

ORAMED PHARMACEUTICALS INC.

Form 10-K

December 12, 2012

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

FORM 10-K

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

For the Fiscal Year Ended August 31, 2012

or

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

Commission file number 000-50298

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

Delaware (State or Other Jurisdiction of Incorporation or Organization)	98-0376008 (I.R.S. Employer Identification No.)
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Hi-Tech Park 2/5 Givat-Ram P.O. Box 39098 Jerusalem, Israel (Address of Principal Executive Offices)	91390 (Zip Code)
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+972-2-566-0001

(Registrant's Telephone Number, Including Area Code)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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 computed by reference to the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter was \$17,492,586 based on a price of \$0.31, being the last price at which the shares of the registrant's common stock were sold on the OTC Bulletin Board prior to the end of the most recently completed second fiscal quarter.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 86,505,020 shares of common stock issued and outstanding as of December 6, 2012.

ORAMED PHARMACEUTICALS INC.

FORM 10-K  
(FOR THE FISCAL YEAR ENDED AUGUST 31, 2012)

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As used in this Annual Report on Form 10-K, the terms “we,” “us,” “our,” the “Company,” and “Oramed” mean Oramed Pharmaceuticals Inc. and our wholly-owned Israeli subsidiary, Oramed Ltd., unless otherwise indicated. All dollar amounts refer to U.S. Dollars unless otherwise indicated.

On August 31, 2012, the exchange rate between the NIS and the dollar, as quoted by the Bank of Israel, was NIS 4.028 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

This Annual Report on Form 10-K (including the section regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements within the meaning of the federal securities laws regarding our business, clinical trials, financial condition, expenditures, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “planned expenditures,” “believes,” “seeks,” “estimates” 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.

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading “Item 1A. Risk Factors” below, as well as those discussed elsewhere in this Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-K. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report on Form 10-K which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

## PART I

### ITEM 1. BUSINESS.

#### DESCRIPTION OF BUSINESS

##### Research and Development

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills for delivery of other polypeptides.

**Oral insulin:** We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801) currently in non-U.S. Food and Drug Administration, or FDA, approved Phase 2 clinical trials. Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables its passage in a more physiological manner than current delivery methods of insulin. Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

**Diabetes:** Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life. The cause of diabetes is attributed both to genetics (type 1 diabetes) and, most often, to environmental factors such as obesity and lack of exercise (type 2 diabetes). According to the World Health Organization, or WHO, an estimated 347 million people worldwide suffered from diabetes in 2010. In 2004, an estimated 3.4 million people died from consequences of high blood sugar, and the WHO projects that diabetes deaths will increase by two thirds between 2008 and 2030. According to the American Diabetes Association, or ADA, in the United States there were approximately 25.8 million people with diabetes, or 8.3% of the United States population in 2010. Diabetes is a leading cause of blindness, kidney failure, heart attack, stroke and amputation.

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

**Management:** We are led by a highly-experienced management team knowledgeable in the treatment of diabetes. Our Chief Medical and Technology Officer, Miriam Kidron, PhD, is a world-recognized pharmacologist and a biochemist and the innovator primarily responsible for our oral insulin technology development and know-how.

**Scientific Advisory Board:** Our management team has access to our internationally recognized Scientific Advisory Board whose members are thought-leaders in their respective areas. The Scientific Advisory Board is comprised of Dr. Nir Barzilai, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Derek LeRoith, Dr. John Amatruda and Dr. Michael Berelowitz acting as Chairman.

##### Strategy

##### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application “Methods and Composition for Oral Administration of Proteins,” which we acquired from Hadasit Medical Research Services and Development Ltd., or Hadasit, in 2006 and which is pending in various foreign jurisdictions, as well as the other patents we have filed in various foreign jurisdictions since then, as discussed below under “—Patents and Licenses” and

“Item 1A. Risk Factors.” Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify the insulin chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug, or IND, application with the FDA. Additional clinical trials are planned in Israel in order to substantiate our results as well as for purposes of making future filings for drug approval. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.



## Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase 3) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

## Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

## Product Development

### Orally Ingestible Insulin

During fiscal year 2007 we conducted several clinical studies of our orally ingestible insulin. The studies were intended to assess both the safety/tolerability and absorption properties of our proprietary oral insulin. Based on the pharmacokinetic and pharmacologic outcomes of these trials, we decided to continue the development of our oral insulin product.

In November 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). In January 2008, we commenced the non-FDA approved Phase 1B clinical trials with our oral insulin capsule, in healthy human volunteers with the intent of dose optimization. In March 2008, we successfully completed our Phase 1B clinical trials.

In April 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. In August 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem, or the IRB, to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule on type 1 diabetic volunteers. In September 2008, we announced the beginning of this trial. In July 2009 we reported positive results from this trial.

In April 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd., or ADRES, (which was amended in February 2012), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. In May 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

In February 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on our oral insulin capsules. In March 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule. The study was completed under conditions prescribed by the FDA Good Laboratory Practices regulations.

In September 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This completed exploratory study was a proof of concept study for defining a novel indication for ORMD0801. We believe the encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

We intend to file an IND application with the FDA for Phase 2 clinical studies of our orally ingested insulin during the fourth calendar quarter of 2012. If we do not receive comments from the FDA on our IND application within 30 days from submission, we intend to immediately commence an FDA approved Phase 2 study to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers.

In September 2012, we entered into a Master Service Agreement with Medpace, Inc., or Medpace, to retain Medpace as a clinical research organization for our upcoming Phase 2 clinical trial for an oral insulin capsule that is expected to start in the first calendar quarter of 2013 in the United States, and is expected to be completed in September 2013.

#### GLP-1 Analog

In September 2008 we announced the launch of pre-clinical trials of ORMD0901, an analog for GLP-1, a gastrointestinal hormone. The pre-clinical trials include animal studies which suggest that the GLP-1 analog (exenatide-4) when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.



Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. In addition to stimulating insulin release, GLP-1 was found to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.

In September 2009, we received approval from the IRB to commence human clinical trials of an oral GLP-1 analog. The approval was granted after successful pre-clinical results were reported. The trials are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. Oramed's first-in-humans clinical trial was testing the safety and efficacy of ORMD0901, an encapsulated oral GLP-1 analog formulation. The study monitored the responses of healthy males to a single dose delivered 60 minutes before a glucose load and was completed in December 2009. ORMD0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

In June 2012, we presented an abstract, which reported on the impact of our oral insulin capsule ORMD0801 delivered in combination with our oral exenatide capsule ORMD0901. The work that was presented assessed the safety and effectiveness of a combination of oral insulin and oral exenatide treatments delivered to pigs prior to food intake. The drug combination resulted in significantly improved blood glucose regulation when compared to administration of each drug separately.

#### Raw Materials

Our oral insulin capsule is currently manufactured by Swiss Caps AG, or Swiss Caps.

In May 2010, Oramed Ltd. entered into an agreement with SAFC Pharma, or SAFC, to develop a process to produce one of our oral capsule ingredients and in June, 2011, Oramed Ltd. issued a purchase order to SAFC for producing the ingredient.

In July 2010, Oramed Ltd. entered into the Manufacturing and Supply Agreement, or MSA, with Sanofi-Aventis Deutschland GMBH, or Sanofi-Aventis. According to the MSA, Sanofi-Aventis will supply Oramed Ltd. with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

We purchase, pursuant to separate agreements with third parties, the raw materials required for the manufacturing of our oral capsule. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions if we would need to change suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could have a material adverse affect on our business, prospects, financial condition and results of operations.

#### Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 36 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 2032.



In January 2012, we filed a provisional patent application with the U.S. Patent and Trademark Office for a combination therapy of our lead compound, ORMD0801, in combination with our oral GLP-1 analog formulation, ORMD0901. We also hold three patents issued by the Australian, Israeli and New Zealand Patent Offices that cover a part of our technology which allows for the oral delivery of peptides.

In February 2012, we filed a provisional patent application with the U.S. Patent and Trademark Office for the composition of a key ingredient of our oral capsules.

In May 2012, we were issued a patent by the New Zealand Patent Office that covers part of our technology with respect to oral exenatide compositions.

Consistent with our strategy to seek protection in key markets worldwide, we have been and will continue to pursue the patent applications and corresponding foreign counterparts of such applications. We believe that our success will depend on our ability to obtain patent protection for our intellectual property.

Our patent strategy is as follows:

Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate,

Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology, and

Establish comprehensive coverage in the United States and in all relevant foreign markets in anticipation of future commercialization opportunities.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. Our policy is to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, our board of directors, or our Board, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of our Company. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

#### Partnerships and Collaborative Arrangements

In April 2009, we entered into a consulting service agreement with ADRES pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study in accordance with FDA requirements. In February 2012, we entered into an amendment agreement with ADRES, according to which we paid the remaining \$51,000 of the original agreement upon execution of the amendment agreement. In addition, beginning March 1, 2012 and until submission of the IND, we will pay ADRES a monthly fee of approximately \$3,600.



In July 2010, we entered into the MSA with Sanofi-Aventis. Pursuant to the MSA, Sanofi-Aventis will supply specified quantities of recombinant human insulin to be used for clinical trials in the United States.

In September 2011, we entered into the fourth agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr, or the Fourth Agreement, to facilitate clinical trials and provide other services. According to the Fourth Agreement, Hadasit will be entitled to total consideration of \$200,000 to be paid in accordance with the actual progress of the study, none of which was recognized or paid through August 31, 2012. See “Item 13. Certain Relationships and Related Transactions, and Director Independence” below for a further description of the terms and conditions of the Fourth Agreement.

In December 2011, we received a quotation for the supply of insulin soft gel capsules for our clinical trials according to which Swiss Caps manufactured insulin capsules for total consideration of CHF 395,000 (approximately \$411,000). The manufacturing was completed during November 2012.

In February 2012, we entered into an advisory agreement with a third party advisor for a period of one year, pursuant to which the advisor agreed to provide investor relations services for share based compensation as follows: 300,000 shares of our common stock will be issued in six installments over the engagement period, commencing as of February 15, 2012, and a warrant to purchase 750,000 shares of our common stock. The warrant has a term of five years and an exercise price of \$0.50 per share and vests in 12 monthly installments over the first year of the agreement. In July 2012, we and the advisor entered into an amendment to the agreement, according to which the original agreement was extended until July 3, 2013 (unless terminated earlier by one of the parties), and a new payment and vesting schedule was determined as of such date for the remaining share based compensation and unvested warrant shares, respectively, until the end of the new term of the agreement. As of August 31, 2012, 100,000 shares of our common stock had been issued to the advisor, and 400,000 of the warrant shares had vested.

#### Out-Licensed Technology

In June 2010, Oramed Ltd. entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd. (formerly Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange, or D.N.A, for the establishment of Entera Bio Ltd., or Entera.

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP-1 analog and is subject to different patent applications. Entera’s initial development effort is for an oral formulation for the treatment of osteoporosis. The license was royalty-free unless our ownership interest in Entera decreased to 30% or less of its outstanding share capital, in which case royalties would have been payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may have received ownership of the licensed technology, in which case we would have received a license back on the same terms.

D.N.A initially invested \$600,000 in Entera, and Entera was initially owned in equal parts by Oramed and D.N.A. Entera’s Chief Executive Officer, Dr. Phillip Schwartz, was granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera’s share capital, upon full exercise.

In March 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera’s outstanding share capital on an undiluted basis. As consideration for the Entera shares, we received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, to be paid within four months after closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$581,977 as of



March 31, 2011 (\$200,311 as of August 31, 2012). The promissory note was secured by a personal guarantee of the D.N.A majority shareholders and its term was extended in August 2011. D.N.A paid off the promissory note in November 2011. The ordinary shares of D.N.A were restricted for six months from the closing. In addition, D.N.A invested \$250,000 in our private placement investment round, which closed in March 2011, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share.

As part of the transaction with D.N.A, we entered into a patent transfer agreement (to replace the original license agreement upon closing) pursuant to which Oramed assigned to Entera all of its right, title and interest in and to the patent application that it had licensed to Entera in August 2010. Under this agreement, Oramed Ltd. is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza.

In March 2011, Oramed Ltd., Entera and D.N.A terminated the joint venture agreement entered into in June 2010 in connection with the formation of Entera.

In September 2011, Entera reported successful Phase 1 clinical trial results. We believe the Phase 1 data supports the continued development of Entera's oral osteoporosis drug. The Phase 1 clinical trial consisted of twelve healthy patients and was conducted at the Hadassah Medical Center in Jerusalem. No adverse events were reported.

## 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 contract research organizations, or CROs.

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

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

- Who must be recruited as qualified participants,

- How often to administer the drug or product,
- What tests to perform on the participants, and
- What dosage of the drug or amount of the product to give to the participants.

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

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

**Phase 1.** Phase 1 studies involve testing a drug or product on a limited number of healthy participants, typically 24 to 100 people at a time. Phase 1 studies determine a product's basic safety and how the product is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year.

**Phase 2.** Phase 2 trials involve testing up to 200 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. If Phase 2 studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will generally continue to review the substance in Phase 3 studies.

**Phase 3.** Phase 3 studies involve testing large numbers of participants, typically several hundred to several thousand persons. The purpose is to verify effectiveness and long-term safety on a large scale. These studies generally last two to three years. Phase 3 studies 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.

**New Drug Approval.** The results of the clinical trials are submitted to the FDA as part of a new drug application, or NDA. Following the completion of Phase 3 studies, assuming the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of its product, the sponsor will generally submit an NDA to the FDA requesting that the product be approved for marketing. The application is a comprehensive, multi-volume filing that includes the results of all clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging and labeling the product. The FDA's review of an application can take a few months to many years, with the average review lasting 18 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA.

**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 studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase 4 studies usually involve thousands of participants. Phase 4 studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug.



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

#### Other Regulations

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

#### Competition

##### Competition in General

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

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

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

#### Competition for Our Oral Insulin Capsule

We anticipate the oral insulin capsule to be a competitive diabetes drug because of its anticipated efficacy and safety profile. The following are treatment options for type 1 and type 2 diabetic patients:

- Insulin injections,
- Insulin pumps,
- Insulin inhalers, or
- A combination of diet, exercise and oral medication which improve the body's response to insulin or cause the body to produce more insulin.

Several entities who are developing oral insulin capsules and other alternative oral insulin as well as the development stage are thought to be: Novo Nordisk (Denmark), Biocon Limited (India) and Apollo Life Sciences Pvt. Limited (India).

#### Scientific Advisory Board

We maintain a Scientific Advisory Board consisting of internationally recognized scientists who advise us on scientific and technical aspects of our business. The Scientific Advisory Board meets periodically to review specific projects and to assess the value of new technologies and developments to us. In addition, individual members of the Scientific Advisory Board meet with us periodically to provide advice in their particular areas of expertise. The Scientific Advisory Board consists of the following members, information with respect to whom is set forth below: Professor Avram Hershko, Professor Nir Barzilai, Professor Ele Ferrannini, Professor Derek LeRoith, Dr. John Amatruda and one of our directors, Dr. Michael Berelowitz, acting as Chairman.

We have entered into an agreement with Dr. Berelowitz pursuant to which we will pay him certain fees as compensation for serving as Chairman. See "Item 10. Directors, Executive Officers and Corporate Governance" and "Item 11. Executive Compensation—Director Compensation" for certain information about Dr. Berelowitz.

Professor Avram Hershko, MD, PhD, joined the Oramed Scientific Advisory Board in July 2008. He earned his MD degree (1965) and PhD degree (1969) from the Hebrew University- Hadassah Medical School of Jerusalem. Professor Hershko served as a physician in the Israel Defense Forces from 1965 to 1967. After a post-doctoral fellowship with Gordon Tomkins at the University of San Francisco (1969-72), he joined the faculty of the Haifa Technion becoming a professor in 1980. He is now Distinguished Professor in the Unit of Biochemistry in the B. Rappaport Faculty of Medicine of the Technion. Professor Hershko's main research interests concern the mechanisms by which cellular

proteins are degraded, a formerly neglected field of study. Professor Hershko and his colleagues showed that cellular proteins are degraded by a highly selective proteolytic system. This system tags proteins for destruction by linkage to a protein called ubiquitin, which had previously been identified in many tissues, but whose function was previously unknown. Subsequent work by Professor Hershko and many other laboratories has shown that the ubiquitin system has a vital role in controlling a wide range of cellular processes, such as the regulation of cell division, signal transduction and DNA repair. Professor Hershko was awarded the Nobel Prize in Chemistry (2004) jointly with his former PhD student Aaron Ciechanover and their colleague Irwin Rose. His many honors include the Israel Prize for Biochemistry (1994), the Gardner Award (1999), the Lasker Prize for Basic Medical Research (2000), the Wolf Prize for Medicine (2001) and the Louisa Gross Horwitz Award (2001). Professor Hershko is a member of the Israel Academy of Sciences (2000) and a Foreign Associate of the U.S. Academy of Sciences (2003).

Professor Derek LeRoith, MD, PhD, joined the Oramed Scientific Advisory Board in January 2007. He is currently the Chief of the Division of Endocrinology, Diabetes and Bone Diseases at Mt. Sinai School of Medicine in New York. Professor LeRoith has worked at the National Institute of Health, or NIH, since 1979 in the field of Endocrinology and Diabetes and rose to be Chief of Diabetes Branch at the MDNIH in Bethesda, Maryland, a position he held until 2005. His main interests have focused on the role of insulin and the insulin-like growth factors, or IGFs, in normal physiology and disease states. In these areas he has published over 500 peer-reviewed articles and reviews in high profile journals. He is also the senior editor of a textbook on diabetes, now in its third edition, and has edited books on IGFs. Professor LeRoith has made major contributions in our understanding of the basic pathophysiology of type 2 diabetes and also the role of the IGFs in various disorders, especially in cancer, and is considered a worldwide expert on these topics. In recognition of his contributions he has received many lecturing positions worldwide and has been the plenary speaker at numerous national and international symposia. He is the editor of a number of diabetes- and growth factor-related journals, has been on the advisory boards of a number of companies and co-chairs two national committees involved in the education of endocrinologist and primary care physicians.

Professor Ele Ferrannini, MD, PhD, joined the Oramed Scientific Advisory Board in February 2007. He is a past President to the, European Association for the Study of Diabetes, which supports scientists, physicians, laboratory workers, nurses and students from all over the world who are interested in diabetes and related subjects in Europe, and performs functions similar to that of the ADA in the United States. Professor Ferrannini has worked with various institutions including the Department of Internal Medicine, University of Pisa School of Medicine, and NRC (National Research Council) Institute of Clinical Physiology, Pisa, Italy; and the Diabetes Division, Department of Medicine, University of Texas Health Science Center at San Antonio, Texas. He has also had extensive training focused on microbiology, immunology, and endocrinology, and specializing in diabetes studies. Professor Ferrannini has received a Certificate of the Educational Council for Foreign Medical Graduates from the University of Bologna, and with cum laude honors completed a subspecialty in Diabetes and Metabolic Diseases at the University of Torino. He has published over 350 original papers and 50 book chapters and he is a “highly cited researcher,” according to the Institute for Scientific Information, or ISI. ISI provides bibliographic database services and publishes list of highly cited researchers.

Professor Nir Barzilai, MD, joined the Oramed Scientific Advisory Board in January 2007. He is the Director of the Institute for Aging Research at the Albert Einstein College of Medicine, New York. He is currently an Associate Professor in the Department of Medicine, Molecular Genetics and the Diabetes Research Center and is a member of the Divisions of Endocrinology and Geriatrics. He is also the Director of the Montefiore Hospital Diabetes Clinic, New York. He has spent over 20 years assisting patients internationally and training in various fields including Medicine, Geriatrics, Endocrinology and Molecular Genetics. Professor Barzilai has had a strong career in diabetes studies in Israel, London and the United States. He has worked for such esteemed institutions as Hadassah Research Hospital, NIH, and many esteemed U.S. based university hospitals, including Cornell and Yale.



Dr. John Amatruda, MD, joined the Oramed Scientific Advisory Board in February 2010. He graduated from Yale University, received his MD degree from the Medical College of Wisconsin and did his internship and residency in Internal Medicine and Fellowship in Endocrinology and Metabolism at The Johns Hopkins Hospital. He is board certified in Internal Medicine and Endocrinology and Metabolism and continues to see patients. From 1977 to 1992, Dr. Amatruda was a Professor of Medicine at The University of Rochester School of Medicine where he was head of the Clinical Research Center, fully funded as principle investigator on two NIH grants, and acting Head of the Endocrine Metabolism Unit. From 1992 to 2002, he started and ran a drug discovery group at Bayer Corp. where he served as Vice President and Therapeutic Area Research Head, as well as a Professor of Medicine Adjunct at Yale University School of Medicine. He assisted in the approval of Acarbose, an anti-diabetic drug distributed by Bayer AG used to treat type 2 diabetes and, in some countries, prediabetes, and his group put several compounds into clinical development including the first glucagon receptor antagonist. From 2002 to 2009, Dr. Amatruda held various positions at Merck & Co. Inc., including Vice President and Therapeutic Area Head for Metabolism and Atherosclerosis and acting Therapeutic Area head for Cardiovascular. These groups filed NDAs for the drugs Vytarin, Januvia and Janumet. Most recently Dr. Amatruda was Senior Vice President and Franchise Head for Diabetes and Obesity and a member of the Research Management Committee at Merck. Dr. Amatruda is an author of over 150 papers, abstracts, reviews and book chapters, primarily in the areas of insulin action in vitro systems and in clinical diabetes and obesity.

#### Employees

We have been successful in retaining experienced personnel involved in our research and development program. In addition, we believe we have successfully recruited the clinical/regulatory, quality assurance and other personnel needed to advance through clinical studies or have engaged the services of experts in the field for these requirements. As of August 31, 2012, we have contracted with eight individuals for employment or consulting arrangements. Of our staff, three are senior management, three are engaged in research and development work, and the remaining two are involved in administration work.

## ITEM 1A. RISK FACTORS.

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this Annual Report on Form 10-K before making an investment decision. Our business, prospects, financial condition, and results of operations may be materially and adversely affected as a result of any of the following risks. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in “Item 1A. Risk Factors” are forward-looking statements. The following risk factors are not the only risk factors facing our Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

### Risks Related to Our Business

We continue and expect to incur losses in the future.

Successful completion of our development programs and our transition to normal operations are dependent upon obtaining necessary regulatory approvals from the FDA prior to selling our products within the United States, and foreign regulatory approvals must be obtained to sell our products internationally. There can be no assurance that we will receive regulatory approval of any of our product candidates, and a substantial amount of time may pass before we achieve a level of revenues adequate to support our operations, 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 cannot predict the outcome of these activities.

Based on our current cash resources and commitments, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that we will not need additional funds prior to such time. If there are unexpected increases in our operating expenses, we may need to seek additional financing during the next 12 months. See “Item 1A. Risk Factors—We will need substantial additional capital in order to satisfy our business objectives.”

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 exempt from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for at least the next 12 months from the date of this Annual Report on Form 10-K. We will require substantial additional financing at various intervals in order to continue our research and development programs, including significant requirements for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals, and for commercialization of our products. We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. In the event that we are unable to obtain such financing, we will not be able to fully develop and commercialize our technology. Our future capital requirements will depend upon many factors, including:

- Continued scientific progress in our research and development programs,
- Costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions,



- Competing technological and market developments,
- Our ability to establish additional collaborative relationships, and
- Effects of commercialization activities and facility expansions if and as required.

If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize ourselves. In such event, our business, prospects, financial condition, and results of operations may be adversely affected as we may be required to scale-back, eliminate, or delay development efforts or product introductions or enter into royalty, sales or other agreements with third parties in order to commercialize our products.

We are a development stage company with a history of losses and can provide no assurance as to our future operating results.

We are a development stage company with no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which could generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of August 31, 2012 and August 31, 2011, we had working capital of \$4,439,438 and \$3,842,790, respectively, and stockholders' equity of \$3,778,013 and \$3,723,916, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through August 31, 2012, the year ended August 31, 2012 and the year ended August 31, 2011, we incurred net losses of \$17,891,777, \$3,344,478 and \$1,561,245, respectively. We may never achieve profitability and expect to incur net losses in the foreseeable future. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

We rely upon patents to protect our technology.

The patent position of biopharmaceutical and biotechnology firms is generally uncertain and involves complex legal and factual questions. We do not know whether any of our current or future patent applications will result in the issuance of any patents. Even issued patents may be challenged, invalidated or circumvented. Patents may not provide a competitive advantage or afford protection against competitors with similar technology. Competitors or potential competitors may have filed applications for, or may have received patents and may obtain additional and proprietary rights to compounds or processes used by or competitive with ours. In addition, laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

Patent litigation is becoming widespread in the biopharmaceutical and biotechnology industry and we cannot predict how this will affect our efforts to form strategic alliances, conduct clinical testing or manufacture and market any products under development. If challenged, our patents may not be held valid. We could also become involved in interference proceedings in connection with one or more of our patents or patent applications to determine priority of invention. If we become involved in any litigation, interference or other administrative proceedings, we will likely incur substantial expenses and the efforts of our technical and management personnel will be significantly diverted. In addition, an adverse determination could subject us to significant liabilities or require us to seek licenses that may not be available on favorable terms, if at all. We may be restricted or prevented from manufacturing and selling our products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses.



We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies. We currently hold several pending patent applications in the United States for our technologies covering oral administration of insulin and other proteins and oral administration of exenatides and proteins, corresponding patent applications filed in Canada, Europe, Japan, China, Russia, Israel, Brazil, Australia, South Africa, New Zealand, Hong Kong and India and three patents issued by the Australian, Israeli ( for our technologies covering oral administration of insulin and other proteins) and New Zealand (for our technologies covering oral administration of insulin and other proteins and oral administration of exenatides) patent offices. 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, 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.

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

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

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

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

- Future clinical trial results may be inconsistent with previous preliminary testing results and data from our earlier studies may be inconsistent with clinical data,
- Even if our oral insulin capsule is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices,
- Our ability to complete the development and commercialization of the oral insulin capsule for our intended use is significantly dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, the oral insulin capsule on a worldwide basis,
- Even if our oral insulin capsule is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance of our product, and
- Our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues.

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

We have limited experience in conducting clinical trials.

Clinical trials must meet FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We have entered into agreements with Hadasit to assist us in designing, conducting and managing our various clinical trials in Israel, as more fully described in “Item 1. Business—Description of Business—Partnerships and Collaborative Agreements.” Any failure of Hadasit or any other consultant to fulfill their obligations could result in significant additional costs as well as delays in designing, consulting and completing clinical trials on our products.

Our clinical trials may encounter delays, suspensions or other problems.

We may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks or if we or they find deficiencies in the clinical trial process or conduct of the investigation. If clinical trials of any of the product candidates fail, we will not be able to market the product candidate which is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials, which would result in increased costs and significant development delays. Our failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development could delay or prevent regulatory approval of the product candidate and could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We can provide no assurance that our products will obtain regulatory approval or that the results of clinical studies will be favorable.

The testing, marketing and manufacturing of any of our products will require the approval of the FDA or regulatory agencies of other countries. We have completed certain non-FDA clinical trials and pre-clinical trials for our products but have yet to conduct any FDA approved trials. We have retained Advanced Regulatory Services Ltd. to assist us in the preparation of an IND application with the FDA to conduct an FDA approved Phase 2 study on our oral insulin capsule product but no application has yet been filed.

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

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

We are dependent on outside vendors for our entire supply of the oral insulin capsule. 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 are highly dependent upon our ability to enter into agreements with collaborative partners to develop, commercialize, and market our products.

Our long-term strategy is to ultimately seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase 3) and sales and marketing of our oral insulin capsule and other products. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere.

While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. We currently lack the resources to manufacture any of our product candidates on a large scale and we have no sales, marketing or distribution capabilities. In the event we are not able to enter into a collaborative agreement with a partner or partners, on commercially reasonable terms, or at all, we may be unable to commercialize our products, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.





The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. These industries are highly competitive, and this competition comes both from biotechnology firms and from major pharmaceutical and chemical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our products from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our products may be subject to competition from products developed using other technologies. See “Item 1. Business—Description of Business—Competition.”

We have limited senior management resources and may be required to obtain more resources to manage our growth.

We expect the expansion of our business to place a significant strain on our limited managerial, operational, and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train, and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition, and results of operations. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human, and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition, and results of operations will be materially adversely affected. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Item 1. Business—Description of Business—Strategy” and “—Employees.”

We have limited financial personnel and may not provide reasonable assurance regarding the reliability of internal control over financial reporting.

Due to the inherent limitations of our Company, derived from our small size and limited number of employees, management’s evaluation of our internal control over financial reporting, as further discussed in “Item 9A. Controls and Procedures”, concluded that there is a material weakness with respect to segregation of duties that may not provide reasonable assurance regarding the reliability of internal control over financial reporting and may not prevent or detect misstatements. Specifically, our Chief Financial Officer serves as our only qualified internal accounting and financial reporting personnel and as such performs all accounting and financial reporting functions without the benefit of independent checks, confirmations or backup other than bookkeeping functions performed by an outside accounting firm. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 Medical and Technology 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.

Fulfilling our obligations incident to being a public company will be expensive and time consuming.

As a public company, the Sarbanes-Oxley Act of 2002, Dodd-Frank Act, and the related rules and regulations of the Securities and Exchange Commission, or the SEC, require us to maintain certain corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations increases our legal and financial compliance costs and place significant additional demands on our finance and accounting staff and on our financial, accounting and information systems.

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 March 2010, the U.S. Congress enacted and President Obama signed into law healthcare reform legislation that may significantly impact the pharmaceutical industry. In addition to requiring most individuals to have health insurance and establishing new regulations on health plans, this legislation will require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the legislation imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the legislation on our business is unclear and there can be no assurance that our business will not be materially adversely affected. In addition, these and other ongoing initiatives in the United States have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product that we may successfully develop.

Various healthcare reform proposals have also emerged at the 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. However, 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.

We became a publicly traded company through the acquisition of a public shell company, and we could be liable for unanticipated claims or liabilities as a result thereof.

We were originally incorporated on April 12, 2002 as an exploration stage company engaged in the acquisition and exploration of mineral properties. We were unsuccessful in implementing our business plan as a mineral exploration company and became a public shell company. On May 27, 2004, we executed a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey corporation, or ISTI. However, due to disappointing results, on May 31, 2005, effective as of May 27, 2004, we terminated the share exchange agreement with the shareholders of ISTI, and we again became a public shell company. We remained a public shell company until March 8, 2006, when we became a pharmaceutical company engaged in the development of innovative pharmacological solutions.

We face substantial risks associated with being a former public shell company, including absence of accurate or adequate public information concerning the public shell company; undisclosed liabilities; improper accounting; claims or litigation from former officers, directors, employees or stockholders; contractual obligations; and regulatory requirements. Although management performed due diligence on us, there can be no assurance that such risks do not occur. The occurrence of any such risk could materially adversely affect our financial condition.

#### Risks Related to our Common Stock

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

The price of our common stock is currently quoted on the OTC Bulletin Board, or the OTCBB, 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, even if our shares begin trading on the Nasdaq Stock Market, or Nasdaq, where we have applied to have our shares listed. These fluctuations may result from a variety of factors, many of which are beyond our control. These factors include:

- Clinical trial results and the timing of the release of such results,
- The amount of cash resources and our ability to obtain additional funding,
- Announcements of research activities, business developments, technological innovations or new products by us or our competitors,
- Entering into or terminating strategic relationships,
- Changes in government regulation,
- Departure of key personnel,
- Disputes concerning patents or proprietary rights,
- Changes in expense level,
- Future sales of our equity or equity-related securities,
- Public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
- Activities of various interest groups or organizations,
- Media coverage, and
- Status of the investment markets.

We may effect a reverse stock split of our shares of common stock.

Our Board and stockholders have approved a reverse stock split of our shares of common stock at a ratio not to exceed one-for-eighteen. Our Board has up to 24 months from July 24, 2012, to effect the reverse stock split and may need to do so in order to meet Nasdaq listing requirements, but there can be no assurance that our Board will do so. While the Board believes that the potential advantages of a reverse stock split outweigh the risks, if the Board does effect a reverse stock split there can be no assurance that:

- Our shares of common stock will trade at a price in proportion to the reduction in the number of outstanding shares resulting from the reverse shares split,
- The reverse stock split will result in a per share price high enough to attract and retain employees and strategic partners,
- The bid price of our shares of common stock after a reverse stock split can be maintained at or above the minimum bid price requirement,
- Our shares of common stock will not be rejected from listing on Nasdaq for other reasons,
- The liquidity of our shares of common stock will not be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split,
- Engaging in a reverse stock split will not be perceived in a negative manner by investors, analysts or other stock market participants, or
- The reverse stock split will not result in some stockholders owning “odd-lots” of less than 100 shares of common stock, potentially resulting in higher brokerage commissions and other transaction costs than the commissions and costs of transactions in “round-lots” of even multiples of 100 shares.

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

Future sales of substantial amounts of our common stock or other equity-related securities in the public market or privately, or the perception that such sales could occur, could adversely affect prevailing trading prices of our common stock and could impair our ability to raise capital through future offerings of equity or other equity-related securities. We anticipate that we will need to raise capital through offerings of equity and equity related securities. We can make no prediction as to the effect, if any, that future sales of shares of our common stock or equity-related securities, or the availability of shares of common stock for future sale, will have on the trading price of our common stock.

Our stockholders may experience significant dilution as a result of any additional financing using our equity securities.

To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Sale of additional equity securities at prices below certain levels may trigger anti-dilution provisions with respect to certain securities we have previously sold.



Our common stock is deemed to be a “penny stock,” which may make it more difficult for investors to sell their shares due to suitability requirements. Low-priced stocks are sometimes the subject of fraud and abuse.

The SEC has adopted regulations that generally define “penny stock” to be an equity security that has a market price of less than \$5.00 per share (as calculated pursuant to SEC rules), subject to specific exemptions, such as if the issuer of the security has net tangible assets in excess of \$2,000,000 and has been in continuous operation for at least three years. The market price of our common stock is currently less than \$5.00 per share, and there are no applicable exemptions available to us. Therefore, our common stock is currently a “penny stock” according to SEC rules. Designation as a “penny stock” requires any broker or dealer selling these securities to, among other things, disclose certain information concerning the transaction, obtain a written agreement from the purchaser, furnish the customer a document describing the risks of investing in penny stocks and send monthly account statements showing the market value of each penny stock held in the customer’s account. Such rules may restrict the ability of brokers or dealers to sell penny stocks.

You should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. These could affect low-priced stocks, such as ours, even if they do not qualify as “penny stocks” under the SEC rules. Such patterns include:

- Control of the market for the security by one or a few broker-dealers,
- “Boiler room” practices involving high-pressure sales tactics,
- Manipulation of prices through prearranged matching of purchases and sales,
- The release of misleading information,
- Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers, and
- Dumping of securities by broker-dealers after prices have been manipulated to a desired level, which hurts the price of the stock and causes investors to suffer losses.

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

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of December 6, 2012, we had outstanding 86,505,020 shares of common stock, a large majority of which are freely tradeable. Giving effect to the exercise in full of all of our outstanding warrants and options, we would have outstanding 111,557,056 shares of common stock.

Our issuance of warrants and options 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 and convertible notes at, above or below the current market price. As of August 31, 2012, we had outstanding warrants and options exercisable for 22,942,310 shares of common stock (15,200,044 as of August 31, 2011). In addition to the dilutive effect of a large number of shares and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.





Delaware law could discourage a change in control, or an acquisition of us by a third party, even if the acquisition would be favorable to you, and thereby adversely affect existing stockholders.

The Delaware General Corporation Law contains provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our Company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with “interested stockholders.” These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

Because we will not pay cash dividends, investors may have to sell shares in order to realize their investment.

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements which we may enter into with institutional lenders or otherwise may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our Board and will be dependent upon our financial condition, results of operations, capital requirements, and any other factors that our Board decides is relevant. See “Item 5. Market Price for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.”

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of December 6, 2012, our directors, executive officers and principal affiliated stockholders beneficially own approximately 35.2% of our outstanding shares of common stock. As a result, these stockholders, should they act together, may have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, should they act together, may have the ability to control the management and affairs of our Company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- Delaying, deferring or preventing a change in corporate control,
- Impeding a merger, consolidation, takeover or other business combination involving us, or
- Discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Our shares of common stock are not yet listed for trading on a national securities exchange.

Although we have applied to have our common stock list for trading on Nasdaq, there is no assurance that such listing will be approved or how long such approval could take. Our common stock currently only trades on the OTCBB and is not listed for trading on any national securities exchange. Investments in securities trading on the OTCBB are generally less liquid than investments in securities trading on a national securities exchange. The failure of our shares to be approved for trading on a national securities exchange may have the effect of limiting the trading activity of our common stock and reducing the liquidity of an investment in our common stock.

## Risks Related to Conducting Business in Israel

We are affected by the political, economic, and military risks of locating our principal operations in Israel.

Our operations are located in the State of Israel, and we are directly affected by political, economic, and security conditions in that country. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Since October 2000, there has been a high level of violence between Israel and the Palestinians. 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 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, 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 may potentially escalate in the future to violent events which may affect Israel and us. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

All adult male permanent residents of Israel, unless exempt, may be required to perform military reserve duty annually. Additionally, all such residents are subject to being called to active duty at any time under emergency circumstances. Some of our officers, directors, and employees currently are obligated to perform annual military reserve duty. We can provide no assurance that such requirements will not have a material adverse effect on our business, prospects, financial condition, and results of operations in the future, particularly if emergency circumstances occur.

Because almost all of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against our management for misconduct.

Almost all of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against such officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state. Additionally, it may be difficult to enforce civil liabilities under U.S. securities law 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 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 the 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

Our principal executive offices are comprised of approximately 117 square meters of leased office space in Givat-Ram, Jerusalem, Israel. The current lease term is from January 1, 2012 until September 30, 2016. The aggregate annual base rent for this space is currently \$11,768 in fiscal year 2013, \$15,338 in 2013 and \$16,713 from 2014 onwards, and will be linked to the increase in the Israeli consumer price index. We believe that our existing facilities are suitable and adequate to meet our current business requirements. In the event that we should require additional or alternative facilities, we believe that such facilities can be obtained on short notice at competitive rates.

As security for our obligations under the lease agreement, we have provided a bank guarantee in an amount equal to three monthly lease payments, valid until November 30, 2016.

ITEM 3. LEGAL PROCEEDINGS.

From time to time we may become subject to litigation incidental to our business. We are not currently a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

## Market Price for our Common Stock

Our common stock is quoted on the OTCBB under the symbol "ORMP." We have applied to have our common stock listed on Nasdaq. The quarterly high and low reported bid prices for our common stock as quoted on the OTCBB for the periods indicated are as follows:

	High	Low
Year Ended August 31, 2011		
Three Months Ended November 30, 2010	\$ 0.42	\$ 0.28
Three Months Ended February 28, 2011	\$ 0.37	\$ 0.27
Three Months Ended May 31, 2011	\$ 0.35	\$ 0.23
Three Months Ended August 31, 2011	\$ 0.34	\$ 0.20
Year Ended August 31, 2012		
Three Months Ended November 30, 2011	\$ 0.44	\$ 0.25
Three Months Ended February 29, 2012	\$ 0.38	\$ 0.27
Three Months Ended May 31, 2012	\$ 0.36	\$ 0.27
Three Months Ended August 31, 2012	\$ 0.36	\$ 0.23

The foregoing quotations were provided by Yahoo! Finance and the quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions. The last reported bid price per share of common stock as quoted on the OTCBB was \$0.30 on December 10, 2012.

## Holders

As of December 6, 2012, there were 86,505,020 shares of our common stock issued and outstanding held of record by approximately 96 registered stockholders. We believe that a significant number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories and are therefore not included in the number of stockholders of record.

## Dividend Policy

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

## Unregistered Sales of Equity Securities and Use of Proceeds

In July 2012, we issued 50,000 shares of our common stock, valued at \$16,000, in the aggregate, to an advisor as remuneration for services provided.

The above issuance and sale was exempt under Section 4(a)(2) of the Securities Act.



## ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

The following discussion and analysis of our financial conditions and results of operations should be read in conjunction with our accompanying consolidated financial statements and notes thereto for the years ended August 31, 2012 and 2011. In addition to our consolidated financial statements, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in "Cautionary Statement Regarding Forward-Looking Statements" and "Item 1A. Risk Factors."

### Overview of Operations

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills for delivery of other polypeptides.

### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins," which we acquired from Hadasit in 2006 and which is pending in various foreign jurisdictions, as well as the other patents we have filed in various foreign jurisdictions since then, as discussed above under "Item 1. Business—Description of Business—Patents and Licenses" and "Item 1A. Risk Factors." Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify the insulin chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an IND application with the FDA. Additional clinical trials are planned in Israel in order to substantiate our results as well as for purposes of making future filings for drug approval. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

### Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase 3) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would

enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.



### Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

### Results of Operations

#### Critical accounting policies

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

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. 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.

Marketable securities: Consist mainly of equity securities classified as available-for-sale and are recorded at fair value. Until September 30, 2011, the fair value of the restricted securities was measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market. As of October 1, 2011, the securities are not restricted and the fair value of the securities is measured based on the quoted prices of the securities on an active market. Changes in fair value, net of taxes, are reflected in other comprehensive income (loss).

Factors considered in determining whether a loss is temporary include the extent to which fair value has been less than the cost basis, and the financial condition and near-term prospects of the investee based on our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The loss is recorded as a charge to earnings.

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

We account for share-based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated– forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the options granted is measured on each reporting date, and the gains (losses) are recorded to earnings over the related service period using the straight-line method.

Valuation of warrants issued as part of capital raisings that are classified as a liability: Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the statement of financial position. The liability is measured both initially and in subsequent periods in fair value, with changes in fair value are charged to finance expenses, net.

The fair value of the warrants was determined by using Monte Carlo type model based on the risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issue dates, then for each path to use the Black-Scholes model to estimate the value of the warrants on the last issue date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant delay in this input would result in a higher fair value measurement.

Taxes on income: 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. We have provided a full valuation allowance with respect to our deferred tax assets.

Regarding our subsidiary, Oramed Ltd., relevant accounting guidance prohibits the recognition of 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 above-mentioned differences were not reflected in the computation of deferred tax assets and liabilities.

## Comparison of Fiscal Year 2012 to Fiscal Year 2011

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2012 and 2011:

Operating Data:	Year ended	
	August 31, 2012	August 31, 2011
Research and development expenses, net	\$ 1,680,845	\$ 1,159,309
General and administrative expenses	1,203,164	1,275,960
Gain on sale of investment	-	(1,033,004)
Impairment of available for sale securities	184,254	197,412
Financial expenses (income), net	185,997	(14,452)
Loss before taxes on income	(3,254,260)	(1,585,225)
Taxes on income	90,218	(23,980)
Net loss for the period	(3,344,478)	(1,561,245)
Loss per common share – basic and diluted	\$ (0.05)	\$ (0.02)
Weighted average common shares outstanding	70,605,814	64,999,026

## 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, payroll taxes, employee benefits, costs of registered patents materials, supplies, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

Clinical trial and pre-clinical trial expenses include regulatory and scientific consultants' compensation and fees, research expenses, purchase of materials, cost of manufacturing of the oral insulin capsules, payments for patient recruitment and treatment, costs related to the maintenance of our registered patents, costs related to the filings of patent applications, as well as salaries and related expenses of research and development staff.

In August 2009, Oramed Ltd. was awarded a government grant amounting to a total net amount of NIS 3.1 million (approximately \$813,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel, or OCS. This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and oral GLP-1-analog. In December 2010, Oramed Ltd. was awarded a second grant, or the Second

Grant, amounting to a total net amount of NIS 2.9 million (approximately \$720,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to November 2011. As a result of a delay in the research and development plan, as of November 30, 2011, Oramed Ltd. had used only NIS 1,473,000 (approximately \$365,000) of the Second Grant. In May 2012, Oramed Ltd. was awarded an extension of nine months to use the funds of the Second Grant until August 2012. In addition, in May 2012, Oramed Ltd. was granted a third grant amounting to a total net amount of NIS 595,000 (approximately \$148,000) from the OCS, which was designated for research and development expenses for the period of September 2012 to December 2012. We used the funds to support further research and development and clinical studies of our oral insulin capsule and oral GLP-1 analog. The three grants are subject to repayment according to the terms determined by the OCS and applicable law. See “—Government grants” below.

During the year ended August 31, 2012, research and development expenses totaled \$1,680,845, compared to \$1,159,309 for the year ended August 31, 2011. The increase is mainly attributed to the preparation for the FDA approved Phase 2 study that will follow the expected IND filing in the fourth calendar quarter of 2012. The research and development costs include stock based compensation costs, which during the year ended August 31, 2012 totaled \$98,688, as compared to \$265,327 during the year ended August 31, 2011. The decrease is mainly attributable to the end of the vesting period at January 31, 2012 of the 864,000 options granted to Dr. Miriam Kidron in April 2010.

#### Government grants

The Government of Israel encourages research and development projects through the OCS, pursuant to the Law for the Encouragement of Industrial Research and Development, 1984, as amended, or the R&D Law. Under the R&D Law, a research and development plan that meets specified criteria is eligible for a grant of up to 50% of certain approved research and development expenditures. Each plan must be approved by the OCS.

In the years ended August 31, 2012 and 2011, we recognized research and development grants in an amount of \$372,959 and \$354,906, respectively. As of August 31, 2012, we had no contingent liabilities to the OCS.

Under the terms of the grants we received from the OCS, we are obligated to pay royalties of 3% to 3.5% on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licensed ancillary services. Pursuant to a proposed amendment to the R&D Law, our royalty rate may be 3% to 6% per annum. Royalties are payable up to 100% of the amount of such grants, or up to 300% as detailed below, linked to the U.S. Dollar, plus annual interest at LIBOR.

The R&D Law generally requires that a product developed under a program be manufactured in Israel. However, upon notification to the OCS (and provided that the OCS does not object within 30 days), up to 10% of a company's approved Israeli manufacturing volume, measured on an aggregate basis, may be transferred outside of Israel. In addition, upon the approval of the OCS, a greater portion of the manufacturing volume may be performed outside of Israel, provided that the grant recipient pays royalties at an increased rate, which may be substantial, and the aggregate repayment amount is increased up to 300% of the grant, depending on the portion of the total manufacturing volume that is performed outside of Israel. The R&D Law further permits the OCS, among other things, to approve the transfer of manufacturing rights outside of Israel in exchange for an import of different manufacturing into Israel as a substitute, in lieu of the increased royalties. The R&D Law also allows for the approval of grants in cases in which the applicant declares that part of the manufacturing will be performed outside of Israel or by non-Israeli residents and an OCS research committee is convinced that doing so is essential for the execution of the program. This declaration will be a significant factor in the determination of the OCS as to whether to approve a program and the amount and other terms of benefits to be granted. For example, an increased royalty rate and repayment amount might be required in such cases.

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred 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 to any third parties outside Israel absent OCS approval which may be granted under special circumstances such as those noted in the following cases: (a) the grant recipient pays to the OCS a portion of the sale price paid in consideration for such OCS-funded know-how or the price paid in consideration for the sale of the grant recipient itself, as the case may be (according to certain formulas; the portion to be paid in respect of a sale of the grant recipient itself changed under the applicable rules that came into effect in November 2012); (b) the grant recipient receives know-how from a third party in exchange for its OCS-funded know-how; or (c) such transfer of OCS-funded know-how arises in connection with certain types of cooperation in research and development activities.

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 and its controlling shareholders and foreign interested parties to notify the OCS 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 becoming an interested party in the recipient, and requires the new interested party to undertake to the OCS to comply with the R&D Law. In addition, the rules of the OCS may require 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 owns 25% or more of the outstanding share capital or voting rights or has the right to appoint 25% or more of the directors. Accordingly, any non-Israeli who acquires 5% or more of our common stock will be required to notify the OCS that it has become an interested party and to sign an undertaking to comply with the R&D Law.

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 OCS programs which may lead to additional royalties being payable on additional products.

#### Grants from Bio-Jerusalem

The Bio-Jerusalem fund was founded by the Jerusalem Development Authority in order to support the biomed industry in Jerusalem. We are committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grants received by the Company (Israeli CPI linked) in the total aggregate amount of \$52,733 as of August 31, 2012. For the year ended August 31, 2012, there were no grants received from the Bio-Jerusalem fund and in the year ended August 31, 2011, we received \$20,950 from said fund. As we have not yet realized any revenues since inception, we have not incurred any royalty liability to the Bio-Jerusalem fund.

#### General and administrative expenses

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

For the year ended August 31, 2012, general and administrative expenses totaled \$1,203,164 compared to \$1,275,960 for the year ended August 31, 2011. The increase in costs incurred related to general and administrative activities during the year ended August 31, 2012 was mainly due to an increase in investor relations costs, which was partially offset by a decrease in consulting fees. During the year ended August 31, 2012, as part of our general and administrative expenses, we incurred \$172,470 related to stock options granted to employees and consultants, as compared to \$263,999 during the year ended August 31, 2011.

#### Financial income/expense, net

Financial expenses for the year ended August 31, 2012 include an expense of \$142,704 for changes in fair value of warrant liabilities, which was mainly derived from an amendment to certain warrants that reduced the exercise prices and increased the number of shares issuable pursuant thereto, as discussed below under “Liquidity and Capital Resources.” During the year ended August 31, 2012, we incurred increased losses, as compared to the year ended August 31, 2011, as a result of exchange rate differences and bank charges that were partially offset by interest income on available cash and cash equivalents. The decrease in the interest income for the year ended August 31, 2012 was also attributable to the use of funds raised by share issuances described below in the year ended August 31, 2011.

As of August 31, 2011, the warrants that were granted to Regals Fund LP, or Regals, during the year ended August 31, 2011 were presented within stockholders’ equity. After further review, we have determined that these instruments should have been classified as liabilities. Changes in the fair value of these warrants require adjustments to the amount of the liabilities recorded on our balance sheet, and the corresponding gain or loss is required to be recorded in our statement of operations. We assessed the materiality of the correction and concluded that it was immaterial to previously reported annual and interim amounts and that the correction of the error in 2012 is not material to the current year end results of operations. Accordingly, we corrected this error during the year ended August 31, 2012, as reflected in the financial expenses for the year ended August 31, 2012, and did not restate our consolidated financial statements for the prior years or interim periods impacted.

#### Gain on sale of investment and impairment of available for sale securities

In March 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera’s outstanding share capital on an undiluted basis, as discussed above under “Item 1. Business—Description of Business—Out-Licensed Technology.” As a result of the transaction, we recognized a gain on sale of investment of \$1,033,004 for the year ended August 31, 2011. Also as a result of the transaction, we received 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$581,977 as of March 31, 2011, the closing date of the Entera sale. The D.N.A shares were recorded at fair value as discussed above under “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Marketable securities.” As of August 31, 2012, these ordinary shares of D.N.A had an aggregate market value of approximately \$200,311. Changes in fair value, net of taxes, are discussed in Note 3 to our accompanying consolidated financial statements for the years ended August 31, 2011 and 2012.

## Liquidity and Capital Resources

From inception through August 31, 2012, we incurred losses in an aggregate amount of \$17,891,777. We have financed our operations through the private placements of equity financing, raising a total of \$15,169,728, net of transaction costs. We will seek to obtain additional financing through similar sources in the future as needed. As of August 31, 2012, we had \$4,430,740 of available cash as well as \$454,381 in short term interest bearing investments. We anticipate that we will require approximately \$5.2 million to finance our activities during the 12 months following August 31, 2012, of which we engaged in equity financings that raised a total amount of \$1,489,518 from September 2012 through November 2012.

Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising 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 ongoing financing discussions with third party investors and existing stockholders as well as through additional funding from the OCS.

During the year ended August 31, 2012, cash and cash equivalents increased by \$2,917,375 from the \$1,513,365 reported as of August 31, 2011, which is primarily due to proceeds from the issuance of common stock and warrants and proceeds from the sale of our investment in Entera.

Operating activities used cash of \$2,301,608 in the year ended August 31, 2012 and \$1,705,844 in the year ended August 31, 2011. Cash used for operating activities in the year ended August 31, 2012 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments, common stock issued for services and increases in accounts payable and accrued expenses. The increase in cash used by operating activities in the year ended August 31, 2012, as compared to the year ended August 31, 2011, is mainly due to the gain on sale of investment of \$1,033,004 from our sale of Entera's shares as discussed above under "Item 1. Business—Description of Business—Out-Licensed Technology," that was recognized in the year ended August 31, 2011.

Investing activities provided cash of \$1,768,898 in the year ended August 31, 2012, as compared to \$1,703,430 used in investing activities in the year ended August 31, 2011. Cash provided by investing activities in the year ended August 31, 2012 consisted primarily of proceeds from short-term bank deposits and proceeds from the sale of our investment in Entera. In the year ended August 31, 2011, cash used in investing activities consisted primarily of purchasing short term investments.

Financing activities provided cash of \$3,488,942 in the year ended August 31, 2012 and \$3,694,212 in the year ended August 31, 2011. Cash provided by financing activities during both periods consisted of proceeds from our issuance of common stock and warrants.

During the year ended August 31, 2012, of the \$372,959 OCS grants we recognized during such period, we received approximately \$305,984 from the OCS towards our research and development expenses, as compared to \$284,817 received in the year ended August 31, 2011. The amounts that were recognized but not received during the year ended August 31, 2012 are expected to be received by the OCS following the submission of periodic and final reports by Oramed Ltd., and their examination by the OCS. The OCS has supported our activity in the past two years. In May 2012, Oramed Ltd. was awarded a nine month extension through August 2012 for its existing Second Grant, and an additional grant amounting to a total net amount of NIS 595,000 (approximately \$148,000) from the OCS, which extended Second Grant and additional grant were designated to support further research and development and clinical studies of our oral insulin capsule and oral GLP-1 analog from December 2011 to December 2012.





During fiscal years 2012 and 2011 we issued a total of 1,079,637 shares of common stock to various third party vendors for services rendered. The aggregate value of those shares was approximately \$335,429. We also consummated three private placements by selling 11,611,875 and 9,622,142 “units” at a purchase price of \$0.32 and \$0.37 per unit, respectively, for total consideration of \$3,715,800 and \$3,560,192, respectively. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 and 0.50, respectively, of a share of common stock at an exercise price of \$0.50 per share.

Our recent financing activities include the following:

- In September 2010 and January 2011, we issued a total of 353,714 shares of our common stock, valued at \$119,800, in the aggregate, to Swiss Caps as remuneration for services rendered.
- In March 2011, we completed a private placement pursuant to which we agreed to sell to the investors an aggregate of 10,487,500 “units” at a purchase price of \$0.32 per unit for total consideration of \$3,356,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per share. We also issued 196,750 shares of common stock and warrants to purchase 70,863 shares of common stock as finders’ fees in connection with the private placement. These amounts include the \$250,000 investment by D.N.A in connection with our technology transaction on March 31, 2011.
- In April 2011, we completed a private placement pursuant to which we agreed to sell to the investors an aggregate of 1,124,375 “units” at a purchase price of \$0.32 per unit for total consideration of \$359,800. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per share. We also issued five year warrants to purchase 67,462 shares of common stock at an exercise price of \$0.50 per share and paid \$21,588 as finders’ fees in connection with the private placement.
- In May 2011, we issued 176,923 shares of our common stock, valued at \$47,769, in the aggregate, to Swiss Caps as remuneration for services rendered in the past.
- In May 2011, we issued 200,000 shares of our common stock, valued at \$60,000, in the aggregate, to New Castle Consulting, LLC as remuneration for services to be rendered.
- In December 2011, we issued 83,000 shares of our common stock, valued at \$24,900, in the aggregate, to an advisor as remuneration for services provided.
- In March 2012, we issued 133,000 shares in the aggregate of our common stock, valued at \$38,570, to two advisory companies as remuneration for services provided.
- In May 2012, we issued 83,000 shares of our common stock, valued at \$24,900, in the aggregate, to an advisor as remuneration for services provided.
- In July 2012, we issued 50,000 shares of our common stock, valued at \$16,000, in the aggregate, to an advisor as remuneration for services provided.
- Between August and November 2012, we completed private placements pursuant to which we agreed to sell to the investors an aggregate of 13,647,866 “units” at a purchase price of \$0.37 per unit for total consideration of \$5,049,710. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.50 of a share of common stock at an exercise price of \$0.50 per share. We paid cash compensation of \$76,635 and might be required to pay additional cash compensation of \$7,500. We also issued 13,514 shares of common stock and warrants to purchase 6,757 shares of common stock as finders’ fees in connection with the private placements and will issue

149,561 shares of common stock and warrants to purchase 74,780 shares of common stock as finder's fee to one of our directors, Leonard Sank.

- In October 2012, we entered into a Securities Purchase Agreement with D.N.A, according to which, we issued to D.N.A 2,390,057 shares of our common stock in consideration for a warrant to purchase up to 21,637,611 ordinary shares of D.N.A at no additional cost. D.N.A. has filed an application for the approval of the Tel Aviv Stock Exchange Board of Directors to list the ordinary shares of D.N.A issuable upon exercise of the warrant. We plan to exercise the warrant if and when such approval is received. Should we exercise this warrant, we would hold approximately 14.5% of D.N.A’s outstanding ordinary shares, including the D.N.A ordinary shares we received in March 2011 as further discussed in “Item 1. Business—Description of Business—Out-Licensed Technology.”
- On November 29, 2012, we entered into a letter agreement, or the Agreement, with Regals in connection with (i) the warrant originally issued in January 2011, as amended in August 2012 and November 2012, to purchase up to 3,485,500 shares of our common stock, (ii) the warrant dated August 28, 2012, to purchase up to 1,351,352 shares of our common stock and (iii) the warrant dated November 5, 2012, to purchase up to 202,703 shares of our common stock, or together, the Warrants. Pursuant to the Agreement, we and Regals agreed to amend the Warrants (and to prepare and execute amendments to the Warrants setting forth such terms as soon as reasonably practicable) to provide that the anti-dilution protection of the Warrants shall be deleted in its entirety. In addition, as to the warrants issued in August and November 2012, the parties agreed that the exercise price shall be reduced to \$0.3138 per share, the current exercise price per share of the warrants originally issued to Regals in January 2011. On that day, we also issued to Regals a warrant, or the New Warrant, pursuant to which Regals shall have the right to purchase up to 1,647,722 shares of our common stock over a period of four years at an exercise price of \$0.60 per share.

In connection with the New Warrant, Nadav Kidron, our President, Chief Executive Officer and a director, in his personal capacity as one of our shareholders, undertook and agreed that following the execution and delivery of the Agreement, in the event that an adjustment pursuant to the anti-dilution protection of the Warrants (had they not been amended by the Agreement) would have been triggered and the number of shares of our common stock that Regals would have been able to purchase under the Warrants would have increased by an aggregate number in excess of 1,647,722 common shares, then Regals shall have the right to purchase from Mr. Kidron such number of shares of our common stock owned by Mr. Kidron equal to such excess, up to a maximum of 1,352,278 shares of our common stock at an exercise price of \$0.3138 per share. The foregoing right shall survive until the termination of the Warrants.

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

#### Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning September 1, 2012 are as follows:

Category	Amount
Research and development, net of OCS funds	\$ 4,198,000
General and administrative expenses	1,038,000
Financial income, net	(10,000 )
Total	\$ 5,246,000



As previously indicated, we are planning to conduct further clinical studies as well as file an IND application with the FDA for our orally ingested insulin during the fourth calendar quarter of 2012. We expect to have a significant increase in research and development expenses as a result of preparation for the FDA approved Phase 2 study that will follow the IND filing, and during the term of the study. Our ability to complete these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us and receiving additional grants from the OCS.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See Item 15 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of August 31, 2012. Based on such review, our Chief Executive Officer and Chief Financial Officer have determined that in light of their conclusion with respect to the effectiveness of our internal control over our financial reporting as of such date (as described below), that the Company did not have in place effective controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is accumulated and communicated to our management, including our Chief Executive and Chief Financial Officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

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 U.S. generally accepted accounting principles. 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 U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting as of August 31, 2012 based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission. Due to the inherent limitations of our Company, derived from our small size and the limited number of employees, the management evaluation concluded that there is a material weakness with respect to segregation of duties that may not provide reasonable assurance regarding the reliability of internal control over financial reporting and may not prevent or detect misstatements. Specifically, our Chief Financial Officer serves as our only qualified internal accounting and financial reporting personnel and as such performs all accounting and financial reporting functions without the benefit of independent checks, confirmations or backup other than bookkeeping functions performed by an outside accounting firm. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of August 31, 2011, we presented warrants that were granted to an investor during the year ended August 31, 2011 within stockholders' equity; after further review, we have determined that these instruments should have been classified as liabilities. Changes in the fair value of these warrants require adjustments to the amount of the liabilities recorded on our balance sheet, and the corresponding gain or loss is required to be recorded in our statement of operations. We assessed the materiality of the correction and concluded that it was immaterial to previously reported annual and interim amounts and that the correction of the error in 2012 is not material to the current year end results of operations. Accordingly, we corrected this error during the year ended August 31, 2012 and did not restate our consolidated financial statements for the prior periods impacted. This error was considered a "material weakness" in our internal control over financial reporting.

Based on this evaluation, our management concluded that the Company's internal control over financial reporting was not effective as of August 31, 2012 at a reasonable assurance level.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended August 31, 2012 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

On August 8, 2012, our Board cancelled the 2006 Stock Option Plan, or the 2006 Plan, and will no longer issue any securities pursuant to the 2006 Plan, and reallocated the pool of 3,000,000 shares of the Company's common stock that were reserved for issuance under the 2006 Plan and transferred such shares to the 2008 Stock Incentive Plan, or the 2008 Plan. As of such date, there were no longer any outstanding securities under the 2006 Plan.

On August 8, 2012, our Board reserved an additional 4,000,000 shares of the Company's common stock for the grant of awards under the 2008 Plan, resulting in a total of 12,000,000 shares of the Company's common stock now being reserved for issuance under the 2008 Plan, including the shares reallocated to the 2008 Plan from the 2006 Plan.



## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

Name	Age	Position
Nadav Kidron	38	President, Chief Executive Officer and Director
Miriam Kidron	72	Chief Medical and Technology Officer and Director
Leonard Sank	47	Director
Harold Jacob	59	Director
Michael Berelowitz	68	Director and Chairman of the Scientific Advisory Board
Gerald Ostrov	62	Director
Yifat Zommer	38	Chief Financial Officer, Treasurer and Secretary

Dr. Miriam Kidron is Mr. Nadav Kidron's mother. There are no other directors or officers of our Company who are related by blood or marriage.

## Business Experience

The following is a brief account of the education and business experience during at least the past five years of each director and our only executive officer who is not a director, 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. He is also a director of Entera (of which the Company owns 3% of the outstanding shares). In 2009, he was a fellow at the Merage Foundation for U.S.-Israel Trade Programs for executives in the life sciences field. From 2003 to 2006, he was the managing director of the Institute of Advanced Jewish Studies at Bar Ilan University. From 2001 to 2003, he was a legal intern at Wine, Mishaiker & Ernstoff Law Offices in Jerusalem, Israel. Mr. Kidron holds an LL.B. and an International MBA from Bar Ilan University, Israel, and is a member of the Israel Bar Association.

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

Dr. Miriam Kidron was appointed Chief Medical and Technology 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. During 2003 and 2004, Dr. Kidron served as a consultant to Emisphere Technologies Inc., a company that specializes in developing broad-based proprietary drug delivery platforms. Dr. Kidron was formerly a visiting professor at the Medical School at the University of Toronto (Canada), and is a member of the American, European and Israeli Diabetes Associations. Dr. Kidron is a recipient of the Bern Schlanger Award.



We believe that Dr. Kidron's qualifications to serve on our Board include her expertise in the Company's technology, as it is based on her research, as well as her experience and relevant education in the fields of pharmacology and diabetes.

Mr. Leonard Sank was appointed a director in October 2007. Mr. Sank is a South African entrepreneur and businessman, who is devoted to entrepreneurial endeavors and initiatives. He has over 20 years of experience playing important leadership roles in developing businesses. Since December 2011, Mr. Sank has served as a director in Eastvaal Motors Pty Ltd., a diversified retail motor business, and served as a director there in the past. Since 2010, Mr. Sank has served as a director in Bradbury Finance Pty Ltd. From 2000 to 2007, Mr. Sank served as a director in Vecto Finance Pty Ltd., a credit lending business. For the past fifteen years Mr. Sank has served as a director of Macsteel Service Centres SA Pty Ltd., South Africa's largest private company. He also serves on the boards of small 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.

Dr. Harold Jacob was appointed a director in July 2008. 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. 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 2003, Dr. Jacob has served as the Chief Executive Officer of NanoVibronix, Inc., a medical device company using surface acoustics to prevent catheter acquired infection as well as other applications. He practiced clinical gastroenterology in New York and served as Chief of Gastroenterology at St. Johns 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.

We believe that Dr. Jacob's qualifications to serve on our Board include his years of experience in the biomed industry, his experience serving in management roles of various companies, as well as his knowledge and familiarity with gastroenterology.

Dr. Michael Berelowitz was appointed a director in June 2010 and Chairman of our Scientific Advisory Board in June 2011. From 2009 to 2010, Dr. Berelowitz served as Senior Vice President and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit at Pfizer, Inc. From 1996 to 2009, he served in various other roles at Pfizer, Inc., beginning as a Medical Director in the Diabetes Clinical Research team and then assuming positions of increasing responsibility until being appointed to his present role. Prior to that, Dr. Berelowitz spent a number of years in academia. Among his public activities, Dr. Berelowitz has served on the board of directors of the ADA, the Clinical Initiatives Committee of the Endocrine Society, and has chaired the Task Force on Research of the New York State Council on Diabetes. He has also served on several editorial boards, including the Journal of Clinical Endocrinology and Metabolism and Endocrinology, Reviews in Endocrine and Metabolic Disorders and Clinical Diabetes. Dr. Berelowitz has authored and co-authored more than 100 peer-reviewed journal articles and book chapters in the areas of pituitary growth hormone regulation, diabetes and metabolic disorders. Dr. Berelowitz holds adjunct appointments as Professor of Medicine in the Divisions of Endocrinology and Metabolism at SUNY – StonyBrook and Mt. Sinai School of Medicine in New York.



We believe that Dr. Berelowitz's qualifications to serve on our Board include his years of experience in management roles in the pharmaceuticals industry, as well as his vast skill and expertise in the fields of endocrinology and diabetes.

Mr. Gerald Ostrov was appointed a director in September 2012. Mr. Ostrov currently serves on the board of directors of Orasure Technologies Inc., a Nasdaq listed company which develops, manufactures, markets and sells oral fluid diagnostic products and specimen collection devices, is a founder and a board of directors member of Adlens Beacon, a privately held company developing self adjustable reading glasses, serves as a board of directors member of the Robert Wood Johnson University Hospital Foundation and serves on the Johnson & Johnson Corporate Contributions Committee. From 2008 to 2010, Mr. Ostrov served as Chairman and Chief Executive Officer of Bausch & Lomb Incorporated, where he helped to stabilize and restructure the business following its privatization. From 1998 to 2006, Mr. Ostrov acted as Company Group Chairman for Johnson & Johnson's Worldwide Vision Care businesses. Mr. Ostrov began his career with Johnson & Johnson's Health Care Division in 1976. In 1982, he left Johnson & Johnson to become Vice President of Marketing for Ciba-Geigy's Consumer Pharmaceuticals Company, where he was named President of Ciba Consumer Pharmaceuticals in 1985 and served in that capacity until rejoining Johnson & Johnson in 1991 as President of the corporation's Personal Products Company. Mr. Ostrov holds a Bachelor of Science degree with distinction in Industrial Engineering and Operations Research from Cornell University and holds an M.B.A. from Harvard University.

We believe that Mr. Ostrov's qualifications to serve on our Board include his years of experience in management roles in the pharmaceuticals industry, as well as his experience serving as a director of many entities.

Ms. Yifat Zommer was appointed as Chief Financial Officer, Treasurer and Secretary in April 2009. From April 2007 to October 2008, Ms. Zommer served as Chief Financial Officer of Witech Communications Ltd., a subsidiary of IIS Intelligence Information Systems Ltd., a company operating in the field of video transmission using wireless communications. From April 2006 to April 2007, Ms. Zommer acted as Chief Financial Officer for CTWARE Ltd., a telecommunication company. Prior to that she was an audit manager in Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, where she served for five years. Ms. Zommer holds a Bachelor of Accounting and Economics degree from the Hebrew University, a Business Administration degree (MBA) from Tel-Aviv University and a Masters degree in Law (LL.M.) from Bar-Ilan University, Israel. Ms. Zommer is a certified public accountant in Israel.

#### Board of Directors

There are no agreements with respect to the election of directors. Each director is elected for a period of one year at our annual meeting of stockholders and serves until the next such meeting and until his or her successor is duly elected. The Board may also appoint additional directors up to a maximum of fifteen directors. A director so chosen or appointed will hold office until the next annual meeting of stockholders. The Board has determined that Leonard Sank, Harold Jacob, Michael Berelowitz and Gerald Ostrov are independent as defined under the rules promulgated by Nasdaq.

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 year ended August 31, 2012, our Board held four meetings and took actions by written consent on five occasions. No incumbent director of the meeting attended fewer than 75% of the aggregate of: (i) the total number of meetings of the Board (during the period for which such director served as a director); and (ii) the total number of meetings held by all committees of the Board on which such director served (during the period for which such director served on such committees). Board members are encouraged to attend our annual meetings of stockholders. At the annual meeting of stockholders held on July 24, 2012, three Board members were present.

#### Committees

##### Audit Committee and Audit Committee Financial Expert

The members of our Audit Committee are Leonard Sank, Michael Berelowitz and Gerald Ostrov. Our Board has determined that Gerald Ostrov 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 charter that was approved by our Board on September 28, 2012. The primary responsibilities of our Audit Committee include:

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

##### Compensation Committee

The members of our Compensation Committee are Leonard Sank, Michael Berelowitz and Gerald Ostrov. 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 was approved by our Board on September 28, 2012. The primary responsibilities of our Compensation Committee include:

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



- Periodically reviewing and making recommendations to our Board with respect to director compensation.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Based solely upon a review of Forms 3, 4 and 5, and amendments thereto, furnished to us during fiscal year 2012, we believe that during fiscal year 2012, 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 as follows:

Dr. Miriam Kidron, our Chief Medical and Technology Officer and a director, failed to timely file a Form 4 reporting her August 14, 2007 grant of a warrant to purchase up to 3,361,360 shares of our common stock, as well as a Form 4 reporting the August 8, 2012 amendment of such warrant, extending the expiration of such warrant from August 14, 2012 to August 6, 2014. Dr. Kidron filed a Form 4 with the SEC reporting such transactions on November 23, 2012.

Leonard Sank, a director, failed to timely file a Form 4 reporting his August 22, 2012 acquisition of 270,270 shares of our common stock and a warrant to purchase 135,135 shares of our common stock in connection with one of our 2012 private placements. Mr. Sank filed a Form 4 reporting this transaction on November 6, 2012.

Dr. Harold Jacob, a director, failed to report ownership of 10,000 shares of our common stock in his initial statement of beneficial ownership on Form 3 filed with the SEC on September 8, 2008. Dr. Jacob filed a Form 3/A with the SEC reporting such ownership on November 30, 2012.

#### 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](http://www.oramed.com).

#### ITEM 11. EXECUTIVE COMPENSATION.

##### Summary Compensation Table

The following table sets forth the compensation earned during the fiscal years ended August 31, 2012 and 2011 by our President and Chief Executive Officer, our Chief Medical and Technology Officer and our Chief Financial Officer, or the Named Executive Officers:

Name and Principal Position	Year (1)	Salary	Option Awards	All Other Compensation	Total (\$)
		(\$) (7)	(\$) (2)	(\$) (3) (7)	
Nadav Kidron President and CEO and director (4)	2012	159,136	88,927	17,989	266,052
	2011	171,167	163,304	28,213	362,684
Miriam Kidron Chief Medical and Technology Officer and director (5)(6)	2012	159,136	88,927	13,200	261,263
	2011	172,172	163,304	13,581	349,057
Yifat Zommer CFO, Treasurer and Secretary	2012	58,686	32,915	29,719	121,320
	2011	85,700	46,162	32,034	163,896



- (1) The information is provided for each fiscal year, which begins on September 1 and ends on August 31.
- (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 for fiscal years ended August 31, 2012 and 2011 are set forth in Note 10 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our Named Executive Officers will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.
- (3) See “All Other Compensation Table” below.
- (4) Mr. Kidron receives compensation from Oramed Ltd. through KNRV, Ltd., an Israeli entity owned by Mr. Kidron, or KNRV. See “—Employment and Consulting Agreements” below.
- (5) Dr. Kidron receives compensation from Oramed Ltd. through KNRV. See “—Employment and Consulting Agreements” below.
- (6) See “Item 13. Certain Relationships and Related Transactions, and Director Independence” for a description of management fees received by Dr. Kidron from Hadasit.
- (7) Amounts paid for Salary and All Other Compensation were originally denominated in NIS and were translated into U.S. Dollars at the then current exchange rate for each payment.

## All Other Compensation Table

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

Name	Year	Automobile-Related Expenses (\$)	Manager’s Insurance* (\$)	Education Fund* (\$)	Total (\$)
Nadav Kidron	2012	17,989	--	--	17,989
	2011	21,044	--	--	21,044
Miriam Kidron	2012	13,200	--	--	13,200
	2011	13,581	--	--	13,581
Yifat Zommer	2012	12,976	11,024	5,719	29,719
	2011	21,017	7,169	3,849	32,035

\* 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.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning stock options and stock awards held by the Named Executive Officers as of August 31, 2012.

Name	Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	
Nadav Kidron	864,000 (1)	-	0.54	05/07/18	
	864,000 (3)	-	0.49	04/20/20	
	288,000 (4)	576,000 (4)	0.34	08/08/22	
Miriam Kidron	864,000 (1)	-	0.54	05/07/18	
	864,000 (3)	-	0.49	04/20/20	
	288,000 (4)	576,000 (4)	0.34	08/08/22	
Yifat Zommer	266,666 (2)	133,334 (2)	0.47	10/19/19	
	21,000 (5)	588,000 (5)	0.34	08/08/22	

(1) On May 7, 2008, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$0.54 per share; 144,000 of such options vested immediately on the date of grant and the remainder vested in twenty equal monthly installments, commencing on June 30, 2008. The options have an expiration date of May 7, 2018.

- (2) On June 3, 2009, 400,000 options were granted to Yifat Zommer under the 2008 Plan at an exercise price of \$0.47 per share; the options vest in three equal annual installments, commencing October 19, 2010, and expire on October 19, 2019.
- (3) On April 21, 2010, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$0.49 per share; 108,000 of such options vested immediately on the date of grant and the remainder vested in twenty-one equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.
- (4) On August 8, 2012, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Plan at an exercise price of \$0.34 per share; 252,000 of such options vested immediately on the date of grant and the remainder vests in seventeen equal monthly installments, commencing on August 31, 2012. The options have an expiration date of August 8, 2022.
- (5) On August 8, 2012, 609,000 options were granted to Yifat Zommer under the 2008 Plan at an exercise price of \$0.34 per share; the options vest in twenty-nine equal monthly installments, commencing on August 31, 2012, and expire on August 8, 2022.

## Employment and Consulting Agreements

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

The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNRY (i) will be paid, under each of the Consulting Agreements, in a gross amount of NIS 50,400 per month and (ii) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements. Pursuant to the Consulting Agreements, KNRY, Nadav Kidron and Miriam Kidron each agree that during the term of the Consulting Agreements and for a 12 month period thereafter, none of them will compete with Oramed Ltd. nor solicit employees of Oramed Ltd.

On March 11, 2011, we entered into new indemnification agreements with our directors and executive officers, pursuant to which we agreed to indemnify each director and executive officer for any liability he or she may incur by reason of the fact that he or she serves as our director or executive officer, to the maximum extent permitted by Delaware law.

We, through Oramed Ltd., have entered into an employment agreement with Yifat Zommer as of April 19, 2009, pursuant to which Ms. Zommer was appointed as Chief Financial Officer, Treasurer and Secretary of the Company and Oramed Ltd. In accordance with the employment agreement, as amended, Ms. Zommer's current gross monthly salary is NIS 24,200.

## Director Compensation

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. Effective June 1, 2010, each independent director is entitled to receive as remuneration for his or her service as a member of the Board a sum equal to \$10,000 per annum, to be paid quarterly and shortly after the close of each quarter. Our executive officers did not receive additional compensation for service as directors. The Board may award special remuneration to any director undertaking any special services on behalf of us other than services ordinarily required of a director.

On June 22, 2011, we appointed one of our directors, Michael Berelowitz, to serve as the Chairman of our Scientific Advisory Board. In this role, Dr. Berelowitz will be actively involved in our scientific decisions, clinical strategy, and partnership negotiations. Dr. Berelwoitz will be paid a fee of \$300 per hour, up to \$1,500 per day, as compensation for serving in this position.

Other than as indicated in this Annual Report on Form 10-K, no director received and/or accrued any compensation for his or her services as a director, including committee participation and/or special assignments, during the year ended August 31, 2012.

The following table sets forth director compensation for the year ended August 31, 2012.

Name of Director	Fees			Total
	Earned or Paid in Cash (\$)	Option Awards (6) (\$)	All Other Compensation (\$)	
Nadav Kidron (1)	-	-	-	-
Miriam Kidron (1)	-	-	-	-
Leonard Sank (2) (4)	10,000	11,106	-	21,106
Harold Jacob (2) (4)	10,000	11,106	-	21,106
Michael Berelowitz (3) (5)	10,000	32,528	4,500	47,028
Gerald Ostrov (7)	-	-	-	-

- (1) Please refer to the summary compensation table for executive compensation with respect to the named individual.
- (2) On January 11, 2009, 300,000 options were granted to each of Leonard Sank and Harold Jacob under the 2008 Plan at an exercise price of \$0.43 per share. The options vested in three equal annual installments, commencing January 1, 2010, and expire on January 10, 2019.
- (3) On July 8, 2010, 300,000 options were granted to Michael Berelowitz under the 2008 Plan at an exercise price of \$0.48 per share. The options vest in three equal annual installments, commencing July 8, 2011, and expire on July 7, 2020.
- (4) On August 8, 2012, 240,000 options were granted to each of Leonard Sank and Harold Jacob under the 2008 Plan at an exercise price of \$0.34 per share. The options vest in two equal annual installments, commencing January 1, 2013, and expire on August 8, 2022.
- (5) On August 8, 2012, 40,000 options were granted to Michael Berelowitz under the 2008 Plan at an exercise price of \$0.34 per share. The options vest in two equal annual installments, commencing January 1, 2013, and expire on August 8, 2022.
- (6) 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 for the fiscal year ended August 31, 2012 are set forth in Note 10 to our audited consolidated financial statements included in this Annual Report on Form 10-K. Our directors will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.
- (7) Mr. Ostrov was appointed as a director on September 24, 2012.

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

### Stock Option Plans

#### 2006 Stock Option Plan

On October 15, 2006, our Board adopted the 2006 Plan in order to attract and retain quality personnel. Under the 2006 Plan, 3,000,000 shares have been reserved for the grant of options by the Board. In addition, under the terms of the 2006 Plan, options that have expired or been terminated for any reason prior to being exercised may be reissued.



On August 8, 2012, our Board cancelled the 2006 Plan and will no longer issue any securities pursuant to the 2006 Plan, and reallocated the pool of 3,000,000 shares of the Company's common stock that were reserved for issuance under the 2006 Plan and transferred such shares to the 2008 Plan. As of such date, there were no longer any outstanding securities under the 2006 Plan.

#### 2008 Stock Incentive Plan

On May 5, 2008, our Board adopted the 2008 Plan in order to attract and retain quality personnel. The 2008 Plan provides for the grant of stock options, restricted stock, restricted stock units and stock appreciation rights, collectively referred to as "awards." Stock options granted under the 2008 Plan may be either incentive stock options under the provisions of Section 422 of the Internal Revenue Code, or non-qualified stock options. Incentive stock options may be granted only to our employees or to employees of our parent or subsidiary. Awards other than incentive stock options may be granted to employees, directors and consultants. Under the 2008 Plan, 8,000,000 shares were reserved for the grant of awards, which may be issued at the discretion of our Board from time to time.

On August 8, 2012, our Board reserved an additional 4,000,000 shares of the Company's common stock for the grant of awards under the 2008 Plan, resulting in a total of 12,000,000 shares of the Company's common stock now being reserved for the issuance of awards under the 2008 Plan, including the shares reallocated to the 2008 Plan from the 2006 Plan.

As of August 31, 2012, options with respect to 9,964,200 shares have been granted under the 2008 Plan, of which 1,034,000 have been forfeited and 100,000 have expired.

#### Other

On August 14, 2007, we granted Dr. Miriam Kidron a warrant to purchase up to 3,361,360 shares at an exercise price of \$0.001 per share; the warrant vested immediately and had an expiration date of August 14, 2012. On August 8, 2012, our Board resolved to extend the term of Dr. Kidron's warrant until August 6, 2014. The warrant is not governed by either of the plans detailed above.

The following table sets forth additional information with respect to our equity compensation plans as of August 31, 2012:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weight-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	--	--	--
Equity compensation plans not approved by security holders	12,923,560	\$ 0.26	3,419,800
Total	12,923,560	\$ 0.26	3,419,800





## 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 December 6, 2012 by: (i) each person who is known by us to own beneficially more than 5% of our common stock; (ii) each director; (iii) each of our Named Executive Officers listed above under “Summary Compensation Table”; and (iv) all of our directors and executive officers as a group. On such date, we had 86,505,020 shares of common stock outstanding.

As used in the table below and elsewhere in this Annual Report on Form 10-K, the term “beneficial ownership” with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following December 6, 2012. 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, 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.

Name and Address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Nadav Kidron †‡ 12 Eliezer Hagadol St. Jerusalem, Israel	12,567,735 (1)	14.2%
Miriam Kidron †‡ 2 Elza St. Jerusalem, Israel	5,557,360 (2)	6.0%
Leonard Sank † 3 Blair Rd Camps Bay Cape Town, South Africa	6,318,050 (3)	7.2%
Harold Jacob † Haadmur Mebuyon 26 Jerusalem, Israel	430,000 (4)	*
Michael Berelowitz † 415 East 37th Street New York, NY, USA	220,000 (5)	*
Yifat Zommer ‡ P.O. Box 39098, Jerusalem, Israel	526,000 (6)	*



Regals Fund LP 767 Fifth Ave. New York, NY, USA	15,814,947 (7)	17.0%
Zeev Bronfeld 6 Uri St. Tel-Aviv, Israel	8,366,212 (8)	9.6%
All current executive officers and directors, as a group (seven persons)	25,619,145 (9)	26.6%

\* Less than 1%

† Indicates Director

‡ Indicates Executive Officer

- (1) Includes 2,196,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (2) Includes 3,361,360 shares of common stock issuable upon the exercise of an outstanding warrant and 2,196,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (3) Includes: (i) 2,763,055 shares of common stock and warrants to purchase 202,703 shares of common stock held by Mr. Sank, (ii) 937,500 shares of common stock and a warrant to purchase 328,125 shares of common stock held by Mr. Sank's wife, (iii) 420,000 shares of common stock issuable upon the exercise of outstanding stock options, and (iv) 1,666,667 shares of common stock owned by a company wholly owned by a trust of which Mr. Sank is a trustee. Mr. Sank disclaims beneficial ownership of the securities referenced in (ii) and (iv) above. The foregoing is based on Form 4's filed by Mr. Sank on January 13, 2009, October 6, 2011, August 9, 2012 and November 6, 2012, and information available to the Company.
- (4) Includes 10,000 shares of common stock indirectly acquired through a corporation wholly-owned by Mr. Jacob, and 420,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (5) Includes 220,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (6) Includes 526,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (7) Include warrants to purchase 6,687,277 shares of common stock. Regals Capital Management LP is the investment manager of Regals Fund LP, the owner of record of these shares of common stock. Mr. David M. Slager is the managing member of the general partner of Regals Capital Management LP. All investment decisions are made by Mr. Slager, and thus the power to vote or direct the votes of these shares of common stock, as well as the power to dispose or direct the disposition of such shares of common stock is held by Mr. Slager through Regals Capital Management LP. The foregoing is based on a Schedule 13G/A and Form 3 filed September 6, 2012, and on a Form 4 filed November 6, 2012, each of which was filed jointly by Regals Fund LP, Regals Capital Management LP and Mr. Slager, and on subsequent information available to the Company.
- (8) Includes 2,390,057 shares of common stock and warrants to purchase 273,438 shares of common stock held by D.N.A. Mr. Bronfeld and Mr. Meni Mor are parties to a voting agreement relating to their joint holdings in D.N.A, which as of December 31, 2011, represented approximately 41.2% of D.N.A's outstanding share capital on an actual basis, as reported by D.N.A to the Israel Securities Authority. As a result, Mr. Bronfeld may be deemed a beneficial owner of, and to share the power to vote and dispose of our securities held by D.N.A. Mr. Bronfeld has disclaimed beneficial ownership of any of our

securities held by D.N.A. The foregoing is based on a Schedule 13G/A filed by Mr. Bronfeld on January 19, 2012 and on subsequent information available to the Company.

- (9) Includes 9,870,188 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced persons and the exercise of outstanding stock options.

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

Except as otherwise indicated below, during fiscal years 2012 and 2011, 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 exceeds 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 February 17, 2006, we entered into an agreement with Hadasit, or the First Agreement, to retain Hadasit to provide consulting and clinical trial services for a total consideration of \$200,000, and to acquire the provisional patent related to our research and development of an orally ingestible insulin pill to be used for the treatment of individuals with diabetes. On January 7, 2009, we entered into a second agreement with Hadasit which replaced in its entirety the First Agreement and confirms that Hadasit has conveyed, transferred and assigned all of its ownership rights in the patents acquired under the First Agreement and certain other patents filed by us after the First Agreement as a result of the collaboration between us and Hadasit, and that Hadasit acknowledges and agrees that the 4,141,532 shares of our common stock that were issued to Hadasit on February 17, 2006 constitute the sole and complete compensation for said sale. On July 8, 2009, we entered into a third agreement with Hadasit to retain consulting and clinical trial services from Hadasit for a total consideration of \$400,000, with \$200,000 of this amount having first been agreed to in the terms of the First Agreement. The clinical trials conducted by Hadasit are managed by Dr. Miriam Kidron, our Chief Medical and Technology Officer and one of our directors, through a research fund account at Hadasit in Dr. Kidron's name. The fees paid by us to Hadasit are deposited into such Hadasit research account. Pursuant to the general policy of Hadasit with respect to its research funds, Dr. Kidron is entitled to receive a management fee in the amount of 10% of all the funds deposited into this research fund account, including the funds paid by us under the aforementioned agreements. Since March 2006, only the funds paid by us have been deposited in this account, of which, \$10,214 has been paid to Dr. Kidron. On September 11, 2011, we entered into the Fourth Agreement to facilitate clinical trials and provide other services. According to this agreement, Hadasit will be entitled to total consideration of \$200,000 to be paid in accordance with the actual progress of the study, none of which was recognized or paid through August 31, 2012. Hadasit will deduct 16.7% of the payments that will be received from us as overhead. All other terms and conditions of this agreement are substantially similar to those of the previous Hadasit agreements.

On June 1, 2010, Oramed Ltd. entered into a joint venture agreement with D.N.A for the establishment of Entera, according to which D.N.A invested \$600,000, Oramed Ltd. entered into a patent license agreement with Entera, and Entera was owned in equal parts by Oramed Ltd. and D.N.A. On February 22, 2011, Oramed Ltd. entered into a share purchase agreement with D.N.A for the sale of 47% of Entera's outstanding share capital on an undiluted basis, for total consideration of approximately \$1,032,000 to be paid in D.N.A shares and in a promissory note. As part of the transaction, Oramed Ltd. entered into a patent transfer agreement with Entera that replaced the original patent license agreement. These two transactions closed on March 31, 2011. In addition, on the closing date, D.N.A participated in our private placement, on the same investment terms as other investors at that time, for which D.N.A received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share for consideration of \$250,000. We currently own 3% of the outstanding shares of Entera. Mr. Zeev Bronfeld, who is one of D.N.A's directors and controlling shareholders, holds approximately 9.6% of our outstanding common stock (see "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related

Stockholder Matters”). Mr. Nadav Kidron, our President, Chief Executive Officer and one of our directors, is also a director of Entera.

On October 30 2012, we entered into a Securities Purchase Agreement with D.N.A, according to which, we issued to D.N.A 2,390,057 shares of our common stock, valued at such time at approximately \$628,630, in consideration for a warrant to purchase up to 21,637,611 ordinary shares of D.N.A at no additional cost. D.N.A. has filed an application for the approval of the Tel Aviv Stock Exchange Board of Directors to list the ordinary shares of D.N.A issuable upon exercise of the warrant. We plan to exercise the warrant if and when such approval is received. Should we exercise this warrant, we would hold approximately 14.5% of D.N.A's outstanding ordinary shares, including the D.N.A ordinary shares we received in March 2011 as further discussed in "Item 1. Business—Description of Business—Out-Licensed Technology."

On November 29, 2012, we entered into the Agreement with Regals in connection with the Warrants. Pursuant to the Agreement, we and Regals agreed to amend the Warrants (and to prepare and execute amendments to the Warrants setting forth such terms as soon as reasonably practicable) to provide that the anti-dilution protection of the Warrants shall be deleted in its entirety. In addition, as to the warrants issued in August and November 2012, the parties agreed that the exercise price shall be reduced to \$0.3138 per share, the current exercise price per share of the warrants originally issued to Regals in January 2011. On that day, we also issued to Regals the New Warrant pursuant to which Regals shall have the right to purchase up to 1,647,722 shares of our common stock over a period of four years at an exercise price of \$0.60 per share.

In connection with the New Warrant, Nadav Kidron, our President, Chief Executive Officer and a director, in his personal capacity as one of our shareholders, undertook and agreed that following the execution and delivery of the Agreement, in the event that an adjustment pursuant to the anti-dilution protection of the Warrants (had they not been amended by the Agreement) would have been triggered and the number of shares of our common stock that Regals would have been able to purchase under the Warrants would have increased by an aggregate number in excess of 1,647,722 common shares, then Regals shall have the right to purchase from Mr. Kidron such number of shares of our common stock owned by Mr. Kidron equal to such excess, up to a maximum of 1,352,278 shares of our common stock at an exercise price of \$0.3138 per share. The foregoing right shall survive until the termination of the Warrants.

See "Item 11. Executive Compensation—Director Compensation" above for information as to one of our directors and the Chairman of our Scientific Advisory Board, Michael Berelowitz.

The Board has determined that Leonard Sank, Harold Jacob, Michael Berelowitz and Gerald Ostrov 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 years ended August 31, 2012 and 2011:

Summary:	2012	2011
Audit Fees(1)	\$ 102,240	\$ 100,390
Audit-Related Fees	-	-
Tax Fees(2)	7,500	-
All Other Fees	-	-
<b>Total Fees</b>	<b>\$ 109,740</b>	<b>\$ 100,390</b>

(1)



Amount represents fees paid for professional services for the audit of our consolidated annual financial statements and 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) Amount represents fees paid for consulting services to assist us with our implementation of FASB ASC Topic 740-10 (formerly FIN 48), "Income Taxes," relating to uncertain tax positions.

During the year ended August 31, 2012, we did not have an audit committee. As such, our three independent directors acted as our audit committee. No formal pre-approval process has been adopted. The Board established our Audit Committee on September 28, 2012.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Index to Financial Statements

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

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<u>Kesselman</u>	
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC</u>	
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CONSOLIDATED FINANCIAL STATEMENTS:	
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of  
Oramed Pharmaceuticals Inc.  
(A Development Stage Company)

We have audited the accompanying consolidated balance sheets of Oramed Pharmaceuticals Inc. (A Development Stage Company) and its subsidiary (the "Company") as of August 31, 2012 and 2011, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended and cumulatively, for the period from September 1, 2007 to August 31, 2012 (not separately presented herein). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We did not audit the cumulative totals of the Company for the period from April 12, 2002 (date of incorporation) to August 31, 2007, which totals reflect a deficit of \$4,478,933 accumulated during the development stage. Those cumulative totals were audited by other independent auditors, whose report, dated December 10, 2007, expressed an unqualified opinion on the cumulative amounts but included an emphasis of a matter. Our opinion, insofar as it relates to amounts included for that period is based on the report of the other independent auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based upon our audits and the report of the other independent auditors, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of August 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for the years then ended and cumulatively, for the period from September 1, 2007 to August 31, 2012 (not separately presented herein), in conformity with accounting principles generally accepted in the United States of America.

Tel Aviv, Israel  
December 11, 2012

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors  
Oramed Pharmaceuticals, Inc.  
(a development stage company)  
Jerusalem, Israel

We have audited the consolidated statements of expenses, changes in stockholders' deficit, and cash flows for the period from April 12, 2002 (Inception) through August 31, 2007. These financial statements are the responsibility of Oramed's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of its consolidated operations and its cash flows for the periods described in conformity with accounting principles generally accepted in the United States of America.

/s/ MALONE & BAILEY, PC  
www.malone-bailey.com  
Houston, Texas

December 10, 2007

ORAMED PHARMACEUTICALS INC.  
(A Development Stage Company)  
CONSOLIDATED BALANCE SHEETS

U.S. dollars

	August 31	
	2012	2011
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$4,430,740	\$1,513,365
Short term deposits (note 2)	454,381	1,801,400
Marketable securities (note 3)	200,311	384,565
Restricted cash (note 1o)	16,000	16,000
Accounts receivable - other (note 4)	87,691	542,891
Prepaid expenses	2,307	1,670
Related parties (note 16)	404	-
Grants receivable from the chief scientist	84,642	24,191
<b>T o t a l c u r r e n t a s s e t s</b>	<b>5,276,476</b>	<b>4,284,082</b>
<b>LONG TERM DEPOSITS AND INVESTMENT (note 9b)</b>	<b>8,867</b>	<b>10,186</b>
<b>AMOUNTS FUNDED IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT (note 8)</b>	<b>4,740</b>	<b>14,293</b>
<b>PROPERTY AND EQUIPMENT, NET (note 6)</b>	<b>4,768</b>	<b>17,376</b>
<b>T o t a l a s s e t s</b>	<b>\$5,294,851</b>	<b>\$4,325,937</b>
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses (note 12)	\$597,173	\$375,538
Related parties (note 16)	-	18,502
Account payable with former shareholder	47,252	47,252
<b>T o t a l c u r r e n t l i a b i l i t i e s</b>	<b>644,425</b>	<b>441,292</b>
<b>LONG TERM LIABILITIES:</b>		
Warrants (note 7)	637,182	-
Employee rights upon retirement (note 8)	6,959	22,675
Provision for uncertain tax position (note 15e)	228,272	138,054
	872,413	160,729
<b>COMMITMENTS (note 9)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$ 0.001 par value (200,000,000 authorized shares; 80,075,725 and 70,104,583 shares issued and outstanding as of August 31, 2012 and 2011, respectively)	80,075	70,104
Additional paid-in capital	21,589,715	18,201,111
Deficit accumulated during the development stage	(17,891,777)	(14,547,299)
<b>T o t a l s t o c k h o l d e r s ' e q u i t y</b>	<b>3,778,013</b>	<b>3,723,916</b>
<b>T o t a l l i a b i l i t i e s a n d s t o c k h o l d e r s ' e q u i t y</b>	<b>\$5,294,851</b>	<b>\$4,325,937</b>

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

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ORAMED PHARMACEUTICALS INC.  
(A Development Stage Company)  
CONSOLIDATED STATEMENTS OF OPERATIONS  
U.S. dollars

	Year ended August 31		Period from April 12, 2002 (inception) through August 31, 2012
	2012	2011	
RESEARCH AND DEVELOPMENT EXPENSES, NET (note 13)	\$1,680,845	\$1,159,309	\$9,532,694
IMPAIRMENT OF INVESTMENT	-	-	434,876
GENERAL AND ADMINISTRATIVE EXPENSES (note 14)	1,203,164	1,275,960	8,161,547
OPERATING LOSS	2,884,009	2,435,269	18,129,117
FINANCIAL INCOME	(13,126 )	(33,232 )	(207,158 )
GAIN ON SALE OF INVESTMENT	-	(1,033,004 )	(1,033,004 )
IMPAIRMENT OF AVAILABLE- FOR-SALE SECURITIES	184,254	197,412	381,666
FINANCIAL EXPENSES	199,123	18,780	380,380
LOSS BEFORE TAXES ON INCOME	3,254,260	1,585,225	17,651,001
TAXES ON INCOME (note 15)	90,218	(23,980 )	240,776
NET LOSS FOR THE PERIOD	\$3,344,478	\$1,561,245	\$17,891,777
BASIC AND DILUTED LOSS PER COMMON SHARE	\$(0.05 )	\$(0.02 )	
WEIGHTED AVERAGE NUMBER OF COMMON SHARES USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	70,605,814	64,999,026	

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

## ORAMED PHARMACEUTICALS INC.

(A development stage company)

## CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. dollars

	Common Stock Shares	Common Stock \$	Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity
BALANCE AS OF APRIL 12, 2002 (inception)	34,828,200	\$34,828	\$18,872	-	\$ 53,700
CHANGES DURING THE PERIOD FROM APRIL 12, 2002 THROUGH AUGUST 31, 2007 :					
SHARES CANCELLED	(19,800,000)	(19,800 )	19,800	-	-
SHARES ISSUED FOR INVESTMENT IN ISTI-NJ	1,144,410	1,144	433,732	-	434,876
SHARES ISSUED FOR OFFERING COSTS	1,752,941	1,753	(1,753 )	-	-
SHARES AND WARRANTS ISSUED FOR CASH—					
NET OF ISSUANCE EXPENSES	27,181,228	27,181	2,095,800	-	2,122,981
SHARES ISSUED FOR SERVICES	125,000	125	98,625	-	98,750
CONTRIBUTIONS TO PAID IN CAPITAL	-	-	18,991	-	18,991
STOCK BASED COMPENSATION RELATED TO					
OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	-	-	1,968,547	-	1,968,547
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	-	-	177,782	-	177,782
DISCOUNT ON CONVERTIBLE NOTE RELATED TO BENEFICIAL CONVERSION FEATURE	-	-	108,000	-	108,000
OTHER COMPREHENSIVE LOSS	-	-	-	(16 )	(16 )
IMPUTED INTEREST	-	-	8,437	-	8,437
NET LOSS	-	-	-	(4,478,917 )	(4,478,917 )
BALANCE AS OF AUGUST 31, 2007	45,231,779	45,231	4,946,833	(4,478,933 )	513,131
RECEIPTS ON ACCOUNT OF SHARES AND WARRANTS	-	-	6,061	-	6,061
SHARES ISSUED FOR CONVERSION OF					
CONVERTIBLE NOTE	550,000	550	274,450	-	275,000
SHARES AND WARRANTS ISSUED FOR CASH – NET OF ISSUANCE EXPENSES	10,178,002	10,178	5,774,622	-	5,784,800



SHARES ISSUED FOR SERVICES	293,025	293	115,817	-	116,110
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	-	-	459,467	-	459,467
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	-	-	203,982	-	203,982
IMPUTED INTEREST	-	-	3,780	-	3,780
NET LOSS	-	-	-	(2,769,271 )	(2,769,271 )
BALANCE AS OF AUGUST 31, 2008	56,252,806	56,252	11,785,012	(7,248,204 )	4,593,060

ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
U.S. dollars

	Common Stock		Additional	Deficit	Total
	Shares	\$	paid-in	accumulated	stockholders'
			capital	during the	equity
				development	
				stage	
BALANCE AS OF AUGUST 31, 2008	56,252,806	56,252	11,785,012	(7,248,204 )	4,593,060
SHARES ISSUED FOR SERVICES RENDERED	203,904	204	152,724	-	152,928
SHARES TO BE ISSUED FOR SERVICES RENDERED	-	-	203,699	-	203,699
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	-	-	436,025	-	436,025
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	-	-	117,174	-	117,174
IMPUTED INTEREST	-	-	3,780	-	3,780
NET LOSS	-	-	-	(2,760,474 )	(2,760,474 )
BALANCE AS OF AUGUST 31, 2009	56,456,710	\$56,456	\$12,698,414	\$(10,008,678)	\$2,746,192
SHARES ISSUED FOR SERVICES RENDERED	1,108,611	1,109	248,741	-	249,850
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	-	-	690,882	-	690,882
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	-	-	116,944	-	116,944
IMPUTED INTEREST	-	-	3,780	-	3,780
NET LOSS	-	-	-	(2,977,376)	(2,977,376)
BALANCE AS OF AUGUST 31, 2010	57,565,321	\$57,565	\$13,758,761	\$(12,986,054)	\$830,272
SHARES ISSUED FOR SERVICES RENDERED	730,636	731	226,838	-	227,569
SHARES AND WARRANTS ISSUED FOR CASH*	11,808,626	11,808	3,682,404	-	3,694,212
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	-	-	502,593	-	502,593
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	-	-	26,733	-	26,733
IMPUTED INTEREST	-	-	3,782	-	3,782
NET LOSS	-	-	-	(1,561,245 )	(1,561,245 )
BALANCE AS OF AUGUST 31, 2011	70,104,583	70,104	18,201,111	(14,547,299)	3,723,916
SHARES ISSUED FOR SERVICES	349,000	349	107,511	-	107,860

SHARES AND WARRANTS ISSUED FOR CASH, INCLUDING RECLASSIFICATION OF WARRANTS	9,622,142	9,622	2,984,842	-	2,944,464
SHARES AND WARRANTS TO BE ISSUED FOR CASH	-	-	25,093	-	25,093
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	-	-	200,866	-	200,866
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	-	-	70,292	-	70,292
NET LOSS	-	-	-	(3,344,478 )	(3,344,478 )
BALANCE AS OF AUGUST 31, 2012	80,075,725	\$80,075	\$21,589,715	\$(17,891,777)	\$ 3,778,013

\* Including 196,750 issued as finders' fee. See also note 10a.

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

ORAMED PHARMACEUTICALS INC.  
(A Development Stage Company)  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
U.S. dollars

	Year ended August 31		Period from April 12, 2002 (inception date) through August 31, 2012
	2012	2011	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(3,344,478)	\$(1,561,245)	\$(17,891,777)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	14,737	28,303	120,844
Amortization of debt discount	-	-	108,000
Exchange differences	62,494	(30,791 )	31,037
Stock based compensation	271,158	529,326	4,971,287
Common stock issued for services	107,860	227,569	1,155,956
Gain on sale of investment	-	(1,033,004)	(1,033,004 )
Impairment of investments	-	-	434,876
Impairment of available for sale securities	184,254	197,412	381,666
Imputed interest	-	3,782	23,559
Changes in fair value of warrant liabilities	142,704	-	142,704
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(31,199 )	(36,105 )	(160,159 )
Restricted cash	-	8	(16,000 )
Accounts payable and accrued expenses	203,133	(17,290 )	597,173
Liability for employee rights upon retirement	(2,489 )	22,675	20,186
Provision for uncertain tax position	90,218	(36,484 )	228,272
Total net cash used in operating activities	(2,301,608)	(1,705,844)	(10,885,380)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(2,129 )	(2,180 )	(125,612 )
Purchase of short term deposits	(475,353 )	(1,700,382)	(5,903,735 )
Proceeds from sale of short term deposits	1,800,000	-	5,428,000
Proceeds from sale of investment	450,000	-	450,000
Funds in respect of employee rights upon retirement	(3,620 )	(3,275 )	(6,895 )
Lease deposits	-	2,407	(7,509 )
Total net cash provided by (used in) investing activities	1,768,898	(1,703,430)	(165,751 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from sales of common stocks and warrants - net of issuance expenses	3,488,942	3,694,212	15,144,635
Receipts on account of shares issuances	-	-	6,061
Proceeds from convertible notes	-	-	275,000
Proceeds from short term note payable	-	-	120,000
Payments of short term note payable	-	-	(120,000 )
Shareholder advances	-	-	66,243

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Net cash provided by financing activities	3,488,942	3,694,212	15,491,939
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(38,857 )	28,789	(10,068 )
INCREASE IN CASH AND CASH EQUIVALENTS	2,917,375	313,727	4,430,740
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	1,513,365	1,199,638	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$4,430,740	\$1,513,365	\$4,430,740
Material non cash investing and financing activities:			
Discount on convertible note related to beneficial conversion feature			\$108,000
Shares and warrants issued as offering costs		\$76,026	\$77,779
Contribution to paid in capital			\$18,991
Shares and warrants to be issued for cash	\$25,093	-	\$25,093
Changes to amounts funded in respect of employee rights upon retirement and long term liability to Employee rights upon retirement	\$13,227	-	\$13,227

As disclosed in note 5, in the year ended August 31, 2011, the Subsidiary sold 47% of Entera's shares for non-cash proceeds of net \$1,031,977.

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

ORAMED PHARMACEUTICALS INC.  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General

Oramed Pharmaceuticals Inc. (the "Company") was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd ("Hadasit") (the "First Agreement") to acquire the provisional patent related to orally ingestible insulin pill to be used for the treatment of individuals with diabetes, see also note 9a.

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

The Company has been in the development stage since its formation and has not yet generated any revenues from its operations.

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd., which is engaged in research and development. Unless the context indicates otherwise, the term "Group" refers to Oramed Pharmaceuticals Inc. and its Israeli subsidiary, Oramed Ltd. (the "Subsidiary"), (together with the Company, "the Group").

The Group is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with the ASC Topic 915 "Development Stage Entities".

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

Based on its current cash resources and commitments, and cash received in private offerings in 2012 (see notes 10g and 17b), 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 it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing during the next 12 months.

ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Accounting principles

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

c. Use of estimates in the preparation of financial statements

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

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to stock based compensation, valuation and impairment of marketable securities and valuation of tax exposure.

d. Functional currency

The currency of the primary economic environment in which the operations of the Group are conducted is the U.S. dollar (" \$" or "dollar").

Most of the group's operating expenses are incurred in dollars. Thus, the functional currency of the Group is the dollar.

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

e. Principles of consolidation

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

ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

f. Property and equipment

Property and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the assets.

Annual rates of depreciation are as follows:

	%
Computers and peripheral equipment	33
Office furniture and equipment	15-33

Leasehold improvements are amortized over the term of the lease which is shorter than the estimated useful life of the improvements.

g. 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.

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

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

2. Uncertainty in income tax

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



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ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

h. Research and development, net

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, employee benefits, costs of registered patents materials, 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 out sources a substantial portion of its clinical trial activities, utilizing external entities such as Contract Research Organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, clinical trial costs are expensed immediately.

Grants received from the OCS and Bio-Jerusalem are recognized as grant income when the grants become receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grants are deducted from the related research and development expenses as the costs are incurred and are presented in R&D expenses, net. See also notes 9j and 9k.

i. 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.

j. Comprehensive loss

The Company has no other comprehensive loss components other than net loss for the fiscal years of 2012 and 2011.

k. Loss per common share

Basic and diluted net loss per common share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding and shares relating to receipts on account of shares in equity during the period. Outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The total number of common stock options and warrants excluded from the calculation of diluted net loss was 21,937,116 for the year ended August 31, 2012 (15,200,044 for the year ended August 31, 2011).

ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Impairment in value of long-lived assets

The Company reviews long-lived assets, to be held and used, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In the event the sum of the expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, an impairment loss would be recognized, and the assets are written down to their estimated fair values.

m. Stock based compensation

Equity awards granted to employees are accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. The Company estimated forfeitures based on historical experience and anticipated future conditions.

The Company elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach. When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

n. Warrants issued as part of capital raisings that are classified as a liability

Warrants that entitle the holder to down-round protection (through ratchet and anti-dilution provisions) are classified as liabilities in the statement of financial position.

The liability is measured both initially and in subsequent periods in fair value, with changes in fair value charged to finance expenses, net. See note 7.

ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

o. Fair value measurement:

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

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of August 31, 2012 the assets or liabilities measured at fair value comprise of:

- available for sale securities (level 1).
- warrants (level 3).

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent.

In order to secure the fulfillment of the Company's obligations under the derivatives agreements, the Company has placed a restricted deposit with the bank in an amount of \$16,000.

Available-for-sale securities are reported at fair value with unrealized gains and losses, net of related tax, recorded as a separate component of other comprehensive income in equity until realized. Unrealized losses that are considered to be other-than-temporary are charged to statement of operations as an impairment charge and are included in the consolidated statement of operations under impairment of available-for-sale securities.

The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost, and the Company's ability and intent to hold the investment. Realized gains and losses on sales of the securities are included in the consolidated statement of operations as financial income or expenses.

p. Concentration of credit risks

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



## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

## q. Newly issued and recently adopted accounting pronouncements:

1. In May 2011, the Financial Accounting Standard Board ("FASB") issued an accounting update that amends ASC No. 820, "Fair Value Measurement" regarding fair value measurements and disclosure requirements. The amendments are effective during interim and annual periods beginning after December 15, 2011 and are to be applied prospectively. The Company adopted the accounting update beginning in the third quarter of fiscal year 2012. As applicable to the Company, the adoption of the new guidance did not have any material impact on the consolidated financial statements.

2. In June 2011, the FASB issued an update to ASC No. 220, "Presentation of Comprehensive Income," which eliminates the option to present other comprehensive income and its components in the statement of shareholders' equity. The Company can elect to present the items of net income and other comprehensive income in a single continuous statement of comprehensive income or in two separate, but consecutive, statements. Under either method the statement would need to be presented with equal prominence as the other primary financial statements. The amended guidance, which must be applied retroactively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with earlier adoption permitted. In December 2011, the FASB issued another update on the topic, which deferred the effective date pertaining only to the presentation of reclassification adjustments on the face of the financial statements. The accounting update will be applicable to the Company beginning in the first quarter of fiscal year 2013. The adoption of the new guidance is not expected to have a material impact on the consolidated financial statements.

## r. Reclassifications

Certain figures in respect of prior years have been reclassified to conform to the current year presentation.

## NOTE 2 - SHORT TERM INVESTMENTS:

Amount represents bank deposits with an original maturity of more than three months but less than one year.

		August 31	
	2012		2011
	Annual interest rate	Amount	Annual interest rate Amount
Dollars deposits	0.85%	\$ 260,371	0.7-0.86% \$ 1,801,400
NIS deposits	1.93-1.97%	194,010	-
		\$ 454,381	\$ 1,801,400

## ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 3 - MARKETABLE SECURITIES:

Marketable securities consist wholly of equity securities of D.N.A Biomedical Solutions Ltd. which were received in March 2011 as part of the consideration for selling the Company's equity method investee Entera. Those securities are classified as available-for-sale and are recorded at fair value. The D.N.A Shares are listed on the Tel Aviv Stock Exchange ("TASE") and their tradability was restricted for a period of 6 months from the closing date of the transaction according to TASE policy with regards to private placements. Until September 30, 2011, the fair value of the restricted securities was measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market. As of the first quarter of 2011, the securities are not restricted and the fair value of the securities is measured based on the quoted prices of the securities on an active market.

Financial assets carried at fair value as of August 31, 2012 and August 31, 2011 are classified in the tables below in one of the three categories described above:

	Level 1	Level 3	Total
Marketable securities:			
August 31, 2012	\$ 200,311	-	\$ 200,311
August 31, 2011	-	\$ 384,565	\$ 384,565

The following table summarizes the activity for those financial assets where fair value measurements are estimated utilizing Level 3 inputs:

	August 31	
	2012	2011
Carrying value at the beginning of the period	\$ 384,565	\$ -
Additions - see note 5	-	581,977
Reclassification to level 1	(384,565 )	-
Impairment of available-for-sale securities - financial expenses	-	(197,412 )
Carrying value at the end of the period	\$ -	\$ 384,565

As of August 31, 2012, the carrying amount of cash and cash equivalents, accounts receivables, other current assets and accounts payables and accrued expenses approximates their fair values due to the short-term maturities of these instruments.

The fair value of long-term deposits also approximates their carrying value, since they bear interest at rates close to the prevailing market rates. The amounts funded in respect of employee rights are stated at cash surrender value which approximates its fair value.

As to financial liabilities carried at fair value, see note 7.





## ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 4 - ACCOUNTS RECEIVABLE:

Composition of accounts receivable , grouped by major classifications, is as follows:

	August 31	
	2012	2011
Receivables from D.N.A (see note 5)	\$ -	\$ 450,844
Tax Authorities	53,341	32,406
Other receivables	34,350	59,641
	\$ 87,691	\$ 542,891

## NOTE 5 - AGREEMENT WITH D.N.A BIOMEDICAL SOLUTIONS LTD

a. In June 2010, the Subsidiary entered into an agreement with D.N.A, for the establishment of a new company, Entera. According to the JV Agreement, D.N.A invested \$600,000, in two stages, in Entera, and Entera was owned in equal parts by the Subsidiary and D.N.A. In consideration for 50% of Entera's shares, the Subsidiary entered into a Patent License Agreement with Entera, according to which, the Subsidiary out-licensed to Entera a technology for the development of oral delivery drugs for certain actions.

Mr. Zeev Bronfeld, who is one of D.N.A 's directors and controlling shareholders, is also an affiliated stockholder of the Company.

The Group has concluded Entera was a variable interest entity (a "VIE"), according to the terms of the JV Agreement until its sale in March 2011, as described below.

b. On February 22, 2011, the Subsidiary entered into a share purchase agreement with D.N.A for the sale of 47% of Entera's outstanding share capital on an undiluted basis. The closing of that transaction took place on March 31, 2011. As consideration for the Entera shares, the Subsidiary received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, which was paid on November 14, 2011, and 8,404,667 ordinary shares of D.N.A (the "D.N.A Shares"), having a fair value of \$581,977 as of the closing date of the transaction. The D.N.A Shares are listed on the Tel Aviv Stock Exchange ("TASE") and their tradability was restricted for a period of 6 months from the closing date of the transaction according to TASE policy with regards to private placements.

D.N.A.'s securities are classified as available-for-sale, during 2012 and 2011 the Company recognized an impairment of \$184,254 and \$197,412, respectively.

In addition, on the closing date, D.N.A participated in the Company's private placement, at same investment terms granted to other investors at that period, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share for \$250,000.

As part of the transaction, the Subsidiary entered into a patent transfer agreement (that replaced the original license agreement) according to which, the Subsidiary assigned to Entera all of its right, title and interest in and to the patent

application that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. On August 31, 2012, Entera had not yet realized any revenues and did not pay any royalties to the Subsidiary.

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## ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 5 - AGREEMENT WITH D.N.A BIOMEDICAL SOLUTIONS LTD (continued):

Upon the closing, Oramed, Entera and D.N.A terminated the joint venture agreement, as amended, entered into on June 1, 2010 in connection with the formation of Entera.

In 2011, the Subsidiary recognized a gain on sale of investment of \$1,033,004 from the transaction, as followed:

Fair value of D.N.A Shares	\$581,977
Receivables from D.N.A	450,000
Re-classification of currency translation adjustments	7,930
	\$1,039,907
Less - net cost of the investment realized	(6,903 )
	\$1,033,004

As a result of the above transaction, the Company no longer has the ability to exert significant influence over Entera and the remaining 3% interest, in the amount of \$1,027, is accounted for at a cost method investment.

## NOTE 6 - PROPERTY AND EQUIPMENT, NET:

- a. Composition of property and equipment, grouped by major classifications, is as follows:

	August 31	
	2012	2011
Cost:		
Leasehold improvements	\$ 76,029	\$ 76,029
Office furniture and equipment	19,941	19,941
Computers and peripheral equipment	29,642	27,513
	125,612	123,483
Less - accumulated depreciation and amortization	120,844	106,107
	\$ 4,768	\$ 17,376

- b. Depreciation expenses totaled \$14,737 and \$28,303 in the years ended August 31, 2012 and 2011, respectively.

ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 7 - WARRANTS

As part of the Company's private placements as described in notes 10a and 10f, warrants were granted to an investor who was considered as a leading investor (the "Leading Investor). 2,187,500 warrants were granted in January 2011 (the "2011 Warrants") and 1,351,352 were granted in August 2012. Each warrant was granted for five years at an initial exercise price of \$0.50 per share. The warrants include anti-dilution protection (the "full ratchet anti-dilution protection"), from the second year anniversary date after issuing the warrant, subject to certain limitations and while the warrant is outstanding. In the event the Company shall issue or sell any common stock for a consideration per share lower than the exercise price then in effect, or shall issue or sell any options, warrants or other rights for the purchase or acquisition of such shares at a consideration per share of less than the exercise price then in effect, the warrants will be amended to (a) reduce the exercise price to an amount equal to the per share consideration payable to the company in such sale or issuance, and (b) the quantity of warrants will be updated, based on certain rules as determined in the Warrants Agreements with the Leading Investor.

As a result of the August 2012 private placements, and pursuant to the adjustment terms of the 2011 Warrants held by the Leading Investor, prior to such private placements, the warrant held by the Leading Investor was amended to: (i) reduce the exercise price from \$0.50 to \$0.37, (ii) increase the number of shares issuable upon the exercise of the warrant from 2,187,500 to 2,956,081, and (iii) delete the limitation which restricted the Leading Investor's ability from receiving more than 9.9% of the Company's outstanding shares.

As to amendment to the Warrant after August 31, 2012, see also note 17d.

As of August 31, 2011, the Warrants that were granted to this investor during the year ended August 31, 2011 were presented within stockholders' equity. After further review, the Company has determined that these instruments should have been classified as liabilities. Changes in the fair value of these Warrants require adjustments to the amount of the liabilities recorded on the Company's balance sheet, and the corresponding gain or loss is required to be recorded in the Company's statement of operations. The Company assessed the materiality of the correction and concluded that it was immaterial to previously reported annual and interim amounts and that the correction of the error in 2012 is not material to the current year results of operations. Accordingly, the Company corrected this error during the year ended August 31, 2012 and did not restate its consolidated financial statements for the prior years or interim periods impacted.

The fair value of the warrants was determined by using Monte Carlo type model based on the risk neutral approach. The model takes as an input the estimated future dates when new capital will be raised, and builds a multi-step dynamic model. The first step is to model the risk neutral distribution of the share value on the new issue dates, then for each path to use the Black-Scholes model to estimate the value of the warrants on the last issue date including all the changes in exercise price and quantity along this path. The significant unobservable input used in the fair value measurement is the future expected issue dates. Significant delay in this input would result a higher fair value measurement.

Financial liabilities carried at fair value as of August 31, 2012 are classified in the tables below in one of the three fair value categories:

	Fair value measurements at reporting date using	
	Level 3	Total
Warrants -		
August 31, 2012	\$ 637,182	\$ 637,182

The following table summarizes the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs:

	August 31 2012
Carrying value at the beginning of the period	-
Additions	\$ 494,478
Changes in fair value of warrant liabilities	142,704
Carrying value at the end of the period	\$ 637,182

As to the change in the terms of the warrants after August 31, 2012, see note 17e.

ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 8 - EMPLOYEES RIGHTS UPON RETIREMENT:

The Subsidiary is required to make a severance payment upon dismissal of an employee, or upon termination of employment in certain circumstances. The severance pay liability to the employees (based upon length of service and the latest monthly salary - one month's salary for each year employed) is recorded on the Subsidiary's balance sheets under "Liability for employee rights upon retirement." The liability is recorded as if it were payable at each balance sheet date on an undiscounted basis.

The liability is funded in part from the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the Subsidiary's balance sheets under "Funds in respect of employee rights upon retirement." These policies are the Subsidiary's assets. However, under labor agreements and subject to certain limitations, any policy may be transferred to the ownership of the individual employee for whose benefit the funds were deposited. In the years ended August 31, 2012 and 2011, the Subsidiary deposited \$3,620 and \$3,275, respectively, with insurance companies in connection with its severance payment obligations.

In accordance with the current employment agreements with certain employees, the Subsidiary makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's rights upon retirement. The Subsidiary is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the Subsidiary's balance sheets, as the amounts funded are not under the control and management of the Subsidiary and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plans").

The amounts of severance pay expenses were \$5,615 and \$10,241 for the years ended August 31, 2012 and 2011, respectively. \$7,089 and \$6,966 in the years ended August 31, 2012 and 2011, respectively, were in respect of a Contribution Plan.

The Subsidiary expects to contribute approximately \$10,155 in the year ending August 31, 2013 to insurance companies in connection with its severance liabilities for its operations for that year, \$7,619 of which will be contributed to one or more Contribution Plans.

NOTE 9 - COMMITMENTS:

- a. Under the terms of the First Agreement with Hadasit (note 1a above), the Company retained Hadasit to provide consulting and clinical trial services. As remuneration for the services provided under the agreement, Hadasit is entitled to \$200,000. The primary researcher for Hadasit is Dr. Miriam Kidron, a director and officer of the Company. The funds paid to Hadasit under the agreement are deposited by Hadasit into a research fund managed by Dr. Kidron. Pursuant to the general policy of Hadasit with respect to its research funds, Dr. Kidron receives from Hadasit a management fee in the rate of 10% of all the funds deposited into this research fund. The total amount paid to Dr. Kidron out of this fund was \$10,214.

On January 7, 2009, the Company entered into a second agreement with Hadasit (the "Second Agreement") which confirms that Hadasit has conveyed, transferred and assigned all of its ownership rights in the patents acquired under

the First Agreement to the Company, and certain other patents filed by the Company after the First Agreement as a result of the collaboration between the Company and Hadasit.

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ORAMED PHARMACEUTICALS INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 9 - COMMITMENTS (continued):

On July 8, 2009, the Company entered into a third agreement with Hadasit, Prof. Itamar Raz and Dr. Miriam Kidron ("the Third Agreement"), to retain consulting and clinical trial services from Hadasit. According to the Third Agreement, Hadasit was entitled to total consideration of \$400,000 to be paid by Oramed. \$200,000 of this amount was agreed in the terms of the First Agreement, and the remaining of \$200,000 was paid in accordance with the actual progress of the study. The total amount was paid through May 31, 2011.

On September 11, 2011, the Company entered into a fourth agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr (the "Fourth Agreement"), to retain consulting and clinical trial services. According to the Fourth Agreement, Hadasit will be entitled to consideration of \$200,000 to be paid by the Company in accordance with the actual progress of the study. None of which was recognized or paid through August 31, 2012.

- b. The Subsidiary has entered into operating lease agreements for vehicles used by its employees for a period of 3 years.

The lease expenses for the years ended August 31, 2012 and 2011 were \$29,543 and \$37,144, respectively. The future lease payments under the lease agreement are \$21,201, \$8,237 and \$686 for the years ending August 31, 2013, 2014 and 2015, respectively.

As security for its obligation under the lease agreements the Subsidiary deposited \$7,840, which are classified as long term deposits.

- c. On March 18, 2012, the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement is for a period of 57 months commencing January 1, 2012. The monthly lease payment will be NIS 3,400 in 2012, NIS 4,225 in 2013 and NIS 5,610 from 2014 onwards, and will be linked to the increase in the Israeli consumer price index (as of August 31, 2012, the monthly payment in the Company's functional currency is \$844, the future annual lease payments under the agreement will be \$11,768 in 2013, \$15,338 in 2013 and \$16,713 from 2014 onwards).

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

- d. On April 21, 2009, the Subsidiary entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. ("ADRES") (the "Original Agreement") pursuant to which ADRES will provide consulting services relating to quality assurance and regulatory processes and procedures in order to assist the Subsidiary in submission of a U.S. Investigational New Drug ("IND") according to the U.S. Food and Drug Administration (the "FDA") regulations. In consideration for the services provided under the agreement, ADRES will be entitled to total cash compensation of \$211,000, of which the amount of \$110,000 will be paid as a monthly fixed fee of \$10,000 each month for 11 months commencing May 2009, and the remaining \$101,000 will be paid based on achievement of certain milestones. \$160,000 of the total amount was paid through November 30, 2011, \$50,000 of which was paid for completing the first three milestones.



On February 26, 2012, the parties entered into an amendment agreement, according to which the Subsidiary paid the remaining \$51,000 of the Original Agreement upon execution of the amendment agreement. In addition, beginning March 1, 2012 and until submission of the IND, the Subsidiary will pay ADRES a monthly fee of approximately \$3,600. The Company recognized the \$51,000 as an expense during 2012.

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ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 9 - COMMITMENTS (continued):

- e. On February 10, 2010, the Subsidiary entered into an agreement with Vetgenerics Research G. Ziv Ltd, a clinical research organization, to conduct a toxicology trial on its oral insulin capsules. The total cost estimated for the studies is €107,100 (\$154,320) of which €89,923 (\$129,570) was paid through August 31, 2012. The Company did not recognize any expense during 2012 with respect to said agreement.
- f. On February 15, 2011, the Subsidiary entered into a consulting agreement with a third party (the "Consultant") for a period of five years, pursuant to which the Consultant will provide consultation on scientific and clinical matters. The Consultant is entitled to a fixed monthly fee of \$8,000, royalties of 8% of the net royalties actually received by the Subsidiary in respect of the patent that was sold to Entera on February 22, 2011 and an option to purchase up to 250,000 shares of common stock of the Company at an exercise price of \$0.50 per share. The option vests in five annual installments commencing February 16, 2012 and expires on February 16, 2021. The initial fair value of the option on the date of grant was \$62,185, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 78.65%; risk-free interest rates of 3.62%; and the remaining expected term of 10 years. The fair value of the option as of August 31, 2012 was \$54,345, using the following assumptions: dividend yield of 0% and expected term of 8.5 years; expected volatility of 75.41%; and risk-free interest rate of 1.29%. The fair value of the option granted is remeasured at each balance sheet reporting date and is recognized over the related service period using the straight-line method.
- g. On June 22, 2011, the Subsidiary issued a purchase order to SAFC Pharma for producing one of its oral capsule ingredients in the amount of \$600,000. During the year ended August 31, 2012, only a quantity valued at approximately \$444,000 was supplied to the Subsidiary, of which \$170,000 was paid through August 31, 2012, and the remaining is presented under accounts payable and accrued expenses.
- h. On December 12, 2011, the Subsidiary entered into a Supply Agreement with Swiss Caps AG ("Swiss Caps"), according to which, Swiss Caps will manufacture insulin capsules for total consideration of CHF 395,000 (approximately \$411,000) of which CHF 340,000 (approximately \$375,000) was paid and recognized through August 31, 2012.
- i. On February 15, 2012, the Company entered into an advisory agreement with a third party for a period of one year, pursuant to which such third party will provide investors relations services and will be entitled to a share based compensation as follows: 300,000 shares of common stock of the Company will be issued in six installments over the engagement period, commencing February 15, 2012, and a warrant to purchase 750,000 shares of common stock of the Company at an exercise price of \$0.50 per share. The warrant vests in 12 monthly installments commencing February 15, 2012 and expires on February 15, 2017. The initial fair value of the option on the date of grant was \$121,304, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.82%; risk-free interest rates of 0.81%; and the remaining expected term of 5 years.

ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 9 - COMMITMENTS (continued):

On July 3, 2012, the Company and the third party entered into an amendment to the agreement, according to which the original agreement will be extended until July 3, 2013 (unless terminated earlier by one of the parties), and a new payment schedule was determined for the remainder of the share based compensation until July 3, 2013. The Company records expenses in respect of this warrant during the term of the services.

The fair value of the option as of August 31, 2012, was \$115,698, using the following assumptions: dividend yield of 0% and expected term of 4.5 years; expected volatility of 75.41%; and risk-free interest rate of 0.52%. The fair value of the option granted is remeasured at each balance sheet reporting date and is recognized over the related service period using the straight-line method.

j. Grants from Bio-Jerusalem

The Subsidiary is committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received by the Company (Israeli CPI linked) at the total amount of \$52,733. As of August 31, 2012, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

During the year ended August 31, 2012 no grants were received from Bio-Jerusalem. For the period from inception on April 12, 2002 through August 31, 2012, the research and development expenses are presented net of Bio-Jerusalem grants, in the total amount of \$52,733.

k. Grants from the Chief Scientist Office ("OCS")

Under the terms of the Company's funding from the Israeli Government, royalties of 3%-3.5% are payable on sales of products developed from a project so funded, up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of annual interest at a rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured. In case of failure of a project that was partly financed as above, the Company is not obligated to pay any such royalties.

On August 31, 2012, the Subsidiary had not yet realized any revenues from the said project and did not incur any royalty liability. The total amount that was actually received through August 31, 2012 was \$1,332,374.

For the years ended August 31, 2012, and 2011, and for the period from inception on April 12, 2002 through August 31, 2012, the research and development expenses are presented net of OCS Grants, in the total amount of \$372,959, \$296,995 and \$1,415,557, respectively.

ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 - STOCK HOLDERS' EQUITY:

The Company's shares are traded on the Over-The-Counter Bulletin Board.

The following are capital stock transactions that took place during the years ended August 31, 2012 and 2011:

a. Between November 2010 and February 2011, the Company entered into Securities Purchase Agreements with a few accredited investors for the sale of 9,706,250 units at a purchase price of \$0.32 per unit for total consideration of \$3,106,000. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase 0.35 a share of common stock exercisable for five years at an exercise price of \$0.50 per share. For finder's fee with respect to these Securities Purchase Agreements, see note 11c..

As to the warrants purchased by the Leading Investor - see note 7.

b. On March 31, 2011, the Company consummated a transaction with D.N.A for the sale of 781,250 shares of common stock and warrants to purchase up to 273,438 shares of common stock, for a total purchase price of \$250,000 in cash. The shares and warrants were sold in units at a price per unit of \$0.32, each unit consisting of one share of common stock and a warrant to purchase 0.35 of a share of common stock. The warrants have an exercise price of \$0.50 per share, and a term of five years commencing from the closing of the transaction. See also note 5.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 - STOCK HOLDERS' EQUITY (continued):

- c. In April 2011, the Company entered into Securities Purchase Agreements with nine accredited investors for the sale of 1,124,375 units at a purchase price of \$0.32 per unit for total consideration of \$359,800.
- d. In May 2011, the Company issued 176,923 shares of its common stock, valued at \$47,769, in the aggregate, to Swiss Caps as settlement of our liability for services rendered in the past.
- e. On August 15, 2011, the Company entered into a consulting agreement with a third party (the "Advisor") for a period of nine months, pursuant to which such Advisor provided investor relations services and received a monthly cash fee and shares of the Company's common stock in that were issued in three equal installments as follows: on each of December 12, 2011, March 14, 2012 and May 15, 2012, the Company issued 83,000 shares of its common stock at fair value of \$24,900, \$26,560 and \$24,900, respectively.
- f. On each of March 14, 2012 and July 5, 2012, the Company issued 50,000 shares of its common stock to an advisor as remuneration for services provided. The fair value of the shares at the dates of grant was \$15,500 and \$16,000, respectively. See also note 9i.
- g. In August 2012, the Company entered into Securities Purchase Agreements with a number of investors for the sale of 9,622,142 units at a purchase price of \$0.37 per unit for total consideration of \$3,560,192. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase 0.50 a share of common stock exercisable for five years at an exercise price of \$0.50 per share. The investors were granted customary registration rights with respect to resales of shares, including the shares underlying the warrants. In addition, in August 2012, the Company entered into a Securities Purchase Agreement with an investor for the sale of 67,819 units at same terms as describe above. As the payment from said investor was received during September 2012, following which, the Company issued him its shares of common stock, the proceeds from that investment, of \$25,093 are presented as shares and warrants to be issued for cash.

As to the units purchased by the Leading Investor and the amendment to the 2011 Warrants, see note 7.

The Company paid cash consideration of \$71,250 as finders' fees in connection with the securities purchase agreements.

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

NOTE 10 - STOCK HOLDERS' EQUITY (continued):

- h. As to shares issued as part of stock based compensation plan see note 11.
- i. As to a Clinical Trial Manufacturing Agreement with Swiss Caps, see note 11a.

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ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - STOCK BASED COMPENSATION:

On October 15, 2006, the Company's Board of Directors adopted the 2006 Stock Option Plan (the "2006 Stock Option Plan") for reserving a pool of 3,000,000 shares of the Company's common stock which may be issued at the discretion of the Company's Board of Directors from time to time.

On May 5, 2008, the Company's Board of Directors adopted the 2008 Stock Option Plan (the "2008 Stock Option Plan") for reserving a pool of 8,000,000 shares of the Company's common stock which may be issued at the discretion of the Company's Board of Directors from time to time.

On August 8, 2012, the Company's Board of Directors decided to cancel the 2006 Stock Option Plan, under which there were no longer any outstanding securities, and to reserve an additional 4,000,000 shares of the Company's common stock to the 2008 Stock Option Plan, which reflected a net increase of 1,000,000 shares with respect to the total amount of shares in both plans.

Under the 2008 Stock Option Plan 12,000,000 shares have been reserved for the grant of options, which may be issued at the discretion of the Company's Board of Directors from time to time. Under this Plan, each option is exercisable into one share of common stock of the Company.

The options may be exercised after vesting and in accordance with vesting schedules which will be determined by the Board of Directors for each grant. The maximum term of the options is 10 years.

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on a historical volatility, by statistical analysis of the daily share price for past periods. The expected term is the length of time until the expected dates of exercising the options, based on estimated data regarding employees' exercise behavior.

The following are stock options and warrants transactions made during the years ended August 31, 2012 and 2011:

- a. On October 30, 2006, the Company entered into a Clinical Trial Manufacturing Agreement with Swiss Caps, pursuant to which Swiss Caps would manufacture and deliver the oral insulin capsule developed by the Company. In consideration for the services being provided to the Company by Swiss Caps, the Company agreed to pay certain predetermined amounts which are to be paid in common stock of the Company, the number of shares to be issued is based on the invoice received from Swiss Caps, and the stock market price 10 days after the invoice is issued. During the year ended on August 31, 2011, the Company issued 530,637 shares of its common stock to Swiss Caps as remuneration for the services provided in the amount of \$167,569. No shares were issued to Swiss Caps during the year ended on August 31, 2012.
- b. On February 15, 2011, the Company granted options under the 2008 Stock Incentive Plan to purchase up to 250,000 shares of our common stock at an exercise price of \$0.50 to a consultant. The options vest in five annual installments commencing February 16, 2012 and expire on February 16, 2021. The initial fair value of the option on the date of grant, was \$62,185, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 78.65%; risk-free interest rates of 3.42%; and the remaining contractual life of 10 years. The fair value of the options granted is measured on a final basis at

the end of the related service period and is recognized over the related service period using the straight-line method.

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ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - STOCK BASED COMPENSATION (continued):

- c. In March 2011, in connection with the securities purchase agreement, as described in note 10a, the Company issued 196,750 shares of the Company's common stock and warrants to purchase 70,864 shares of common stock to three individuals, as finders' fees. The fair value of the shares at the date of grant was \$59,778, and the fair value of the warrants at that date was \$12,630, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 78.54% - 78.68%; risk-free interest rates of 2.11% - 2.19%; and the remaining expected term of 5 years. The warrants have an exercise price of \$0.50 per share
- d. In April 2011, the Company entered into Securities Purchase Agreements with nine accredited investors for the sale of 1,124,375 units at a purchase price of \$0.32 per unit for total consideration of \$359,800. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase 0.35 a share of common stock exercisable for five years at an exercise price of \$0.50 per share. The Company paid \$21,588 and issued on July 2011, 67,462 warrants as finders' fees. The fair value of the warrants at that date was \$11,050, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 79.28%; risk-free interest rates of 2.09%; and the remaining expected term of 5 years.
- e. On April 27, 2011, 43,000 options were granted to ExperiMind Ltd as remuneration for services rendered at an exercise price of \$0.50 per share (higher than the traded market price on the date of grant). The options vested immediately on the date of grant and will expire on April 26, 2016. The fair value of these options on the date of grant, was \$10,000, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 79.24%; risk-free interest rates of 2.06%; and the remaining expected term of 5 years.
- f. In May 2011, the Company issued 200,000 shares of its common stock, valued at \$60,000, in the aggregate, to New Castle Consulting, LLC as remuneration for services rendered in the six month period that commenced on May 4, 2011.
- g. On July 25, 2011, the Company issued warrants to purchase 32,000 shares of its common stock at an exercise price of \$0.50 per share to The Trout Group, LLC as remuneration for services to be rendered during the 12 month period commencing May 13, 2011. The warrants vest in twelve equal annual installments commencing on October 13, 2011 and will expire on July 25, 2016. The fair value of these warrants on the date of grant, was \$5,057, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 77.39%; risk-free interest rates of 1.55%; and the remaining expected term of 5 years. The fair value of the option as of August 31, 2012, was \$4,548, using the following assumptions: dividend yield of 0% and expected term of 4 years; expected volatility of 75.41%; and risk-free interest rate of 0.45%. The fair value of the option granted is remeasured at each balance sheet reporting date and is recognized over the related service period using the straight-line method.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - STOCK BASED COMPENSATION (continued):

- h. On August 8, 2012, an aggregate of 1,728,000 options was granted to Nadav Kidron, the Company's President, Chief Executive Officer and director, and Miriam Kidron, the Company's Chief Medical and Technology Officer and director, both related parties, at an exercise price of \$0.34 per share (equivalent to the traded market price on the date of grant) 504,000 of the options vested immediately on the date of grant and the remainder will vest in seventeen equal monthly installments of 72,000 each. These options expire on August 7, 2022. The fair value of these options on the date of grant was \$373,565, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.03%; risk-free interest rates of 0.83%; and expected term of 5.5 years.
- i. On August 8, 2012, an aggregate of 520,000 options was granted to three Board of Directors members at an exercise price of \$0.34 per share (equivalent to the traded market price on the date of grant). The options vest in two equal annual installments, commencing January 1, 2013, and expire on August 7, 2022. The fair value of these options on the date of grant was \$114,694, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.03%; risk-free interest rates of 1.0375%; and expected term of 5.75 years.
- j. On August 8, 2012, 609,000 options were granted to an employee of the Subsidiary, at an exercise price of \$0.34 per share (equivalent to the traded market price on the date of grant). The options vest in 29 equal monthly installments of 21,000, commencing August 31, 2012, and expire on August 7, 2022. The fair value of these options on the date of grant was \$134,324, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.03%; risk-free interest rates of 1.0375%; and expected term of 5.75 years.
- k. On August 8, 2012, 75,000 options were granted to an employee of the Subsidiary, at an exercise price of \$0.34 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual installments, commencing January 1, 2013, and expire on August 7, 2022. The fair value of these options on the date of grant was \$16,780, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.03%; risk-free interest rates of 0.935%; and expected term of 6 years.
- l. On August 8, 2012, the Company's Board of Directors approved an extension of the term of the 3,361,360 warrants held by Dr. Miriam Kidron by approximately two years from such approval, expiring on August 6, 2014. The incremental fair value of the warrant extension was negligible.

m. As to options granted to third parties, see note 9i.

## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 11 - STOCK BASED COMPENSATION (continued):

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

	For options granted in the year ended August 31	
	2012	2011
Expected option life (years)	5-6	5-10
Expected stock price volatility (%)	76.0	76.8-78.7
Risk free interest rate (%)	0.8-1.0	1.6-3.6
Expected dividend yield (%)	0.0	0.0

A summary of the status of the stock options granted to employees and directors as of August 31, 2012 and 2011, and changes during the years ended on those dates, is presented below:

	Year ended August 31,			
	2012		2011	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	10,009,360	0.32	10,009,360	0.32
Changes during the year:				
Granted - at market price	2,932,000	0.34	-	
Expired	(1,700,000 )	0.45	-	
Forfeited	(56,000 )	0.47	-	
Options outstanding at end of year	11,185,360	0.31	10,009,360	0.32
Options exercisable at end of year	8,605,026		8,925,359	
Weighted average fair value of options granted during the year	\$ 0.28		-	

Costs incurred in respect of stock based compensation for employees and directors, for the years ended August 31, 2012 and 2011 were \$200,866 and \$502,593, respectively.

## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 11 - STOCK BASED COMPENSATION (continued):

The following table presents summary information concerning the options granted to employees and directors outstanding as of August 31, 2012:

Range of exercise prices \$	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.001	3,361,360	1.93	0.001	1,072,274
0.34 to 0.54	7,824,000	7.95	0.44	-
	11,185,360	6.14	0.31	1,072,274

The following table presents summary information concerning the options granted to employees and directors exercisable as of August 31, 2012:

Range of exercise prices \$	Number exercisable	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.001	3,361,360	1.93	0.001	1,072,274
0.34 to 0.54	5,243,666	7.08	0.48	-
	8,605,026	5.07	0.29	1,072,274

As of August 31, 2012, there were \$574,758 of unrecognized compensation costs related to non-vested employees and directors, to be recorded over the next 28 months.

## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 11 - STOCK BASED COMPENSATION (continued):

A summary of the status of the stock options granted to non-employees as of August 31, 2012, and changes during the years ended on this date, is presented below:

	2012		Year ended August 31 2011	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	988,200	0.60	813,200	0.63
Changes during the year:				
Granted - at market price	-		-	
Granted - at an exercise price above market price	750,000	0.50	325,000	0.50
Expired	-		(150,000)	(0.71)
Options outstanding at end of year	1,738,200	0.56	988,200	0.60
Options exercisable at end of year	1,064,201		606,200	

The Company recorded stock compensation of \$117,098 and \$26,733 during the years ended August 31, 2012 and 2011, respectively, related to consulting services.

The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2012:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.34 to 0.54	1,338,200	4.79	0.49	-
0.76	400,000	4.83	0.76	-
	1,738,200	4.80	0.56	-

## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 11 - STOCK BASED COMPENSATION (continued):

The following table presents summary information concerning the options granted to non-employee exercisable as of August 31, 2012:

Range of exercise prices	Number exercisable	Weighted Average Remaining Contractual Life Years	Weighted average exercise price	Aggregate intrinsic value
\$			\$	\$
0.34 to 0.54	697,535	4.15	0.49	-
0.76	366,666	5.25	0.76	-
	1,064,201	4.53	0.58	-

As of August 31, 2012 there were \$124,948 of unrecognized compensation costs related to non-vested non-employees, to be recorded over the next 45 months.

## NOTE 12 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

	Year ended August 31,	
	2012	2011
Service providers	\$ 580,714	\$ 339,052
Payroll and related expenses	16,459	36,486
	\$ 597,173	\$ 375,538

## NOTE 13 - RESEARCH AND DEVELOPMENT EXPENSES, NET:

	Year ended August 31,		Period from April 12, 2002 (inception) through August 31, 2012
	2012	2011	2012
Clinical trials	\$ 1,298,310	\$ 591,733	\$ 5,163,353
Payroll and consulting fees	385,646	413,191	1,921,533
Costs for registration of patents	110,811	189,342	451,610
Compensation costs in respect of options granted to employees, directors and consultants	98,688	265,327	2,921,881

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Other	160,350	49,444	547,608
Less - grants from the OCS and Bio Jerusalem Fund	(372,959 )	(349,728 )	(1,468,290)
	\$ 1,680,845	\$ 1,159,309	\$ 9,532,694

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## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 14 - GENERAL AND ADMINISTRATIVE EXPENSES

	Year ended August 31		Period from April 12, 2002 (inception) through August 31, 2012
	2012	2011	
Compensation costs in respect of options granted to employees, directors and consultants	\$ 172,470	\$ 263,999	\$ 2,049,406
Professional services	221,218	344,277	1,899,744
Consulting fees	159,136	171,167	970,900
Travel costs	71,529	54,976	545,930
Write off of debt	-	-	275,000
Business development	284,899	151,886	815,945
Payroll and related expenses	144,101	174,229	753,208
Insurance	22,375	23,890	118,921
Other	127,436	91,536	732,493
	\$ 1,203,164	\$ 1,275,960	\$ 8,161,547

## NOTE 15 - TAXES ON INCOME:

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

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

The applicable corporate tax rate for the Company is 35%.

As of August 31, 2012, the Company has an accumulated tax loss carryforward of approximately \$4,896,605 (as of August 31, 2011, approximately \$3,468,280). Under U.S. tax laws, carryforward tax losses expire 20 years after the year in which incurred. In the case of the Company the net loss carryforward will expire in the years 2025 through 2032.

## b. Corporate taxation in Israel:

The Subsidiary is taxed in accordance with Israeli tax laws. The regular corporate tax rate in Israel for 2012 is 25%.



## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 15 - TAXES ON INCOME (continued):

On December 6, 2011, the "Tax Burden Distribution Law" Legislation Amendment (2011) was published in the Official Gazette. Under this law, the previously approved gradual decrease in the corporate tax rate was cancelled. The Corporate tax rate will increase to 25% beginning 2012.

As of August 31, 2012, the Subsidiary has an accumulated tax loss carryforward of approximately \$5,905,361 (as of August 31, 2011, approximately \$3,328,946).

## Deferred income taxes:

	August 31	
	2012	2011
In respect of:		
Net operating loss carryforward	3,190,152	1,813,108
Less - Valuation allowance	(3,190,152)	(1,813,108)
Net deferred tax assets	-,-	-,-

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

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

	Year ended August 31		Period from April 12, 2002 (inception) through August 31, 2012
	2012	2011	
Loss before taxes on income:			
U.S.	599,067	415,836	8,440,543
Outside U.S.	2,655,193	1,169,389	9,210,458
	\$ 3,254,260	\$ 1,585,225	\$ 17,651,001
Taxes on income:			
Current:			
U.S.	(7,569 )	(33,567 )	62,001
Outside U.S.	97,787	9,587	202,755
	\$ 90,218	\$ (23,980 )	\$ 264,756

## ORAMED PHARMACEUTICALS INC.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 15 - TAXES ON INCOME (continued):

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

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

	Year ended August 31		Period from April 12, 2002 (inception) through August 31, 2012
	2012	2011	2012
Loss before income taxes as reported in the consolidated statement of operations	\$ (3,254,260)	\$ (1,585,225)	\$ (17,651,001)
Statutory tax benefit	(1,138,991)	(554,829 )	(6,177,851 )
Increase (decrease) in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax losses	516,749	(58,357 )	2,762,468
Disallowable deductions	120,156	481,122	2,244,091
Increase in taxes resulting from different tax rates applicable to Subsidiary	502,086	132,064	1,183,796
Uncertain tax position	90,218	(23,980 )	228,272
Taxes on income for the reported year	\$ 90,218	\$ (23,980 )	\$ 240,776

## e. Uncertainty in Income Taxes

ASC No.740 "Income Taxes" requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company. The Company recognizes interest and penalties related to its tax contingencies as income tax expense. As of August 31, 2012 and 2011, the Company recorded \$15,539 and \$34,105, respectively, of penalties related to tax contingencies.

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

	Year ended August 31	
	2012	2011
Balance at Beginning of Year	\$ 138,054	\$ 162,034
Increase (decrease) in tax positions for the current year	90,218	(23,980 )
Balance at End of Year	\$ 228,272	\$ 138,054



ORAMED PHARMACEUTICALS INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 15 - TAXES ON INCOME (continued):

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

The Company and the Subsidiary are subject to Israeli income tax examinations and to U.S. Federal income tax examinations for the tax years of 2008 through 2012. As of August 31, 2012, the Group did not record any change to its unrecognized tax benefits.

NOTE 16 - RELATED PARTIES - TRANSACTIONS:

a. During each of the fiscal years of 2012 and 2011 the Company paid to directors \$30,000, for managerial services.

b. As to the agreements with Hadasit, see note 9a.

c. On July 1, 2008, the Subsidiary entered into a consulting agreement with KNRV Ltd. ("KNRV"), an Israeli company owned by Nadav Kidron, whereby Mr. Nadav Kidron, through KNRV, will provide services as President and Chief Executive Officer of both Oramed and the Subsidiary (the "Nadav Kidron Consulting Agreement"). Additionally, on July 1, 2008, the Subsidiary entered into a consulting agreement with KNRV whereby Dr. Miriam Kidron, through KNRV, will provide services as Chief Medical and Technology Officer of both Oramed and the Subsidiary (the "Miriam Kidron Consulting Agreement" and together with the Nadav Kidron Consulting Agreement, the "Consulting Agreements"). The Consulting Agreements replaced the employment agreements entered into between the Company and KNRV, dated as of August 1, 2007, pursuant to which Nadav Kidron and Miriam Kidron, respectively, provided services to the Company and the Subsidiary. The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNRV (i) will be paid, under each of the Consulting Agreements, in NIS a gross amount of NIS50,400 per month (as of August 31, 2012 the monthly payment in the Company's functional currency is \$12,512) and (ii) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements.

d. As to options granted to related parties, see note 11h.

e. According to the JV Agreement (note 5), Entera rented office space and services from the Subsidiary for a period of up to 24 months commencing August 19, 2010, for a non-refundable, up-front fee in the amount of \$36,000. The rent period ended on March 31, 2011, when the JV Agreement was terminated.

f. According to the JV agreement (note 5), the subsidiary of the Company provided accounting services to Entera at a monthly fee in the amount of NIS 3,500 (\$869). These services were ceased on March 31, 2011, when the JV agreement was terminated.

g. Balances with related parties:

	August 31	
	2012	2011
Accounts Receivables - KNRV	\$ 404	-
Accounts payable and accrued expenses - KNRV	-	\$ 18,502

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 17 - SUBSEQUENT EVENTS:

- a. In September 2012, the Company issued 67,819 shares of its common stock and 33,910 common stock purchase warrant to an investor. See also note 10g.
- b. Between September and November 2012, the Company entered into Securities Purchase Agreements with a number of investors for the sale of 3,957,905 units at a purchase price of \$0.37 per unit for total consideration of \$1,464,425. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase 0.50 a share of common stock exercisable for five years at an exercise price of \$0.50 per share. The investors were granted customary registration rights with respect to resales of shares, including the shares underlying the warrants. In addition, the Leading Investor, who purchased 405,405 of the units, was granted the right to maintain its percentage of the shares of the Company's common stock outstanding by purchasing more shares whenever the Company proposes to issue certain additional shares to other investors. Such right only exists so long as such investor holds at least 5% of the Company's outstanding common stock. In addition, such investor's warrants contain full ratchet anti-dilution protection and cashless exercise provisions not contained in the other investors' warrants. The terms of the Leading Investor's Securities Purchase Agreement are substantially the same as those from 2011. See note 10a above.

As finder's fee, in connection with the securities purchase agreements, the Company paid cash consideration of \$5,385 and might be required to pay additional \$7,500, as well as issued 13,514 shares of the Company's common stock 6,757 common stock purchase warrant for other individual. The Company will also issue 152,939 shares of the Company's common stock and 76,470 common stock purchase warrant to a director as finder's fee with respect to the Securities Purchase Agreements described above and in note 10g.

- c. On September 27, 2012, the Subsidiary entered into a Master Services Agreement with Medpace, Inc. ("Medpace"), to retain it as a CRO, for its upcoming Phase 2 clinical trial for an oral insulin capsule, that is expected to start in the first calendar quarter of 2013 in the United States. As consideration for its services, the subsidiary will pay Medpace a total amount of approximately \$3,500,000 that will be paid during the term of the engagement and based on achievement of certain milestones.
- d. On October 30, 2012, the Company entered into a Securities Purchase Agreement with D.N.A, according to which, the Company issued on that day to D.N.A 2,390,057 shares of its common stock, valued at approximately \$628,630 at the day of the transaction, in consideration for the option to purchase up to 21,637,611 ordinary shares of D.N.A with no additional cost. Following the exercise of the option by the Company, it will hold approximately 14.5% of D.N.A shareholders equity, including D.N.A shares that were received in March 2011, see note 5.

In addition, as a result of this agreement with D.N.A, and pursuant to the adjustment terms of the 2011 Warrants held by the Leading Investor, as described in note 10a and 10g, the Company further amended the 2011 Warrants by: (i) reducing the exercise price from \$0.37 to \$0.3138 and (ii) increasing the number of shares issuable upon the exercise of the 2011 Warrants from 2,956,081 to 3,485,500.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 17 - SUBSEQUENT EVENTS (continued):

e. On November 29, 2012, the Company and the Leading Investor entered into a letter agreement (the "Agreement") in connection with three warrants issued by the Company to the Leading Investor in January 2011, August 2012 and November 2012 (together, the "Three Warrants"). Pursuant to the Agreement, the Company and the Leading Investor agreed to amend the Three Warrants to provide that the anti-dilution protection of each of the Three Warrants shall be removed in its entirety. In addition, as to the Warrants issued in August and November 2012, the parties agreed that the exercise price shall be reduced to \$0.3138. On that day, the Company also issued to the Leading Investor a Common Stock Purchase Warrant (the "New Warrant") pursuant to which, the Leading Investor shall have the right to purchase up to 1,647,722 shares of the common stock of the Company over a period of four years at an exercise price of \$0.60 per share.

In addition to the New Warrant, Nadav Kidron, the Company's President, Chief Executive Officer and director, in his personal capacity as a shareholder of the Company, undertook and agreed that following the execution and delivery of the Agreement, in the event that an adjustment pursuant to the anti-dilution protection of any of the Three Warrants (had it not been amended by the Agreement thereof) would have been triggered and the number of shares of common stock of the Company that the Leading Investor would have been able to purchase under the Three Warrants would have increased by an aggregate number in excess of 1,647,722 shares, then the Leading Investor shall have the right to purchase from Mr. Kidron such number of shares of common stock of the Company owned by Mr. Kidron equal to such excess, up to a maximum of 1,352,278 shares of common stock of the Company at an exercise price of \$0.3138. The foregoing right shall survive until the termination of such Three Warrants.

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 Certificate of Incorporation (incorporated by reference from our current report on Form 8-K filed March 14, 2011).

3.2 By-laws (incorporated by reference from our current report on Form 8-K filed March 14, 2011).

4.1 Specimen Stock Certificate (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).

4.2 Common Stock Purchase Warrant issued to Attara Fund, Ltd. on January 10, 2011 (incorporated by reference from our quarterly report on Form 10-Q filed January 13, 2011).

4.3 Form of Common Stock Purchase Warrant used in 2010-2011 private placement (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).

4.4\* Form of Common Stock Purchase Warrant used in 2012 private placements.

10.1+ Consulting Agreement by and between Oramed Ltd. and KNRV, Ltd., entered into as of July 1, 2008 for the services of Nadav Kidron (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).

10.2+ Consulting Agreement by and between Oramed Ltd. and KNRV, 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 on July 2, 2008).



- 10.3+Oramed Pharmaceuticals Inc. 2008 Stock Incentive Plan (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.4+Form of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.5+Employment Agreement dated as of April 19, 2009, by and between Oramed Ltd. and Yifat Zommer (incorporated by reference from our current report on Form 8-K filed on April 22, 2009).
- 10.6Consulting Service Agreement dated April 21, 2009, between Oramed Ltd. and ADRES Advanced Regulatory Services Ltd. (incorporated by reference from our current report on Form 8-K filed April 22, 2009).
- 10.7\*Amendment to Consulting Service Agreement dated February 26, 2012, between Oramed Ltd. and ADRES Advanced Regulatory Services Ltd.
- 10.8\*+Clinical Trial Agreement dated September 11, 2011, between Oramed Ltd.. and Hadasit Medical Research Services and Development Ltd.
- 10.9+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).
- 10.10Agreement 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).
- 10.11Joint Venture Agreement dated June 1, 2010, between Oramed Ltd. and LASER Detect Systems Ltd (now known as D.N.A Biomedical Solutions Ltd.) (incorporated by reference from our quarterly report on Form 10-Q filed July 14, 2010).
- 10.12Manufacturing and Supply Agreement dated July 5, 2010, between Oramed Ltd. and Sanofi-Aventis Deutschland GMBH (incorporated by reference from our current report on Form 8-K filed July 14, 2010).
- 10.13Securities Purchase Agreement between Oramed Pharmaceuticals Inc. and Attara Fund, Ltd., dated as of December 21, 2010 (incorporated by reference from our quarterly report on Form 10-Q filed January 13, 2011).
- 10.14Share Purchase Agreement dated February 22, 2011, between Oramed Ltd. and D.N.A Biomedical Solutions Ltd. (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).
- 10.15Patent 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 24, 2011).
- 10.16Form of Securities Purchase Agreement used in 2010-2011 private placement (incorporated by reference from our registration statement on Form S-1 filed March 24, 2011).

- 10.17+Form of Indemnification Agreements dated March 11, 2011, between Oramed Pharmaceuticals Inc. and each of our directors and officers (incorporated by reference from our definitive proxy statement on Schedule 14A filed on January 31, 2011).
- 10.18+Agreement dated June 21, 2011, with Dr. Michael Berelowitz (incorporated by reference from our current report on Form 8-K filed June 22, 2011).
- 10.19\* Form of Securities Purchase Agreement used in 2012 private placements.
- 10.20\*Form of Securities Purchase Agreement used in 2012 private placement with Regals Fund LP.
- 10.21\* Master Service Agreement dated September 27, 2012, between Oramed Ltd. and Medpace, Inc.
- 10.22\* MEDPACE Task Order Number: 1 dated September 27, 2012, between Oramed Ltd. and Medpace, Inc. (portions of this exhibit have been omitted pursuant to a request for confidential treatment)
- 10.23\* Securities Purchase Agreement dated October 30, 2012, between Oramed Pharmaceuticals Inc. and D.N.A Biomedical Solutions Ltd.
- 21.1\* Subsidiary.
- 23.1\* Consent of Kesselman & Kesselman, Independent Registered Public Accounting Firm.
- 23.2\* Consent of Malone & Bailey, PC, Independent Registered Public Accounting Firm.
- 31.1\* Certification Statement of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 31.2\* Certification Statement of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1\*\* Certification Statement of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
- 32.2\*\* Certification Statement of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
- 101.1\*\*The following financial statements from the Company's annual report on Form 10-K for the year ended August 31, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (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.

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\* Filed herewith.

\*\* Furnished herewith.

+ Management contract or compensation plan.

SIGNATURES

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

ORAMED PHARMACEUTICALS INC.

By: /s/ NADAV KIDRON  
Nadav Kidron,  
President and Chief Executive Officer

Date: December 11, 2012

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 December  
11, 2012

Nadav Kidron,  
President and Chief  
Executive Officer and  
Director  
(principal executive  
officer)

/s/ YIFAT ZOMMER December  
11, 2012

Yifat Zommer,  
Chief Financial  
Officer  
(principal financial  
and accounting  
officer)

/s/ MIRIAM KIDRON December  
11, 2012

Miriam Kidron,  
Chief Medical and  
Technology Officer  
and Director

/s/ LEONARD SANK December  
11, 2012

Leonard Sank,  
Director

/s/ HAROLD JACOB December  
11, 2012

Harold Jacob,

Director

/s/ MICHAEL                      December  
BERELOWITZ                    11, 2012  
Michael Berelowitz,  
Director

/s/ GERALD                      December  
OSTROV                         11, 2012  
Gerald Ostrov,