ORAMED PHARMACEUTICALS INC.

2022 ANNUAL REPORT

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 December 31, 2022

or

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

Commission file number 001-35813

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $169,594,349 based on a price of $4.58, 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.

As of March 6, 2023, the registrant had 39,783,813 shares of common stock issued and outstanding.

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INTRODUCTION AND USE OF CERTAIN TERMS

On February 28, 2022, our Board of Directors, or our Board, approved a change of the Company's fiscal year from the period beginning on September 1 and ending on August 31 to the period beginning on January 1 and ending on December 31. As a result, the Company filed a Transition Report on Form 10-Q with the Securities and Exchange Commission, or the SEC, on March 30, 2022 that included financial information for the transition period from September 1, 2021 through December 31, 2021, or the Transition Period. Subsequent to that report, the Company's fiscal year now begins on January 1 and ends on December 31. This Annual Report on Form 10-K is the Company's first annual report presenting its new fiscal year, and reports financial results for the 12 month period ended December 31, 2022.

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, unless otherwise indicated. All dollar amounts refer to U.S. dollars unless otherwise indicated.

On December 31, 2022, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.519 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 and the Israeli securities law. 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:

- our comprehensive analysis of data from our ORA-D-013-1 Phase 3 trial to understand if there is a path forward for our oral insulin candidate;
- our plan to evaluate potential strategic opportunities;
- our ability to enhance value for our stockholders;
- the expected development and potential benefits from our products;
- 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 our license agreements;
- expected timing of a clinical study for the potential Oravax Medical Inc., or Oravax, vaccine and its potential to protect against the coronavirus, or COVID-19, pandemic;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials;
- our belief that our technology has the potential to deliver medications and vaccines orally that today can only be delivered via injection;
- the competitive ability of our technology based on product efficacy, safety, patient convenience, reliability, value and patent position;
- the potential market demand for our products;

- our ability to obtain patent protection for our intellectual property;
- our expectation that our research and development expenses will continue to be our major expenditure;
- our expectations regarding our short- and long-term capital requirements;
- our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses; and
- information with respect to any other plans and strategies for our business.

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors known by us at the time of such statements. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those discussed herein, including those risks described in "Item 1A. Risk Factors," and expressed from time to time in our other filings with the 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

We are currently a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions with a technology platform that allows for the oral delivery of therapeutic proteins.

Through our research and development efforts, we have developed an oral dosage form intended to withstand the harsh environment of the stomach and effectively deliver active biological insulin or other proteins. 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.

On January 11, 2023, we announced that our Phase 3 trial, or the ORA-D-013-1 Phase 3 trial, did not meet its primary and secondary endpoints. As a result, we terminated both ORA-D-013-1 and ORA-D-013-2 Phase 3 clinical trials. In parallel, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. We are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

Research and Development

Oral insulin

Type 2 Diabetes: We conducted the ORA-D-013-1 Phase 3 trial on patients with type 2 diabetes, or T2D, with inadequate glycaemic control who were on two or three oral glucose-lowering agents. The primary endpoint of the trial was to evaluate the efficacy of our oral insulin capsule, 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. On January 11, 2023, we announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. Following the results of the ORA-D-013-1 Phase 3 trial, we also terminated the ORA-D-013-2 Phase 3 trial, a second Phase 3 trial that included T2D patients with inadequate glycaemic control who were attempting to manage their condition with either diet alone or with diet and metformin.

NASH: In December 2020, we initiated a double blind, placebo controlled clinical trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis, or NASH, in T2D. On September 13, 2022, we reported positive top line results from this trial, demonstrating that ORMD-0801 was safe and well tolerated at 8 mg twice daily dosing, meeting the primary endpoint of no difference in adverse events for ORMD-0801 compared to placebo. The trial also evaluated the effectiveness of ORMD-0801 in reducing liver fat content over the 12-week treatment period by observing several independent measures. All the measurements showed a consistent clinically meaningful trend in favor of ORMD-0801. We are currently evaluating our path forward for ORMD-0801 for NASH.

Oral Vaccine

On March 18, 2021, we entered into a license agreement, or the Oravax License Agreement, with Oravax, our 63% owned joint venture, pursuant to which we granted to Oravax an exclusive, worldwide license of our rights in certain patents and related intellectual property relating to our proprietary oral delivery technology to further develop, manufacture and commercialize oral vaccines for COVID-19 and other novel coronaviruses based on Premas Biotech Pvt. Ltd.'s, or Premas's, proprietary vaccine technology involving a triple antigen virus like particle, or the Oravax product, which was previously owned by Cystron Biotech LLC, and later acquired by Akers Biosciences Inc., or Akers. Effective January 1, 2022, Oravax transferred its rights and obligations under the Oravax License Agreement to its wholly-owned subsidiary, Oravax Medical Ltd. For further details regarding the Oravax License Agreement, see note 12 to our audited consolidated financial statements.

In October 2021, Oravax's oral virus-like particle, or VLP, COVID-19 vaccine received clearance from the South African Health Products Regulatory Authority (SAPHRA) to initiate a Phase 1 trial. On December 14, 2021, Oravax screened and enrolled the first participant in this Phase 1 clinical trial. The trial protocol was divided into two cohorts each comprised of 12 participants, with a 42-day safety waiting period between cohorts. Due to several factors, including the fact that many volunteers did not qualify during screening due to prior asymptomatic COVID-19 infection and other conditions, the rate of enrollment was slower than anticipated and as a result, we added an additional clinical site. On October 11, 2022, Oravax reported positive preliminary Phase 1 data for Cohort A of this trial, meeting primary and secondary endpoints of safety and immunogenicity. These results included significant antibody response (2-6 fold

over baseline) as measured by multiple markers of immune response to VLP vaccine antigens observed in the majority of the patients dosed, and no safety issues were observed, including mild symptoms. Cohort B completed dosing on January 5, 2023 and data is expected in the first half of 2023.

On December 29, 2021, Oravax signed a cooperation and purchase agreement for an initial pre-purchase of 10 million doses of oral COVID-19 vaccines with Tan Thanh Holdings to commercialize the vaccine in Southeast Asia.

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 with Sanofi-Aventis Deutschland GMBH, or Sanofi-Aventis. According to the agreement, Sanofi-Aventis supplies Oramed Ltd. with specified quantities of recombinant human insulin to be used for clinical trials.

We have purchased, 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, or T1D) and, most often, to environmental factors such as obesity and lack of exercise (T2D). According to the International Diabetes Federation, or IDF, an estimated 537 million adults (20-79 years) worldwide suffered from diabetes in 2021 and the IDF projects this number will increase to 783 million by 2045. Also, according to the IDF, in 2021, an estimated 6.7 million people died from diabetes. According to the American Diabetes Association, or ADA, in the United States there were approximately 37.3 million people with diabetes, or 11.3% of the United States population in 2019. Diabetes is a leading cause of blindness, kidney failure, heart attack, stroke and amputation.

Impact of COVID-19

We do not expect any material impact on our development timeline and our liquidity due to COVID-19. However, we experienced approximately six months of delays in clinical trials due to slow-downs of recruitment for trials generally. On the other hand, Oravax continues to develop its oral vaccine, the demand for which may be reduced if COVID-19 continues to abate. We continue to assess the effect on our operations by monitoring the status of COVID-19.

Intellectual Property and Patents

We own a portfolio of patents and patent applications covering our technologies, and we are aggressively protecting these technology developments on a worldwide basis.

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 37 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 112 patents, twenty of which were issued during the fiscal year ended December 31, 2022, 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, Brazilian 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.

Trademarks and Trade Secrets

We have trademark applications pending in Israel, with Corresponding international trademark applications in Australia, Brazil, Canada, China, Colombia, the European Union, India, Indonesia, Japan, Kazakhstan, Korea, Malaysia, Mexico, New Zealand, Norway, Oman, Philippines, Russia, Singapore, Switzerland, Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom, U.S.A., Uzbekistan and Vietnam.

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, 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 the 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

Entera Bio

In June 2010, our wholly-owned subsidiary, Oramed Ltd., entered into a joint venture agreement with DNA GROUP (T.R.) Ltd. (formerly D.N.A Biomedical Solutions Ltd.), or DNA, for the establishment of Entera Bio Ltd., or Entera.

In March 2011, Oramed Ltd. sold shares of Entera to DNA, retaining 117,000 ordinary shares (after giving effect to a stock split by Entera in July 2018). In consideration for the shares sold to DNA, the Company received, among other payments, ordinary shares of DNA (see also note 3 to our audited consolidated financial statements).

As part of this agreement, Oramed Ltd. entered into a patent transfer agreement, or the Patent Transfer Agreement, according to which Oramed Ltd. assigned to Entera all of its rights to a patent application related to the oral administration of proteins that it has licensed to Entera since August 2010, in return for royalties of 3% of Entera's net revenues and a license back of that patent application for use in respect of diabetes and influenza. As of December 31, 2022, Entera had not paid any royalties to Oramed Ltd. On December 11, 2018, Entera announced that it had entered into a research collaboration and license agreement with Amgen, Inc., or Amgen. To the extent that the license granted to Amgen results in net revenues as defined in the Patent Transfer Agreement, Oramed Ltd. will be entitled to the aforementioned royalties. As part of a consulting agreement with a third party dated February 15, 2011, Oramed Ltd. 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. During the years ended December 31, 2022, 2021 and four month period ended December 2021, we did not sell any of DNA's ordinary shares. As of December 31, 2022, we held approximately 1.4% of DNA's outstanding ordinary shares and approximately 0.4% of Entera's outstanding ordinary shares.

HTIT

On November 30, 2015, we entered into a Technology License Agreement, or TLA, with Hefei Tianhui Incubator of Technologies Co., Ltd., or HTIT, 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 HTIT License Agreement. According to the HTIT License Agreement, we granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong, related to our oral insulin capsule, ORMD-0801, or the Product. Pursuant to the HTIT License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to our technology and ORMD-0801 capsule, and will pay (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the territory, or Royalties, and (ii) an aggregate of $37.5 million, of which $3 million 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. The HTIT License Agreement shall remain in effect until the expiration of the royalty term. The HTIT License Agreement contains customary termination provisions. Through December 31, 2022, we received aggregate milestone payments of $20.5 million out of the aggregate amount of $37.5 million.

On August 21, 2020, we received a letter from HTIT, disputing certain pending payment obligations of HTIT under the TLA. We wholly dispute said claims and we are in discussions with HTIT in an attempt to reach a mutually agreeable solution. We are currently evaluating with HTIT a path forward to continue our collaboration, following the results of our ORA-D-013-1 Phase 3 trial.

Oravax License

In consideration for the grant of the license under the Oravax License Agreement, we will receive (i) royalties equal to 7.5% on net sales, as defined in the Oravax License Agreement, of each product commercialized by Oravax, its affiliates and permitted sublicensees related to the license during the term specified in the Oravax License Agreement, (ii) sublicensing fees equal to 15% of any non-sales-based consideration received by Oravax from a permitted sublicensee and (iii) other payments ranging between $25 million to $100 million, based on certain sales milestones being achieved by Oravax. The parties further agreed to establish a development and steering committee, which will consist of three members, of which two members will be appointed by us, that will oversee the ongoing research, development, clinical and regulatory activity with respect to the Oravax product. In addition, we agreed to buy and Oravax agreed to issue to us 1,890,000 shares of common stock of Oravax, representing 63% of the common stock of Oravax for the aggregate amount of $1.5 million. Akers contributed $1.5 million in cash to Oravax and a license agreement to the Oravax product. Nadav Kidron, the Company's President and Chief Executive Officer, was one of the former members of Cystron. See note 12 to our audited consolidated financial statements.

Medicox License

On November 13, 2022, we entered into a distribution license agreement with Medicox Co., Ltd., or Medicox. an emerging biotech company with a consortium of proven partnerships in the Republic of Korea. The agreement grants Medicox the exclusive license to apply for regulatory approval and distribute ORMD-0801 for ten years in the Republic of Korea. Medicox will comply with agreed distribution targets and will purchase ORMD-0801 at an agreed upon transfer price per capsule. In addition, Medicox will pay Oramed up to $15 million in developmental milestones, $2 million of which have already been received by Oramed to date, and up to 15% royalties on gross sales. Medicox will also be responsible for gaining regulatory approval in the Republic of Korea.

We are currently evaluating with Medicox a path forward to continue our collaboration, following the results of our ORA-D-013-1 Phase 3 trial.

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

Protocols. Before commencing human clinical trials, 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 trials 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 trials 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 trials. 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 trials.

Clinical Trials. Human clinical trials or testing of a potential product are generally done in three stages known as Phase 1 through Phase 3 testing. The names of the phases are derived from the regulations of the FDA. Generally, there are multiple trials conducted in each phase.

Phase 1. Phase 1 trials involve testing a drug or product on a limited number of healthy or patient participants, typically 24 to 100 people at a time. Phase 1 trials 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 2. Phase 2 trials involve testing of no more than 300 participants at a time who may suffer from the targeted disease or condition. Phase 2 testing typically lasts an average of one to two years. In Phase 2, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase 2 testing also involves determining acceptable dosage levels of the drug. Phase 2 trials may be split into Phase 2a and Phase 2b sub-trials. Phase 2a trials may be conducted with patient volunteers and are exploratory (non-pivotal) trials, typically designed to evaluate clinical efficacy or biological activity. Phase 2b trials are conducted with patients defined to evaluate definite dose range and evaluate efficacy. If Phase 2 trials 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 3 trials.

Phase 3. Phase 3 trials 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 trials generally last two to three years. Phase 3 trials are conducted at multiple locations or sites. Like the other phases, Phase 3 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 Biological License Application, or BLA. Following the completion of Phase 3 trials, 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 trials, 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 4. The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase 4 trials, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase 4 trials usually involve thousands of participants. Phase 4 trials also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug.

European Regulation. Similar to the U.S., a European sponsor of a biological product may submit a Marketing Approval Application to the European Medicines Agency, or 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 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.

We anticipated that our oral insulin capsule would be a competitive diabetes drug because of its anticipated efficacy and safety profile; however, there are other treatment options for T1D and T2D patients, such as insulin injections, insulin pumps or a combination of diet, exercise and oral medication which improve the body's response to insulin or cause the body to produce more insulin.

Scientific Advisory Board

We maintain a Scientific Advisory Board consisting of internationally recognized scientists who advise us on scientific and technical aspects of our business. The Scientific Advisory Board meets periodically to review specific projects and to assess the value of new technologies and developments to us. In addition, individual members of the Scientific Advisory Board meet with us periodically to provide advice in their particular areas of expertise. The Scientific Advisory Board consists of the following members, information with respect to whom is set forth below: Dr. Roy Eldor, Professor Ele Ferrannini, Dr. Alexander Fleming, Professor Avram Hershko, Dr. Harold Jacob, Dr. Julio Rosenstock, Dr. Jay Skyler and Dr. Anne Peters.

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 at the Tel-Aviv Sourasky Medical Center. Prior to that, Dr. Eldor served as Principal Scientist at Merck Research Laboratories, Clinical Research – Diabetes & Endocrinology. He previously served as a senior physician in internal medicine at the Diabetes Unit in Hadassah Hebrew University Hospital in Jerusalem, Israel; and the Diabetes Division at the University of Texas Health Science Center in San Antonio, Texas. Dr. Eldor is a recognized expert, with over 50 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 (EASD), 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 American Diabetes Association in the United States. Professor Ferrannini has worked with various institutions including the Department of Clinical & Experimental Medicine at the University of Pisa School of Medicine, and CNR (National Research Council) Institute of Clinical Physiology in Pisa, Italy; and the Diabetes Division, Department of Medicine at the University of Texas Health Science Center in San Antonio, Texas. He has extensive training in internal medicine and endocrinology, and has specialized in diabetes trials. Professor Ferrannini has received a Certificate of the Educational Council for Foreign Medical Graduates from the University of Bologna, and completed a subspecialty in Diabetes and Metabolic Diseases at the University of Torino, *cum laude*. He has published over 500 original papers and 50 book chapters and he is a "highly cited researcher," according to the Institute for Scientific Information.

Dr. Alexander Fleming, MD, joined the Oramed Scientific Advisory Board in December 2019. Dr. Fleming, an endocrinologist, is Founder and Executive Chairman of Kinexum, a strategic advisory firm. From 1986 to 1998, he served at the FDA as a supervisory medical officer in the Division of Metabolism and Endocrine Drug Products and was responsible for landmark approvals of the first statin, metformin, and other endocrine and metabolic therapies. He also represented the FDA at the World Health Organization and on multiple expert working groups of the International Conference on Harmonization (ICH). Dr. Fleming coined the term, Metabesity, which refers to the constellation of major chronic diseases and the aging process itself, all which share common metabolic root causes and potential preventive therapies. He organized the first Congress on Metabesity in London in October 2017, followed by annual conferences. In 2020, Dr. Fleming founded the non-profit Kitalys Institute as a means of producing Metabesity conferences and advancing interventions of any kind that can improve health and healthspan.

Professor Avram Hershko, MD, PhD, joined the Oramed Scientific Advisory Board in July 2008. 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 from 1969 to 1972, 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 in Haifa, Israel. 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 in 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 since 2000 and a Foreign Associate of the U.S. Academy of Sciences since 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 in Jerusalem, Israel, 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 Senior Scientific Advisor and Director of Velocity Clinical Research at Medical City, Dallas, Texas, and a Clinical Professor of Medicine at the University of Texas Southwestern Medical Center in Dallas, Texas. He is board certified in Internal Medicine, Endocrinology and Metabolism. His clinical and research activities have focused on exploring novel agents and therapeutic strategies to improve glycemic control, particularly early combination therapies in Type 2 Diabetes. 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, incretin-related therapies and insulin formulations, often acting as a lead clinical investigator and scientific advisor on the design and reporting of these clinical trials. Dr. Rosenstock has been the author or co-author of 360 peer-reviewed manuscripts (*H-index 119*) and several hundreds of scientific abstracts. He has also contributed to 13 book chapters on various topics in the field of diabetes and is considered a key opinion leader in Type 2 Diabetes.

Dr. Jay Skyler, MD, MCAP, FRCP, joined the Oramed Scientific Advisory Board in January 2020. Dr. Skyler is Professor of Medicine, Pediatrics and Psychology in the Division of Endocrinology, Diabetes and 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 and 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 at the University of Colorado in Denver. Dr. Skyler's research focuses on the clinical aspects of diabetes, specifically the conduct of randomized controlled clinical trials. From 1993 to 2015, he was Chairman of the National Institute of Health (NIDDK)-sponsored Diabetes Prevention Trial–- Type 1 (DPT-1) and its successor Type 1 Diabetes Trial Net, a nationwide and global network conducting clinical trials to prevent T1D.

Dr. Anne Peters, MD, joined the Oramed Scientific Advisory Board in June 2022. Dr. Peters is Professor of Medicine at the Keck School of Medicine of the University of Southern California (USC) and Director of the USC Clinical Diabetes Programs. Dr. Peters earned her medical degree from the Pritzker School of Medicine at the University of Chicago and performed an internal medicine residency at Stanford University and an endocrinology fellowship at Cedars-Sinai Medical Center. She previously directed the clinical diabetes programs at Cedars-Sinai Medical Center and UCLA in California. Her research has focused on testing new approaches for diagnosing and treating diabetes and developing systems of care to improve outcomes in diabetic populations. Dr. Peters is the chair of the Endocrine Society Committee on Diabetes Devices and is on the EASD/ADA Technology Safety Committee. Additionally, she is a member

of the JDRF Panel on Management of Exercise in type 1 Diabetes and a member of the ABIM Endocrinology Subspecialty Board. Dr. Peters has consulted for many entities, including the FDA, Optum Rx and CVS/Caremark to help guide the development and use of treatments for diabetes. In addition to being an investigator for more than 40 research studies, Dr. Peters has published over 200 articles, has written four books, and has given more than 500 lectures locally, nationally, and internationally. She has been on multiple guideline writing committees for the treatment of both type 1 and type 2 diabetes. She was a recipient of the ADA Outstanding Physician Clinician Award, the Bernardo Houssay Award from the National Minority Quality Forum and received a 2021 Endocrine Society Laureate Award for Public Service.

Employees

We believe it is imperative to attract and retain top talent for all positions in the Company. We seek to make Oramed an inclusive, diverse and safe workplace, with meaningful compensation, benefits and wellness programs and opportunities.

We have experienced personnel involved in our research and development programs, as well as appropriate clinical/regulatory, quality assurance and other personnel needed to advance through clinical trials or have engaged the services of experts in the field for these requirements. As of December 31, 2022, we have contracted with seventeen individuals for employment or consulting arrangements, including employees of Oravax. Of our staff, six are senior management, four are engaged in research and development work, and the remaining seven are involved in corporate and administration work.

We provide competitive compensation, health and retirement programs for our employees. We offer variable pay in the form of bonuses and stock-based compensation for eligible employees. We also provide our employees with additional benefits such as team-building and educational offsite activities and gym facilities. We believe that this provides a comprehensive package to engage, motivate and retain our employees as a cohesive unit unified in its goal to achieve the Company's strategy and objectives.

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. 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, are available free of charge on our website under "SEC Filings" as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Reports filed with the SEC are made available on its website at www.sec.gov and are also available on the website of the Israeli Securities Authority at www.magna.isa.gov.il or on the website of the Tel Aviv Stock Exchange at www.tase.co.il. 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 the 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

Our strategic review process may not be successful or timely.

Following the results of the ORA-D-013-1 Phase 3 trial, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. Concurrently, we are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, including among others, continuation as a stand-alone business, capital raises, or one or more acquisitions, mergers or business combinations or other strategic transactions. Potential counterparties in a strategic transaction involving us may place minimal or no value on our assets. While we are devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, or lead to any stockholder value. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. The process of reviewing alternative strategic paths may be time consuming, may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could negatively impact our ability to attract, retain and motivate employees, and expose us to potential litigation in connection with this process or any resulting transaction. If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and other stakeholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly. There can be no guarantee that the process of evaluating alternative strategic paths will result in our entering into or completing potential transactions within the anticipated timing or at all.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management and may disrupt our business. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- impairment of relationships with key suppliers of any acquired business due to changes in management and ownership;

- inability to retain our key employees ; and
- possibility of future litigation.

Any of the above risks could have a material adverse effect on our business, financial condition, and prospects.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. Our cash conservation activities may yield unintended consequences, such as attrition and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

We may become involved in securities and stockholder litigation that could divert management's attention and harm the Company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities and stockholder litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. The market price of our common stock dropped substantially when we announced the results of the ORA-D-013-1 Phase 3 trial. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

We continue, and in the future expect, to incur losses.

Successful evaluation and completion of our remaining 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 our strategic evaluation process, as well as the regulatory approval process for each of our current or future 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 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 may require substantial additional financing at various intervals in order to implement any potential strategic alternative, to continue our remaining or potential future 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 remaining or future 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 may not be able to implement the actions we decide to take as part of our strategic review process, and we will not be able to fully develop and commercialize our technology or pursue new technology. Our future capital requirements will depend upon many factors, including:

- the results of our strategic review process and any new strategic direction we decide to take;
- 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 existing or planned courses of action or 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. For example, in January 2023, the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. 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 or in pursuing a successful strategic alternative. As of December 31, 2022 and 2021, we had working capital of $151,363,000 and $140,569,000, respectively, and stockholders' equity of $151,812,000 and $166,453,000, respectively. During the year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended August 31, 2021, we generated revenues of $2,703,000, $904,000 and $2,703,000, respectively. For the period from our inception on April 12, 2002 through December 31, 2022, the year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended August 31, 2021, we incurred net losses of $163,081,000, $126,520,000 and $114,852,000, 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 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 112 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, Brazilian 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. 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— Intellectual Property and Patents."

Our success was primarily dependent on the successful commercialization of our oral insulin capsule.

The successful commercialization of our principal product, the oral insulin capsule, was crucial for our success. On January 12, 2023, we announced top-line results from the phase 3 trial of our oral insulin capsule, which did not meet its primary or secondary endpoints, and indicated that we expect to discontinue oral insulin clinical activities for T2D. At present, following the results of the ORA-D-013-1 Phase 3 trial, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. Concurrently, we are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities. Even if our analysis results in a path forward for our oral insulin capsule, there are a variety of risks and uncertainties related to its development. Principally, these risks include the following:

- Future clinical trial results may show the same results as the ORA-D-013-1 Phase 3 trial;
- Future clinical trial results may be inconsistent with previous preliminary testing results and data from our earlier trials may be inconsistent with clinical data;
- Even if our oral insulin capsule is shown to be safe and effective for its intended purposes in future clinical trials, 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.

Our business may be seriously harmed if our analysis does not produce positive results, if we are unable to find a path forward to continue development of our oral insulin capsule, if we are unsuccessful in realizing new strategic opportunities or dealing with any of these risks, or if we are unable to successfully commercialize our oral insulin capsule for some other reason.

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 trials and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We have entered into agreements with Integrium LLC and other consultants to assist us in designing, conducting and managing our various clinical trials in the United States, Europe and Israel. 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. For example, the rate of enrollment for our Phase 1 clinical trial for our oral COVID-19 vaccine in South Africa was slower than anticipated due to several factors, including the fact that many volunteers did not qualify during screening due to prior asymptomatic COVID-19 infection and other conditions, and as a result we had to add an additional clinical site. 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. For example, see "Item 1. Business—Description of Business—Research and Development During 2022" regarding the results of the ORA-D-013-1 Phase 3 trial that did not meet its primary and secondary endpoints. Finally, the COVID-19 pandemic has impacted clinical trials generally. However, we experienced approximately six months of delays in clinical trials due to slow-downs of recruitment for trials generally related to COVID-19. We may experience further 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.

Initial success in the completed and ongoing early-stage clinical trials does not ensure success in later stage trials, regulatory approval or commercial viability of a product.

Positive results in a clinical trial may not be replicated in subsequent or confirmatory trials. Additionally, success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful or that regulatory approval will be obtained. Any of our product's failure to show sufficient efficacy in patients with the targeted indication, or if such studies are discontinued for any other reason, could negatively impact our development and commercialization goals for these products and our stock price could decline. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse

safety profiles, notwithstanding promising results in earlier trials. As a result, preliminary and interim data should be viewed with caution until the final data are available. We have invested in clinical studies of medicines that have not met the primary clinical endpoints in their Phase 3 studies or have been discontinued for other reasons. For example, in January 2023, we reported that ORA-D-013-1 trial did not meet its primary or secondary endpoint. Even if later stage clinical trials are successful, regulatory authorities may delay or decline approval of our product candidates.

There are a number of factors that could cause a clinical study to fail or be delayed, including: (i) the clinical study may produce negative or inconclusive results; (ii) regulators may require that we hold, suspend or terminate clinical research for noncompliance with regulatory requirements; (iii) we, our partners, the FDA or foreign regulatory authorities could suspend or terminate a clinical study due to adverse side effects of a product on subjects or lack of efficacy in the trial; (iv) we, or our partners, may decide, or regulators may require us, to conduct additional preclinical testing or clinical studies; (v) change in rates of enrollment and dropout among clinical trial participants; (vi) differences in the size and type of the patient populations; (vii) changes in and adherence to the dosing regimen and other clinical trial protocols; and (viii) people who enroll in the clinical study may later drop out due to adverse events, a perception they are not benefiting from participating in the study, fatigue with the clinical study process or personal or other issues. The occurrence of any of these events could result in significant costs and expense, have an adverse effect on our business, financial condition and results of operations and/or cause our stock price to decline or experience periods of volatility.

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. For example, the rate of enrollment for our Phase 1 clinical trial for our oral COVID-19 vaccine in South Africa was slower than anticipated due to several factors, including the fact that many volunteers did not qualify during screening due to prior asymptomatic COVID-19 infection and other conditions, and as a result we had to add an additional clinical site. 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 trials 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 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. For example, in January 2023, we announced that our ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, we decided to terminate our ORA-D-013-2 Phase 3 trial and have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. 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 and for other services.

We are dependent on outside vendors for our entire supply of the oral insulin capsules and do not currently have any long-term agreements in place for the supply of oral insulin capsules, which is still necessary if we decide to continue development of these projects. While we believe that there are numerous sources of supply available, if the third party suppliers were to cease production, or otherwise fail to supply us with quality raw materials in sufficient quantities on a

timely basis and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct testing and clinical trials would be materially adversely affected.

We rely on suppliers, vendors, outsourcing partners, alliance partners and other third parties to research, develop, manufacture, commercialize, co-promote and sell our products, manage certain marketing, IT, data and other business unit and functional services and meet their contractual, regulatory and other obligations. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements, for example, in relation to the outsourcing of significant clinical development activities for innovative medicines to some CROs; (ii) they may not produce reliable products; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) they may incur a significant cyberattack or business disruption; (vi) they may be subject to government orders or mandates that require them to give priority to the government and set aside pre-existing commercial orders; (vii) disputes may arise with respect to ownership of rights to technology developed with our partners; and (viii) disagreements could cause delays in, or termination of, the research, development or commercialization of the product or result in litigation or arbitration. The failure of any critical third party to meet its obligations; to adequately deploy business continuity plans in the event of a crisis; and/or to satisfactorily resolve significant disagreements with us or address other factors, could have a material adverse impact on our operations and results. In addition, if these third parties violate, or are alleged to have violated, any laws or regulations, including the local pharmaceutical code, the U.S. Foreign Corrupt Practice Act of 1977, the U.K. Bribery Act of 2010, the EU's General Data Protection Regulations, and other similar laws and regulations, during the performance of their obligations for us, we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

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

Any 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. Any 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 for the years ended December 31, 2022 and 2021. 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 may not realize a return on the ordinary shares of DNA and Entera that we own.

DNA's ordinary shares are traded on the Tel Aviv Stock Exchange and Entera's ordinary shares are traded on the Nasdaq Stock Market, both of which are 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 DNA and Entera have historically experienced low trading volume. As a result, there is no guarantee that we will be able to resell the ordinary shares of DNA or Entera at the prevailing market prices or that we will realize a positive return on such shares.

We may not realize the full benefit from our distribution license agreement with Medicox.

Our distribution license agreement with Medicox provides that Medicox will comply with agreed distribution targets and will purchase ORMD-0801 at an agreed upon transfer price per capsule and pay us up to $15 million in developmental milestones, $2 million of which have already been received by us. Following the results of the ORA-D-013-1 Phase 3 trial, we are currently evaluating with Medicox a path forward to continue our collaboration. If we are not successful in finding a mutually agreed way to continue our collaboration, or if Medicox is not successful in independently advancing the oral insulin candidate, we may not realize the benefits from this collaboration.

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. 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 trials, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. 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. We face the risk that new market entrants and existing competition may try to replicate our business model or introduce a more innovative offering that renders our services less competitive or obsolete. In addition, our research and development efforts may target diseases and conditions for which there are existing therapies or therapies that are being developed by our competitors. Further, any products resulting from our research and development efforts might not be able to compete successfully with others' existing and future products. See "Item 1. Business—Description of Business—Competition."

Our financial position or results could be negatively affected by product liability claims.

It is possible that we will be responsible for potential product liability stemming from product research, development or manufacturing and may face an even greater risk if any product candidate that we develop is commercialized. If we cannot successfully defend ourselves against claims that products we develop independently or with our partners caused injuries, we could incur substantial liabilities. Regardless of the merit or eventual outcome of such claims, any liability claims may result in, among other things, decreased demand for any product that we may develop, loss of revenues, significant time and costs to defend the related litigation, initiation of investigations by regulators and injury to our reputation and significant negative media attention. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. Our clinical trials are covered by liability insurance, but notwithstanding such coverage, our financial position or results could be negatively affected by product liability claims.

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, as well as the activities we take as a result of our strategic review process, 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—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.

Our existing and any future joint ventures may limit our flexibility with jointly owned investments and we may not realize the benefits we expect from these arrangements.

We are currently party to a joint venture, and we may in the future sell or contribute additional assets or acquire, develop or recapitalize assets to or in this joint venture or other joint ventures that we may enter.

Our participation in our existing joint venture is subject to risks, including the following:

- We share approval rights over certain major decisions affecting the ownership or operation of the joint venture and any assets owned by the joint venture;
- We may need to contribute additional capital in order to preserve, maintain or grow the joint venture and its investments;
- Our joint venture investors may have economic or other business interests or goals that are inconsistent with our business interests or goals and that could affect our ability to fully benefit from the assets owned by the joint venture;
- Our joint venture investors may be subject to different laws or regulations than us, which could create conflicts of interest;
- Our joint venture has license and other agreements with other investors, which we are not party to and have no control over;
- Our ability to sell our interest in, or sell additional assets to, the joint venture or the joint venture's ability to sell additional interests of, or assets owned by, the joint venture when we so desire are subject to the approval rights of the other joint venture investors under the terms of the agreements governing the joint venture; and
- Disagreements with our joint venture investors could result in litigation or arbitration that could be expensive and distracting to management and could delay important decisions.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and results of operations. Further, these, similar, enhanced or additional risks, including possible risks of the other joint venture investors having licensed assets to the joint venture, may apply to any future additional or amended joint ventures that we may enter into.

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, an executive order was issued that modified certain aspects of the ACA. Following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further 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 trials 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 years ended December 31, 2017, 2019, 2020 and 2021, 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 year ended December 31, 2018 and 2022, 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 clinical trial operations, our business and operations.

The spread of COVID-19 may 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.

However, we experienced approximately six months of delays in clinical trials due to slow-downs of recruitment for trials generally. Although we do not expect any material impact on our development timeline and our liquidity due to COVID-19, the ongoing development of the COVID-19 pandemic 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. We continue to assess the effect on our operations by monitoring the status of COVID-19.

We face uncertainties related to Oravax's oral COVID-19 vaccine.

We face uncertainties related to Oravax's oral COVID-19 vaccine, including uncertainties related to the risk that our continued development programs may not be successful, commercially viable or receive approval from regulatory authorities. Other companies may produce superior or competitive oral or other products that make Oravax's oral COVID-19 vaccine not commercially worthwhile. Even if we succeed in developing the product, the demand for any

product we may develop may no longer exist, given the fluid nature of the COVID-19 pandemic, including possible decreased demand for vaccines due to weaker strains, the need for different vaccines for new variants of the virus or an end of the pandemic that may render Oravax's vaccine obsolete.

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. We experienced a significant decline in the market price of our common stock and a significant increase in trading volume after announcing the results of our ORA-D-013-1 Phase 3 trial in January 2023. Any strategic decision we make as a result of our strategic review process may also negatively affect our common stock price or cause volatility in the market price of our common stock. Sales of large amounts of our securities or large variations in trading volume 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 March 6, 2023, we had outstanding 39,783,813 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 43,386,638 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 March 6, 2023, we had outstanding warrants and options exercisable for 1,548,256 shares of common stock at a weighted average exercise price of $4.71. We also had outstanding RSUs exercisable for 265,302 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.

Our failure to maintain compliance with the Nasdaq Capital Market's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. Nasdaq Listing Rule 5550(a)(2) requires the minimum bid price of our common stock on the Nasdaq Capital Market to remain above $1.00. If the bid price of our common stock closes below $1.00 per share for 30 consecutive business days, we would be in violation of Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we would have 180 calendar days to regain compliance with the minimum bid requirement to achieve compliance with the minimum bid price requirement.

While we intend to engage in efforts to maintain compliance, and thus maintain our listing, there can be no assurance that we will continue to meet all applicable Nasdaq Capital Market requirements in the future, especially in light of any strategic transaction we may choose to undertake. If our common stock were removed from listing with the Nasdaq Capital Market, it may be subject to the so-called "penny stock" rules. The SEC has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange, which is the exception on which we currently rely. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

If our common stock is delisted and there is no longer an active trading market for our shares, it may, among other things:

- cause stockholders difficulty in selling our shares without depressing the market price for the shares or selling our shares at all;
- substantially impair our ability to raise additional funds;
- result in a loss of institutional investor interest and fewer financing opportunities for us; and/or
- result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

A delisting would also reduce the value of our equity compensation plans, which could negatively impact our ability to retain employees.

As the market price of our common stock may fluctuate significantly, this may make it difficult for you to sell your shares of common stock when you want or at prices you find attractive.

The price of our common stock is currently listed on The Nasdaq Capital Market 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. For example, we experienced a significant decline in the market price of our common stock after announcing the results of our ORA-D-013-1 Phase 3 trial in January 2023. These factors include:

- market acceptance of our new strategy, once determined and announced;
- clinical trial results and the timing of the release of such results;
- the amount of cash resources and our ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by us or our competitors;
- entering into or terminating strategic relationships;
- changes in government regulation;
- departure of key personnel;
- disputes concerning patents or proprietary rights;
- changes in expense level;
- future sales of our equity or equity-related securities;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed;
- activities of various interest groups or organizations;
- media coverage; and
- status of the investment markets.

Future sales of common stock or the issuance of securities senior to our common stock or convertible into, or exchangeable or exercisable for, our common stock could materially adversely affect the trading price of our common stock, and our ability to raise funds in new equity offerings.

Future sales of substantial amounts of our common stock, including pursuant to any strategic opportunity, the Cantor Equity Distribution Agreement (as defined below), 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, including in connection with any strategic opportunity or pursuant to the Cantor Equity Distribution Agreement, our stockholders may experience significant dilution. Additionally, we may, from time to time or in connection with a strategic alternative, issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of convertible debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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 the year ended December 31, 2022, the four month period ended December 31,2021 and the year ended August 31, 2021. 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. 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.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our clinical trial efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed.

We also maintain compliance programs to address the potential applicability of restrictions against trading while in possession of material, nonpublic information generally and in connection with a cyber-security breach. However, a breakdown in existing controls and procedures around our cyber-security environment may prevent us from detecting, reporting or responding to cyber incidents in a timely manner and could have a material adverse effect on our financial position and value of our stock.

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 and we will necessarily be using our capital when we decide on new strategic initiatives. 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 the 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.

Common Stock

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

Holders

As of March 6, 2023, there were 39,783,813 shares of our common stock issued and outstanding held of record by approximately 34 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

During the three months ended December 31, 2022, we issued an aggregate amount of 3,000 unregistered shares of common stock to a service provider, as part of the compensation for services provided, pursuant to the exemption under Section 4(a)(2) of the Securities Act. 1,500 unregistered shares of common stock were issued to the service provider on each of October 15, 2022 and December 15, 2022.

ITEM 6. [RESERVED]

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 audited consolidated financial statements and the related notes included elsewhere herein and in our audited consolidated financial statements.

In addition to our audited 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 currently a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions with a technology platform that allows for the oral delivery of therapeutic proteins.

Through our research and development efforts, we have developed an oral dosage form intended to withstand the harsh environment of the stomach and effectively deliver active biological insulin or other proteins. 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.

On January 11, 2023, we announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. Concurrently, we are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

Impact of COVID-19

We do not expect any material impact on our development timeline and our liquidity due to COVID-19. However, we experienced approximately six months of delays in clinical trials due to slow-downs of recruitment for trials generally. On the other hand, Oravax continues to develop its oral vaccine, the demand for which may be reduced if COVID-19 continues to abate. We continue to assess the effect on our operations by monitoring the status of COVID-19.

Results of Operations

The table and discussion that follows includes a comparison of our results of operations and liquidity and capital resources for the year ended December 31, 2022 and the year ended December 31, 2021 and the four month periods ended December 31, 2021 and 2020. For a comparison of our results of operations and financial condition for the fiscal years ended August 31, 2021 and 2020, see "Item 7. 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, 2021, filed with the SEC on November 24, 2021. For information regarding the change in the Company's fiscal year from the period beginning on September 1 and ending on August 31 to the period beginning on January 1 and ending on December 31, see note 1 to our audited consolidated financial statements.

	Year ended December 31,		Four months ended December 31,	Four months ended December 31,	Year ended August 31,
	2022	2021	2021	2020	2021
	(Unaudited)			(Unaudited)	
	(dollar amounts in thousands, except share and per share data)				
Revenues	$ 2,703	$ 2,703	$ 904	$ 904	$ 2,703
Cost of revenues	-	-	-	-	-
Research and development expenses	27,639	23,203	9,037	6,889	20,989
Sales and marketing expenses	1,851	898	898	-	-
General and administrative expenses	13,811	7,591	3,295	1,576	5,937
Financial income (expense), net	2,934	1,068	71	237	1,234
Loss before taxes on income	37,664	27,921	12,255	7,324	22,989
Taxes on income	100	-	-	-	-
Net loss for the period	$ 37,764	$ 27,921	$ 12,255	$ 7,324	$ 22,989
Net loss attributable to Company's stockholders	36,561	26,583	11,668	7,324	22,238
Net loss attributable to non-controlling interest	1,203	1,338	587	-	751
Net loss for the period	$ 37,764	$ 27,921	$ 12,255	$ 7,324	$ 22,989
Basic and diluted loss per share of common stock	$ 0.94	$ 0.81	$ 0.31	$ 0.30	$ 0.78
Weighted average shares of common stock outstanding used in computing basic and diluted loss per share of common stock	38,997,649	32,641,288	37,113,137	24,394,010	28,469,068

Revenues

Revenues consist of proceeds related to the HTIT License Agreement that are recognized on a cumulative basis when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, through the expected product submission date by HTIT of June 2023, using the input method.

Revenues for the years ended December 31, 2022 and 2021 were both $2,703.

Revenues for the four month periods ended December 31, 2021 and 2020 were both $904.

Cost of Revenues

Cost of revenues consists of royalties related to the HTIT License Agreement that will be paid over the term of the HTIT 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.

There was no cost of revenues for the years ended December 31, 2022 and 2021 and the four month periods ended December 31, 2021 and 2020.

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 trials.

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.

Research and development expenses for the year ended December 31, 2022 increased by 19% to $27,639,000, compared to $23,203,000 for the year ended December 31, 2021. The increase was mainly due to an increase in expenses related to our Phase 3 clinical trials and to stock-based compensation expenses. Stock-based compensation expenses for the year ended December 31, 2022, were $3,176,000, compared to $1,598,000 for the year ended December 31, 2021. The increase was mainly due to new grants in 2022.

Research and development expenses for the four month period ended December 31, 2021 increased by 31% to $9,037,000, compared to $6,889,000 for the four month period ended December 31, 2020. The increase was mainly due to an increase in expenses related to our Phase 3 and NASH clinical trials in addition to expenses related to in process research and development costs related to Oravax. Stock-based compensation expenses for the four month period ended December 31, 2021, were $649,000, compared to $171,000 for the four month period ended December 31, 2020. The increase was mainly due to equity awards granted to a consultant and to new grants awarded in 2021.

Following the results of the ORA-D-013-1 Phase 3 trial, which did not meet its primary and secondary endpoints, we terminated both ORA-D-013-1 and ORA-D-013-2 Phase 3 clinical trials. In parallel, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. We are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

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.

From August 2009 to March 2014, our subsidiary Oramed Ltd. was awarded five government grants amounting to a total net amount of NIS 8 million (approximately $2,194,000 during such period) from the IIA. We used these funds to support further research and development and clinical trials of our oral insulin capsule and oral GLP-1 analog candidate 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.

In the years ended December 31, 2022 and 2021, the four month periods ended December 31, 2021 and 2020 and the year ended August 31, 2021, we did not recognize any research and development grants. As of December 31, 2022, we had incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy and Industry of $133,000.

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.

Sales and Marketing Expenses

Sales and marketing expenses include the salaries and related expenses of our commercial functions, consulting costs and other general costs.

Sales and marketing expenses for the year ended December 31, 2022 increased by 106% to $1,851,000, compared to $898,000 for the year ended December 31, 2021. The increase was mainly due to stock-based compensation expenses, salary related expenses and consulting expenses, mainly resulting from hiring our Chief Commercial Officer.

Stock-based compensation expenses for the year ended December 31, 2022 were $1,172,000, compared to $579,000 for the year ended December 31, 2021. The increase was mainly due to equity awards granted to an employee during 2022.

Sales and marketing expenses for the four month period ended December 31, 2021 were $898,000, compared to no expenses for the four month period ended December 31, 2020. The increase was mainly due to stock-based compensation expenses, salary related expenses and consulting expenses. Stock-based compensation costs for the four month period ended December 31, 2021 were $579,000, compared to no stock-based compensation expenses during the four month period ended December 31, 2020. The increase was mainly due to equity awards granted to an employee during 2021.

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 for the year ended December 31, 2022 increased by 82% to $13,811,000, compared to $7,591,000 for the year ended December 31, 2021. The increase was mainly due to higher stock-based compensation costs, an increase in legal expenses and higher salary expenses due to the recruitment of new employees in the year ended December 31, 2022, partially offset by lower bonuses in the year ended December 31, 2022. Stock-based compensation expenses for the year ended December 31, 2022 were $7,160,000, compared to $2,368,000 for the year ended December 31, 2021. The increase was mainly due to equity awards granted to employees during 2022.

General and administrative expenses for the four month period ended December 31, 2021 increased by 109% to $3,295,000, compared to $1,576,000 for the four month period ended December 31, 2020. The increase was mainly due to an increase in stock-based compensation expenses and professional fees as well as public relations and investor relations expenses. Stock-based compensation costs for the four month period ended December 31, 2021 were $1,034,000, compared to $242,000 during the four month period ended December 31, 2020. The increase was mainly due to equity awards granted to employees during the four month period ended December 31, 2021 and to new award grants during 2021.

Financial Income (Expense), Net

Net financial income was $2,934,000 for the year ended December 31, 2022, compared to net financial income of $1,068,000 for the year ended December 31, 2021. The increase is mainly due to interest from short and long-term bank deposits, partially offset by loss from revaluation of the shares we hold in Entera and DNA.

Net financial income was $71,000 for the four month period ended December 31, 2021, compared to $237,000 for the four month period ended December 31, 2020. The decrease is mainly due to a decrease in fair value of the ordinary shares of Entera.

Basic and Diluted Loss Per Share of Common Stock

Basic and diluted loss per share of common stock for the year ended December 31, 2022 increased by 16% to $0.94, compared to $0.81 for the year ended December 31, 2021. The increase in loss was mainly due to the higher net loss in the year ended December 31, 2022 compared to the year ended December 31, 2021.

Basic and diluted loss per share of common stock for the four month period ended December 31, 2021 increased by 3% to $0.31, compared to $0.30 for the four month period ended December 31, 2020. The increase in loss per share was due to a higher net loss and a higher number of weighted average shares of common stock in the four month period ended December 31, 2021 compared to the four month period ended December 31, 2020.

Weighted Average Shares of Common Stock Outstanding

Weighted average shares of common stock outstanding for the year ended December 31, 2022 were 38,997,649, compared to 32,641,288 for the year ended December 31, 2021. The increase was mainly due to shares issued in connection with our controlled equity offering and registered direct offering.

Weighted average shares of common stock outstanding for the four month period ended December 31, 2021 were 37,113,137, compared to 24,394,010 for the four month period ended December 31, 2020. The increase was mainly due to shares issued in connection with our controlled equity offering and registered direct offering.

Liquidity and Capital Resources

From our inception through December 31, 2022, we have incurred losses in an aggregate amount of $163,081,000. During that period and through December 31, 2022, 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 $252,946,000, net of transaction costs. During that period, we also received cash consideration of $28,001,000 from the exercise of warrants and options. We expect to seek additional financing through similar sources in the future, as needed. As of December 31, 2022, we had $40,464,000 of available cash, $111,513,000 of short-term bank deposits, $3,743,000 of marketable securities and $2,700,000 of long-term investments.

From inception through December 31, 2022, we have not generated significant revenues from our operations. Management continues to evaluate various financing alternatives for funding new strategic activities, 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 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 increases in our operating expenses, we may need to seek additional financing during the next 12 months. Successful completion of our development programs and our transition to normal operations is dependent upon obtaining necessary regulatory approvals from the FDA prior to selling our products within the United States, obtaining foreign regulatory approvals to sell our products internationally, or entering into licensing agreements with third parties. There can be no assurance that we will receive regulatory approval of any of our product candidates, and a substantial amount of time may pass before we achieve a level of revenues adequate to support our operations, if at all. We also expect to incur substantial expenditures in connection with the regulatory approval process for each of our product candidates during their respective developmental periods. Obtaining marketing approval will be directly dependent on our ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. We may also need additional funds to realize the decisions made as part of our strategic review process. We cannot predict the outcome of these activities.

As of December 31, 2022, our total current assets were $157,109,000 and our total current liabilities were $5,746,000. On December 31, 2022, we had a working capital surplus of $151,363,000 and an accumulated loss of $163,081,000. As of December 31, 2021, our total current assets were $147,937,000 and our total current liabilities were $7,368,000. On December 31, 2021, we had a working capital surplus of $140,569,000 and an accumulated loss of $126,520,000. The increase in working capital surplus from December 31, 2021 to December 31, 2022 was mainly due to an increase in cash and cash equivalents.

During the year ended December 31, 2022, cash and cash equivalents decreased to $40,464,000 from $77,245,000 as of August 31, 2021. The decrease was mainly due to the reasons described below.

Operating activities used cash of $27,918,000 in the year ended December 31, 2022, compared to $21,181,000 used in the year ended August 31, 2021. Cash used in operating activities consisted mainly of net loss resulting from research and development, general and administrative and sales and marketing expenses.

Investing activities provided cash of $30,211,000 in the year ended December 31, 2022, compared to cash used by investing activities of $23,764,000 in the year ended August 31, 2021. Cash provided in investing activities is mainly due to proceeds from short-term investments, partially offset by the acquisition of short-term investments.

Financing activities provided cash of $10,779,000 in the year ended December 31, 2022, compared to $102,892,000 in the year ended August 31, 2021. Cash provided by financing activities consisted mainly of proceeds from our issuance of common stock and proceeds from exercise of warrants and options. Our primary financing activities since the beginning of the year ended December 31, 2022 were as follows:

- During the year ended December 31, 2022, 4,200 warrants were exercised and 71,607 options were exercised, resulting in the issuance of 38,651 shares of common stock. Out of these exercised options, 10,750 options were exercised for cash and 60,857 via a cashless method. The cash consideration received for the exercise of options and warrants was $62,490. During the four month period ended December 31, 2021, 73,800 warrants were exercised and 18,166 options were exercised for cash, resulting in the issuance

of 91,966 shares of common stock. The cash consideration received for the exercise of options and warrants was $638,267.

- On September 1, 2021, we entered into a controlled equity offering agreement, or the Cantor Equity Distribution Agreement, with Cantor Fitzgerald & Co., as agent, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $100,000,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3, including a prospectus dated July 26, 2021 and prospectus supplement dated September 1, 2021. We paid 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 Cantor Equity Sales Agreement. As of December 31, 2022 and through March 6, 2023, 1,778,147 and 1,971,447 shares, respectively, were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $23,823,000 and $26,253,000, respectively.

During the four month period ended December 31, 2021, cash and cash equivalents decreased to $27,456,000 from the $77,245,000 reported as of August 31, 2021, which is due to the reasons described below.

Operating activities used cash of $11,122,000 in the four month period ended December 31, 2021, compared to $8,263,000 used in the four month period ended December 31, 2020. Cash used in operating activities primarily consisted of research and development, sales and marketing and general and administrative expenses, as well as changes in deferred revenue due to the HTIT License Agreement, partially offset by changes in accounts payable and accrued expenses and stock-based compensation.

Investing activities used cash of $99,248,000 in the four month period ended December 31, 2021, compared to cash used in investing activities of $2,405,000 in the four month period ended December 31, 2020. Cash used in investing activities in the four month period ended December 31, 2021 consisted primarily of the purchase of short-term deposits. Cash used in investing activities in the four month period ended December 31, 2020 consisted primarily of the purchase of short-term deposits, offset by the proceeds from bonds held to maturity.

Financing activities provided cash of $60,572,000 in the four month period ended December 31, 2021, compared to $13,001,000 provided in the four month period ended December 31, 2020. Cash provided by financing activities consisted primarily of proceeds from the issuance of our common stock.

On November 3, 2021, we entered into a securities purchase agreement with several institutional and accredited investors, or the Purchasers, pursuant to which we agreed to sell, in a registered direct offering, or the Offering, an aggregate of 2,000,000 shares of our common stock to the Purchasers for an offering price of $25.00 per share. The closing of the sale of the shares occurred on November 5, 2021. The net proceeds to us from the Offering, after deducting the placement agent's fees and expenses and the Company's Offering expenses, were approximately $46,375,000.

Trend Information

Following the results of the Phase 3 trials for our oral insulin capsule candidate, ORMD-0801, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. Concurrently, we are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders. At this time, we cannot foresee how these strategic decisions will impact our financial results and operations in 2023.

Planned Expenditures

We invest heavily in research and development, and we expect that in the upcoming years our research and development expenses will continue to be our major operating expense. As of December 31, 2022, we had expected obligations with respect to an aggregate of approximately $21 million of clinical research obligations over the next three years.

Following the results of the Phase 3 trials for our oral insulin capsule candidate, ORMD-0801 and the current strategic review initiated by the Company, our obligations may change significantly.

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 RSUs, 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 by HTIT in June 2023, amounts received relating to the HTIT 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 by HTIT 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.

On November 13, 2022, we entered into a distribution license agreement with Medicox, or the Medicox License Agreement. The Medicox License Agreement grants Medicox an exclusive license to apply for regulatory approval and distribute ORMD-0801 in the Republic of Korea.

Under ASC 606, we identified Medicox as a customer and the Medicox License Agreement as a contract with a customer.

We identified a performance obligation in the Medicox License Agreement to stand-ready and provide Medicox with support in its commercialization efforts in the Republic of Korea. This performance obligation includes a non-distinct distribution license for ORMD-0801, which we view a predominant item in the combined performance obligation. We concluded that the license is not distinct, as no party other than us is capable of providing related services to Medicox, and both the license and related services are necessary for the customer to obtain a regulatory approval in the Republic of Korea. In addition, the agreement covers the terms of future manufacturing services, that are contingent on the completion and success of the commercialization efforts.

The Medicox License Agreement contains a fixed consideration of $2 million, which was received by Oramed as of December 31, 2022 and is presented under long-term deferred revenues. It also contains variable consideration of contractual milestone payments and sales-based royalties.

Our obligation to stand-ready and support Medicox will be recognized on a straight-line basis over the period we expect to provide support to Medicox. As of December 31, 2022, this support has not commenced, and no revenue was recognized from the Medicox License Agreement.

If Medicox proceeds with the regulatory approval process in the Republic of Korea, we expect most of the revenue to be recognized in 2024, going forward. We note that our Phase 3 trial did not meet its primary and secondary endpoints. If Medicox chooses to terminate the agreement as a result of the outcome of the Phase 3 trials, we will accelerate revenue recognition and recognize it in 2023.

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 December 31, 2022, we had $40.5 million in cash and cash equivalents, $111.5 million in short term and long term bank deposits and $3.7 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 common shares of DNA and 117,000 ordinary shares of Entera, which are presented in our financial statements as marketable securities. Marketable securities are presented at fair value and their realization is subject to certain limitations if sold through the market, and we are therefore exposed to market risk. There is no assurance that at the time of sale of the marketable securities the price per share will be the same or higher, nor that we will be able to sell all of the securities at once given the volume of securities we hold. Entera shares are traded on Nasdaq in U.S. dollars, while DNA shares are traded on the Tel Aviv Stock Exchange in NIS. We are also exposed to changes in the market price of the Entera and DNA shares, as well as to exchange rates fluctuations in the NIS currency compared to the U.S. dollar with respect to the DNA 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.

Foreign Currency Exchange Risk

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 December 31, 2022, we own net balances in NIS of approximately $1,854,000. Assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience an exchange rate gain of approximately $206,000, while assuming a 10% devaluation of the NIS against the U.S. dollar, we would experience an exchange rate loss of approximately $169,000.

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 December 31, 2022	Year Ended December 31, 2021	Four months ended December 31, 2021	Four months ended December 31, 2020	Year Ended August 31, 2021
Average rate for period	3.358	3.229	3.165	3.533	3.292
Rate at period-end	3.519	3.11	3.11	3.215	3.207

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 December 31, 2022. 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 December 31, 2022 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 December 31, 2022 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 December 31, 2022 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors and Executive Officers

The name and age of each of our directors and executive officers, his or her position with us and the period during which such person has served as a director or executive officer of the Company are set forth below.

Name	Age	Position	Serving Since
Nadav Kidron	48	President, Chief Executive Officer, Director and Chairman (effective as of June 30, 2022)	2006
Dr. Miriam Kidron	82	Chief Scientific Officer and Director	2006
David Silberman	39	Chief Financial Officer and Treasurer	2021
Joshua Hexter	52	Chief Operating & Business Officer	2019
Michael Rabinowitz	57	Chief Commercial Officer	2021
Netanel Derovan	47	Chief Legal Officer and Secretary	2022
Dr. Arie Mayer	66	Director	2019
Yadin Rozov	45	Director	2022
Leonard Sank	57	Director	2007

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 of our directors and of 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 director*** in March 2006, and ***Chairman of the Board*** effective as of June 30, 2022. 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.

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 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. 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. David Silberman was appointed ***Chief Financial Officer and Treasurer*** in July 2021. Prior to his appointment, from April 2018 to May 2021, Mr. Silberman served as a Corporate Financial Planning and Analysis associate director and director at Teva Pharmaceutical Industries Ltd., a global pharmaceutical company, committed to helping patients around the world to access affordable medicines and benefit from innovations to improve their health. From 2014 to 2018, Mr. Silberman served as Global Internal Audit senior manager at Teva Pharmaceutical Industries Ltd. From 2009 to 2014, Mr. Silberman provided internal audit and risk management services in the advisory department of Grant Thornton Fahn Kanne Control Management. From January 2009 until June 2009, Mr. Silberman worked in the audit department of KPMG, a certified public accounting firm. Mr. Silberman holds DCG and DSCG degrees from the French Ministry of Higher Study and Research and is a certified public accountant in Israel.

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

Mr. Michael Rabinowitz was appointed ***Chief Commercial Officer*** in August 2021. Prior to his appointment, Mr. Rabinowitz served for over 25 years, from 1993 to 2021, in various marketing, sales, business development, and financial leadership roles at the global biopharmaceutical company Merck & Co., where he launched and marketed products in over 30 countries across several disease areas, including launching billion-dollar oral agents in diabetes and managing a global business. Mr. Rabinowitz holds a bachelors' degree *summa cum laude* from Northwestern University and a masters' degree from The Carlson School of Management at the University of Minnesota. He has also participated in executive health care programs at the Harvard Business School and the Wharton School of the University of Pennsylvania.

Mr. Netanel Derovan was appointed ***Chief Legal Officer and Secretary*** in January 2022. Prior to his appointment, from 2012 to 2021, Mr. Derovan served as executive counsel, corporate and securities, in the legal department of Teva Pharmaceutical Industries Ltd. From 2004 to 2012, he served as senior counsel in the International Corporate and Securities Department of Goldfarb Seligman & Co. From 2002 to 2004, he served as an associate attorney in the International Corporate Department at Caspi & Co. From 2001 to 2002, he served as a legal intern at Gornitzky & Co. Mr. Derovan holds an LLB degree from Bar Ilan University and is a member of the Israel Bar Association.

Dr. Arie Mayer became a ***director*** in December 2019. Dr. Mayer is currently the Managing Director and Chairman of the Board of 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. Yadin Rozov became a ***director*** in April 2022. Mr. Rozov is the founder and managing partner of Terrace Edge Ventures LLC, a financial advisory firm, since January 2022. From 2019 to 2021, Mr. Rozov was a Partner of GoldenTree Asset Management LLC, a leading global credit asset management firm. From 2019 to 2021, Mr. Rozov also served as the Chief Executive Officer and President of Syncora Guarantee Inc. and from 2020 to 2021, as Chief Executive Officer of Financial Guaranty UK Ltd, each of which is a stand-alone specialty insurance company owned by GoldenTree. From 2009 to 2019, he was a Partner and Managing Director at Moelis & Company where he headed the Financial Institution Advisory group and was on the Management Committee of Moelis Asset Management. From 2014 to 2019, Mr. Rozov helped co-found College Avenue Student Loans LLC and served on its board and co-founded Chamonix Partners Capital Management LLC. From 2007 to 2009, Mr. Rozov was a Managing Director at UBS AG, where he was the Head of the Americas for the Repositioning Group. Mr. Rozov serves on the board of directors of Midwest Holding Inc. since June 2022, and on the board of directors of Neo Performance Materials Inc. since August 2022. Mr. Rozov holds an M.Sc. in data science from Columbia University and a bachelor's degree with highest honors in physics and materials engineering from Rutgers University.

We believe Mr. Rozov's qualifications to serve on the Board include his many years of experience in capital markets, corporate finance, investment banking and investment management, with substantial experience in corporate strategy and governance.

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 25 years' experience of playing significant leadership roles in developing businesses. Mr. Sank serves on the boards of a few national businesses and local non-profit charity organizations in Cape Town, where he resides.

We believe that Mr. Sank's qualifications to serve on our Board include his years of experience in development stage businesses, as well as his experience serving as a director of many entities.

Board of Directors

There are no agreements with respect to the election of directors. Each director is currently 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 Dr. Arie Mayer, Yadin Rozov and Leonard Sank are independent as defined under the rules promulgated by the Nasdaq. Except for Dr. Arie Mayer, who serves on the Board of Directors of Oravax, a company 63% owned by us, none of the independent directors has any relationship with us besides serving on our Board.

We have determined that each of the directors is qualified to serve as a director of the Company based on a review of the experience, qualifications, attributes and skills of each director. In reaching this determination, we have considered a variety of criteria, including, among other things: character and integrity; ability to review critically, evaluate, question and discuss information provided, to exercise effective business judgment and to interact effectively with the other directors; and willingness and ability to commit the time necessary to perform the duties of a director.

Board Meeting Attendance

During the fiscal year ended December 31, 2022, our Board held six meetings and took action by written consent on nine occasions. During the Transition Period, our Board held five meetings and took action by written consent on one occasion. All of our directors attended at least 75% of the aggregate number of meetings of the Board and the committees that were held during the period such director served on the Board. Board members are encouraged to attend our annual meetings of stockholders.

Board Evaluation Process

Our Board is committed to continuous improvement and conducts a board and committee evaluation process each year, to ensure that our Board maintains optimal composition and functions effectively.

As part of this process, the members of our Board complete a confidential written assessment of the performance, oversight and composition of the Board and its committees that is submitted to the Company secretary. The results are then reported back to the full Board. After the evaluations, the Board and management work to improve upon any issues presented during the evaluation process and to identify opportunities that may lead to further improvement.

Committees

Audit Committee and Audit Committee Financial Expert

The members of our Audit Committee are Dr. Arie Mayer, Yadin Rozov and Leonard Sank. Our Board has determined that Yadin Rozov 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;
- Reviewing the Company's policies with respect to cyber security risks and relevant contingent liabilities and risks that may be material to the Company;

- Recommending, establishing and monitoring procedures designed to improve the quality and reliability of the disclosure of our financial condition and results of operations; and
- Reviewing major financial risk exposures and the steps management has taken to monitor and control such exposures, and discussing the guidelines and polices to govern the process by which risk assessment and management is undertaken.

Our Audit Committee met six times and took action by written consent on four occasions during the fiscal year ended December 31, 2022. Our Audit Committee met three times and took action by written consent on two occasions during the Transition Period.

Compensation Committee

The members of our Compensation Committee are Dr. Arie Mayer, Leonard Sank and Yadin Rozov. 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.

The Compensation Committee meets as often as it deems necessary, without the presence of any executive officer when approving compensation, except that the Company's Chief Executive Officer, at the discretion of the Compensation Committee, may be present during the approval of, or deliberations with respect to, the compensation of other executive officers. The Compensation Committee may delegate any authority granted to it to one or more subcommittees of the Compensation Committee, in its sole discretion.

Our Compensation Committee met twice and took action by written consent on four occasions during the fiscal year ended December 31, 2022. Our Compensation Committee met once and took action by written consent on two occasions during the Transition Period.

Nominating Committee

The members of our Nominating Committee are Dr. Arie Mayer, Leonard Sank and Yadin Rozov. 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 based on background, skills, experience and diversity, 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.

Our Nominating Committee took action by written consent on two occasions during the fiscal year ended December 31, 2022. Our Nominating Committee did not meet or take action by written consent during the Transition Period.

Delinquent Section 16(a) Reports

Based solely upon a review of Forms 3, 4 and 5, and amendments thereto, furnished to us during the fiscal year ended December 31, 2022 and the Transition Period, we believe that during the fiscal year ended December 31, 2022 and

the Transition Period, 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 that Dr. Arie Mayer, one of our directors, failed to timely file a Form 4 reporting his November 1, 2021 sale of 3,000 shares of our common stock. Mr. Mayer filed a Form 4 reporting this transaction on May 10, 2022.

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, 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 the year ended December 31, 2022 and the Transition Period are those three individuals listed in the "Summary Compensation Table" below. The Compensation Committee believes that our executive compensation is appropriately designed to incentivize our NEOs 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 NEOs 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 Securities Exchange Act of 1934, as amended, or the Exchange Act. The Compensation Committee has the authority and responsibility to review and approve the compensation of our President and Chief Executive Officer 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 Amended and Restated 2019 Incentive Plan. Executive compensation is paid or granted based on such matters as the Compensation Committee deems appropriate, including our financial and operating performance and the alignment of the interests of the executive officers and our stockholders.

Elements of Compensation

Our executive officer compensation program is comprised of: (i) base salary or monthly compensation; (ii) discretionary bonus; (iii) long-term equity incentive compensation in the form of stock option and RSU grants; and (iv) benefits and perquisites.

In establishing overall executive compensation levels and making specific compensation decisions for our NEOs in the year ended December 31, 2022 and the Transition Period, 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 President and Chief Executive Officer's recommendations for executive compensation of the other NEOs. The President and Chief Executive Officer generally presents these recommendations at the time of our Compensation Committee's review of executive compensation arrangements.

During the fiscal year ended December 31, 2022, the Compensation Committee received consulting services from Deloitte Israel & Co., or Deloitte, with regard to management compensation. The Compensation Committee engaged the consultant to review the Company's current compensation plans for its management and collect and analyze data regarding management compensation at other companies comparable to the Company, in order to provide a competitive compensation benchmark. Deloitte collected SEC filings data regarding U.S. and Israeli compensation practices and developed a peer group of the following U.S. and Israeli companies: Theseus Pharmaceuticals Inc., Athira Pharma Inc., Zomedica Corp., Rallybio Corp., Verastem Inc., VistaGen Therapeutics Inc., Acumen Pharmaceuticals Inc., Enochian Biosciences Inc., Aldeyra Therapeutics Inc., Viking Therapeutics Inc., Eliem Therapeutics Inc., Werewolf Therapeutics Inc., Compugen Ltd., Urogen Pharma Ltd., Kamada Ltd., Gamida Cell Ltd., Sol Gel Technologies Ltd., Redhill Biopharma Ltd., Collplant Biotechnologies Ltd., Enlivex Therapeutics Ltd., Vascular Biogenics Ltd., PolyPid Ltd. and BioLine RX Ltd. Following its review, Deloitte provided recommendations for cash and equity compensation at various percentiles for the Compensation Committee's consideration.

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 NEOs, 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 the year ended December 31, 2022, our Compensation Committee increased the base salary of one of our NEOs by 10% (effective January 1, 2023) as it deemed this to be a reasonable rate based on, among other factors, such NEO's responsibilities and the report from Deloitte, as it determined the salary was not in line with market compensation. In the Transition Period, our Compensation Committee increased the base salary of most of our NEOs by 15% based on the report from an independent compensation consultant, as it determined salaries were not in line with market compensation.

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.

As part of its engagement in the year ended December 31, 2022 described above, Deloitte also provided consulting services in connection with grants of equity awards to our executive officers. Deloitte reviewed annual long-term incentive grants at peer companies, as well as such grants made by companies in the broader market, based on a blend of Black-Scholes valuations and grants as a percentage of the applicable company's capitalization. Following such consultation, the Compensation Committee is considering alternative models and equity vehicles for future equity-based grants.

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 some of our NEOs with a cellular 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 paid for certain direct costs, related taxes and expenses incurred in connection with the relocation of our President and Chief Executive Officer to the United States. During the fiscal year ended December 31, 2022 and the Transition Period, such relocation expenses totaled approximately $331,000 and $109,000, respectively, 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 June 30, 2022. 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 the fiscal year ended December 31, 2022 and the Transition Period.

SUMMARY COMPENSATION TABLE

The following table sets forth the compensation earned by our NEOs for the Transition Period and fiscal years ended December 31, 2022 and August 31, 2021.

Name and Principal Position	Year (1)	Salary ($) (2)	Bonus ($) (2)(3)	RSUs Awards ($) (4)	Option Awards ($) (4)(5)	All Other Compensation ($) (2)(6)	Total ($)
Nadav Kidron ..	2022	491,131	275,150	4,847,380	875,241	344,718	6,833,620
President, Chief Executive Officer and chairman[7]	Transition Period	183,543	565,634	-	-	117,294	866,471
	2021	465,982	300,000	1,995,666	876,693	382,240	4,020,581
Dr. Miriam Kidron.....	2022	378,569	140,231	1,938,580	588,947	23,879	3,070,206
Chief Scientific Officer and director[8]		134,505	285,273	-	-	5,327	425,105
	Transition Period 2021	319,868	86,000	1,330,451	584,462	14,193	2,334,974
David Silberman.....	2022	155,125	49,732	759,405	261,754	43,184	1,269,200
Chief Financial Officer[9]		60,388	41,759	661,654	573,744	9,546	1,347,091
	Transition Period 2021	27,762	-	-	-	4,376	32,138

(1) The information is provided for the fiscal year ended December 31, 2022, the Transition Period, which began on September 1, 2021 and ended on December 31, 2021, and the fiscal year ended August 31, 2021.

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

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

(4) For RSU awards, the amounts reflect the grant date fair value, as calculated pursuant to FASB ASC Topic 718. The assumptions used to determine the fair value of the RSU awards are set forth in note 8 to our audited consolidated financial statements included in the Annual Report. Our NEOs will not realize the value of these awards in cash unless and until the awards vest and the underlying shares are issued and subsequently sold.

(5) The amounts reflect the grant date fair value, as calculated pursuant to FASB ASC Topic 718, of these option awards. The assumptions used to determine the fair value of the option awards are set forth in note 8 to our audited consolidated financial statements included in the Annual Report. Our NEOs will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.

(6) Amounts exclude the fair market value of the options that were re-granted on September 11, 2019, 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 7a to our audited consolidated financial statements included in the Annual Report.

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

(7) Until November 1, 2022, Mr. Kidron received certain compensation from Oramed Ltd. through KNRY, Ltd., an Israeli entity owned by Dr. Miriam Kidron, or KNRY. Beginning on November 1, 2022, Mr. Kidron receives certain compensation from the Company through Shnida Ltd., an Israeli entity owned by Mr. Kidron, and certain compensation from Oramed Ltd. For additional information see “—Employment and Consulting Agreements” below.

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

(9) Mr. Silberman was appointed as Chief Financial Officer, effective July 5, 2021.

All Other Compensation Table

The "All Other Compensation" amounts set forth in the Summary Compensation Table above consist of the following:

Name	Year (1)	Automobile-Related Expenses ($)	Manager's Insurance (2)($)	Education Fund* ($)	Relocation Expenses (3)($)	Total ($)
Nadav Kidron.....	2022	9,774	3,703	682	330,559	344,718
	Transition Period	8,568	-	-	108,726	117,294
	2021	4,926	-	-	377,314	382,240
Dr. Miriam Kidron....	2022	23,879	-	-	-	23,879
	Transition Period	5,327	-	-	-	5,327
	2021	14,193	-	-	-	14,193
David Silberman.....	2022	16,095	21,835	5,254	-	43,184
	Transition Period	-	7,677	1,869	-	9,546
	2021	-	3,527	849	-	4,376

(1) The information is provided for the fiscal year ended December 31, 2022, the Transition Period, which began on September 1, 2021 and ended on December 31, 2021, and the fiscal year ended on August 31, 2021.

(2) 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.

(3) 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 Nadav Kidron, through KNRY, provided services as President and Chief Executive Officer of both the Company and Oramed Ltd., or the Nadav Kidron Consulting Agreement. The Nadav Kidron Consulting Agreement was terminated, effective November 1, 2022, and replaced with the agreements as further described below. 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.

The Miriam Kidron Consulting Agreement is terminable by either party upon 140 days prior written notice. The agreement, as amended, provides that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the agreement. Pursuant to the agreement, KNRY, Dr. Miriam Kidron agrees that during the term of the agreement and for a 12-month period thereafter, none of them will compete with Oramed Ltd. nor solicit employees of Oramed Ltd. Starting September 1, 2021, Dr. Miriam Kidron receives a monthly consulting fee of NIS 106,400.

The Nadav Kidron Consulting Agreement was terminable by either party upon 140 days prior written notice. The agreement, as amended, provided that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the agreement. Pursuant to the agreement, KNRY and Nadav Kidron each agreed that during the term of the agreement and for a 12-month period thereafter, none of them will compete with Oramed Ltd. nor solicit employees of Oramed Ltd. From September 1, 2021 until termination, Nadav Kidron received a monthly consulting fee of NIS 146,705.

Following the relocation of Nadav Kidron to the State of Israel, the Company entered into two agreements with Mr. Kidron, replacing the Nadav Kidron Consulting Agreement, substantially on the same terms, in order to allocate his time and services between the Company and Oramed Ltd.

Effective November 1, 2022, the Company entered into a consulting agreement with Shnida Ltd., whereby Nadav Kidron, through Shnida Ltd., provides services as President and Chief Executive Officer of the Company. The agreement is terminable by either party upon 140 days prior written notice. The agreement provides that Shnida Ltd. will be reimbursed for reasonable expenses incurred in connection with performance of the agreement and that Nadav Kidron will receive a monthly consulting fee of NIS 88,023. Pursuant to the agreement, Shnida Ltd. and Nadav Kidron each agree that during the term of the agreement and for a 12-month period thereafter, none of them will compete with the Company nor solicit employees of the Company.

In addition, we, through Oramed Ltd., have entered into an employment agreement with Nadav Kidron, effective as of November 1, 2022, pursuant to which Mr. Kidron receives gross monthly salary of NIS 46,901 in consideration for his services as President and Chief Executive Officer of Oramed Ltd. In addition, Mr. Kidron 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 David Silberman as of May 23, 2021, pursuant to which Mr. Silberman was appointed as Chief Financial Officer, Treasurer and Secretary of the Company and Oramed Ltd., effective July 5, 2021. Mr. Silberman resigned as Secretary on January 9, 2022, upon the appointment of Mr. Netanel Derovan as Chief Legal Officer and Secretary. In accordance with the employment agreement, as amended, Mr. Silberman's current gross monthly salary is NIS 47,438, effective January 1, 2023. In addition, Mr. Silberman is provided with a cellular phone and a company car allowance 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 NEOs 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.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2022

The following table sets forth information concerning stock options and stock awards held by the NEOs as of December 31, 2022.

	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	47,134[1]	-	12.45	4/9/24		
	49,000[2]	-	7.77	6/30/27		
	97,000[3]	-	8.14	1/31/28		
	196,500[4][5]	-	3.16	2/26/29		
	142,500[6]	47,500[6]	4.80	1/8/30		
	75,000[7]	75,000[7]	10.40	2/3/31		
	-	107,000[8]	13.89	1/3/32		
	58,063[9]	58,064[9]	3.91	9/17/32		
					452,000[10][11][12][13][14][15]	5,437,560
Dr. Miriam Kidron	47,134[1]	-	12.45	4/9/24		
	69,999[16]	-	7.77	6/30/27		
	47,000[17]	-	8.14	1/31/28		
	104,000[18][5]	-	3.16	2/26/29		
	75,000[19]	25,000[19]	4.80	1/8/30		
	50,000[20]	50,000[20]	10.40	2/3/31		
	-	72,000[21]	13.89	1/3/32		
	16,039[22]	16,040[22]	3.91	9/17/32		
					301,334[23][24][25][26][27]	3,625,048
David Silberman....	12,500[28]	37,500[28]	20.19	9/1/31		
	-	32,000[29]	13.89	1/3/32		
	4,747[30]	4,748[30]	3.91	9/17/32		
					127,500[31][32][33][34]	1,533,825

(1) On April 9, 2014, 47,134 options were granted to each of Nadav Kidron and Dr. 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.

(2) 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 vested 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 December 31, 2021, 98,000 of these options were forfeited.

(3) 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; 97,000 of such options vested in four equal installments of 24,250 on each of January 1, 2019, January 1, 2020, January 1, 2021 and January 1, 2022. The options expire on January 31, 2028.

(4) 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; 196,500 of such options vested in four equal installments of 49,125 on each of December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022. The options expire on February 26, 2029. For additional information please see note 6 below.

(5) On September 11, 2019, these options were canceled and re-granted under the 2019 Incentive Plan in the same amounts and under the same terms as the original grants.

(6) On January 8, 2020, 190,000 options were granted to Nadav Kidron under the 2019 Incentive Plan at an exercise price of $4.80 per share. 142,500 of the options vested in three equal installments of 47,500 on each of December 31, 2020, December 31, 2021 and December 31, 2022 and the remainder of 47,500 shall vest on December 31, 2023. The options expire on January 8, 2030.

(7) On February 3, 2021, 150,000 options were granted to Nadav Kidron under the 2019 Incentive Plan at an exercise price of $10.40 per share. 75,000 of the options vested in two equal installments of 37,500 on each of December 31, 2021 and December 31, 2022, and the remainder shall vest in two equal installments of 37,500 on each of December 31, 2023 and December 31, 2024. The options expire on February 3, 2031.

(8) On January 3, 2022, 107,000 options were granted to Nadav Kidron under the 2019 Incentive Plan at an exercise price of $13.89 per share. 107,000 of the options shall vest in four equal installments of 26,750 on each of January 1, 2023, January 1, 2024, January 1, 2025 and January 1, 2026. The options expire on January 3, 2032.

(9) On September 18, 2022, 116,127 options were granted to Nadav Kidron under the Oravax Medical Inc. 2021 Long-Term Incentive Plan at an exercise price of $3.91 per share. 58,063 of the options vested in two installments on each of September 18, 2022 and December 31, 2022 and the remaining 58,064 options shall vest in two installments on each of December 31, 2023 and December 31, 2024. The options expire on September 17, 2032.

(10) 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.

(11) 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.

(12) On February 3, 2021, 300,000 RSUs, representing a right to receive shares of the Company's common stock, were granted to Nadav Kidron. 100,000 RSUs vested in one installment on August 31, 2021 and the remainder shall vest per the following: 100,000 shares shall vest upon our common stock achieving a specified price per share, and 100,000 shall vest upon our achievement of certain business objectives.

(13) On January 3, 2022, 63,000 RSUs representing a right to receive shares of the Company's common stock were granted to Nadav Kidron. 63,000 shall vest in four equal installments of 15,750 on each of January 1, 2023, January 1, 2024, January 1, 2025 and January 1, 2026.

(14) On July 28, 2022, 126,000 RSUs representing a right to receive shares of the Company's common stock were granted to Nadav Kidron. 126,000 shall vest in three equal installments of 42,000 on each of January 1, 2024, January 1, 2025 and January 1, 2026.

(15) On July 28, 2022, 63,000 performance based RSUs representing a right to receive shares of the Company's common stock were granted to Nadav Kidron. 42,000 were to vest upon receipt of positive topline data in the first oral insulin Phase 3 clinical trial and 21,000 were to vest upon completion of enrollment of the second oral insulin Phase 3 clinical trial by June 30,2023. Following the results of the ORA-D-013-1 Phase 3 trial and the termination of the ORA-D-013-2 Phase 3 trial, these performance goals have not been met and the RSUs did not vest.

(16) On June 30, 2017, 69,999 options were granted to Dr. Miriam Kidron under the 2008 Plan at an exercise price of $7.77 per share; Such options vested in three 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.

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

(18) On February 26, 2019, 104,000 options were granted to Dr. Miriam Kidron under the 2008 Plan at an exercise price of $3.16 per share; 104,000 of such options vested in four equal installments of 26,000 on each of

December 31, 2019, December 31, 2020, December 31, 2021 and December 31, 2022. The options expire on February 26, 2029. For additional information please see note 5 above.

(19) On January 8, 2020, 100,000 options were granted to Dr. Miriam Kidron under the 2019 Incentive Plan at an exercise price of $4.80 per share. 75,000 of the options vested in three equal installments of 25,000 on each of December 31, 2020, December 31, 2021 and December 31, 2022 and the remaining 25,000 options shall vest on December 31, 2023. The options expire on January 8, 2030.

(20) On February 3, 2021, 100,000 options were granted to Dr. Miriam Kidron under the 2019 Incentive Plan at an exercise price of $10.40 per share. 50,000 of such options vested in two equal installments of 25,000 on each of on each of December 31, 2021 and December 31, 2022 and the remaining 50,000 options shall vest in two equal installments of 25,000 on each of December 31, 2023 and December 31, 2024. The options expire on February 3, 2031.

(21) On January 3, 2022, 72,000 options were granted to Dr. Miriam Kidron under the 2019 Incentive Plan at an exercise price of $13.89 per share. 72,000 of the options shall vest in four equal installments of 18,000 on each of January 1, 2023, January 1, 2024, January 1, 2025 and January 1, 2026. The options expire on January 3, 2032.

(22) On September 18, 2022, 32,079 options were granted to Dr. Miriam Kidron under the Oravax Medical Inc. 2021 Long-Term Incentive Plan at an exercise price of $3.91 per share. 16,039 of the options vested in two installments on each of September 18, 2022 and December 31, 2022 and the remaining 16,040 options shall vest in two installments on each of December 31, 2023 and December 31, 2024. The options expire on September 17, 2032.

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

(24) On February 3, 2021, 200,000 RSUs, representing a right to receive shares of the Company's common stock, were granted to Dr. Miriam Kidron. 66,666 RSUs vested in one installment on August 31, 2021 and the remainder shall vest per the following: 66,667 shares shall vest upon our common stock achieving a specified price per share, and 66,667 shall vest upon our achievement of certain business objectives. The shares of common stock underlying the RSUs will be issued upon request of the grantee.

(25) On January 3, 2022, 42,000 RSUs representing a right to receive shares of the Company's common stock were granted to Dr. Miriam Kidron. 42,000 shall vest in four equal installments of 10,500 on each of January 1, 2023, January 1, 2024, January 1, 2025 and January 1, 2026.

(26) On July 28, 2022, 84,000 RSUs representing a right to receive shares of the Company's common stock were granted to Dr. Miriam Kidron. 84,000 shall vest in three equal installments of 26,000 on each of January 1, 2024, January 1, 2025 and January 1, 2026.

(27) On July 28, 2022, 42,000 performance based RSUs representing a right to receive shares of the Company's common stock were granted to Dr. Miriam Kidron. 28,000 were to vest upon receipt of positive topline data in the first oral insulin Phase 3 clinical trial and 14,000 were to vest upon completion of enrollment of the second oral insulin Phase 3 clinical trial by June 30,2023. Following the results of the ORA-D-013-1 Phase 3 trial and the termination of the ORA-D-013-2 Phase 3 trial, these performance goals have not been met and the RSUs did not vest.

(28) On September 1, 2021, 50,000 options were granted to David Silberman under the 2019 Incentive Plan at an exercise price of $20.19 per share. 12,500 options vested on June 27, 2022 and the remainder shall vest in three equal installments of 12,500 options on each of June 27, 2023, June 27, 2024 and June 27, 2025. The options expire on September 1, 2031.

(29) On January 3, 2022, 32,000 options were granted to David Silberman under the 2019 Incentive Plan at an exercise price of $13.89 per share. 8,000 options vested on January 1, 2023 and the remainder shall vest in three equal installments of 8,000 on each of January 1, 2024, January 1, 2025 and January 1, 2026. The options expire on January 3, 2032.

(30) On September 18, 2022, 9,495 options were granted to David Silberman under the Oravax Medical Inc. 2021 Long-Term Incentive Plan at an exercise price of $3.91 per share. 4,747 of the options vested in two installments on each of September 18, 2022 and December 31, 2022 and the remaining 4,748 options shall vest in two installments on each of December 31, 2023 and December 31, 2024. The options expire on September 17, 2032.

(31) On September 1, 2021, 50,000 RSUs, representing a right to receive shares of the Company's common stock, were granted to David Silberman. These RSUs vest as follows: (i) 33,333 shall vest upon our common stock achieving a price per share of $25 for at least 20 days out of any 30-day trading period and (a) if the first condition was met any time before June 27, 2022, then the RSUs would have vested in three equal installments (on June 27, 2022, June 27, 2023 and June 27, 2024), (b) if the first condition is met any time between June 27, 2022 and June 27, 2023, then 1/3 of the RSUs will vest immediately, and the remainder will vest in two equal installments (on June 27, 2023 and June 27, 2024), (c) if the first condition is met any time between June 27, 2023 and June 27, 2024, then 2/3 of the RSUs will vest immediately, and the remaining 1/3 will vest on June 27, 2024) and (d) if the first condition is met any time after June 27, 2024, then the RSUs will vest immediately; and (ii) 16,667 upon achievement of a certain licensing agreement as specified by the Board and (a) if the first condition was met any time before June 27, 2022, then the RSUs would have vested in three equal installments (on June 27, 2022, June 27, 2023 and June 27, 2024), (b) if the first condition is met any time between June 27, 2022 and June 27, 2023, then 1/3 of the RSUs will vest immediately, and the remainder will vest in two equal installments (on June 27, 2023 and June 27, 2024), (c) if the first condition is met any time between June 27, 2023 and June 27, 2024, then 2/3 of the RSUs will vest immediately, and the remaining 1/3 will vest on June 27, 2024) and (d) if the first condition is met any time after June 27, 2024, then the RSUs will vest immediately.

(32) On January 3, 2022, 19,000 RSUs representing a right to receive shares of the Company's common stock were granted to David Silberman. 19,000 shall vest in four equal installments of 4,750 on each of January 1, 2023, January 1, 2024, January 1, 2025 and January 1, 2026.

(33) On July 28, 2022, 39,000 RSUs representing a right to receive shares of the Company's common stock were granted to David Silberman. 30,000 shall vest in three equal installments of 13,000 on each of January 1, 2024, January 1, 2025 and January 1, 2026.

(34) On July 28, 2022, 19,500 performance based RSUs representing a right to receive shares of the Company's common stock were granted to David Silberman. 13,000 were to vest upon receipt of positive topline data in the first oral insulin Phase 3 clinical trial and 6,500 were to vest upon completion of enrollment of the second oral insulin Phase 3 clinical trial by June 30,2023. Following the results of the ORA-D-013-1 Phase 3 trial and the termination of the ORA-D-013-2 Phase 3 trial, these performance goals have not been met and the RSUs did not vest.

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 the fiscal year ended December 31, 2022:

Name of Director	Fees Earned or Paid in Cash ($)	Stock Awards (1)(2)($)	Option Awards (1)(2)($)	All Other Compensation ($)	Total ($)
Dr. Arie Mayer[4][5]	103,308	184,980	112,974	-	401,262
Yadin Rozov	30,094	124,770	24,061	-	178,925
Leonard Sank	39,188	184,980	81,798	-	305,966
Aviad Friedman[3]	15,000	83,340	81,798	-	180,138
Kevin Rakin[3]	34,688	83,340	81,798	-	199,826

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 the Transition Period:

Name of Director	Fees Earned or Paid in Cash ($)	Stock Awards (2)($)	Option Awards (2)($)	All Other Compensation ($)	Total ($)
Aviad Friedman[3]	8,344	-	-	-	$ 8,344
Dr. Arie Mayer[4]	70,561	-	-	-	$ 70,561
Kevin Rakin[3]	10,781	-	-	-	$ 10,781
Leonard Sank	7,875	-	-	-	$ 7,875

(1) As of December 31, 2022, our non-employee directors then in office held options to purchase shares of our common stock and RSUs as follows:

Name of Director	Aggregate Number of Shares Underlying Stock Awards	Aggregate Number of Shares Underlying Option Awards
Dr. Arie Mayer[5]	18,000	45,398
Yadin Rozov	16,500	7,500
Leonard Sank	18,000	59,867

(2) 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 the Annual Report. 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.

(3) The terms of each of Aviad Friedman and Kevin Rakin as directors expired on June 30, 2022.

(4) Includes $62,280 and $61,683 as remuneration for Dr. Mayer's service as a member of the Board of Directors of Oravax during the Transition Period and during the year ended December 31, 2022, respectively.

(5) Includes 15,398 option awards granted by Oravax for Dr. Mayer's service as a member of the Board of Directors of Oravax.

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. Based on a report provided to the Compensation Committee by Aon Consulting, Inc. during 2021, effective as of December 1, 2021, each independent director is entitled to receive as remuneration for his or her service as a member of the Board a sum equal to $30,000 per annum. The Chairman of our Board is entitled to receive an additional sum equal to $25,500. The members of our Audit Committee are each entitled to receive an additional sum equal to $5,625. The members of our Compensation Committee are each entitled to receive an additional sum equal to $4,500. The members of our Nominating Committee are each entitled to receive an additional sum equal to $3,750. All remuneration is 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 the Transition Period and the year ended December 31, 2022.

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 December 31, 2022, options with respect to 2,287,989 shares had been granted, of which 275,673 had been forfeited, 308,804 had been exercised and 1,310,586 have expired. As of December 31, 2022, 525,824 RSUs had been granted, of which 164,636 have vested and the shares of common stock underlying those RSUs have not been issued and 34,118 have been forfeited.

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. On June 30, 2022, 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 3,000,000 shares to 7,500,000 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 amended 2019 Plan, 7,500,000 shares are reserved for the grant of awards, which may be issued at the discretion of our Board from time to time. As of December 31, 2022, options with respect to 1,863,646 shares have been granted, of which 100,918 had been forfeited, 66,978 had been exercised and none of them were expired. As of December 31, 2022, 1,881,600 RSUs had been granted, of which 100,666 have vested and the shares of common stock underlying those RSUs have not been issued and 85,334 have been forfeited. 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 December 31, 2022:

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	3,654,246	$ 4.79	4,106,898
Equity compensation plans not approved by security holders	-	-	-
Total	3,654,246	$ 4.79	4,106,898

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 March 6, 2023 by: (1) each person who is known by us to own beneficially more than 5% of our common stock; (2) each of our current directors; (3) each of our NEOs; and (4) all of our directors and executive officers as a group. On such date, we had 39,783,813 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 60 days following March 6, 2023. 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, New York 10036.

Name and Address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Nadav Kidron #+	1,735,966[1]	4.3%
Dr. Miriam Kidron #+	597,299[2]	1.5%
David Silberman+	25,250[3]	*
Dr. Arie Mayer #	24,000[4]	*
Yadin Rozov #	-	*
Leonard Sank #.	64,563[5]	*
All current executive officers and directors, as a group (nine persons)	2,743,637[6]	6.8%

* Less than 1%

\# Director

\+ NEO

(1) Includes 633,884 shares of common stock issuable upon the exercise of outstanding stock options and 105,386 shares of common stock underlying vested RSUs that are issuable upon request. Mr. Nadav's beneficial ownership includes the 218,603 shares of common stock held by Xiaopeng Li, a former director of the Company, over which he holds a proxy.

(2) Includes 411,133 shares of common stock issuable upon the exercise of outstanding stock options and 186,166 shares of common stock underlying vested RSUs that are issuable upon request.

(3) Includes 20,500 shares of common stock issuable upon the exercise of outstanding stock options.

(4) Includes 22,500 shares of common stock issuable upon the exercise of outstanding stock options.

(5) Includes 52,367 shares of common stock issuable upon the exercise of outstanding stock options.

(6) Includes 1,143,451 shares of common stock issuable upon the exercise of options beneficially owned by the referenced persons and 291,552 shares of common stock underlying vested RSUs that are issuable upon request.

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

During the years ended December 31, 2022 and 2021, 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 entered into the TLA with HTIT, which was further amended as the HTIT License Agreement. For further details, see "Item 1. Business—Description of Business— Out-Licensed Technology—HTIT."

On November 30, 2015, we also entered into a Stock Purchase Agreement with HTIT, pursuant to which, among other things, Mr. Kidron would 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 deemed appropriate except for matters related to our activities in the People's Republic of China, on which Mr. Kidron would consult with HTIT before taking any action as proxy. On August 19, 2021, the proxy was revoked in accordance with its terms by HTIT.

The Board has determined that Dr. Arie Mayer, Yadin Rozov and Leonard Sank are independent as defined under the rules promulgated by Nasdaq.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The aggregate fees billed by Kesselman & Kesselman, independent registered public accounting firm, and member firm of PricewaterhouseCoopers International Limited, for services rendered to us during the fiscal year ended December 31, 2022, during the Transition Period and during the fiscal year ended August 31, 2021:

	2022	Transition Period	2021
Audit Fees[1]	$ 130,000	$ 39,000	$ 90,000
Audit-Related Fees[2]	45,000	42,000	47,500
Tax Fees[3]	20,000	-	1,400
All Other Fees	-	-	-
Total Fees	$ 195,000	$ 81,000	$ 138,900

(1) Amount represents fees paid for professional services for the audit of our consolidated 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 July 2021 public offering of common stock for fiscal year 2021, our November 2021 registered direct offering of common stock for the Transition Period, at-the-market offering related fees, and fees rendered in connection with the Israeli Innovation Authority requirements.

(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 (PCAOB name: Kesselman & Kesselman C.P.A.s, PCAOB ID: 1309 and Auditor Location: Tel Aviv, Israel)	F-1
CONSOLIDATED FINANCIAL STATEMENTS:	
Balance sheets	F-2
Statements of loss	F-3
Statements of changes in equity	F-4
Statements of cash flows	F-5
Notes to financial statements	F-6 - F-35

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 December 2022 and 2021, and the related consolidated statements of loss, changes in stockholders' equity and cash flows for the year ended December 31, 2022, for the four-months ended December 2021 and for the year ended August 31,2021, 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 December 31, 2022 and 2021 and the results of its operations and its cash flows for the year ended December 31, 2022, for the four-months ended December 2021 and for the year ended August 31,2021, in conformity with accounting principles generally accepted in the United States of America.

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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

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

Tel Aviv, Israel
March 6, 2023

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)

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 40,464	$ 27,456
Short-term deposits (note 2)	111,513	111,077
Marketable securities (note 3)	3,743	7,747
Prepaid expenses and other current assets	1,389	1,657
Total current assets	157,109	147,937
LONG-TERM ASSETS:		
Long-term deposits (note 4)	7	25,094
Marketable securities (note 3)	-	3,875
Long-term investment (note 6j)	2,700	-
Amounts funded in respect of employee rights upon retirement	24	26
Property and equipment, net	815	388
Operating lease right of use assets	987	500
Total long-term assets	4,533	29,883
Total assets	$ 161,642	$ 177,820
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses (note 5)	$ 4,158	$ 4,535
Deferred revenues	1,340	2,703
Payable to related parties (note 11b)	1	-
Operating lease liabilities	247	130
Total current liabilities	5,746	7,368
LONG-TERM LIABILITIES:		
Long-term deferred revenues	4,000	3,340
Employee rights upon retirement	21	22
Provision for uncertain tax position (note 10f)	11	11
Operating lease liabilities	647	370
Other liabilities	61	99
Total long-term liabilities	4,740	3,842
COMMITMENTS (note 6)		
EQUITY		
EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS':		
Common stock, $ 0.012 par value (60,000,000 authorized shares as of December 31, 2022 and December 31, 2021; 39,563,888 and 38,158,792 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively)	476	459
Additional paid-in capital	314,417	292,514
Accumulated deficit	(163,081)	(126,520)
Total stockholders' equity	151,812	166,453
Non-controlling interests	(656)	157
Total equity	151,156	166,610
Total liabilities and equity	$ 161,642	$ 177,820

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

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

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
REVENUES	$ 2,703	$ 904	$ 2,703
RESEARCH AND DEVELOPMENT EXPENSES	27,639	9,037	20,989
SALES AND MARKETING	1,851	898	-
GENERAL AND ADMINISTRATIVE EXPENSES	13,811	3,295	5,937
OPERATING LOSS	40,598	12,326	24,223
FINANCIAL INCOME (note 9a)	3,754	158	1,242
FINANCIAL EXPENSES (note 9b)	820	87	8
LOSS BEFORE TAX EXPENSES	37,664	12,255	22,989
TAX EXPENSES	100	-	-
NET LOSS	$ 37,764	$ 12,255	$ 22,989
NET LOSS ATTRIBUTABLE TO:			
COMPANY'S STOCKHOLDERS	36,561	11,668	22,238
NON-CONTROLLING INTERESTS	1,203	587	751
NET LOSS	$ 37,764	$ 12,255	$ 22,989
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.94	$ 0.31	$ 0.78
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	38,997,649	37,113,137	28,469,068

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

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

	Attributable to Company's Stockholders						
	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total Equity
	Shares	$					
	In thousands						
BALANCE AS OF JANUARY 1, 2022	38,158	459	292,514	(126,520)	166,453	157	166,610
SHARES ISSUED FOR SERVICES	3	*	22	-	22	-	22
ISSUANCE OF COMMON STOCK, NET	1,213	15	11,485	-	11,500	-	11,500
EXERCISE OF WARRANTS AND OPTIONS	39	*	62	-	62	-	62
STOCK-BASED COMPENSATION	151	2	11,117	-	11,119	-	11,119
STOCK-BASED COMPENSATION OF SUBSIDIARY	-	-	-	-	-	390	390
TAX WITHHOLDINGS RELATED TO STOCK-BASED COMPENSATION SETTLEMENTS	-	-	(783)	-	(783)	-	(783)
NET LOSS	-	-	-	(36,561)	(36,561)	(1,203)	(37,764)
BALANCE AS OF DECEMBER 31, 2022	39,564	476	314,417	(163,081)	151,812	(656)	151,156

* Represents an amount of less than $1.

	Attributable to Company's Stockholders						
	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total Equity
	Shares	$					
	In thousands						
BALANCE AS OF SEPTEMBER 1, 2021	35,293	424	230,201	(114,852)	115,773	744	116,517
ISSUANCE OF COMMON STOCK, NET	2,631	32	59,901	-	59,933	-	59,933
EXERCISE OF WARRANTS AND OPTIONS	92	1	638	-	639	-	639
STOCK-BASED COMPENSATION	142	2	1,774	-	1,776	-	1,776
NET LOSS	-	-	-	(11,668)	(11,668)	(587)	(12,255)
BALANCE AS OF DECEMBER 31, 2021	38,158	459	292,514	(126,520)	166,453	157	166,610

	Attributable to Company's Stockholders						
	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total Equity
	Shares	$					
	In thousands						
BALANCE AS OF SEPTEMBER 1, 2020	23,675	284	125,209	(92,614)	32,879	-	32,879
ISSUANCE OF COMMON STOCK, NET	8,467	102	79,881	-	79,983	-	79,983
EXERCISE OF WARRANTS AND OPTIONS	3,151	38	21,371	-	21,409	-	21,409
STOCK-BASED COMPENSATION	-	-	2,695	-	2,695	-	2,695
ASSET ACQUISITION TRANSACTION	-	-	1,045	-	1,045	1,495	2,540
NET LOSS	-	-	-	(22,238)	(22,238)	(751)	(22,989)
BALANCE AS OF AUGUST 31, 2021	35,293	424	230,201	(114,852)	115,773	744	116,517

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

ORAMED PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
In thousands

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (37,764)	$ (12,255)	$ (22,989)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	58	18	77
Gain from selling fixed assets	(13)	-	-
Non-cash expense for acquired In-Process Research & Development ("IPR&D")	-	-	1,040
Exchange differences and interest on deposits and held to maturity bonds	(1,550)	(34)	187
Changes in fair value of investments	763	72	(876)
Stock-based compensation	11,509	1,776	2,695
Shares issued for services	22	-	-
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	268	(460)	(586)
Accounts payable, accrued expenses and related parties	(376)	689	2,060
Net changes in operating lease	(93)	-	-
Deferred revenues	(703)	(904)	(2,703)
Liability for employee rights upon retirement	(1)	1	3
Other liabilities	(38)	(25)	(89)
Total net cash used in operating activities	(27,918)	(11,122)	(21,181)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(496)	(9)	(375)
Proceeds from selling fixed assets	24	-	-
Investment in short-term deposits	(151,700)	(100,000)	(18,460)
Investment in long-term deposits	(5)	-	(25,000)
Proceeds from sale of mutual funds	-	-	3,765
Purchase of held to maturity securities	-	-	(10,362)
Proceeds from redemption of short-term deposits	178,200	-	18,460
Proceeds from maturity of held to maturity securities	6,886	761	8,209
Long-term investments	(2,700)	-	-
Funds in respect of employee rights upon retirement	2	-	(1)
Total net cash provided by (used in) investing activities	30,211	(99,248)	(23,764)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock, net of issuance costs	11,500	59,933	79,983
Proceeds from exercise of warrants and options	62	639	21,409
Tax withholdings related to stock-based compensation settlements	(783)	-	-
Transaction with non-controlling interests	-	-	1,500
Total net cash provided by financing activities	10,779	60,572	102,892
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(64)	9	2
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	13,008	(49,789)	57,949
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	27,456	77,245	19,296
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 40,464	$ 27,456	$ 77,245
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS:			
Taxes paid	$ 100	$ -	$ -
Interest received	$ 1,844	$ 128	$ 563
(B) SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:			
Recognition of operating lease right of use assets and liabilities	730	-	582
(C) ASSET ACQUISITION TRANSACTION (see note 12):			
IPR&D	-	-	1,040
Transaction with non-controlling interests	-	-	1,500
Additional paid in capital	-	-	(1,045)
Non-controlling interests	-	-	(1,495)

The accompanying notes are an integral part of the consolidated 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), a Delaware corporation, was incorporated on April 12, 2002.

On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd. to acquire the provisional patent related to an 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 July 30, 2019, the Subsidiary incorporated a wholly-owned subsidiary in Hong Kong, Oramed HK Limited (the "Hong Kong Subsidiary"). As of December 31, 2022, the Hong Kong Subsidiary has no operations.

On March 18, 2021, the Company entered into a license agreement (the "Oravax License Agreement") with Oravax Medical Inc. ("Oravax") and into a stockholders agreement (the "Stockholders Agreement") with Akers Biosciences Inc. ("Akers"), Premas Biotech Pvt. Ltd. ("Premas"), Cutter Mill Capital LLC ("Cutter Mill") and Run Ridge LLC ("Run Ridge"). According to the Stockholders Agreement, Oravax issued 1,890,000 shares of its capital stock to the Company, representing 63% of the issued and outstanding share capital of Oravax, on a fully diluted basis, as of the date of issuance. Consequently, Oramed consolidates Oravax in its consolidated financial statements since that time.

On November 23, 2021, Oravax incorporated a wholly-owned subsidiary in Israel, Oravax Medical Ltd., which is engaged in research and development. Effective January 1, 2022, Oravax transferred its rights and obligations under the Oravax License Agreement to Oravax Medical Ltd.

On January 11, 2023, the Company announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. The Company evaluated this subsequent event and determined that it was non-adjusting to the consolidated financial statements for the year ended December 31, 2022, as it was not known or expected as of that date. The Company has initiated a comprehensive analysis of the data to understand if there is a path forward for its oral insulin candidate. Concurrently, the Company is examining its existing pipeline and has commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for the Company's stockholders. See note 13.

2) Change in Fiscal Year

On February 28, 2022, the Company's Board of Directors (the "Board of Directors") approved a change of the Company's fiscal year from the period beginning on September 1 and ending on August 31 to the period beginning on January 1 and ending on December 31. As a result, the Company filed a Transition Report on Form 10-Q with the Securities and Exchange Commission (the "SEC") on March 30, 2022 that included financial information for the transition period from September 1, 2021 through December 31, 2021. Subsequent to that report, the Company's fiscal year now begins on January 1 and ends on December 31. This Annual Report on Form 10-K is the Company's first annual report presenting its new fiscal year, and reports financial results for the 12 month period ended December 31, 2022.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

3) 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 may also need additional funds to realize the decisions made as part of its strategic review process. 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 COVID-19. However, the Company experienced approximately six months of delays in clinical trials due to slow-downs of recruitment for trials generally. The Company continues to assess the effect on its operations by monitoring the status of COVID-19.

b. Basis of presentation

The consolidated financial statements included herein 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.

	December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Fair Value**
Assets:				
Marketable Securities				
DNA	352	-	-	352
Entera	85	-	-	85
	$ 437	-	-	$ 437

In thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

	December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Fair Value**
Assets:				
Marketable Securities				
DNA	863	-	-	863
Entera	337	-	-	337
	$ 1,200	-	-	$ 1,200

As of December 31, 2022, 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 December 31, 2022, 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 December 31, 2022, 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.

h. Marketable securities

1. Equity securities

   The Company classified the securities (investments in equity securities of DNA GROUP (T.R.) Ltd. ("DNA"), Entera Bio Ltd. ("Entera") and other mutual funds) to financial assets measured at fair value through profit or loss.

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. Long-term investment

The Company also invested in non-marketable equity securities, through an investment in a privately held company. This equity investment does not have a readily determinable fair value. The investment is measured under the measurement alternative in Accounting Standard Codification ("ASC") 321 "Investments – Equity Securities" to the extent such an investment is not subject to consolidation or the equity method. Under the measurement alternative, this equity investment is carried at cost, less any impairment, adjusted for changes resulting from observable price changes in transactions for an identical or similar investment of the same issuer. The investment would be impaired in accordance with the provisions of ASC 820 "Fair Value Measurement" if, based on a qualitative assessment of impairment indicators, the fair value of the investment is less than its carrying amount. If considered impaired, the difference between the carrying amount and fair value would be recorded in the consolidated statement of operations. See note 6j.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

j. 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, which are deposited in major financial institutions, and marketable securities. The Company is of the opinion that the credit risk in respect of these balances is remote.

k. 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 Israeli 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.

Until the year ended August 31, 2019, the Israeli subsidiary measured its results for tax purposes in nominal terms in NIS. In order to avoid unfavorable tax implications derived from the fluctuations in the exchange rate, the Israeli subsidiary's results for tax purposes are measured is U.S. dollars starting from the year ended August 31, 2020.

Taxes that would apply in the event of disposal of investments in the Israeli 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 12 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.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Revenue recognition

HTIT

On November 30, 2015, the Company entered into a Technology License Agreement (the "TLA"), with Hefei Tianhui Incubator 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 "HTIT License Agreement"). The HTIT License Agreement and a Stock Purchase Agreement, dated November 30, 2015, between the Company and HTIT (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 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.

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

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

As of December 31, 2022, an aggregate amount of $22,382 was allocated to the HTIT License Agreement, all of which were received through the balance sheet date. Through December 31, 2022, the Company recognized revenue associated with this agreement in the aggregate amount of $19,042 (of which $2,703 was recognized in the year ended December 31, 2022), and deferred the remaining amount of $3,340, which is presented as a contract liability on the consolidated balance sheet.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Medicox

On November 13, 2022, the Company entered into a distribution license agreement ("Medicox License Agreement") with Medicox Co., Ltd. ("Medicox"). The Medicox License Agreement grants Medicox an exclusive license to apply for regulatory approval and distribute ORMD-0801 in the Republic of Korea. For further details, see note 6f.

Under ASC 606, the Company identified Medicox as a customer and the Medicox License Agreement as a contract with a customer.

The Company identified a performance obligation in the Medicox License Agreement to stand-ready and provide Medicox with support in its commercialization efforts in the Republic of Korea. This performance obligation includes a non-distinct distribution license for ORMD-0801, which the Company views a predominant item in the combined performance obligation. The Company concluded that the license is not distinct, as no party other than the Company is capable of providing related services to Medicox, and both the license and related services are necessary for the customer to obtain a regulatory approval in the Republic of Korea. In addition, the agreement covers the terms of future manufacturing services, that are contingent on the completion and success of the commercialization efforts.

The Medicox License Agreement contains a fixed consideration of $2,000, which was received by the Company as of December 31, 2022 and is presented under long-term deferred revenues. It also contains variable consideration of contractual milestone payments and sales-based royalties.

The Company's obligation to stand-ready and support Medicox will be recognized on a straight-line basis over the period the Company expects to provide support to Medicox. As of December 31, 2022, this support has not commenced, and no revenue was recognized from the Medicox License Agreement.

If Medicox proceeds with the regulatory approval process in the Republic of Korea, the Company expects most of the revenue to be recognized in 2024, going forward. The Company notes that its Phase 3 trial did not meet its primary and secondary endpoints (see note 13). If Medicox chooses to terminate the agreement as a result of the outcome of the Phase 3 trials, the Company will accelerate revenue recognition and recognize it in 2023.

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 trials. 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 and RSUs 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.

The Company elects to account for forfeitures as they occur.

o. Loss per common share

Basic and diluted net loss per common share are computed by dividing the net loss attributable to stockholders for the period by the weighted average number of shares of common stock outstanding for each period, including vested RSUs. 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 3,356,203 for the year ended December 31, 2022, 3,894,588 for the four month period ended December 31, 2021 and 5,042,299 for the year ended August 31, 2021.

p. Asset acquisition

When determining whether a transaction gives rise to an acquisition of a business or asset group, the Company applies a screening test to determine whether substantially all of the fair value of the gross assets acquired in the transaction is concentrated in a single identifiable asset or group of similar identifiable assets. If so, then the assets are not considered a business and the transaction is accounted for as an asset acquisition.

When a transaction is accounted for as an asset acquisition, an IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. Otherwise, amounts allocated to IPR&D that have no alternative use are expensed.

The Company has elected an accounting policy to measure non-controlling interests in an asset acquisition at fair value on the date of acquisition.

q. Leases

The Company leases real estate and cars for use in its operations, which are classified as operating leases. In addition to rent, the leases may require the Company to pay directly for fees, insurance, maintenance and other operating expenses.

In thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right of use assets and operating lease liabilities in the consolidated balance sheets. Right of use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments. Lease expenses are recognized on a straight-line basis over the lease term.

The Company elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. This means that for those leases, the Company does not recognize ROU assets or lease liabilities but recognizes lease expenses over the lease term on a straight line basis. The Company also elected the practical expedient to not separate lease and non-lease components for all of its leases.

Lease terms will include options to extend or terminate the lease when it is reasonably certain that the Company will either exercise or not exercise the option to renew or terminate the lease.

The Company's lease agreements have remaining lease terms ranging from 1 year to 4 years. Some of these agreements include options to extend the leases for up to an additional 5 years and some include options to terminate the leases immediately. See also note 6h.

r. Recently issued Accounting Pronouncements, not yet adopted

In June 2016, the Financial Accounting Standards Board 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 is not expected to have a significant impact on the Company's consolidated financial statements.

NOTE 2 - SHORT-TERM DEPOSITS:

Composition:

	December 31,			
	2022		2021	
	Annual interest rate	Amount	Annual interest rate	Amount
Dollar deposits	0.93-6.81%	$ 111,513	0.73-0.93%	$ 111,077

a. Composition:

The Company's marketable securities include investments in equity securities of DNA and Entera and in held to maturity securities.

In thousands (except share and per share data)

NOTE 3 - MARKETABLE SECURITIES:

Composition:

	December 31, 2022	December 31, 2021
Short-term:		
DNA (see b below)	$ 352	$ 863
Entera (see c below)	85	337
Held to maturity securities (see d below)	3,306	6,547
	$ 3,743	$ 7,747
Long-term:		
Held to maturity securities (see d below)	$ -	$ 3,875
	$ 3,743	$ 11,622

b. DNA

DNA's 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 year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended August 31, 2021 the Company did not sell any of DNA's ordinary shares. As of December 31, 2022, the Company owns approximately 1.4% of DNA's outstanding ordinary shares.

The cost of the securities as of both December 31, 2022 and 2021 was $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)).

d. Held to maturity securities

The amortized cost and estimated fair value of held-to-maturity securities at December 31, 2022, were as follows:

	December 31, 2022			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 3,258	$ (82)	$ 3,176	1.07%
Accrued interest	48	-	48	
	$ 3,306	$ (82)	$ 3,224	

In thousands (except share and per share data)

NOTE 3 - MARKETABLE SECURITIES (continued):

The amortized cost and estimated fair value of held-to-maturity securities at December 31, 2021, are as follows:

	December 31, 2021			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 6,432	$ (115)	$ 6,317	1.37%
Accrued interest	115	-	115	
Long-term	3,875	(29)	3,846	1.20%
	$ 10,422	$ (144)	$ 10,278	

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.

NOTE 4 - LONG-TERM DEPOSITS:

	December 31,	
	2022	2021
Composition:		
Long-term deposits*	$ -	$ 25,092
Lease car deposits	7	2
	$ 7	$ 25,094

* Long term deposits include one deposit of $25,000 with an annual interest rate of 0.93% and a maturity date of August 10, 2023.

NOTE 5 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

Composition:

	December 31,	
	2022	2021
Accounts payable	$ 2,175	$ 1,692
Payroll and related accruals	529	1,197
Institutions	11	531
Accrued liabilities	1,443	1,115
	$ 4,158	$ 4,535

NOTE 6 - COMMITMENTS:

a. In March 2011, the Subsidiary sold shares of its investee company, Entera, to DNA, retaining 117,000 ordinary shares (after giving effect to a stock split by Entera in July 2018). In consideration for the shares sold to DNA, the Company received, among other payments, ordinary shares of DNA (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 rights to a patent application related to the oral administration of proteins that it has licensed to Entera since August 2010, in return for royalties of 3% of Entera's net revenues and a license back of that patent application for use in respect of diabetes and influenza. As of December 31, 2022, Entera 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 with Amgen, Inc. ("Amgen"). To the extent that the license granted to Amgen results in net revenues as defined in the Patent Transfer Agreement, the Subsidiary will be entitled to the aforementioned royalties. As part of a consulting agreement with a third party dated February 15, 2011, the Subsidiary is obliged to pay this third party royalties of 8% of the net royalties received in respect of the patent that was sold to Entera in March 2011.

b. According to the HTIT 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 HTIT 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 HTIT 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.

As of December 31, 2022, 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.

NOTE 6 - COMMITMENTS (continued):

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 $6,000, 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 years ended December 31, 2022, and December 31, 2021. 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 the SPA with HTIT, according to which, the Company issued 1,155,367 shares of common stock to HTIT for $12,000. The transaction closed on December 28, 2015.

The HTIT License Agreement and the SPA were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $49,500 between the HTIT 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 HTIT License Agreement. The Company determined that revenues are recognized over time through the expected product submission date in June 2023.

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 HTIT License Agreement.

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

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 $1,592 was recognized in research and development expenses through December 31, 2022.

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. The CRO Services Agreement was amended effective May 26, 2022 and as consideration for its services, the Subsidiary will pay the CRO a total amended amount of $22,684 during the term of the engagement and based on achievement of certain milestones, of which $16,356 was recognized in research and development expenses through December 31, 2022.

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 The CRO Services Agreement was amended effective May 26, 2022 and as consideration for its services, the Subsidiary will pay the CRO a total amended amount of $15,796 during the term of the engagement and based on achievement of certain milestones, of which $7,586 was recognized in research and development expenses through December 31, 2022.

NOTE 6 - COMMITMENTS (continued):

f. On November 13, 2022, the Company entered the Medicox License Agreement with Medicox.

The Medicox License Agreement grants Medicox an exclusive license to apply for regulatory approval and distribute ORMD-0801 in the Republic of Korea. The Medicox License Agreement is for ten years, but the parties have the right to terminate it with a 180 days-notice.

Medicox will comply with agreed distribution targets and will purchase ORMD-0801 at an agreed upon transfer price per capsule. In addition, Medicox will pay the Company up to $15,000 in developmental milestones, $2,000 of which have already been received by the Company, and up to 15% royalties on gross sales. Medicox will also be responsible for obtaining a regulatory approval in the Republic of Korea.

The Company is currently evaluating with Medicox a path forward to continue its collaboration, following the results of our ORA-D-013-1 Phase 3 trial.

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

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

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

At the time the grants were received, successful development of the related projects was not assured. The total amount that was received through December 31, 2022 was $2,208 ($2,536 including LIBOR). All grants were received before the year ended August 31, 2020 and recorded as a reduction of research and development expenses at that time.

As of December 31, 2022, the liability to the IIA was $133.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the relevant periods.

h. Leases

On August 2, 2020, the Subsidiary entered into a lease agreement for its facilities in Israel. The lease agreement is for a period of 60 months commencing September 1, 2020. The Subsidiary has the option to extend the period for another 60 months. The annual lease payment, including management fees, as of December 31, 2022 is approximately NIS 435 ($124). As security for its obligation under this lease agreement, the Company provided a bank guarantee in an amount equal to three monthly lease payments. For accounting purposes, the lease period is 60 months.

On December 2, 2021, the Subsidiary entered into an addendum (the "Addendum") to the current lease agreement for its facilities in Israel. The Addendum refers to the lease of an additional space of 264 square meters for a period of 60 months commencing February 1, 2022. The Subsidiary has the option to extend the period for another 60 months. The annual lease payment, including management fees, is approximately NIS 435 ($124). As security for its obligation under the Addendum, the Company provided a bank guarantee in an amount equal to three monthly lease payments. For accounting purposes, the lease commenced on February 1, 2022 as the Subsidiary did not have access to the space until that date. For accounting purposes, the lease period is 60 months.

The total expenses related to leases were $264 for the year ended December 31, 2022, $61 for the four month period ended December 31, 2021 and $124 for the year ended August 31, 2021.

In thousands (except share and per share data)

NOTE 6 - COMMITMENTS (continued):

The right-of-use asset and lease liability are initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate based on the information available at the date of determining the present value of the lease payments. The Company's incremental borrowing rate is estimated to approximate the interest rate on similar terms and payments and in economic environments where the leased asset is located.

The Company has various operating leases for office space and vehicles that expire through 2027. Below is a summary of the Company's operating right-of-use assets and operating lease liabilities as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Operating right-of-use assets	$ 987	$ 500
Operating lease liabilities, current	247	130
Operating lease liabilities long-term	647	370
Total operating lease liabilities	$ 894	$ 500
Weighted Average of Remaining Lease Term		
Operating leases	3.41	3.58
Weighted Average Discount Rate		
Operating leases	3.15%	3.00%

Lease payments for the Company's right-of-use assets over the remaining lease periods as of December 31, 2022 are as follows:

	December 31, 2022
2023	$ 291
2024	291
2025	228
2026	124
2027	10
Total undiscounted lease payments	**944**
Less: Interest*	(50)
Present value of lease liabilities	**$ 894**

* Future lease payments were discounted by 3%-3.15% interest rate.

i. Legal expenses

Following the Company's 2019 annual meeting of stockholders, a complaint was filed in the Court of Chancery of the State of Delaware against the Company and the members of the Board of Directors. On April 27, 2022, the Court of Chancery of the State of Delaware approved the terms of a settlement between the Company and the plaintiff in the complaint, awarding the plaintiff an amount of $850 in attorneys' fees, which was paid on April 28, 2022 and included in general and administrative expenses in the first quarter of 2022. All other details of the settlement were previously agreed by the parties and acted upon at the Company's 2021 annual meeting of stockholders.

NOTE 6 - COMMITMENTS (continued):

j. Investment in Diasome Pharmaceuticals, Inc.

On August 26, 2022, the Company entered into a stock purchase agreement with Diasome Pharmaceuticals, Inc. ("Diasome") pursuant to which the Company purchased shares of Series B preferred stock of Diasome for an aggregate purchase price of approximately $2,700. Following the purchase, the Company holds less than 5% of the issued and outstanding stock of Diasome on a diluted basis. The stock purchase agreement provides the Company with the option to purchase additional preferred shares of stock on a pro rata basis at similar terms to the terms and conditions of the current round contingent upon Diasome achieving certain milestones.

The Company accounts for the investment under the measurement alternative in ASC 321 "Investments – Equity Securities," whereby the equity investment is recorded at cost, less impairment. The carrying amount will be subsequently remeasured to its fair value in accordance with the provisions of ASC 820 "Fair Value Measurement" when observable price changes occur as of the date the transaction occurred, or it is impaired. Any adjustments to the carrying amount are recorded in net income.

NOTE 7 - STOCKHOLDERS' EQUITY:

The following are the significant capital stock transactions that took place during the year ended December 31, 2022, four month period ended December 31, 2021 and the year ended August 31, 2021:

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 Board of Directors on September 11, 2019. Out of the available options under the 2019 Plan, the Company 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.

On June 30, 2022, the stockholders of the Company adopted the amended and restated 2019 Plan, which increased the shares available for grant under the plan by an additional 4,500,000 to 7,500,000 options.

b. On September 5, 2019, the Company entered into an Equity Distribution Agreement (the "Sales Agreement"), pursuant to which the Company could, 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 were to 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 paid 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 December 31, 2022, 3,212,621 shares were issued under the Sales Agreement for aggregate net proceeds of $14,397.

NOTE 7 - STOCKHOLDERS' EQUITY (continued):

c. On December 1, 2020, the Company entered into a new equity distribution agreement (the "New Sales Agreement"), pursuant to which the Company could, 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 $40,000, 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 dated February 10, 2020 as supplemented by a prospectus supplement dated December 1, 2020. The Company paid 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 New Sales Agreement. As of December 31, 2022, 4,061,956 shares were issued under the New Sales Agreement for aggregate net proceeds of $38,799.

d. On June 16, 2021, the Company entered into an equity distribution agreement (the "Equity Distribution Agreement") with Canaccord Genuity LLC, as agent ("Canaccord Genuity"), pursuant to which the Company could issue and sell shares of its common stock having an aggregate offering price of up to $28,000 from time to time through Canaccord Genuity. The Equity Distribution Agreement replaced the New Sales Agreement, once it had been exhausted. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus dated February 10, 2020 and prospectus supplement dated June 16, 2021. The Company paid 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 Equity Distribution Agreement. As of December 31, 2022, 1,823,287 shares were issued under the Equity Distribution Agreement for aggregate net proceeds of $27,119.

e. On July 15, 2021, the Company entered into a new equity distribution agreement (the "New Equity Distribution Agreement") with Canaccord Genuity, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000 from time to time through Canaccord Genuity. The New Equity Distribution Agreement replaced the Equity Distribution Agreement, once it had been exhausted. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus dated July 15, 2021. The Company paid 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 New Equity Distribution Agreement. As of December 31, 2022, 273,997 shares were respectively issued under the New Equity Distribution Agreement for aggregate net proceeds of $5,129.

f. On September 1, 2021, the Company entered into a controlled equity offering agreement (the "Cantor Equity Distribution Agreement") with Cantor Fitzgerald & Co., as agent, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000, 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 dated July 26, 2021 and prospectus supplement dated September 1, 2021. The Company paid 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 Cantor Equity Distribution Agreement. As of December 31, 2022 and through March 6, 2023, 1,778,147 and 1,971,447 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $23,823 and $26,253, respectively.

g. On November 3, 2021, the Company entered into a securities purchase agreement with several institutional and accredited investors (the "Purchasers"), pursuant to which the Company agreed to sell, in a registered direct offering (the "Offering"), an aggregate of 2,000,000 shares of the Company's common stock to the Purchasers for an offering price of $25 per share. The closing of the sale of the shares occurred on November 5, 2021. The net proceeds to the Company from the Offering, after deducting the placement agent's fees and expenses and the Company's Offering expenses, were approximately $46,375.

h. As of December 31, 2022, the Company had outstanding warrants exercisable commencing January 6, 2019 for 150,705 shares of common stock at exercise prices ranging from $4.13 to $4.80 per share and expiring from April 10, 2023 to April 15, 2029.

In thousands (except share and per share data)

NOTE 7 - STOCKHOLDERS' EQUITY (continued):

The following table presents the warrant activity for the year ended December 31, 2022, four month period ended December 31, 2021 and year ended August 31, 2021:

	Year ended December 31, 2022		Four months ended December 31, 2021		Year ended August 31, 2021	
	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price
Warrants outstanding at beginning of the period	158,375	$ 4.78	232,175	$ 5.57	3,407,820	$ 6.98
Issued	-	$ -	-	$ -		$
Exercised	4,200	$ 4.8	73,800	$ 7.25	3,175,645	$ 7.07
Expired	3,470	$ 7.81	-	$ -	-	$ -
Warrants outstanding at end of the period	150,705	$ 4.71	158,375	$ 4.78	232,175	$ 5.57
Warrants exercisable at end of the period	150,705	$ 4.71	158,375	$ 4.78	232,175	$ 5.57

NOTE 8 - STOCK-BASED COMPENSATION:

The Company makes awards only under the 2019 Plan, under which, the Company had reserved a pool of 7,500,000 shares of the Company's common stock which may be issued at the discretion of the Board of Directors from time to time. Under this 2019 Plan, each option or RSU 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 and RSUs is 10 years.

The following are the significant stock options and RSUs transactions with employees, board members and non-employees made during the year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended August 31, 2021:

a. On February 3, 2021, the Company granted options to purchase an aggregate of 340,000 shares of common stock of the Company at an exercise price of $10.40 per share (equivalent to the closing price of the Company's common stock on the date of grant) as follows: 150,000 to the CEO, 100,000 to the CSO, 40,000 to the Company's former Chief Financial Officer and 50,000 to the Company's Chief Operating & Business Officer. The options shall vest in four equal annual installments, on each of December 31, 2021, 2022, 2023 and 2024. As of December 31, 2022, 160,000 of such options are vested. These options expire on February 3, 2031. The fair value of all these options on the date of grant was $1,987, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $10.40; dividend yield of 0% for all years; expected volatility of 61.07%; risk-free interest rates of 0.64%; and expected term of 6.21 years.

On February 3, 2021, the Company granted a total of 680,000 RSUs as follows: 300,000 to the CEO, 200,000 to the CSO, 80,000 to the Company's former Chief Financial Officer and 100,000 to the Company's Chief Operating and Business Officer. These RSUs were granted under the Company's 2019 Plan and shall vest as follows: 226,666 shall vest upon the Company's common stock achieving a price per share of $15 during 20 days out of any 30-day trading period, 226,667 shall vest upon the Company's common stock achieving a price per share of $25 during 20 days out of any 30-day trading period, and 226,667 upon achievement of a certain licensing agreement as specified by the Board of Directors. The total fair value of these RSUs on the date of the grant was $4,511, using the Monte-Carlo model.

NOTE 8 - STOCK-BASED COMPENSATION (continued):

b. On February 17, 2021, the Company granted options to purchase an aggregate of 15,000 shares of common stock of the Company at an exercise price of $11.33 per share (equivalent to the closing price of the Company's common stock on the date of grant) to the former chairman of the Board of Directors. The options shall vest in three equal annual installments, on each of December 31, 2021, 2022 and 2023. These options expired upon the expiration of the former chairman's term as a director. The total fair value of these options on the date of grant was $98, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $11.33; dividend yield of 0% for all years; expected volatility of 64.39%; risk-free interest rates of 0.76%; and expected term of 5.94 years.

On February 17, 2021, the Company granted a total of 30,000 RSUs to the former chairman of the Board of Directors. These RSUs were granted under the Company's 2019 Plan and shall vest as follows: 10,000 shall vest upon the Company's common stock achieving a price per share of $15 during 20 days out of any 30-day trading period, 10,000 shall vest upon the Company's common stock achieving a price per share of $25 during 20 days out of any 30-day trading period, and 10,000 upon achievement of a certain licensing agreement as specified by the Board of Directors. 10,000 RSUs vested on August 31, 2021 and the remainder expired upon the expiration of the former chairman's term as a director. The total fair value of these RSUs on the date of the grant was $217, using the Monte-Carlo model.

c. On August 4, 2021, the Company granted options to purchase an aggregate of 100,000 shares of common stock of the Company at an exercise price of $15.10 per share (equivalent to the closing price of the Company's common stock on the date of grant) to the Chief Commercial Officer. The options shall vest as follows: 12,500 on December 31, 2021, three equal annual installments of 25,000 on each of December 31, 2022, 2023 and 2024 and 12,500 on August 4, 2025. As of December 31, 2022, 37,500 of such options are vested. These options expire on August 4, 2031. The fair value of all these options on the date of grant was $860, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $15.10; dividend yield of 0% for all years; expected volatility of 61.98%; risk-free interest rates of 0.82%; and expected term of 6.17 years.

On August 4, 2021, the Company granted a total of 100,000 RSUs to the Chief Commercial Officer. These RSUs were granted under the Company's 2019 Plan and shall vest as follows: 33,333 shall vest upon the Company's common stock achieving a price per share of $15 during 20 days out of any 30-day trading period, 33,333 shall vest upon the Company's common stock achieving a price per share of $25 during 20 days out of any 30-day trading period, and 33,334 upon achievement of a certain licensing agreement as specified by the Board of Directors. The total fair value of these RSUs on the date of the grant was $985, using the Monte-Carlo model.

d. On September 1, 2021, the Company granted options to its Chief Financial Officer to purchase an aggregate of 50,000 shares of common stock of the Company at an exercise price of $20.19 per share. The options shall vest in four equal installments of 12,500 options on each of June 27, 2022, June 27, 2023, June 27, 2024 and June 27, 2025. As of December 31, 2022, 12,500 of such options are vested. In addition, the Company granted 50,000 RSUs that shall vest as follows:

33,333 if the closing price per share of the Company's common stock will be at least $25 for at least 20 days out of any 30-trading; and

1. If the first condition was met any time before June 27, 2022, then the RSUs would have vested in three equal installments (on June 27, 2022, June 27, 2023 and June 27, 2024).

NOTE 8 - STOCK-BASED COMPENSATION (continued):

2. If the first condition is met any time between June 27, 2022 and June 27, 2023, then 1/3 of the RSUs will vest immediately, and the remainder will vest in two equal installments (on June 27, 2023 and June 27, 2024).
3. If the first condition is met any time between June 27, 2023 and June 27, 2024, then 2/3 of the RSUs will vest immediately, and the remaining 1/3 will vest on June 27, 2024).

4. If the first condition is met any time after June 27, 2024, then the RSUs will vest immediately.

16,667 upon achievement of a certain licensing agreement as specified by the Board of Directors; and

1. If the first condition was met any time before June 27, 2022, then the RSUs would have vested in three equal installments (on June 27, 2022, June 27, 2023 and June 27, 2024).

2. If the first condition is met any time between June 27, 2022 and June 27, 2023, then 1/3 of the RSUs will vest immediately, and the remainder will vest in two equal installments (on June 27, 2023 and June 27, 2024).

3. If the first condition is met any time between June 27, 2023 and June 27, 2024, then 2/3 of the RSUs will vest immediately, and the remaining 1/3 will vest on June 27, 2024).

4. If the first condition is met any time after June 27, 2024, then the RSUs will vest immediately.

These options and RSUs expire on September 1, 2031.

The total value of the options and RSUs is $1,572. The fair value of the options was calculated using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $20.19; dividend yield of 0% for all years; expected volatility of 61.62%; risk-free interest rates of 0.93%; and expected term of 6.16 years.

e. On January 3, 2022, the Company granted an aggregate of 150,000 shares of the Company's common stock to its President and Chief Executive Officer. The total fair value of these shares on the date of grant was $2,084, using the quoted closing market share price of $13.89 on the Nasdaq Capital Market on the date of grant.

f. On January 3, 2022, the Company granted an aggregate of 207,500 RSUs representing a right to receive shares of the Company's common stock to the Company's employees and members of the Board of Directors as follows: 63,000 to the President and Chief Executive Officer; 42,000 to the Chief Scientific Officer; 21,000 to the Chief Operating and Business Officer, 19,000 to the Chief Financial Officer and Treasurer, 19,000 to the Chief Commercial Officer, 18,000 to the Chief Legal Officer and Secretary (effective as of the time his employment with the Company commenced on January 9, 2022), an aggregate of 24,000 to four board members and 1,500 to an employee. The RSUs vest in four equal annual installments on each of January 1, 2023, 2024, 2025 and 2026. The total fair value of these RSUs on the date of grant was $2,849, using the quoted closing market share price of $13.89 on the Nasdaq Capital Market on the date of grant and $12.03 for the Chief Legal Officer's grant (equivalent to the closing price of the Company's common stock on January 10, 2022, which represents the first trading date after his employment with the Company commenced).

NOTE 8 - STOCK-BASED COMPENSATION (continued):

g. On January 3, 2022, the Company granted options to purchase an aggregate of 321,500 shares of the Company's common stock to the Company's employees and board members at an exercise price of $13.89 per share (equivalent to the closing price of the Company's common stock on the date of grant) as follows: 107,000 to the President and Chief Executive Officer; 72,000 to the Chief Scientific Officer; 36,000 to the Chief Operating and Business Officer, 32,000 to the Chief Financial Officer and Treasurer and 32,000 to the Chief Commercial Officer, an aggregate of 40,000 to four board members and 2,500 to an employee. The options vest in four equal annual installments on each of January 1, 2023, 2024, 2025 and 2026. As of December 31, 2022, none of such options are vested. These options expire on January 3, 2032. The total fair value of these options on the date of grant was $2,630, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $13.89; dividend yield of 0% for all years; expected volatility of 63.05%; risk-free interest rates of 1.46%; and expected term of 6.25 years.

h. On January 3, 2022, the Company granted options to purchase an aggregate of 30,000 shares of the Company's common stock to the Company's Chief Legal Officer and Secretary (effective as of the time his employment with the Company commenced on January 9, 2022), at an exercise price of $12.03 per share (equivalent to the closing price of the Company's common stock on January 10, 2022, which represents the first trading date after his employment with the Company commenced). The options vest in four equal annual installments on each of January 1, 2023, 2024, 2025 and 2026. As of December 31, 2022, none of such options are vested. These options expire on January 3, 2032. The total fair value of these options on the date of grant was $214, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $12.03; dividend yield of 0% for all years; expected volatility of 63.22%; risk-free interest rates of 1.60%; and expected term of 6.25 years.

i. On May 2, 2022, the Company granted 4,500 RSUs representing a right to receive shares of the Company's common stock to Mr. Yadin Rozov, a member of the Company's board of directors. The RSUs shall vest in four equal annual installments on each of May 2, 2023, 2024, 2025 and 2026. The total fair value of these RSUs on the date of grant was $23, using the quoted closing market share price of $5.14 on the Nasdaq Capital Market on the last trading day before the date of grant.

j. On May 2, 2022, the Company granted options to purchase an aggregate of 7,500 shares of the Company's common stock to Mr. Yadin Rozov, a member of the Company's board of directors, at an exercise price of $5.14 per share (equivalent to the closing price of the Company's common stock on the last trading day before the date of grant). The options shall vest in four equal annual installments on each of May 2, 2023, 2024, 2025 and 2026. As of December 31, 2022, none of such options are vested. These options expire on May 2, 2032. The total fair value of these options on the date of grant was $24, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $5.14; dividend yield of 0% for all years; expected volatility of 65.26%; risk-free interest rates of 3.03% and expected term of 6.26 years.

k. On July 28, 2022, the Company granted an aggregate of 404,100 RSUs representing a right to receive shares of the Company's common stock to the Company's executive officers, employees and board members. The RSUs granted to certain employees, executive officers and board members shall vest in three equal annual installments on each of January 1, 2024, 2025 and 2026 and the RSUs granted to certain employees will vest in three equal annual installments on each of January 1, 2023, 2024 and 2025. The total fair value of these RSUs on the date of grant was $3,423, using the quoted closing market share price of $8.47 on the Nasdaq Capital Market on the date of grant.

In thousands (except share and per share data)

NOTE 8 - STOCK-BASED COMPENSATION (continued):

l. On July 28, 2022, the Company granted 34,000 shares of the Company's common stock to each of the Company's President and Chief Executive Officer and Chief Scientific Officer. These shares vested in full on August 1, 2022. The total fair value of these shares on the date of grant was $576, using the quoted closing market share price of $8.47 on the Nasdaq Capital Market on the date of grant.

m. On July 28, 2022, the Company granted an aggregate of 175,500 performance based RSUs ("PSUs") representing a right to receive shares of the Company's common stock to the Company's executive officers. The PSUs were to vest in two installments upon achievement of the following milestones: (i) two thirds were to vest upon receipt of positive topline data in the first oral insulin Phase 3 clinical trial; and (ii) one third was to vest upon completion of enrollment of the second oral insulin Phase 3 clinical trial by June 30, 2023. Following the results of the ORA-D-013-1 Phase 3 trial and the termination of the ORA-D-013-2 Phase 3 trial, these performance goals have not been met and the PSUs did not vest. The total fair value of these PSUs on the date of grant was $1,486, using the quoted closing market share price of $8.47 on the Nasdaq Capital Market on the date of grant.

n. On September 18, 2022, Oravax granted options to purchase an aggregate of 328,318 shares of Oravax's common stock to employees and board members of Oravax and to other service providers at an exercise price of $3.91 per share. The options will vest in four annual installments as follows: the first installment vested immediately on the grant date and the remaining three installments shall vest on each of December 31, 2022, 2023 and 2024. These options expire on September 18, 2032. The total fair value of these options on the date of grant was $665, using the Black Scholes option pricing model and was based on the following assumptions: stock price of $3.91; dividend yield of 0% for all years; expected volatility of 52.87%; risk-free interest rates of 3.62%; and expected term of 5.49 years.

o. 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 December 31, 2022	For options granted in the four months ended December 31, 2021	For options granted in the year ended August 31, 2021
Expected option life (years)	6.25-6.26	6.16	5.94-6.21
Expected stock price volatility (%)	63.05-65.26	61.62	61.07-64.39
Risk free interest rate (%)	1.46-3.03	0.93	0.64-0.82
Expected dividend yield (%)	0.0	0.0	0.0

In thousands (except share and per share data)

NOTE 8 - STOCK-BASED COMPENSATION (continued):

A summary of the status of the stock options granted to employees and directors as of December 31, 2022 and 2021 and August 31, 2021 and changes during the year ended December 31, 2022, for the four month period ended December 31, 2021 and for the year ended August 31, 2021, is presented below:

	Year ended December 31, 2022		Four months ended December 31, 2021		Year ended August 31, 2021	
	Number of options	Weighted average exercise price $	Number of options	Weighted average exercise price $	Number of options	Weighted average exercise price $
Options outstanding at beginning of the period	1,942,117	7.14	1,905,783	6.79	1,597,149	5.47
Changes during the period:						
Granted	359,000	13.55	50,000	20.19	455,000	11.46
Forfeited	(48,334)	10.59	-	-	(52,584)	7.78
Expired	(144,000)	4.08	-	-	-	-
Exercised	(67,107)	5.03	(13,666)	6.32	(93,782)	6.42
Options outstanding at end of the period	2,041,676	8.47	1,942,117	7.14	1,905,783	6.79
Options exercisable at end of the period	1,261,426	6.86	852,031	6.22	859,447	
Weighted average fair value of options granted during the period	$ 7.99		$ 11.47		$ 6.47	

Expenses recognized in respect of stock options granted to employees and directors, for the year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended August 31, 2021 were $2,662, $859 and $1,409, respectively.

The total intrinsic value of employees' options exercised during the year ended December 31, 2022 was $243, during the four month period ended December 31, 2021 was $257 and $1,287 during the year ended August 31, 2021.

The following table presents summary information concerning the options granted to employees and directors outstanding as of December 31, 2022:

Exercise prices $	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price $
1.00 to 6.00	857,250	6.85	3.94
6.23 to 9.12	283,008	4.8	7.96
10.40 to 20.19	901,418	7.69	12.94
	2,041,676	6.94	8.47

In thousands (except share and per share data)

NOTE 8 - STOCK-BASED COMPENSATION (continued):

1,261,426 options granted to employees and directors were outstanding and exercisable as of December 31, 2022, compared to 852,031 as of December 31, 2021 and 859,447 as of August 31, 2021.

As of December 31, 2022, there were $2,252 of unrecognized compensation costs related to non-vested options previously granted to employees and directors. The unrecognized compensation costs are expected to be recognized over a weighted average period of 2.5 years.

A summary of the status of the stock options granted to non-employees outstanding as of December 31, 2022 and 2021 and August 31, 2021 and changes during the year ended December 31, 2022, for the four month period ended December 31, 2021 and for the year ended August 31, 2021, is presented below:

	Year ended December 31, 2022		Four months ended December 31, 2021		Year ended August 31, 2021	
	Number of options	Weighted average exercise price $	Number of options	Weighted average exercise price $	Number of options	Weighted average exercise price $
Options outstanding at beginning of the period	51,500	4.26	56,000	4.22	103,152	6.64
Changes during the period:						
Granted	-	-	-	-	-	-
Exercised	(4,500)	3.74	(4,500)	3.74	(10,000)	7.36
Forfeited	-	-	-	-	-	-
Expired	-	-	-	-	(37,152)	6.00
Options outstanding at end of the period	47,000	4.31	51,500	4.26	56,000	4.22
Options exercisable at end of the period	47,000	4.31	41,500	4.06	46,000	4.03
Weighted average fair value of options granted during the period	$ -		$ -		$ -	

The Company recorded no stock-based compensation related to non-employees' awards during the year ended December 31, 2022, $2 during the four month period ended December 31, 2021 and $22 during the year ended August 31, 2021.

During year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended August 31, 2021, 4,500, 4,500 and 10,000 options, respectively, were exercised by non-employees for a total intrinsic value of $24, $49 and $100, respectively.

The following table presents summary information concerning the options granted to non-employees outstanding as of December 31, 2022:

Range of exercise prices $	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted Average Exercise Price $
3.74-5.08	47,000	6.98	4.31

In thousands (except share and per share data)

NOTE 8 - STOCK-BASED COMPENSATION (continued):

47,000 options granted to non-employees were outstanding and exercisable as of December 31, 2022.

As of December 31, 2022, there were no unrecognized compensation costs related to non-vested options previously granted to non-employees.

q. Restricted stock units

The following table summarizes the activities for unvested RSUs granted to employees and directors for the year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended December 31, 2021:

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
	Number of RSUs		
Outstanding at the beginning of period	801,303	921,302	164,636
Granted	1,009,600	50,000	810,000
Issued	(217,333)	(169,999)	-
Forfeited	(32,000)	-	(53,334)
Outstanding at the end of the period	1,561,570	801,303	921,302
Vested during the period	218,000	33,333	236,665
Vested and unissued at period end	265,302	264,635	401,301

The Company recorded compensation expenses related to RSUs of $8,365 for the year ended December 31, 2022, $1,286 for the four the month period ended December 31, 2021 and $1,265 for the year ended August 31, 2021.

As of December 31, 2022, there were unrecognized compensation costs of $5,262 related to RSUs. The unrecognized compensation costs are expected to be recognized over a weighted average period of 2.04 years.

The following table summarizes the activities for unvested RSUs granted to non-employees for the year ended December 31, 2022, the four month period ended December 31, 2021 and the year ended December 31, 2021:

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
	Number of RSUs		
Outstanding at the beginning of period	8,000	-	-
Granted	-	12,000	-
Issued	(4,000)	(4,000)	-
Forfeited	-	-	-
Outstanding at the end of the period	4,000	8,000	-
Vested during the period	4,000	4,000	-
Vested and unissued at period end	-	-	-

The Company recorded compensation expenses related to RSUs of $92 for the year ended December 31, 2022, and $115 for the four the month period ended December 31, 2021, compared to no compensation expenses recorded for the year ended August 31, 2021.

As of December 31, 2022, there were unrecognized compensation costs of $26 related to RSUs. The unrecognized compensation costs are expected to be recognized over a weighted average period of 2.01 years.

In thousands (except share and per share data)

NOTE 9 - FINANCIAL INCOME AND EXPENSES:

a. Financial income

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31 2021
Income from interest on deposits	$ 3,473	$ 114	$ 130
Exchange rate differences, net	176	-	-
Income from interest on corporate bonds	100	43	217
Gain from securities, net	-	-	6
Revaluation of securities, net	-	-	889
Other	5	1	-
	$ 3,754	$ 158	$ 1,242

b. Financial expenses

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31 2021
Exchange rate differences, net	$ -	$ 11	$ 2
Bank and broker commissions	14	2	5
Loss from securities, net	43	-	-
Revaluation of securities, net	763	72	-
Other	-	2	1
	$ 820	$ 87	$ 8

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 Israeli subsidiary.

a. Corporate taxation in the U.S.

The applicable corporate tax rate for the Company is 21%.

As of December 31, 2022, the Company has an accumulated tax loss carryforward of approximately $31,600 (as of December 31, 2021, $21,211). 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 2029 through 2041.

b. Corporate taxation in Israel

The Subsidiary is taxed in accordance with Israeli tax laws. The corporate tax rate applicable to 2022 and 2021 is 23%.

As of December 31, 2022, the Subsidiary has an accumulated tax loss carryforward of approximately $87,291 (as of December 31, 2021, approximately $75,836). 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

	December 31,	
	2022	**2021**
In respect of:		
Net operating loss carryforward	$ 27,610	$ 22,230
Research and development expenses	5,195	4,429
Less - valuation allowance	(32,805)	(26,659)
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.

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

	Year ended December 31, 2022	**Four months ended December 31, 2021**	**Year ended August 31, 2021**
Loss before taxes on income:			
U.S.	$ 11,164	$ 3,639	$ 5,307
Outside U.S.	26,500	8,616	17,682
	$ 37,664	$ 12,255	$ 22,989
Taxes on income (tax benefit):			
Current:			
U.S.	-	-	-
Outside U.S.	100	-	-
	$ 100	$ -	$ -

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 December 31, 2022	**Four months ended December 31, 2021**	**Year ended August 31 2021**
Loss before income taxes as reported in the consolidated statement of comprehensive loss	$ (37,664)	$ (12,255)	$ (22,989)
Statutory tax benefit	(7,909)	(2,574)	(4,828)
Increase in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax	7,290	2,497	4,872
Disallowable deductions	1,152	249	310
Influence of different tax rate applicable to the Subsidiary and changes in tax rates from previous years	(533)	(172)	(354)
Withholding tax, see note 10d above	100	-	-
Uncertain tax position	-	-	-
Taxes on income for the reported year	$ 100	$ -	$ -

In thousands (except share and per share data)

NOTE 10 - TAXES ON INCOME (continued):

f. Uncertainty in Income Taxes

ASC 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 December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
Balance at Beginning of Period	$ 11	$ 11	$ 11
Decrease in uncertain tax positions for the current period	-	-	-
Balance at End of Period	$ 11	$ 11	$ 11

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

The Company is subject to U.S. Federal income tax examinations for the tax years of 2018 through 2020.

The Subsidiary is subject to Israeli income tax examinations for the tax years of 2016 through 2021.

g. Valuation Allowance Rollforward

	Period ended		
	Balance at beginning of period	Additions	Balance at end of period
Allowance in respect of carryforward tax losses:			
Year ended December 31, 2022	$ 26,659	$ 6,146	$ 32,805
Four months ended December 31, 2021	25,073	1,585	26,659
Year ended August 31, 2021	19,392	5,681	25,073

NOTE 11 - RELATED PARTY TRANSACTIONS:

a. On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer, whereby the President and Chief Executive Officer and the Chief Scientific Officer, 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 President and Chief Executive Officer and the Chief Scientific Officer is NIS 146,705 ($42) and 106,400 ($30), respectively.

In thousands (except share and per share data)

NOTE 11 - RELATED PARTIES - TRANSACTIONS (continued):

In addition to the Consulting Agreements, based on a relocation cost analysis, the Company paid for certain direct costs, related taxes and expenses incurred in connection with the relocation of the President and Chief Executive Officer to New York. During the ten month period ended October 31, 2022, the four month period December 31, 2021 and the year ended August 31, 2021, such relocation expenses totaled $331, $109 and $377, respectively.

Following the relocation of the President and Chief Executive Officer to the State of Israel, the Company entered into two agreements with the President and Chief Executive Officer, replacing his above-mentioned consulting agreement through KNRY, substantially on the same terms, in order to allocate his time and services between the Company and the Subsidiary.

Effective November 1, 2022, the Company entered into a consulting agreement with Shnida Ltd., whereby the President and Chief Executive Officer, through Shnida Ltd., provides services as President and Chief Executive Officer of the Company. The agreement is terminable by either party upon 140 days prior written notice. The agreement provides that Shnida Ltd. will be reimbursed for reasonable expenses incurred in connection with performance of the agreement and that the President and Chief Executive Officer will receive a monthly consulting fee of NIS 88,023 ($25), plus value added tax. Pursuant to the agreement, Shnida Ltd. and the President and Chief Executive Officer each agree that during the term of the agreement and for a 12-month period thereafter, none of them will compete with the Company nor solicit employees of the Company.

In addition, the Company, through the Subsidiary, has entered into an employment agreement with the President and Chief Executive Officer, effective as of November 1, 2022, pursuant to which the President and Chief Executive Officer receives gross monthly salary of NIS 46,901 ($13) in consideration for his services as President and Chief Executive Officer of the Subsidiary. In addition, the President and Chief Executive Officer is provided with a cellular phone and a company car pursuant to the terms of his agreement.

b. Balances with related parties:

	December 31,	
	2022	**2021**
Accounts payable and accrued expenses - KNRY	$ 1	$ -

c. Expenses to related parties:

	Year ended December 31, 2022	**Four months ended December 31, 2021**	**Year ended August 31, 2021**
KNRY	$ 800	$ 818	$ 872
Shnida	146	-	-
Nadav Kidron (President and Chief Executive Officer)	$ 674	$ 447	$ 687

NOTE 12 - ASSET ACQUISITION TRANSACTION:

On March 18, 2021, the Company entered into the Oravax License Agreement and into the Stockholders Agreement with Oravax. On that date, Oravax's assets were (1) in process research and development of COVID-19 vaccine technology; and (2) $1,500 to be received in cash. According to the Stockholders Agreement, Oravax issued 1,890,000 shares of its capital stock to the Company, representing 63% of the issued and outstanding share capital of Oravax, on a fully diluted basis, as of the date of issuance, for which the Company paid $1,500. Consequently, the Company consolidates Oravax in its consolidated financial statements since that time. In addition, under the terms of the Oravax License Agreement, the Company has licensed out to Oravax certain patent rights, know-how and information related to the Company's oral drug delivery technology with respect to the combination with the COVID-19 vaccine technology (the "Licensed IP").

NOTE 12 - ASSET ACQUISITION TRANSACTION (continued):

In consideration for the grant of the License, the Oravax License Agreement provides that the Company will receive (i) royalties equal to 7.5% on net sales, as defined in the Oravax License Agreement, of each product commercialized by Oravax, its affiliates and permitted sublicensees related to the License during the term specified in the Oravax License Agreement, (ii) sublicensing fees equal to 15% of any non-sales-based consideration received by Oravax from a permitted sublicensee and (iii) other payments ranging between $25,000 to $100,000, based on certain sales milestones being achieved by Oravax. The parties further agreed to establish a development and steering committee, which will consist of three members, of which two members will be appointed by the Company, that will oversee the ongoing research, development, clinical and regulatory activity with respect to the Oravax product. Akers contributed $1,500 in cash to Oravax and a license agreement to the Oravax product which includes a maximum of 2.5% royalties of all net sales. Effective January 1, 2022, Oravax transferred its rights and obligations under the Oravax License Agreement to its wholly-owned subsidiary, Oravax Medical Ltd.

Concurrently with the execution and delivery of the Oravax License Agreement, the Company entered into the Stockholders Agreement with Akers, Premas, Cutter Mill and Run Ridge, entities controlled by Michael Vasinikovich and Craig Schwabe, former members of Cystron Biotech LLC ("Cystron," and collectively with Akers, Premas, Cutter Mill and Run Ridge, the "Stockholders Parties"). Pursuant to the Stockholders Agreement, among other things, the Company has the right to appoint two out of the three members to the board of directors of Oravax (the "Oravax Board"), one of which is the Company's Chief Executive Officer who will serve as the chairman of the Oravax Board, conditioned upon the Company maintaining certain ownership thresholds. Akers has the right, until the third anniversary of the Stockholders Agreement effective date, to appoint one member to the Oravax Board. Oravax's common stock held by the Stockholders Parties is subject to certain transfer restrictions. In addition, the Stockholders Parties have certain rights of participation in future financings as well as rights of first refusal and co-sale related to future potential transactions. Nadav Kidron, the Company's President and Chief Executive Officer, was one of the former members of Cystron.

According to ASC 805, the transaction was accounted for as an asset acquisition. No gain or loss was recognized on the transfer of the cash or the Licensed IP to Oravax while the Company retained control of those assets. The Company has recognized an increase in non-controlling interests of $1,495 based on the carrying amount of the contributed assets and, according to the Company's accounting policy, the fair value of Oravax excluding the contributed assets. Any difference between the fair value of consideration paid and the increase in the non-controlling interests' carrying amount was recognized in equity. As a result of the acquisition, the Company recognized IPR&D expense in the amount of $1,040.

NOTE 13 - SUBSEQUENT EVENTS:

On January 11, 2023, the Company announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, the Company has initiated a comprehensive analysis of the data to understand if there is a path forward for its oral insulin candidate. Concurrently, the Company is examining its existing pipeline and has commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for the Company's stockholders.

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 (incorporated by reference from our annual report on Form 10-K filed November 24, 2020)
3.3	Fourth Amended and Restated By-laws (incorporated by reference from our current report on Form 8-K filed February 27, 2023).
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 Pharmaceuticals Inc. and Shnida Ltd., entered into as of November 1, 2022, for the services of Nadav Kidron.
10.2+*	Employment Agreement by and between Oramed Ltd. and Nadav Kidron, entered into as of November 1, 2022.
10.3+	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).
10.4+	Amendment, dated November 13, 2014, 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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	Amendment, dated September 19, 2021, 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 24, 2021).

10.11+	Employment Agreement, dated May 23, 2021, by and between Oramed Ltd. and David Silberman (incorporated by reference from our quarterly report on Form 10-Q filed July 14, 2021).
10.12+	First Amendment, dated September 19, 2021, to Employment Agreement, by and between Oramed Ltd. and David Silberman (incorporated by reference from our annual report on Form 10-K filed November 24, 2021).
10.13+*	Second Amendment, dated October 25, 2022, to Employment Agreement, by and between Oramed Ltd. and David Silberman.
10.14+*	Representative Form of Indemnification Agreements between Oramed Pharmaceuticals Inc. and each of our directors and officers.
10.15+	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).
10.16+	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).
10.17+	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).
10.18+	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).
10.19+	Oramed Pharmaceuticals Inc. 2019 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed August 6, 2019).
10.20+	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).
10.21+	Amendment to Oramed Pharmaceuticals Inc. Amended and Restated 2019 Stock Incentive Plan (incorporated by reference from our definitive proxy statement on Schedule 14A filed June 2, 2022).
10.22+	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).
10.23+*	Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement.
10.24+	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).
10.25+	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).
10.26	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).
10.27	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).
10.28	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).

10.29 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).

10.30 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).

10.31 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).

10.32 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).

10.33 Equity Distribution Agreement, dated September 1, 2021, by and between the Company and Cantor Fitzgerald & Co. (incorporated by reference from our current report on Form 8-K filed September 1, 2021).

10.34 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).

10.35 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).

10.36 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).

10.37 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).

10.38 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).

10.39 License Agreement, dated as of March 18, 2021, between the Company, Oramed Ltd. and Oravax Medical Inc. (incorporated by reference from our Form 8-K filed March 19, 2021).

10.40 Stockholders Agreement, dated as of March 18, 2021, between Oramed Pharmaceuticals Inc., Akers Biosciences Inc., Premas Biotech PVT Ltd., Cutter Mill Capital LLC, and Run Ridge LLC. (incorporated by reference from our Form 8-K filed March 19, 2021).

10.41* Oravax Medical, Inc. 2021 Long-Term Incentive Plan.

10.42* Oravax Stock Option Agreement.

21.1	Subsidiaries (incorporated by reference from our annual report on Form 10-K filed November 24, 2021).
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 December 31, 2022, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of 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.
104.1*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* 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: March 6, 2023

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

/s/ Nadav Kidron Nadav Kidron, President and Chief Executive Officer and Director (principal executive officer)	March 6, 2023
/s/ David Silberman David Silberman, Chief Financial Officer (principal financial and accounting officer)	March 6, 2023
/s/ Miriam Kidron Miriam Kidron, Director	March 6, 2023
/s/ Arie Mayer Arie Mayer, Director	March 6, 2023
/s/ Yadin Rozov Yadin Rozov, Director	March 6, 2023
/s/ Leonard Sank Leonard Sank, Director	March 6, 2023

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: March 6, 2023

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, David Silberman, 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: March 6, 2023

By: /s/ David Silberman
David Silberman
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 December 31, 2022, 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.

Date: March 6, 2023

By: /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 December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, David Silberman, 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.

Date: March 6, 2023

By: /s/ David Silberman
David Silberman
Chief Financial Officer

ORAMED PHARMACEUTICALS INC.
("ORAMED")

CORPORATE INFORMATION

Executive Officers

Nadav Kidron
President and Chief Executive Officer

Miriam Kidron
Chief Scientific Officer

David Silberman
Chief Financial Officer and Treasurer

Joshua Hexter
Chief Operating and Business Officer

Michael Rabinowitz
Chief Commercial Officer

Netanel Derovan
Chief Legal Officer

Directors

Nadav Kidron
Miriam Kidron
Arie Mayer
Yadin Rozov
Leonard Sank
Benjamin Shapiro

Corporate Address

1185 Avenue of the Americas, Third Floor,
New York, New York 10036

Independent Auditors

Kesselman & Kesselman, independent registered public accounting firm, and member firm of PricewaterhouseCoopers International Limited

Counsel

Sullivan & Worcester LLP

Transfer Agent

Continental Stock Transfer & Trust Company

Stock Market Information

Oramed's shares of common stock are listed on the Nasdaq Capital Market and on the Tel Aviv Stock Exchange, in each case under the symbol "ORMP"

Annual Meeting

The Annual Meeting of Stockholders will be held at 4:00 p.m., Israel time, on July 13, 2023, at Oramed's offices in Israel, located at 20 Mamilla Avenue, Jerusalem

Annual Report on Form 10-K

Oramed's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (without exhibits) is available free of charge by writing to Oramed at the address set forth below. You can also obtain a copy of the filings by going to the following website: http://www.sec.gov

Website

www.oramed.com