. After BLA submission and review, if the BLA is approved by the FDA, a full 12 years of marketing exclusivity would be granted.

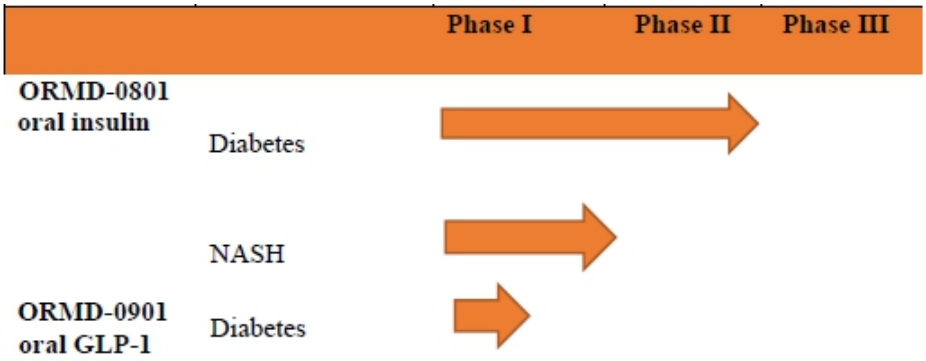
NASH Study: In June 2020, we presented preliminary data from our open-label study of the first 8 patients of a planned 40-patient multi-center (U.S., Europe and Israel) pilot study, aimed to assess the safety, tolerability, and early effects of 16 mg ORMD-0801 (2x8 mg capsules) on liver fat in type 2 diabetic patients with nonalcoholic steatohepatitis, or NASH. The 12-week, once-daily treatment had no serious adverse events, and induced an observed mean 6.9±6.8% reduction in liver fat content (p value: 0.035), and the relative reduction was 30%, as measured by MRI-derived proton density fat fraction. In parallel, concentrations of gamma-glutamyltransferase (GGT), a key marker of chronic hepatitis, were significantly lower after 12 weeks of treatment as compared to baseline (-14.6±13.1 U/L; p value: 0.008).

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. This study showed no statistically significant, or clinically meaningful differences in total exogenous insulin requirements, or plasma glucose levels in type 1 diabetic subjects treated with ORMD-0801 8mg dosed once daily in the evening compared to those dosed with ORMD-0801 three times daily.

Oral GLP-1: GLP-1 is an incretin hormone, which stimulates the secretion of insulin from the pancreas. 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 pharmacokinetic trial to evaluate the safety and pharmacokinetics of ORMD-0901 compared to placebo. Based on this trial results, we will conduct a follow-up Phase I trial in type 2 diabetic patients which will start its enrollment by the end of 2020 in the United States under an IND submitted to the FDA.

The following table gives an overview of the above described primary R&D pipeline:



Our 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.

Other Products: We are 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 this candidate to evaluate its pharmacokinetics and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients. During the third quarter of 2020, we finalized the study without any safety issues, and we are waiting for the final lab results.

Raw Materials

Our oral insulin capsule is currently manufactured by Fidelio Healthcare, a diversified European Contract Development and Manufacturing Organization (CDMO) in the pharmaceutical and healthcare industries.

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 also entered into an Insulin Supply Agreement in September 2020 with Hefei Tianmai Biological Technology Development Limited, who will also 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.

Market Overview

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 463 million adults (20-79 years) worldwide suffered from diabetes in 2019 and the IDF projects this number will increase to 700 million by 2045. Also, according to the IDF, in 2019, an estimated 4.2 million people died from diabetes. According to the American Diabetes Association, or ADA, in the United States there were approximately 34.2 million people with diabetes, or 10.5% of the United States population in 2018. Diabetes is a leading cause of blindness, kidney failure, heart attack, stroke and amputation. The latest report of the ADA that analyzed the economic costs of diabetes in the U.S in 2017 indicates that the total cost of diagnosed diabetes in the United States in 2017 was $327 billion.

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.

Leadership

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, Professor Avram Hershko, Dr. Harold Jacob, Dr. Julio Rosenstock and Dr. Jay Skyler.

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 2015 we successfully executed this strategy when we, Oramed Ltd. and HTIT entered into a Technology License Agreement pursuant 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. 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.

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.

Potential Material Impact of COVID-19

The COVID-19 pandemic has negatively impacted the global economy, disrupted consumer spending and global supply chains and created significant volatility and disruption of financial markets. Although to date the COVID-19 pandemic has not had a material adverse effect on us, the COVID-19 pandemic may have a material adverse effect on our business and financial performance in the future. The extent of the impact of the COVID-19 pandemic, including our ability to execute our business strategies as planned, will depend on future developments, including the duration and severity of the pandemic, which are highly uncertain and cannot be predicted.

Although, as of the date of this Annual Report on Form 10-K, we do not expect any material impact on our long-term activity, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

Patents and Licenses

We maintain a proactive intellectual property strategy, which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 26 patent applications currently pending, with respect to various compositions, methods of production and oral administration of proteins and exenatide. Expiration dates for pending patents, if granted, will fall between 2026 and 2039.

We hold 79 patents, 2 of which were issued during the fiscal year ended August 31, 2020, or fiscal 2020, 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, as amended, 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 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, 2020, 2019 and 2018, we did not sell any of the D.N.A ordinary shares. As of August 31, 2020, we held approximately 5.6% of D.N.A's outstanding ordinary shares.

As of August 31, 2020, Entera had not yet realized any revenues. 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. To the extent the Amgen License results in net revenues as defined in the Patent Transfer Agreement, Oramed Ltd. will be entitled to the aforementioned royalties.

On November 30, 2015, we, Oramed Ltd. and HTIT entered into a Technology License Agreement, or TLA, 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, 2020, we received aggregate milestone payments of $20.5 million.

On August 21, 2020, we received a letter from HTIT, disputing certain pending payment obligations of HTIT under the TLA. The payment obligation being disputed is $4 million, out of which only an amount of $2 million has been received and has been included in Deferred revenue in each of the consolidated balance sheets as of the fiscal years ended August 31, 2020, and 2019. In addition, the dispute includes a payment obligation of $2 million for certain milestones that we assert it met under the TLA subsequent to the fiscal year ended August 31, 2020. We wholly dispute the claims made by HTIT and has been engaged in discussions and exchanges with HTIT in an attempt to clarify and resolve disagreements between the parties regarding milestone payments and work plan implementation.

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. In connection with the License Agreement and the SPA, we received a non-refundable payment of $500,000 as a no-shop fee.

Government Regulation

The Drug Development Process

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

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

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

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

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

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

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

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

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

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

Biological License Application. The results of the clinical trials for a biological product are submitted to the FDA as part of a BLA. Following the completion of Phase III studies, assuming the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of its product, the sponsor will generally submit a BLA to the FDA requesting that the product be approved for marketing. The application is a comprehensive, multi-volume filing that includes the results of all clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging and labeling the product. The FDA's review of an application can take a few months to many years, with the average review lasting 18 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA. Approval of a BLA provides 12 years of exclusivity in the U.S. market.

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

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

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

Other Regulations

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

Competition

Competition in General

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

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

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

Competition for Our Oral Insulin Capsule

We anticipate the oral insulin capsule to be a competitive diabetes drug because of its anticipated efficacy and safety profile. The following are 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, Professor Avram Hershko, Dr. Harold Jacob, Dr. Julio Rosenstock and Dr. Jay Skyler.

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.

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. Julio Rosenstock, MD, joined the Oramed Scientific Advisory Board in January 2020. Dr. Rosenstock is the current Director of the Dallas Diabetes Research Center at Medical City Dallas and a Clinical Professor of Medicine at the University of Texas Southwestern Medical Center, Dallas. He received his medical degree from the University of Costa Rica School of Medicine and completed Fellowships in Endocrinology and Diabetes at the Royal Postgraduate Medical School, Hammersmith Hospital, London, UK, and at the University of Texas Southwestern Medical Center. His clinical research efforts focus on exploring novel agents and therapeutic strategies to improve glycemic control. Over the last 30 years, he has participated in hundreds of clinical trials and has had an active role in the development of new oral agents and insulin preparations acting often as a lead clinical investigator and scientific advisor. He has authored or co-authored 296 peer-reviewed manuscripts and numerous abstracts. Dr. Rosenstock is a member of the National Board of Directors of the ADA and is currently an Associate Editor of Diabetes Care.

Dr. Jay Skyler, MD, MCAP, joined the Oramed Scientific Advisory Board in January 2020. Dr. Skyler is Professor of Medicine, Pediatrics, & Psychology in the Division of Endocrinology, Diabetes & Metabolism, Department of Medicine, University of Miami Leonard M. Miller School of Medicine. He previously held the position of Director of the Division of Endocrinology, Diabetes & Metabolism. In addition, Dr. Skyler is Deputy Director of Clinical Research and Academic Programs at the Diabetes Research Institute, and an Adjunct Professor of Pediatrics at the Barbara Davis Center for Childhood Diabetes, University of Colorado at Denver. Dr. Skyler's research focuses on the clinical aspects of diabetes, specifically the conduct of randomized controlled clinical trials. From 1993 until 2015, he was Chairman of the NIH (NIDDK)-sponsored Diabetes Prevention Trial - Type 1 (DPT-1) and its successor Type 1 Diabetes TrialNet, a nationwide (and global) network conducting clinical trials to prevent type 1 diabetes.

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, 2020, we have contracted with twelve individuals for employment or consulting arrangements. Of our staff, four are senior management, four are engaged in research and development work, and the remaining four are involved in administration work.

Additional Information

Additional information about us is contained on our Internet website at www.oramed.com. Information on our website is not incorporated by reference into this report. On our website, under "Investors", "SEC Filings", we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or 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, 2020, August 31, 2019 and August 31, 2018, we had working capital of $35,975,000, $28,016,000 and $26,484,000, respectively, and stockholders' equity of $32,879,000, $19,393,000 and $31,112,000, respectively. During fiscal 2020 and the fiscal years ended August 31, 2019, or fiscal 2019, and 2018, we generated revenues of $2,710,000, $2,703,000 and $2,449,000, respectively. For the period from our inception on April 12, 2002 through August 31, 2020, fiscal 2020, fiscal 2019 and fiscal 2018, we incurred net losses of $92,614,000, $11,511,000, $14,355,000 and $12,727,000, 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 79 patents issued by the United States, Australian, Canadian, Chinese, Israeli, Japanese, New Zealand, South African, Russian, European, Hong Kong, Swiss, German, Spanish, French, United Kingdom, Italian, Indian, Austrian, Belgian, Irish, Swedish, Denmark, Luxembourg, Monaco, Norway and Netherlands patent offices for our technologies covering oral administration of insulin and other proteins, or for our technologies covering oral administration of exenatide, or for methods and compositions for treating diabetes. Further, we intend to rely on a combination of trade secrets and non-disclosure and other contractual agreements and technical measures to protect our rights in our technology. We intend to depend upon confidentiality agreements with our officers, directors, employees, consultants, and subcontractors, as well as collaborative partners, to maintain the proprietary nature of our technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid our confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition and results of operations. We believe that our technology is not subject to any infringement actions based upon the patents of any third parties; however, our technology may in the future be found to infringe upon the rights of others. Others may assert infringement claims against us or against companies to which we have licensed our technology, and if we should be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on terms acceptable to us, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition and results of operations. Further, we may need to indemnify companies to which we licensed our technology in the event that such technology is found to infringe upon the rights of others.

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

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

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

- Future clinical trial results may show that the oral insulin capsule is not well tolerated by recipients at its effective doses or is not efficacious as compared to placebo,

- Future clinical trial results may be inconsistent with previous preliminary testing results and data from our earlier studies may be inconsistent with clinical data,

- Even if our oral insulin capsule is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices,

- Our ability to complete the development and commercialization of the oral insulin capsule for our intended use is significantly dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, the oral insulin capsule on a worldwide basis,

- Even if our oral insulin capsule is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance of our product, and

- Our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues.

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

We have limited experience in conducting clinical trials.

Clinical trials must meet FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We have entered into agreements with Integrium LLC to assist us in designing, conducting and managing our various clinical trials in the United States and Europe. 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. Finally, the COVID-19 pandemic has impacted clinical trials broadly. We may experience delays in site initiation and patient enrollment, failures to comply with study protocols, delays in the manufacture of our product candidates for clinical testing and other difficulties in starting or competing our clinical trials.

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. For example, a number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials.

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

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

We are dependent on outside vendors for our entire supply of the oral insulin and GLP-1 capsules and do not currently have any long-term agreements in place for the supply of oral insulin or GLP-1 capsules. While we believe that there are numerous sources of supply available, if the third party suppliers were to cease production, including as a result of the COVID-19 pandemic, 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.

If we do not resolve our dispute with HTIT favorably, we may need to reverse deferred revenue of up to $2 million and may not receive an additional $4 million in royalties.

On August 21, 2020, we received a letter from HTIT, disputing certain pending payment obligations of HTIT under the TLA. We estimate this obligation to be between $2 million and $6 million. While we wholly dispute said claims and have been engaged in discussions and exchanges with HTIT in an attempt to clarify and resolve disagreements between the parties regarding milestone payments and work plan implementation, we may be subsequently required to repay to HTIT up to $2 million, which has been received and has been included in our deferred revenue in each of the consolidated balance sheets fiscal years ended August 31, 2020 and 2019. In addition, we may not receive an additional $4 million in Royalties if HTIT is entitled to the full disputed amount of $6 million.

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. Although phase III clinical trials for our oral insulin candidate, ORMD-0801 will start without a partner, if we engage such a partner, we anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials, 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 for our expected phase III clinical trials, 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. Various litigation to invalidate parts of the ACA are pending in court and, despite an upcoming change in presidential administration, attempts to repeal or to repeal and replace the ACA may continue. In addition, various other healthcare reform proposals have also emerged at the federal and state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us.

We are exposed to fluctuations in currency exchange rates.

A considerable amount of our expenses are generated in dollars or in dollar-linked currencies, but a significant portion of our expenses such as some clinical studies and payroll costs are generated in other currencies such as NIS 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, 2019 and 2020, 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.

The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business and operations.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread globally, including to the United States, Israel and other European countries where we expected to initiate clinical trials. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. While COVID-19 is still spreading and the final implications of the pandemic are difficult to estimate at this stage, it is clear that it has affected the lives of a large portion of the global population. At this time, the pandemic has caused states of emergency to be declared in various countries, travel restrictions imposed globally, quarantines established in certain jurisdictions and various institutions and companies being closed. On March 10, 2020, the Government of Israel announced that effective March 12, 2020 foreign travelers arriving from any country will be required to remain in home quarantine until 14 days have passed since the date of entry into Israel, and effective March 18, 2020, non-Israeli residents or citizens, except for non-nationals whose lives are based in Israel, are not allowed to enter Israel. In addition, the Ministry of Health in the State of Israel issued guidelines on March 11, 2020, which were most recently updated in October 2020, recommending people avoid gatherings in one space and providing that no gathering of more than 10 people should be held under any circumstances.

Employers (including us) are also required to prepare and increase as much as possible the capacity and arrangement for employees to work remotely. In addition, on March 11, 2020, the President of the United States issued a proclamation to restrict travel to the United States from foreign nationals who have recently been in certain European and Latin America countries. Although to date these restrictions have not impacted our operations other than the delay of one of our trials, the effect on our business, from the spread of COVID-19 and the actions implemented by the governments of the State of Israel, the United States and elsewhere across the globe, may worsen over time.

The spread of COVID-19 may also result in the inability of our suppliers to deliver supplies to us on a timely basis. In addition, health professionals may reduce staffing and reduce or postpone meetings with clients in response to the spread of an infectious disease. Though we have not yet experienced such events, if they would occur, they could result in a period of business disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. Although, as of the date of this Annual Report on Form 10-K, we do not expect any material impact on our long-term activity, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. We are actively monitoring the pandemic and we are taking any necessary measures to respond to the situation in cooperation with the various stakeholders.

The outbreak of COVID-19 may materially and adversely affect our clinical trial operations and our financial results.

The outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States, Israel and several European countries where we expected to initiate clinical trials. The extent to which COVID-19 may impact our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat for COVID-19. The continued spread of COVID-19 globally could adversely impact our clinical trial operations in the United States, Israel and in Europe, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography or due to government or institutional quarantines or stay-at-home measures.

Moreover, COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out such enrollments and trials. Any negative impact COVID-19 has to patient enrollment or treatment could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Risks Related to our Common Stock

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

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of November 24, 2020, we had outstanding 23,675,530 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 28,948,286 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 24, 2020, we had outstanding warrants and options exercisable for 3,407,819 shares of common stock at a weighted average exercise price of $6.97. 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.

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 24, 2020, our directors, executive officers and principal affiliated stockholders beneficially own approximately 16.7% 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 2020, 2019 and 2018. 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.

General Risk Factors

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 or other 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. Further, a new presidential administration in 2021 may result in additional amendments to the Code or reversal of 2017 changes. 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.

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,
- The impact of the recent outbreak of COVID-19 on our business or on the economy generally,
- 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.

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.

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 24, 2020, there were 23,675,530 shares of our common stock issued and outstanding held of record by approximately 36 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, 2020.

ITEM 6. SELECTED FINANCIAL DATA.

The selected data presented below under the captions Statements of Comprehensive Loss and Balance Sheet for, and as of the end of, each of the fiscal years in the five-year period ended August 31, 2020, 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 2020 and 2019 and the selected consolidated balance sheet data as of August 31, 2020 and 2019, 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, 2018, 2017 and 2016 and the balance sheet data as of August 31, 2018, 2017 and 2016 are derived from financial statements not included in this Annual Report. The historical results presented below are not necessarily indicative of future results.

	For the year ended August 31,				
	2020	**2019***	**2018**	**2017**	**2016**
	(in thousands except share and per share data)				
Statements of Comprehensive Loss:					
Revenues	$ 2,710	$ 2,703	$ 2,449	$ 2,456	$ 641
Cost of revenues (income)	-	90	(86)	187	490
Research and development expenses	10,235	13,522	11,979	10,281	7,709
General and administrative expenses	4,232	3,722	4,083	2,759	2,452
Financial income	690	1,061	903	792	474
Financial expenses	444	485	103	101	93
Loss before taxes on income	11,511	14,055	12,727	10,080	9,629
Taxes on income	-	300	-	400	1,335
Net loss for the year	$ 11,511	$ 14,355	$ 12,727	$ 10,480	$ 10,964
Loss per common share – basic and diluted	$ 0.56	$ 0.82	$ 0.86	$ 0.79	$ 0.87
Weighted average common shares outstanding	20,532,347	17,454,489	14,882,356	13,309,372	12,624,356

	As of August 31,				
	2020	2019*	2018	2017	2016
	(in thousands of dollars)				
Balance Sheet Data:					
Cash, cash equivalents, short-term deposits, restricted cash and marketable securities	$ 39,900	$ 32,282	$ 30,463	$ 20,138	$ 31,032
Other current assets	611	1,042	574	159	198
Long-term deposits and other assets	2	1	13,575	16,262	11,070
Long-term marketable securities	3,928	1,295	2,785	2,151	530
Total assets	44,633	34,663	47,397	38,712	42,830
Current liabilities	4,536	5,308	4,553	5,165	3,621
Long-term liabilities	7,218	9,962	11,732	14,309	13,019
Stockholders' equity	32,879	19,393	31,112	19,238	26,190

* As discussed in Note 1(k) to our audited consolidated financial statements included in this Annual Report on Form 10-K, the Company changed the manner in which it accounts for revenues from contracts with customers during fiscal 2019.

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

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

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

Overview of Operations

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills for delivery of other polypeptides. An overview of our current clinical studies can be found in "Item 1. Business - Research and Development."

Results of Operations

Critical accounting policies

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

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

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

We account for share-based payments to employees, directors and consultants in accordance with the guidance that requires awards classified as equity awards to be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is based on the Black Scholes option-pricing model or Monte Carlo model when appropriate and is recognized as an expense over the vesting period.

We elected to recognize compensation cost for awards to employees, directors and consultants that have a graded vesting schedule using the accelerated method based on the multiple-option award approach.

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 our 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 2020 to Fiscal 2019

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2020 and 2019:

	Year ended August 31,	
Operating Data:	**2020**	**2019**
	(dollar amounts in thousands)	
Revenues	$ 2,710	$ 2,703
Cost of revenues	-	90
Research and development expenses	10,235	13,522
General and administrative expenses	4,232	3,722
Financial income, net	246	576
Loss before taxes on income	11,511	14,055
Taxes on income	-	300
Net loss for the year	11,511	14,355
Loss per common share – basic and diluted	$ 0.56	$ 0.82
Weighted average common shares outstanding	20,532,347	17,454,489

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 2020 totaled $2,710,000, consistent with $2,703,000 for fiscal 2019.

Cost of revenues

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 2020 decreased to no expense compared to expense of $90,000 for fiscal 2019. The decrease is attributable to a milestone payment which was received during fiscal 2019.

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 2020 decreased by 24% to $10,235,000 from $13,522,000 for fiscal 2019. The decrease is mainly attributed to expenses related to our Phase IIb three-month dose-ranging clinical trial which was terminated during fiscal 2020 and is partially offset by an increase in regulatory expenses and an increase in raw material expenses related to our phase III trial. During fiscal 2020, stock-based compensation costs totaled $458,000, as compared to $218,000 during fiscal 2019. The increase is mainly attributable to new grants in fiscal 2020.

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 2020 and 2019, we did not recognize any research and development grants. As of August 31, 2020, our liability to pay royalties to the IIA was $317,000.

Under the terms of the grants we received from the IIA, we are obligated to pay royalties of 3% on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licensed ancillary services. Royalties are generally payable up to a maximum amount equaling 100% of the grants received (dollar linked) with the addition of interest at an annual rate based on the LIBOR rate.

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

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred or licensed to third parties in Israel without the approval of the research committee. Such approval is not required for the sale or export of any products resulting from such research or development. The R&D Law further provides that the know-how developed under an approved research and development program may not be transferred or licensed to any third parties outside Israel absent IIA approval which may be granted in certain circumstances as follows: (a) the grant recipient pays to the IIA a portion of the sale or license price paid in consideration for the purchase or license of such IIA-funded know-how or the price paid in consideration for the sale of the grant recipient itself, as the case may be, in accordance with certain formulas included in the R&D Law; (b) the grant recipient receives know-how from a third party in exchange for its IIA-funded know-how; or (c) such transfer of IIA-funded know-how is made in the context of IIA approved research and development cooperation projects or consortia.

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

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

General and administrative expenses

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

General and administrative expenses increased by 14% from $3,722,000 for fiscal 2019 to $4,232,000 for fiscal 2020. The increase in costs incurred related to general and administrative activities during fiscal 2020, is primarily attributable to an increase in costs related to the directors and officers insurance policy and an increase in legal expenses and increase in stock-based compensation costs and is partially offset by a decrease in travel expenses and a decrease in costs related to patents. During fiscal 2020, as part of our general and administrative expenses, we incurred expenses of $714,000 related to stock-based compensation costs, as compared to an expense of $591,000 during fiscal 2019. The increase is mainly attributable to new grants during fiscal 2020.

Financial income, net

Net financial income, was $246,000 for fiscal 2020 as compared to net financial income of $576,000 for fiscal 2019. The decrease is mainly attributable to a decrease in the fair market value of some investments.

Taxes on income

No taxes on income were recognized for fiscal 2020 as compared to $300,000 for fiscal 2019. The decrease is due to withholding taxes in connection with the receipt of a milestone payment pursuant to the License Agreement during 2019.

Fiscal 2019 compared with Fiscal 2018

For a discussion of fiscal 2019 compared with fiscal 2018, 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, 2019.

Liquidity and Capital Resources

From our inception through August 31, 2020, we have incurred losses in an aggregate amount of $92,614,000. 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 $101,509,000, net of transaction costs. During that period we also received cash consideration of $5,892,000 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, 2020, we had $19,296,000 of available cash, $11,060,000 of short term deposits and $13,472,000 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, 2020, our total current assets were $40,511,000 and our total current liabilities were $4,536,000. On August 31, 2020, we had a working capital surplus of $35,975,000 and an accumulated loss of $92,614,000. 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. The increase in working capital surplus from August 31, 2019 to August 31, 2020 was primarily due to an increase in cash and cash equivalents.

During fiscal 2020, cash and cash equivalents increased to $19,296,000 from $3,329,000 as of August 31, 2019, which is due to the reasons described below.

Operating activities used cash of $12,440,000 in fiscal 2020 compared to $12,940,000 used in fiscal 2019. Cash used in operating activities in fiscal 2020 and 2019 primarily consisted of net loss resulting from research and development and general and administrative expenses and changes in stock based compensation.

Investing activities provided cash of $4,626,000 in fiscal 2020, as compared to $11,259,000 used in fiscal 2019. Cash provided in investing activities in fiscal 2020 consisted primarily of the proceeds from short term deposits and redemption of held to maturity securities, partially offset by the acquisition of short and long terms marketable securities, while 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.

Financing activities provided cash of $23,786,000 in fiscal 2020, as compared to no financing activities in fiscal 2019. Cash provided by financing activities during fiscal 2020 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 2020 were as follows:

- During fiscal 2020, no warrants were exercised and 12,253 options were exercised for cash and resulted in the issuance of 12,253 shares of common stock. The cash consideration received for the exercise of options was $12,253. During fiscal 2019, no warrants or options were exercised.

- In September and November 2019 and February and May 2020, we issued a total of 10,000 shares of our common stock, valued approximately $38,000, 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 and prospectus supplement, each dated February 10, 2020 (which superseded a prior registration statement, prospectus and prospectus supplement that related to shares sold under the Sales Agreement). 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, 2020, 839,537 shares were issued under the Sales Agreement for aggregate net proceeds of $3,879,000.

- On February 27, 2020, we entered into an underwriting agreement with National Securities Corporation, or the Underwriter, in connection with a public offering, or the Offering of 5,250,000 shares of our common stock, at an offering price of $4.00 per share. We also granted the Underwriter a 45-day option to purchase from us up to an additional 787,500 shares of common stock at the public offering price, or the Over-Allotment Option. In connection with the Offering, we also agreed to issue to the Underwriter, or its designees, warrants, or the Underwriter's Warrants, to purchase up to an aggregate of 7% of the shares of common stock sold in the Offering (including any additional shares sold during the 45-day option period), at an exercise price of $4.80 per share. The Underwriter's Warrants issued in the Offering will be exercisable at any time and from time to time, in whole or in part, commencing six months from issuance for a period of three years from the date of issuance. The closing of the sale of the Offering occurred on March 2, 2020. On April 9, 2020, we issued 180,561 shares of our common stock and 12,640 Underwriter's Warrants pursuant to a partial exercise by the Underwriter of the Over-Allotment Option, or the Partial Over-Allotment Option Exercise. The net proceeds to us from the Offering, including from the Partial Over-Allotment Option Exercise, after deducting the underwriting discount and our Offering expenses were $19,894,000.

Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments at August 31, 2020, and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	Over 5 years
Clinical research study obligations	$ 4,801	$ 2,967	$ 1,834	$ -	$ -
Operating lease obligations	698	147	292	259	-
Royalty payment obligations	289	81	208	-	-
Accrued severance pay, net	18	-	-	-	18
Total	**$ 5,806**	**$ 3,195**	**$ 2,334**	**$ 259**	**$ 18**

Off-Balance Sheet Arrangements

As of August 31, 2020, 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, 2020, we had $19.3 million in cash and cash equivalents, $11 million in short term bank deposits and $13.5 million in marketable securities.

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

Marketable securities

We own 1,701,357[1] common shares of D.N.A,117,000 ordinary shares of Entera and other tradable mutual funds 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.

1 On November 10, 2019, D.N.A announced a reverse split so that every 6 common shares will become 1 common share. Consequently, our 10,208,144 shares become 1,701,357 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, 2020, we own net balances in NIS of approximately $160,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate gain of approximately $18,000, while assuming a 10% devaluation of the NIS against the U.S. dollar, we would experience an exchange rate loss of approximately $15,000.

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

	Year Ended August 31,		
	2020	**2019**	**2018**
Average rate for period	3.490	3.623	3.544
Rate at period-end	3.326	3.535	3.604

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, 2020. 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, 2020 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, 2020 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, 2020 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

Name	Age	Position
Nadav Kidron	46	President, Chief Executive Officer and Director
Miriam Kidron	80	Chief Scientific Officer and Director
Avraham Gabay	35	Chief Financial Officer, Treasurer and Secretary
Joshua Hexter	50	Chief Operating & Business Officer
Aviad Friedman	49	Director
Arie Mayer	64	Director
Kevin Rakin	60	Chairman, Director
Leonard Sank	55	Director
Gao Xiaoming	58	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 2015 until 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, 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. 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 2001 to 2005. Mr. Friedman served as Chief Operating Officer of one of Israel's premier newspapers, Ma'ariv from 2003 to 2007, and has more than 18 years of experience serving on boards of public and private companies including Maayan Ventures, Capital Point, Rosetta Green Ltd. and Aerodrome Groupe 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.

Dr. Arie Mayer became a ***director*** in December 2019. Dr. Mayer is currently the Managing Director and Chairman of the Board of Merck Life Science Israel (formerly Sigma-Aldrich Israel Ltd.) and has held that position since January 2010. Dr. Mayer has held various roles with Sigma-Aldrich Israel Ltd. since 1995 and was instrumental in introducing and developing the Cell Culture and Molecular Biology business for Sigma Aldrich Israel Ltd. Dr. Mayer holds a Bachelor of Science degree in chemistry from Hebrew University and a Ph.D. in biochemistry from Israel Institute of Technology.

We believe that Dr. Mayer's qualifications to serve on our Board include his experience as an executive in the biotechnology industry, as well as his experience and relevant education in the fields of chemistry and biochemistry.

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 boards of Nyxoah SA, HighCape Capital Acquisition Corp., Aziyo Biologics, Inc. and on the boards of 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 nineteen years, Mr. Sank has served on the boards of a few national businesses and local non-profit charity organizations in Cape Town and South Africa, 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, Arie Mayer, Kevin Rakin, Leonard Sank and Gao Xiaoming are independent as defined under the rules promulgated by the Nasdaq. Mr. Gao is the chief executive officer of HTIT, a stockholder holding more than 5% of our common stock and was initially appointed to serve on our Board pursuant to the terms of the securities purchase agreement with HTIT dated November 30, 2015, 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 2020, our Board held 7 meetings and took actions by written consent on 8 occasions. Board members are encouraged to attend our annual meetings of stockholders.

All of our directors, except Mr. Gao Xiaoming, 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.

Committees

Audit Committee and Audit Committee Financial Expert

The members of our Audit Committee are Aviad Friedman, Arie Mayer and Kevin Rakin. Our Board has determined that Aviad Friedman is an "audit committee financial expert" as set forth in Item 407(d)(5) of Regulation S-K and that all members of the Audit Committee are "independent" as defined by the rules of the SEC and the Nasdaq rules and regulations. The Audit Committee operates under a written charter that is posted on the "Investors" section of our website, www.oramed.com. The primary responsibilities of our Audit Committee include:

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

Compensation Committee

The members of our Compensation Committee are Aviad Friedman, Kevin Rakin and Leonard Sank. 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 Aviad Friedman and Leonard Sank. 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 2020, we believe that during fiscal 2020, 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) Aviad Friedman, one of our directors, failed to timely file a Form 4 reporting his January 8, 2020 acquisition of options to purchase 20,000 shares of our common stock. Mr. Friedman filed a Form 4 reporting this transaction on January 14, 2020, (b) Gao Xiaoming, one of our directors, failed to timely file a Form 4 reporting his January 8, 2020 acquisition of options to purchase 20,000 shares of our common stock. Mr. Gao filed a Form 4 reporting this transaction on January 14, 2020, (c) Miriam Kidron, our Chief Scientific Officer and one of our directors, failed to timely file a Form 4 reporting her January 8, 2020 acquisition of options to purchase 100,000 shares of our common stock. Ms. Kidron filed a Form 4 reporting this transaction on January 14, 2020, (d) Nadav Kidron, our President, Chief Executive Officer and one of our directors, failed to timely file a Form 4 reporting his January 8, 2020 acquisition of options to purchase 190,000 shares of our common stock. Mr. Kidron filed a Form 4 reporting this transaction on January 14, 2020, (d) Arie Mayer, one of our directors, failed to timely file a Form 4 reporting his January 8, 2020 acquisition of options to purchase 20,000 shares of our common stock. Mr. Mayer filed a Form 4 reporting this transaction on January 14, 2020, (e) Kevin Rakin, one of our directors, failed to timely file a Form 4 reporting his January 8, 2020 acquisition of options to purchase 20,000 shares of our common stock. Mr. Rakin filed a Form 4 reporting this transaction on January 14, 2020, and (f) Leonard Sank, one of our directors, failed to timely file a Form 4 reporting his January 8, 2020 acquisition of options to purchase 20,000 shares of our common stock. Mr. Sank filed a Form 4 reporting this transaction on January 14, 2020.

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 2020 are those four individuals listed in the "Summary Compensation Table" below. The Compensation Committee believes that our executive compensation is appropriately designed to incentivize our named executive officers to work for our long-term prosperity, is reasonable in comparison with the levels of compensation provided by comparable companies and reflects a reasonable cost. We believe our named executive officers are critical to the achievement of our corporate goals, through which we can drive stockholder value.

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

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

- attract, hire, and retain talented and experienced executives;
- motivate, reward and retain executives whose knowledge, skills and performance are critical to our success;
- ensure fairness among the executive management team via recognizing the contributions of each executive to our success;
- focus executive behavior on achievement of our corporate objectives and strategy; and
- align the interests of management and stockholders by providing management with longer-term incentives through equity ownership.

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

With respect to equity compensation, the Compensation Committee makes awards to executives under our 2019 Stock Incentive Plan, as amended and restated, or the 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 2020, 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 2020, our Compensation Committee increased the base salaries of two of our NEOs by 10% and 15% as it deemed this to be a reasonable rate based on, among other factors, such NEO's increased responsibilities and time passed since the last salary increase.

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, as well as performance-based vesting. The Compensation Committee believes that time-based vesting encourages recipients to build stockholder value over a long period of time and that performance-based vesting encourages recipients to achieve goals that benefit the Company.

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 United States. During fiscal 2020, such relocation expenses totaled approximately $515,693, 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 annual meeting of stockholders held on August 3, 2020. 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 2020.

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 2020, 2019 and 2018.

Name and Principal Position	Year (1)	Salary ($) (2)	Bonus ($) (2)(3)	Option Awards ($) (4)(5)	All Other Compensation ($) (2)(6)	Total ($)
Nadav Kidron	2020	439,076	220,582	569,062	539,131	1,767,851
President and CEO and director[7]	2019	419,460	224,975	398,910	507,750	1,551,095
	2018	436,310	148,795	522,569	442,326	1,550,000
Miriam Kidron	2020	305,840	70,000	299,506	13,354	688,700
Chief Scientific Officer and director[8]	2019	267,386	123,149	211,128	14,503	616,166
	2018	273,595	46,614	253,204	13,643	587,056
Avraham Gabay	2020	130,554	15,591	-	44,912	191,418
Chief Financial Officer[9]	2019	32,122	-	73,928	9,441	115,491
Joshua Hexter	2020	190,801	12,169	351,128	54,735	608,833
Chief Operating & Business Officer(10)	2019	52,848	-	-	9,022	61,870
	2018	161,002	26,895	269,196	50,505	507,598

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

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

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

(4) The amounts reflect the grant date fair value, as calculated pursuant to FASB ASC Topic 718, of these option awards. The assumptions used to determine the fair value of the option awards 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.

(5) Amounts exclude the fair market value of the options that were re-granted on September 11, 2020, as it was offset by the negative amount created by the cancelled options (that is, it was accounted for as a modification under FASB ASC Topic 718, and no incremental compensation expense was recorded). For more information about the regrant see Note 7(a) to our audited consolidated financial statements included in this Annual Report on Form 10-K. For more information about the regrant fair market value see "Grants of Plan-Based Awards" below.

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

(7) Mr. Kidron receives certain compensation from Oramed Ltd. through KNRY, Ltd., an Israeli entity owned by Dr. Miriam Kidron, or KNRY. See "—Employment and Consulting Agreements" below.

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

(9) Mr. Gabay was appointed as Chief Financial Officer, effective June 1, 2019.

(10) Mr. Hexter was appointed Chief Operating & Business Officer, effective September 19, 2019. From 2013 to 2018, Mr. Hexter served as Chief Operating Officer and VP Business Development of the Company.

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	2020	23,438	--	--	515,693	539,131
	2019	21,090	--	--	486,660	507,750
	2018	12,596	--	--	429,730	442,326
Miriam Kidron	2020	13,354	--	--	--	13,354
	2019	14,503	--	--	--	14,503
	2018	13,643	--	--	--	13,643
Avraham Gabay	2020	16,625	18,606	9,681	--	44,912
	2019	2,808	4,405	2,228	--	9,441
Joshua Hexter	2020	13,685	26,820	14,230	--	54,735
	2019	4,409	1,985	2,628	--	9,022
	2018	13,909	24,623	11,973	--	50,505

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

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

Employment and Consulting Agreements

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

The Consulting Agreements are both terminable by either party upon 140 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements and that Nadav Kidron receives a monthly consulting fee of NIS 127,570 and Miriam Kidron receives a monthly consulting fee of NIS 92,522. Pursuant to the Consulting Agreements, KNRY, Nadav Kidron and Miriam Kidron each agree that during the term of the Consulting Agreements and for a 12-month period thereafter, none of them will compete with Oramed Ltd. nor solicit employees of Oramed Ltd.

We, through Oramed Ltd., have entered into an employment agreement with Avraham 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 38,500. In addition, Mr. Gabay is provided with a cellular phone and a company car pursuant to the terms of his agreement.

We, through Oramed Ltd., have entered into an employment agreement with Joshua Hexter as of August 5, 2019, pursuant to which Mr. Hexter was appointed as Chief Operating & Business Officer of the Company and Oramed Ltd., effective September 19, 2019. In accordance with the employment agreement, as amended, Mr. Hexter's current gross monthly salary is NIS 56,000. In addition, Mr. Hexter is provided with a cellular phone and a company car pursuant to the terms of his agreement.

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

Potential Payments upon Termination or Change-in-Control

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

Pension, Retirement or Similar Benefit Plans

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

GRANTS OF PLAN-BASED AWARDS

The following table shows grants of plan-based equity awards made to our NEOs during fiscal 2020:

Name	Grant Date	Options Awards: Number of Securities Underlying Options (#)	Grant Date Fair Value of Stock Awards ($)
Avraham Gabay[1]	9/11/2019	33,146	61,893
Joshua Hexter[2]	9/11/2019	100,000	224,123
Joshua Hexter[3]	9/11/2019	100,000	127,005
Miriam Kidron[4]	9/11/2019	104,000	211,128
Nadav Kidron[5]	9/11/2019	196,500	398,910
Miriam Kidron[6]	1/8/2020	100,000	299,506
Nadav Kidron[7]	1/8/2020	190,000	569,062

(1) These options were canceled and re-granted under our 2019 Plan, in the same amounts and under the same terms as the original grants. These options were originally granted on June 17, 2019. 5,396 vested on December 31, 2019, and the balance vests in 3 equal installments of 9,250 on each of December 31, 2020, December 31, 2021 and December 31, 2022.

(2) These options were granted under our 2019 Plan and vest in 16 equal installments of 6,250 on the first day of each three months period beginning November 1, 2019. 25,000 of the options vested as of August 31, 2020.

(3) These options were granted under the 2019 Plan and vest upon achievement of certain performance conditions, such as consummating licensing agreements and entering into R&D collaboration agreements.

(4) These options were canceled and re-granted under the 2019 Plan in the same amounts and under the same terms as the original grants. These options were originally granted on February 26, 2019. 26,000 vested on December 31, 2019, and the balance vests in 3 equal installments of 26,000 on each of December 31, 2020, December 31, 2021 and December 31, 2022.

(5) These options were canceled and re-granted under the 2019 Plan in the same amounts and under the same terms as the original grants. These options were originally granted on February 26, 2019. 49,125 vested on December 31, 2019, and the balance vests in 3 equal installments of 49,125 on each of December 31, 2020, December 31, 2021 and December 31, 2022.

(6) These options were granted under our 2019 Plan and vest in 4 equal installments of 25,000 on each of December 31, 2020, December 31, 2021, December 31, 2022 and December 31, 2023.

(7) These options were granted under our 2019 Plan and vest in 4 equal installments of 47,500 on each of December 31, 2020, December 31, 2021, December 31, 2022 and December 31, 2023.

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, 2020.

	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)	-	4.08	8/8/22		
	47,134(2)	-	12.45	4/9/24		
	49,000(3)	-	7.77	6/30/27		
	48,500(4)	48,500(4)	8.14	1/31/28		
					0 (7)	0
					(8)	
	49,125(10)	147,375(10)(13)	3.16	2/26/29		
		190,000(15)	4.80	1/8/30		
Miriam Kidron						
	72,000(1)	-	4.08	8/8/22		
	47,134(2)	-	12.45	4/9/24		
	69,999(5)	-	7.77	6/30/27		
	23,500(6)	23,500(6)	8.14	1/31/28		
					0 (9)	0
	26,000(11)	78,000(11)(13)	3.16	2/26/29		
		100,000(16)	4.80	1/8/30		
Avraham Gabay	5,396(12)	27,750(12)(13)	3.55	6/17/29		
Joshua Hexter	25,000(14)	175,000(14)	3.69	9/11/29		

(1) On August 8, 2012, 72,000 options were granted to each of Nadav Kidron and Miriam Kidron under the Second Amended and Restated 2008 Stock Incentive Plan, or 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.

(2) 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.

(3) On June 30, 2017, 147,000 options were granted to Nadav Kidron under the 2008 Plan at an exercise price of $7.77 per share; 49,000 of such options vested on December 31, 2017 and the remainder vest in two equal installments of 49,000 on each of December 31, 2018 and December 31, 2019, subject to the Company share price reaching the target of $9.50 and $12.50 per share, respectively. The options expire on June 30, 2027. As of August 31, 2020, 98,000 options were forfeited.

(4) 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; 48,500 of such options vested on each of January 1, 2019 and January 1, 2020 and the reminder vest in two equal installments of 24,250 on each of January 1, 2021 and January 1, 2022. The options expire on January 31, 2028.

(5) On June 30, 2017, 69,999 options were granted to Miriam Kidron under the 2008 Plan at an exercise price of $7.77 per share; Such options vested in 3 equal installments of 23,333 on each of December 31, 2017, December 31, 2018 and December 31, 2019. The options have an expiration date of June 30, 2027.

(6) 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; 23,500 of such options vested in 2 equal installments of 11,750 on each of January 1, 2019 and January 1, 2020 and the reminder shall vest in 2 equal installments of 11,750 on each of January 1, 2021 and January 1, 2022. The options expire on January 31, 2028.

(7) 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.

(8) 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.

(9) 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.

(10) 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; 49,125 of such option vested on December 31, 2019 and the reminder shall vest in three equal installments of 49,125 on each of December 31, 2020, December 31, 2021 and December 31, 2022. The options expire on February 26, 2029. For additional information please see note 13 below.

(11) 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; 26,000 of such option vested on December 31, 2019 and the reminder shall vest in three equal installments of 26,000 on each of December 31, 2020, December 31, 2021 and December 31, 2022. The options expire on February 26, 2029. For additional information please see note 13 below.

(12) 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 vested 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. The options expire on June 17, 2029. For additional information please see note 13 below.

(13) 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.

(14) On September 11, 2019, 200,000 options were granted to Joshua Hexter under the 2019 Plan at an exercise price of $3.69 per share; 100,000 of such options shall vest in 16 equal installments of 6,250 on the first day of every three month period beginning November 1, 2019 and the remaining 100,000 shall vest upon achievement of certain performance conditions, such as consummating licensing agreements and entering into R&D collaboration agreements. The options expire on November 9, 2029.

(15) On January 8, 2020, 190,000 options were granted to Nadav Kidron under the 2019 Plan at an exercise price of $4.80 per share. Such options will vest in 4 equal installments of 47,500 on each of December 31, 2020, December 31, 2021, December 31, 2022 and December 31, 2023. The options expire on January 8, 2030.

(16) On January 8, 2020, 100,000 options were granted to Miriam Kidron under the 2019 Plan at an exercise price of $4.80 per share. Such options will vest in 4 equal installments of 25,000 on each of December 31, 2020, December 31, 2021, December 31, 2022 and December 31, 2023. The options expire on January 8, 2030.

Compensation Committee Interlocks and Insider Participation

During fiscal 2020, 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 2020:

Name of Director	Fees Earned or Paid in Cash ($)	Stock Awards (2) ($)	Option Awards (3) ($)	All Other Compensation ($)	Total ($)
Nadav Kidron[(1)]	-	-	-	-	-
Miriam Kidron[(1)]	-	-	-	-	-
Aviad Friedman	20,000	-	55,505	-	75,505
Arie Mayer[(4)]	15,000	-	55,505	-	70,505
Kevin Rakin	20,000	-	55,505	-	75,505
Leonard Sank	20,000	-	55,505	-	75,505
Gao Xiaoming	20,000	-	55,505	-	75,505

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

(2) As of August 31, 2020, our non-employee directors then in office held options to purchase shares of our common stock as follows:

Name of Director	Aggregate Number of Shares Underlying Stock Awards
Aviad Friedman	40,857
Arie Mayer	20,000
Kevin Rakin	92,470
Leonard Sank	69,867
Gao Xiaoming	20,000

(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) Mr. Mayer joined the Board as of December 5, 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 2020.

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

Stock Option Plans

Our Board adopted the 2008 Plan and the 2019 Plan in order to attract and retain quality personnel.

The 2008 Plan, which is no longer utilized for new grants, provided for the grant of stock options, restricted stock, RSUs, and stock appreciation rights, collectively referred to as "awards." Under the 2008 Plan, as amended, 2,400,000 shares were reserved for the grant of awards. As of August 31, 2020, options with respect to 2,287,989 shares had been granted, of which 563,804 had been forfeited, 182,227 had been exercised and 841,303 have expired. As of August 31, 2020, 525,824 RSUs had been granted, of which 164,636 have vested and the shares of common stock underlying those RSUs have been issued and 33,248 have been forfeited.

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 on August 29, 2019, at the Company's 2019 shareholders meeting.

The 2019 Plan provides for the grant of stock options, restricted stock, RSUs, and stock appreciation rights, collectively referred to as "awards." Under the 2019 Plan, 1,000,000 shares were initially reserved for the grant of awards. On June 29, 2020, and August 3, 2020, respectively, our Board and stockholders approved to amend and restate the 2019 Plan, the principal change being an increase in the number of shares of common stock available under the 2019 Plan from 1,000,000 shares to 3,000,000 shares. Stock options granted under the 2019 Plan may be either incentive stock options under the provisions of Section 422 of the Code, or non-qualified stock options. Under the 2019 Plan, as amended, 3,000,000 shares are reserved for the grant of awards, which may be issued at the discretion of our Board from time to time. As of August 31, 2020, options with respect to 999,646 shares have been granted, of which 20,000 have expired and none of them were exercised or forfeited. No RSUs have been granted under the 2019 Plan. Since the Company had 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 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, 2020:

Plan category	Number of securities to be issued upon exercise of outstanding options, RSUs and rights (a)	Weight-average exercise price of outstanding options, RSUs and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,864,664	$ 4.97	2,000,354
Equity compensation plans not approved by security holders	--	--	--
Total	1,864,664	$ 4.97	2,000,354

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our common stock as of November 24, 2020 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 23,675,530 shares of common stock outstanding.

As used in the table below and elsewhere in this form, the term "beneficial ownership" with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following November 24, 2020. 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, Third Floor, New York, NY 10036.

Name and Address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Regals Fund LP 152 West 57th Street, 9th Floor New York, NY 10019	1,317,123(1)	5.6%
Nadav Kidron #+	2,718,813(2)	11.4%
Miriam Kidron #+	376,383(3)	1.6%
Aviad Friedman #	49,714(4)	*
Avraham Gabay+	14,646(5)	*
Joshua Hexter+	101,250(6)	*
Arie Mayer #	9,666(7)	*
Kevin Rakin #	79,136(8)	*
Leonard Sank #	628,546(9)	2.7%
Gao Xiaoming #	1,162,033(10)	4.9%
All current executive officers and directors, as a group (nine persons)	3,999,881(11)	16.7%

* Less than 1%

\# Director

\+ NEO

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

(2) Includes 386,634 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. 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. Mr. Nadav's beneficial ownership includes the 1,155,367 shares of common stock held by HTIT, as well as 218,603 shares of common stock held by Xiaopeng Li, a former director of the Company, over which he holds a similar proxy.

(3) Includes 301,383 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.

(4) Includes 27,523 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.

(5) Includes 14,646 shares of common stock issuable upon the exercise of outstanding stock options.

(6) Includes 31,250 shares of common stock issuable upon the exercise of outstanding stock options.

(7) Includes 6,666 shares of common stock issuable upon the exercise of outstanding stock options.

(8) Includes 79,136 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) 36,533 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 6,666 shares of common stock issuable upon the exercise of outstanding stock options and 1,155,367 shares of Common Stock held by HTIT. Mr. Gao is the chairman of HTIT.

(11) Includes 890,467 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 2020 and 2019, 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 Aviad Friedman, Arie Mayer, Kevin Rakin, Leonard Sank and Gao Xiaoming 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 2020 and 2019:

	2020	2019
Audit Fees[1]	$ 95,000	$ 96,000
Audit-Related Fees[2]	101,000	-
Tax Fees[3]	2,000	1,000
All Other Fees	-	-
Total Fees	$ 198,000	$ 97,000

(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 services rendered in connection with our Offering.
(3) 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 ACCOUNTING 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-28

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, 2020 and 2019, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, 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, 2020 and 2019, and the results of their operations and its cash flows for the years then ended 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 audited 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 24, 2020

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

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS
In thousands (except share and per share data)

	August 31,	
	2020	**2019**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,296	$ 3,329
Short-term deposits (note 2)	11,060	25,252
Marketable securities (note 3)	9,544	3,701
Prepaid expenses and other current assets	611	1,042
Total current assets	40,511	33,324
LONG-TERM ASSETS:		
Long-term deposits and investment (note 4)	2	1
Marketable securities (note 3)	3,928	1,295
Amounts funded in respect of employee rights upon retirement	18	19
Property and equipment, net	99	24
Operating lease right of use assets	75	-
Total long-term assets	4,122	1,339
Total assets	$ 44,633	$ 34,663
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses (note 5)	$ 1,699	$ 2,541
Deferred revenues	2,703	2,703
Payable to related parties (note 11c)	90	64
Operating lease liabilities	44	-
Total current liabilities	4,536	5,308
LONG-TERM LIABILITIES:		
Deferred revenues	6,947	9,658
Employee rights upon retirement	18	22
Provision for uncertain tax position (note 10f)	11	11
Operating lease liabilities	31	-
Other liabilities	211	271
Total long-term liabilities	7,218	9,962
COMMITMENTS (note 6)		
STOCKHOLDERS' EQUITY:		
Common stock, $ 0.012 par value (60,000,000 authorized shares as of August 31, 2020 and 30,000,000 authorized shares as of August 31, 2019; 23,675,530 and 17,383,359 shares issued and outstanding as of August 31, 2020 and 2019, respectively)	284	208
Additional paid-in capital	125,209	100,288
Accumulated deficit	(92,614)	(81,103)
Total stockholders' equity	32,879	19,393
Total liabilities and stockholders' equity	$ 44,633	$ 34,663

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

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
In thousands (except share and per share data)

	Year ended August 31,	
	2020	**2019**
REVENUES	$ 2,710	$ 2,703
COST OF REVENUES (INCOME) (note 6f)	-	90
RESEARCH AND DEVELOPMENT EXPENSES	10,235	13,522
GENERAL AND ADMINISTRATIVE EXPENSES	4,232	3,722
OPERATING LOSS	11,757	14,631
FINANCIAL INCOME (note 9a)	690	1,061
FINANCIAL EXPENSES (note 9b)	444	485
LOSS BEFORE TAXES ON INCOME	11,511	14,055
TAXES ON INCOME (note 10d)	-	300
NET LOSS FOR THE YEAR	$ 11,511	$ 14,355
UNREALIZED INCOME ON AVAILABLE FOR SALE SECURITIES	-	-
TOTAL OTHER COMPREHENSIVE INCOME	-	-
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	$ 11,511	$ 14,355
LOSS PER SHARE OF COMMON STOCK:		
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.56	$ 0.82
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	20,532,347	17,454,489

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

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
in thousands

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	$				
	In thousands					
BALANCE AS OF SEPTEMBER 1, 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	-	(81,103)	19,393
SHARES ISSUED FOR SERVICES	10	*	38			38
ISSUANCE OF COMMON STOCK, NET	6,270	75	23,698			23,773
EXERCISE OF WARRANTS AND OPTIONS	12	1	12			13
STOCK-BASED COMPENSATION	-	-	1,173			1,173
NET LOSS					(11,511)	(11,511)
BALANCE AS OF AUGUST 31, 2020	23,675	284	125,209	-	(92,614)	32,879

* Represents an amount of less than $1.

The accompanying notes are an integral part of the financial statements

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
In thousands

	Year ended August 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (11,511)	$ (14,355)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	7	8
Exchange differences and interest on deposits and held to maturity bonds	546	(183)
Stock-based compensation	1,173	808
Change at fair value of investments	465	437
Shares issued for services	38	55
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	431	(468)
Accounts payable, accrued expenses and related parties	(816)	501
Deferred revenue	(2,710)	297
Liability for employee rights upon retirement	(4)	2
Other liabilities	(59)	(42)
Total net cash used in operating activities	(12,440)	(12,940)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(82)	(15)
Purchase of short-term deposits	(27,204)	(24,990)
Purchase of mutual funds	(3,750)	-
Purchase of long-term deposits	-	(4,237)
Purchase of held to maturity securities	(8,428)	(1,357)
Proceeds from sale of short-term deposits	40,891	38,611
Proceeds from maturity of held to maturity securities	3,200	3,250
Funds in respect of employee rights upon retirement	(1)	(3)
Total net cash provided by (used in) investing activities	4,626	11,259
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of issuance costs	23,773	-
Proceeds from exercise of warrants and options	13	-
Total net cash provided by financing activities	23,786	-
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(5)	14
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	15,967	(1,667)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,329	4,996
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 19,296	$ 3,329
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Taxes paid	-	300
Interest received	$ 1,313	$ 929

The accompanying notes are an integral part of the financial statements

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General

1) Incorporation and operations

Oramed Pharmaceuticals Inc. (collectively with its subsidiaries, 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 (the "Hong Kong Subsidiary"). As of August 31, 2020, the Hong Kong Subsidiary has no operation.

On November 30, 2015, the Company entered into a Technology License Agreement (the "TLA"), 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 pre-commercialization activities in the Territory, as well as advisory services to HTIT on an ongoing basis.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

As of August 31, 2020, 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.

On August 21, 2020, the Company received a letter from HTIT, disputing certain pending payment obligations of HTIT under the TLA. The payment obligation being disputed is $4,000, out of which only an amount of $2,000 has been received and has been included in Deferred revenue in each of the consolidated balance sheets as of the fiscal years ended August 31, 2020, and 2019. In addition, the dispute includes a payment obligation of $2,000 for certain milestones that the Company asserts it met under the TLA subsequent to the fiscal year ended August 31, 2020. The Company wholly disputes the claims made by HTIT and has been engaged in discussions and exchanges with HTIT in an attempt to clarify and resolve disagreements between the parties regarding milestone payments and work plan implementation.

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.

For the Company's revenue recognition policy see note 1k.

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. Based on the Company's current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that the Company will not need additional funds prior to such time. If there are unexpected increases in its operating expenses, the Company 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.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is continuing to assess the effect on its operation by monitoring the spread of COVID-19 and the actions implemented by the governments to combat the virus throughout the world.

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.

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 Subsidiaries are conducted is the U.S. dollar ("$" or "dollar"). Therefore, the functional currency of the Company and its Subsidiaries 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 Subsidiaries. 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, 2020, 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, 2020, 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, 2020, 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, 2020 and 2019.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

h. Marketable securities

1) Equity 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"), Entera Bio Ltd. ("Entera") and other mutual funds) 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. However, the balance of prepaid expenses and other current assets composed of $290 was due as an expenses reimbursement from HTIT.

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.

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.

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 at the earlier of the time (a) when the related sale has occurred and (b) the Company has fulfilled the related performance obligation. 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, 2020 aggregated $22,383, all of which was received through the balance sheet date. Through August 31, 2020, the Company recognized revenue associated with this agreement in the aggregate amount of $12,732 (of which $2,710 was recognized in the twelve-months period ended August 31, 2020), and deferred the remaining amount of $9,650, which is presented as a contract liability on the condensed consolidated balance sheet.

l. Cost of revenues

Cost of revenues consists of royalties to the 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.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

n. Stock-based compensation

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

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

The Company elects to account for forfeitures as they occur.

On September 1, 2019 the Company adopted the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees. As a result, nonemployee share-based transactions are being measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions.

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 5,025,723 and 4,423,325 for the years ended August 31, 2020 and 2019, respectively.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

p. Newly issued and recently adopted Accounting Pronouncements

1. In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", which supersedes the existing guidance for lease accounting, Leases (Topic 840). The new standard requires a lessee to record assets and liabilities on its balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the lessee's income statement. The Company adopted this standard as of September 1, 2019 on a modified retrospective basis and will not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which, among other things, allows the Company to carryforward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of its balance sheet. The Company recognized those lease payments in its statements of operations on a straight-line basis over the lease period. As of the adoption date, the Company recognized an operating lease asset and liability of $168 and $168, respectively, as of September 1, 2019 on its balance sheet.

2. On September 1, 2019 the Company adopted the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees. As a result, nonemployee share-based transactions are being measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions. The adoption of this slandered had no material impact on the Company's consolidated financial statements.

q. Recently issued Accounting Pronouncements, not yet adopted

In June 2016, the FASB issued ASU 2016-13 "Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments." This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for the fiscal year beginning after December 15, 2022, including interim periods within that year. The adoption of this guidance will not have a significant impact on the Company's consolidated financial statements.

In thousands (except share and per share data)

NOTE 2 - SHORT-TERM DEPOSITS:

Composition:

	August 31,			
	2020		2019	
	Annual interest rate	Amount	Annual interest rate	Amount
Dollar deposits	0.85-1.60%	$ 11,060	1.80-3.44%	$ 25,252

NOTE 3 - MARKETABLE SECURITIES:

a. Composition:

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

Composition:

	August 31,	
	2020	2019
Short-term:		
D.N.A (see b below)	$ 246	$ 557
Entera (see c below)	150	304
Held to maturity bonds (see d below)	5,369	2,840
Preferred equity	481	-
Mutual funds*	3,298	-
	$ 9,544	$ 3,701
Long-term:		
Held to maturity bonds (see d below)	$ 3,928	$ 1,295
	$ 13,472	$ 4,996

* Mutual funds include equity funds only

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, 2020 and 2019, the Company did not sell any of the D.N.A ordinary shares. As of August 31, 2020, the Company owns approximately 5.6% of D.N.A's outstanding ordinary shares.

The cost of the securities as of August 31, 2020 and 2019 is $595.

c. Entera

Entera ordinary shares have been traded on The Nasdaq Capital Market 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)).

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, 2020, are as follows:

	August 31, 2020			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 5,295	$ (29)	$ 5,266	2.26%
Accrued interest	74	-	74	
Long-term	3,928	56	3,984	2.20%
	$ 9,297	$ 27	$ 9,324	

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

	August 31, 2019			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 2,808	$ 6	$ 2,814	2.90%
Accrued interest	32	-	32	
Long-term	1,295	4	1,299	2.47%
	$ 4,135	$ 10	$ 4,145	

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.

In thousands (except share and per share data)

NOTE 4 - LONG-TERM DEPOSITS AND INVESTMENT:

Composition:

	August 31,	
	2020	**2019**
Lease car deposits	2	1
	$ 2	$ 1

NOTE 5 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

Composition:

	August 31,	
	2020	**2019**
Accounts payable	$ 594	$ 1,337
Payroll and related accruals	54	25
Institutions	19	33
Accrued liabilities	1,032	1,146
	$ 1,699	$ 2,541

NOTE 6 - COMMITMENTS:

a. In March 2011, the Subsidiary sold shares of its investee company, Entera, to D.N.A, retaining 117,000 ordinary shares (after giving effect to a stock split 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. As of August 31, 2020, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary. 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.

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 ($35) from October 2016 through September 2018 and NIS 132,000 ($39) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index ("CPI").

On August 2, 2020, the Subsidiary entered into a new lease agreement for its facilities in Israel. The new lease agreement is for a period of 60 months commencing September 1, 2020. The Company has the option to extend the period in another 60 months. The annual lease payment, including management fees, is NIS 435,000 ($130). The Company intends to terminate its current lease agreement before moving to the new office.

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

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, of which $1,542 was recognized in research and development expenses through August 31, 2020.

d. On September 2, 2020 (effective as of January 15, 2020), the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's phase 3 clinical trial for its oral insulin. As consideration for its services, the Subsidiary will pay the CRO a total amount of $21,589 during the term of the engagement and based on achievement of certain milestones, of which $178 was recognized in research and development expenses through August 31, 2020.

e. On September 16, 2020 (effective as of January 15, 2020), the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's phase 3 clinical trial for its oral insulin. As consideration for its services, the Subsidiary will pay the CRO a total amount of $12,343 during the term of the engagement and based on achievement of certain milestones, of which $400 was recognized in research and development expenses through August 31, 2020.

f. 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.

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, 2020 was $2,207. All grants were received before fiscal year 2020 and recorded as a reduction of Research and development expenses at that time.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the year ended August 31, 2020 and in prior periods.

g. Grants from the European Commission ("EC")

During fiscal year 2020, the Company received an aggregate payment of €50 from the EC under The European Innovation Council Accelerator (previously known as SME Instrument) of the European Innovation Programme Horizon 2020.

As part of the grant terms, the Company is required to use the proceeds from the grant in Europe. The Company intends on using the grant to explore the possibility of running clinical trials in Europe.

In thousands (except share and per share data)

NOTE 7 - STOCKHOLDERS' EQUITY:

The following are the significant capital stock transactions that took place during the years ended August 31, 2020 and 2019:

a. In August 2019, the Company became aware of a shareholder derivative claim and putative class action alleging, among other things, that the Second Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan") may have terminated in 2018. However, the Company disputed 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 a new option plan, which was approved at its 2019 shareholder meeting. Such 2019 Stock Incentive Plan, as amended and restated (the "2019 Plan") originally allowed 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 reissued the options under the new option plan in the same amounts and under the same terms as the original grants. The cancelation and grants were approved by the Company's board on September 11, 2019. Out of the available options under the 2019 Plan, the Company have been 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. On August 3, 2020, the stockholders of the Company adopted the amended and restated 2019 Plan which increased the shares available to grant under the plan by an additional 2,000,000 to 3,000,000 options.

b. On September 5, 2019, the Company entered into an Equity Distribution Agreement (the "Sales Agreement"), pursuant to which the Company may, from time to time and at the Company's option, issue and sell shares of Company common stock having an aggregate offering price of up to $15,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus and prospectus supplement, each dated February 10, 2020 (which superseded a prior registration statement, prospectus and prospectus supplement that related to shares sold under the Sales Agreement). The Company 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, 2020, 839,357 shares were issued under the Sales Agreement for aggregate net proceeds of $3,879.

c. On February 27, 2020, the Company entered into an underwriting agreement ("Agreement") with National Securities Corporation ("Underwriter"), in connection with a public offering ("Offering") of 5,250,000 shares of the Company's common stock, at an offering price of $4.00 per share. Under the terms of the Agreement, the Company granted the Underwriter a 45-day option to purchase from the Company up to an additional 787,500 shares of common stock at the public offering price ("Over-Allotment Option"). In connection with the Offering, the Company also agreed to issue to the Underwriter, or its designees, warrants ("Underwriter's Warrants"), to purchase up to an aggregate of 7% of the shares of common stock sold in the Offering (including any additional shares sold during the 45-day option period), at an exercise price of $4.80 per share. The Underwriter's Warrants issued in the Offering will be exercisable at any time and from time to time, in whole or in part, commencing six months from issuance for a period of three years from the date of issuance. The closing of the sale of the Offering occurred on March 2, 2020. On April 9, 2020, the Company issued 180,561 shares of Common Stock and 12,640 Underwriter's Warrants pursuant to a partial exercise by the Underwriter of the Over-Allotment Option ("Partial Over-Allotment Option Exercise"). The net proceeds to the Company from the Offering, including from the Partial Over-Allotment Option Exercise, after deducting the underwriting discount and the Company's estimated Offering expenses were $19,894.

d. As of August 31, 2020, the Company had outstanding warrants exercisable commencing January 6, 2019 for 3,407,820 shares of common stock at exercise prices ranging from $4.80 to $7.8125 per share and expiring from January 6, 2022 to April 10, 2029.

The following table presents the warrant activity for the years ended August 31, 2020 and 2019:

	Year ended August 31,			
	2020		2019	
	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price
Warrants outstanding at beginning of year	3,007,680	$ 7.27	3,007,680	$ 7.27
Issued	400,140	$ 4.77	-	$ -
Exercised	-	$ -	-	$ -
Expired	-	$ -	-	$ -
Warrants outstanding at end of year	3,407,820	$ 6.98	3,007,680	$ 7.27
Warrants exercisable at end of year	3,407,820	$ 6.98	3,007,680	$ 7.27

NOTE 8 - STOCK-BASED COMPENSATION:

The Company makes awards only under the 2019 Plan, under which, the Company had reserved a pool of 3,000,000 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 this 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, 2020 and 2019:

a. 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 CEO; 104,000 to the CSO; and 59,500 to employees of the Subsidiary. 49,125, 26,000 and 14,875 options of the CEO, CSO and the employees, respectively, were vested and the remainder will vest in three equal annual installments on each of December 31, 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.

b. 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 vested 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.

c. 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 vested 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.

d. On September 11, 2019, the Company granted options to its chief business and operation officer to purchase an aggregate of 100,000 shares of common stock of the Company at an exercise price of $3.69 per share (equivalent to the closing price of the Company's common stock on the date of grant). The options shall vest in 16 equal installments of 6,250 on the first day of every three months period beginning November 1, 2019. As of August 31, 2020, 25,000 of such options are vested. The options expire on September 11, 2029. The fair value of all these options on the date of grant was $224, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $3.69; dividend yield of 0% for all years; expected volatility of 65.60%; risk-free interest rates of 1.89%; and expected term of 6.14 years.

e. On September 11, 2019, the Company granted options to its chief business and operation officer to purchase an aggregate of 100,000 shares of common stock of the Company at an exercise price of $3.69 per share (equivalent to the closing price of the Company's common stock on the date of grant). The options shall vest in 4 installments upon achievement of certain performance conditions. As of August 31, 2020, no such options are vested. The options expire on September 11, 2029. The fair value of all these options on the date of grant was $127, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $3.69; dividend yield of 0% for all years; expected volatility of 67.96%; risk-free interest rates of 1.68%; expected term of 6.91 years; and the probability that such performance conditions will occur.

f. On January 8, 2020, the Company granted options to its directors to purchase an aggregate of 100,000 shares of common stock of the Company at an exercise price of $4.80 per share (equivalent to the closing price of the Company's common stock on the date of grant). The options shall vest in three equal installments on each of December 31, 2020, December 31, 2021 and December 31, 2022. The options expire on January 8, 2030. The fair value of all these options on the date of grant was $278, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $4.80; dividend yield of 0% for all years; expected volatility of 62.55%; risk-free interest rates of 1.67%; and expected term of 5.99.

In thousands (except share and per share data)

NOTE 8 - STOCK-BASED COMPENSATION (continued):

g. On January 8, 2020, the Company granted options to purchase an aggregate of 290,000 shares of common stock of the Company at an exercise price of $4.80 per share (equivalent to the closing price of the Company's common stock on the date of grant) as follows: 190,000 to the CEO and 100,000 to the CSO. The options will vest in four equal annual installments, on each of December 31, 2020, 2021, 2022 and 2023. These options expire on January 8, 2030. The fair value of all these options on the date of grant was $868, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $4.80; dividend yield of 0% for all years; expected volatility of 67.87%; risk-free interest rates of 1.67%; and expected term of 6.24 years.

h. 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,	
	2020	**2019**
Expected option life (years)	5.74-6.24	5-6.25
Expected stock price volatility (%)	57.77-68.14	54.64-69.05
Risk free interest rate (%)	1.67-1.89	2.03-2.54
Expected dividend yield (%)	0.0	0.0

A summary of the status of the stock options granted to employees and directors as of August 31, 2020, and 2019, and changes during the years ended on those dates, is presented below:

	Year ended August 31,			
	2020		**2019**	
	Number of options	**Weighted average exercise price**	**Number of options**	**Weighted average exercise price**
		$		**$**
Options outstanding at beginning of year	1,264,645	6.11	1,208,634	7.25
Changes during the year:				
Granted	943,646	3.98	423,146	3.26
Forfeited	(392,646)	3.79	(136,084)	5.79
Expired	(206,243)	6.02	(231,051)	7.07
Exercised	(12,253)	1.00	-	
Options outstanding at end of year	1,597,149	5.47	1,264,645	6.11
Options exercisable at end of year	687,024		709,383	
Weighted average fair value of options granted during the year	$ 2.79		$ 2.06	

Expenses recognized in respect of stock options granted to employees and directors, for the years ended August 31, 2020 and 2019 were $1,086 and $791, respectively.

The total intrinsic value of employees' options exercised during the year ended August 31, 2020 was $27. None of the options were exercised by employees during the year ended August 31, 2019.

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, 2020:

Exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted average exercise price
$		Years	$
1.00 to 6.00	1,117,980	8.06	3.98
6.23 to 7.88	225,251	6.82	7.73
8.14 to 12.45	253,918	5.77	10.01
	1,597,149	7.52	5.47

687,024 of options granted to employees and directors that were outstanding as of August 31, 2020, were also exercisable as of August 31, 2020.

As of August 31, 2020, there were $1,167 of unrecognized compensation costs related to non-vested options previously granted to employees and directors. The unrecognized compensation costs are expected to be recognized over a weighted average period of 2.1 years.

A summary of the status of the stock options granted to non-employees outstanding as of August 31, 2020 and 2019, and changes during the years ended on those dates, is presented below:

	Year ended August 31,			
	2020		2019	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
		$		$
Options outstanding at beginning of year	47,152	9.51	55,486	6.71
Changes during the year:				
Granted	56,000	4.21	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	(8,334)	9.12
Options outstanding at end of year	103,152	6.64	47,152	9.51
Options exercisable at end of year	65,152	5.58	41,992	6.32
Weighted average fair value of options granted during the year	$ 2.47		-	

The Company recorded stock-based compensation of $87 and $22 during the years ended August 31, 2020 and 2019, respectively, related to non-employees' awards.

None of the options were exercised by non-employees during the years ended August 31, 2020 and 2019.

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, 2020:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$		Years	$
3.74-5.08	56,000	9.30	4.22
6.00-7.36	47,152	5.21	6.29
	103,152	7.43	5.16

65,152 options granted to non-employees that were outstanding as of August 31, 2020, were also exercisable as of August 31, 2019.

As of August 31, 2020, there were $51 of unrecognized compensation costs related to non-vested options previously granted to non-employees. The unrecognized compensation costs are expected to be recognized over a weighted average period of 1.5 years.

i. Restricted stock units

The following table summarizes the activities for unvested RSUs granted to employees and directors for the years ended August 31, 2020 and 2019:

	Year ended August 31,	
	2020	2019
	Number of RSUs	
Unvested at the beginning of period	164,636	165,796
Vested and issued	-	(290)
Forfeited	-	(870)
Outstanding at the end of the period	164,636	164,636
Vested and unissued	164,636	164,636

The Company recorded compensation income related to RSUs of $5 for the year ended August 31, 2019, related to RSU awards. During the year ended August 31, 2020, the Company did not record expense or income related to RSU.

As of August 31, 2020, there are no unrecognized compensation costs related to RSUs.

In thousands (except share and per share data)

NOTE 9 - FINANCIAL INCOME AND EXPENSES

a. Financial income

	Year ended August 31,	
	2020	**2019**
Income from interest on deposits	$ 552	$ 909
Income from interest on corporate bonds	138	152
	$ 690	$ 1,061

b. Financial expenses

	Year ended August 31,	
	2020	**2019**
Exchange rate differences	$ 6	$ 14
Bank and broker commissions	6	4
Loss (gain) from securities, net	432	436
Other	-	31
	$ 444	$ 485

NOTE 10 - TAXES ON INCOME:

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

a. Corporate taxation in the U.S.

The applicable corporate tax rate for the Company is 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, 2020, the Company has an accumulated tax loss carryforward of approximately $15,880 (as of August 31, 2019, $13,013). Under U.S. tax laws, subject to certain limitations, carryforward tax losses originating in tax years beginning after January 1, 2018, have no expiration date, but they are limited to 80% of the company's taxable income in any given tax year. carryforward tax losses originating in tax years beginning prior to January 1, 2018, 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 2027 through 2039.

b. Corporate taxation in Israel:

The Subsidiary is taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2020 and 2019 is 23%.

As of August 31, 2020, the Subsidiary has an accumulated tax loss carryforward of approximately $57,900 (as of August 31, 2019, approximately $44,469). Under the Israeli tax laws, carryforward tax losses have no expiration date.

In thousands (except share and per share data)

NOTE 10 - TAXES ON INCOME (continued):

c. Deferred income taxes:

	August 31,	
	2020	**2019**
In respect of:		
Net operating loss carryforward	$ 16,652	$ 13,239
Research and development expenses	2,740	2,999
Less - valuation allowance	(19,392)	(16,238)
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,	
	2020	**2019**
Loss before taxes on income:		
U.S.	$ 2,868	$ 2,283
Outside U.S.	8,643	11,772
	$ 11,511	$ 14,055
Taxes on income (tax benefit):		
Current:		
U.S.	-	-
Outside U.S.	-	300
	$ -	$ 300

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, 2020, 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.

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,	
	2020	**2019**
Loss before income taxes as reported in the consolidated statement of comprehensive loss	$ (11,511)	$ (14,055)
Statutory tax benefit	(2,417)	(2,952)
Increase in income taxes resulting from:		
Change in the balance of the valuation allowance for deferred tax	3,154	3,356
Disallowable deductions	135	86
Influence of different tax rate applicable to the Subsidiary and changes in tax rates from previous years	(872)	(490)
Withholding tax, see note 10d above	-	300
Uncertain tax position	-	-
Taxes on income for the reported year	$ -	$ 300

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,	
	2020	**2019**
Balance at Beginning of Year	$ 11	$ 11
Decrease in uncertain tax positions for the current year	-	-
Balance at End of Year	$ 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 2016 through 2018.

The Subsidiary is subject to Israeli income tax examinations for the tax years of 2014 through 2019.

In thousands (except share and per share data)

NOTE 10 - TAXES ON INCOME (continued):

g. Valuation Allowance Rollforward

	Year ended August 31,		
	Balance at beginning of period	**Additions**	**Balance at end of period**
Allowance in respect of carryforward tax losses:			
Year ended August 31, 2020	$ 16,238	$ 3,154	$ 19,392
Year ended August 31, 2019	12,882	3,356	16,238

NOTE 11 - RELATED PARTIES - TRANSACTIONS:

a. During each of the fiscal years of 2020 and 2019, the Company paid to directors $95 and $100, respectively, as directors' fees.

b. On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the 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 ($38) and NIS 92,522 ($28), 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 2020 and 2019 such relocation expenses totaled $516 and $486, respectively.

c. Balances with related parties:

	August 31,	
	2020	**2019**
Accounts payable and accrued expenses - KNRY	$ 90	$ 64

d. Expenses to related parties:

	Year ended August 31,	
	2020	**2019**
KNRY	$ 766	$ 730
Nadav Kidron (CEO)	$ 801	785

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

(b) Exhibits

3.1*	Composite Copy of Certificate of Incorporation, as amended as of January 22, 2013, corrected February 8, 2013, as amended as of July 25, 2014, corrected September 5, 2017 and as further amended as of August 3, 2020.
3.2*	Composite Copy of Certificate of Incorporation, as amended as of January 22, 2013, corrected February 8, 2013, as amended as of July 25, 2014, corrected September 5, 2017 and as further amended as of August 3, 2020 (marked copy).
3.3	Amended and Restated By-laws (incorporated by reference from our current report on Form 8-K filed February 1, 2013).
4.1	Specimen Common Stock Certificate (incorporated by reference from our registration statement on Form S-1 filed February 1, 2013).
4.2	Form of Common Stock Purchase Warrant (incorporated by reference from our current report on Form 8-K filed July 5, 2018).
4.3	Form of Underwriter's Warrant (incorporated by reference from our current report on Form 8-K filed February 28, 2020).
4.4*	Description of Securities.
10.1+	Consulting Agreement by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Nadav Kidron (incorporated by reference from our current report on Form 8-K filed July 2, 2008).
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).
10.9+	Amendment, dated July 21, 2015, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2015).
10.10+	Amendment, dated June 27, 2016, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.11+	Amendment, dated June 30, 2017, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our annual report on Form 10-K filed November 29, 2017).
10.12+	Amendment, dated January 10, 2020, to Consulting Agreements by and between Oramed Ltd. and KNRY, Ltd., entered into as of July 1, 2008, for the services of Miriam Kidron (incorporated by reference from our quarterly report on Form 10-Q filed April 6, 2020).
10.13+	Oramed Pharmaceuticals Inc. Second Amended and Restated 2008 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed August 4, 2016).
10.14+	Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement (incorporated by reference from our annual report on Form 10-K filed November 14, 2014).

10.15+	Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement between the Company and the CSO or CEO (incorporated by reference from our annual report on Form 10-K filed November 29, 2017).
10.16+	Form of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our current report on Form 8-K filed July 2, 2008).
10.17+	Oramed Pharmaceuticals Inc. 2019 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed August 6, 2019).
10.18+	Oramed Pharmaceuticals Inc. Amended and Restated 2019 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed June 30, 2020).
10.19+	Form of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our annual report on Form 10-K filed November 27, 2019).
10.20+	Employment Agreement, dated May 16, 2019, by and between Oramed Ltd. and Avraham Gabay (incorporated by reference from our current report on Form 8-K filed May 16, 2019).
10.21+	First Amendment, dated December 19, 2019, to Employment Agreement, entered into as of May 16, 2019, by and between Oramed Ltd. and Avraham Gabay (incorporated by reference from our quarterly report on Form 10-Q filed January 9, 2020).
10.22+	Clinical Trial Agreement, dated September 11, 2011, between Oramed Ltd., Hadasit Medical Research Services and Development Ltd., Miriam Kidron and Daniel Schurr (incorporated by reference from our annual report on Form 10-K/A filed December 21, 2012).
10.23+	Clinical Trial Agreement, dated July 8, 2009, between Oramed Ltd., Hadasit Medical Research Services and Development Ltd., Miriam Kidron and Itamar Raz (incorporated by reference from our current report on Form 8-K filed July 9, 2009).
10.24	Agreement, dated January 7, 2009, between Oramed Pharmaceuticals Inc. and Hadasit Medical Research Services and Development Ltd. (incorporated by reference from our current report on Form 8-K filed January 7, 2009).
10.25	Patent Transfer Agreement, dated February 22, 2011, between Oramed Ltd. and Entera Bio Ltd. (incorporated by reference from our registration statement on Form S-1 filed March 25, 2011).

10.26+	Representative Form of Indemnification Agreements between Oramed Pharmaceuticals Inc. and each of our directors and officers (incorporated by reference from our quarterly report on Form 10-Q filed January 9, 2020).
10.27+	Employment Agreement, dated August 18, 2019, between Oramed Ltd. and Joshua Hexter (incorporated by reference from our annual report on Form 10-K filed November 27, 2019).
10.28	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).
10.29	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).
10.30	Amendment to the Amended and Restated Technology License Agreement, dated June 3, 2016, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.31	Amendment to the Amended and Restated Technology License Agreement, dated July 24, 2016, between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd. (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission) (incorporated by reference from our annual report on Form 10-K filed November 25, 2016).
10.32	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).
10.33	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).

10.34	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).
10.35	Amendment to the Equity Distribution Agreement, dated February 10, 2020, by and between the Company and Canaccord Genuity LLC (incorporated by reference from our quarterly report on Form 10-Q filed April 6, 2020).
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).
10.39	Clinical Research Organization Services Agreement, dated September 2, 2020 and effective as of January 15, 2020, between Oramed Ltd. and Integrium, LLC (incorporated by reference from our Form 8-K filed September 9, 2020).
10.40	Clinical Research Organization Services Agreement, dated September 16, 2020 and effective as of January 15, 2020, between Oramed Ltd. and Integrium, LLC (incorporated by reference from our Form 8-K filed September 18, 2020).
21.1	Subsidiaries (incorporated by reference from our annual report on Form 10-K filed November 27, 2019).
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, 2020, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.

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

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

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

ORAMED PHARMACEUTICALS INC.

/s/ NADAV KIDRON

Nadav Kidron,
President and Chief Executive Officer

Date: November 24, 2020

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 24, 2020
Nadav Kidron, President and Chief Executive Officer and Director (principal executive officer)	
/s/ AVRAHAM GABAY	November 24, 2020
Avraham Gabay, Chief Financial Officer (principal financial and accounting officer)	
/s/ AVIAD FRIEDMAN	November 24, 2020
Aviad Friedman, Director	
/s/ MIRIAM KIDRON	November 24, 2020
Miriam Kidron, Director	
/s/ ARIE MAYER	November 24, 2020
Arie Mayer, Director	
/s/ KEVIN RAKIN	November 24, 2020
Kevin Rakin, Director	
/s/ LEONARD SANK	November 24, 2020
Leonard Sank, Director	
/s/ GAO XIAOMING	November 24, 2020
Gao Xiaoming, Director	

Exhibit 3.1

CERTIFICATE OF INCORPORATION

OF

ORAMED PHARMACEUTICALS INC.

As amended as of January 22, 2013
corrected February 8, 2013
further amended July 25, 2014
corrected September 5, 2017
and further amended August 3, 2020

FIRST: The name of the Corporation is:

ORAMED PHARMACEUTICALS INC.

SECOND: The address of the Corporation's registered office in the State of Delaware is 1811 Silverside Road, in the City of Wilmington, County of New Castle, 19810. The name of its registered agent at such address is Vcorp Services, LLC.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the laws of the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of capital stock which the Corporation shall have authority to issue is sixty million (60,000,000) shares of Common Stock, at a par value of $0.012 per share.

FIFTH: The name and address of the sole incorporator is as follows:

Name	**Address**
Nadav Kidron	Hi-Tech Park 2/5 Givat-Ram PO Box 39098 Jerusalem 91390 Israel

SIXTH: Unless required by law or determined by the chairman of the meeting to be advisable, the vote by stockholders on any matter, including the election of directors, need not be by written ballot.

SEVENTH: The Corporation reserves the right to increase or decrease its authorized capital stock, or any class or series thereof, and to reclassify the same, and to amend, alter, change or repeal any provision contained in the Certificate of Incorporation under which the Corporation is organized or in any amendment thereto, in the manner now or hereafter prescribed by law, and all rights conferred upon stockholders in said Certificate of Incorporation or any amendment thereto are granted subject to the aforementioned reservation.

EIGHTH: The Board of Directors shall have the power at any time, and from time to time, to adopt, amend and repeal any and all By-laws of the Corporation.

NINTH: To the fullest extent permitted by the Delaware General Corporation Law, as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Any repeal or modification of the foregoing provisions of this Article NINTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

TENTH: 1. The Corporation shall indemnify to the maximum extent permitted by law any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, all as more fully set forth in the By-laws of the Corporation, as amended or repealed from time to time.

2. The indemnification and other rights set forth in this Article TENTH shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any Bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

3. Any repeal or modification of the foregoing provisions of this Article TENTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director, officer, employee or agent of the Corporation existing at the time of such repeal or modification.

Exhibit 3.2

CERTIFICATE OF INCORPORATION

OF

ORAMED PHARMACEUTICALS INC.

As amended as of January 22, 2013
corrected February 8, 2013
further amended July 25, 2014
~~and~~ corrected September 5, 2017
and further amended August 3, 2020

FIRST: The name of the Corporation is:

ORAMED PHARMACEUTICALS INC.

SECOND: The address of the Corporation's registered office in the State of Delaware is 1811 Silverside Road, in the City of Wilmington, County of New Castle, 19810. The name of its registered agent at such address is Vcorp Services, LLC.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the laws of the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of capital stock which the Corporation shall have authority to issue is ~~thirty million (30,000,000)~~ sixty million (60,000,000) shares of Common Stock, at a par value of $0.012 per share.

FIFTH: The name and address of the sole incorporator is as follows:

Name	**Address**
Nadav Kidron	Hi-Tech Park 2/5 Givat-Ram PO Box 39098 Jerusalem 91390 Israel

SIXTH: Unless required by law or determined by the chairman of the meeting to be advisable, the vote by stockholders on any matter, including the election of directors, need not be by written ballot.

SEVENTH: The Corporation reserves the right to increase or decrease its authorized capital stock, or any class or series thereof, and to reclassify the same, and to amend, alter, change or repeal any provision contained in the Certificate of Incorporation under which the Corporation is organized or in any amendment thereto, in the manner now or hereafter prescribed by law, and all rights conferred upon stockholders in said Certificate of Incorporation or any amendment thereto are granted subject to the aforementioned reservation.

EIGHTH: The Board of Directors shall have the power at any time, and from time to time, to adopt, amend and repeal any and all By-laws of the Corporation.

NINTH: To the fullest extent permitted by the Delaware General Corporation Law, as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Any repeal or modification of the foregoing provisions of this Article NINTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

TENTH: 1. The Corporation shall indemnify to the maximum extent permitted by law any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, all as more fully set forth in the By-laws of the Corporation, as amended or repealed from time to time.

2. The indemnification and other rights set forth in this Article TENTH shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any Bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

3. Any repeal or modification of the foregoing provisions of this Article TENTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director, officer, employee or agent of the Corporation existing at the time of such repeal or modification.

Exhibit 4.4

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, 2020 and are incorporated by reference herein.

Common Stock

Pursuant to the Company's Charter, the Company is authorized to issue up to sixty million (60,000,000) 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.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-236194 and 333-190497) and Form S-8 (Nos. 333-244380, 333-234303, 333-213835, 333-199120, 333-190222 and 333-163919) of Oramed Pharmaceuticals Inc. of our report dated November 24, 2020 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel
November 24, 2020

/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

Exhibit 31.1

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 24, 2020

By: /s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Exhibit 31.2

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 24, 2020

By: /s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer

Exhibit 32.1

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, 2020, 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 24, 2020

/s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Exhibit 32.2

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, 2020, 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 24, 2020

/s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer