

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended August 31, 2010

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-50298

**ORAMED PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction of  
incorporation or organization)

**98-0376008**  
(IRS Employer Identification  
No.)

**Hi-Tech Park 2/5**  
**Givat-Ram**  
**PO Box 39098**  
**Jerusalem 91390 Israel**  
(Address of principal executive offices)(Zip Code)

**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, \$0.001 par value

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

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

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

Yes  No

Indicate by check mark whether the registrant has submitted electronically 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 \$15,857,742 based on a price of \$0.41, 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: 58,756,535 shares issued and outstanding as of November 23, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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ORAMED PHARMACEUTICALS, INC.

FORM 10-K

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## PART I

### ITEM 1 - BUSINESS

*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 regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements.*

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 "Risks Related to Our Business" 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. 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.

We file reports with the Securities and Exchange Commission (the "SEC" or the "Commission"). We make available on our website under "Investor Information/SEC Filings," free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Our website address is [www.oramed.com](http://www.oramed.com). You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

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 subsidiary, Oramed Ltd., unless otherwise indicated.

## DESCRIPTION OF BUSINESS

### General

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

Through our research and development efforts, we are developing an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The proteins and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically, and the insulin and the dosage form must be safe to ingest.

Our research and development team has performed numerous animal studies to optimize the composition and functionality of their oral insulin (ORMD0801) modality and to demonstrate its safety and efficacy. Our studies have confirmed the feasibility of lowering blood glucose levels with an orally administered form of insulin that is both safe and effective.

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 International Diabetes Federation ("IDF"), an estimated 285 million people worldwide currently live with diabetes. In the United States there are approximately 26.8 million people with diabetes, or 8.7% of the United States population. The IDF predicts that the number of people worldwide with diabetes will exceed 435 million in 2030 if the current rate of growth continues unchecked.

Diabetes now affects seven percent of the world's adult population and claims four million lives every year. The disease is a leading cause of blindness, kidney failure, heart attack, stroke and amputation. Diabetes will cost the world economy at least \$376 billion in 2010, or 11.6% of total world healthcare expenditure. By 2030, this number is projected to exceed \$490 billion. More than 80% of diabetes spending is in the world's richest countries and not in the poorer countries, where over 70% of people with diabetes now live.

The regions with the highest comparative prevalence rates are North America, where 10.2% of the adult population has diabetes, followed by the Middle East and North Africa with 9.3%. The regions with the highest number of people living with diabetes are the Western Pacific, where some 77 million people have diabetes and South East Asia with 59 million.

Each year seven million people develop diabetes. The most dramatic increases in type 2 diabetes have occurred in populations where there have been rapid and major improvements in living standards, demonstrating the important role played by lifestyle factors and the potential for reversing the global epidemic.

**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 Advisory Board is comprised of Dr. Nir Barzilai, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Derek LeRoith and Dr. John Amatruda.

## Strategy

We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct studies and other tests necessary to file an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (the “FDA”). Additional clinical trials are planned in other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of future filings for drug approval in these countries. 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, flu vaccines, and use of rectal application for delivery of other polypeptides.

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to ensure 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.

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.

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD 0801). On January 22, 2008, we commenced non-FDA approved Phase 1B clinical trials with our oral insulin capsule, in healthy human volunteers with the intent of dose optimization. On March 11, 2008, we successfully completed our Phase 1B clinical trials.

On April 13, 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 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 to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”), 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 (ORMD 0801) on type 2 diabetic volunteers. On May 6, 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. We are considering whether and when to conduct an additional non-FDA approved Phase 2B study in India.

**GLP-1 Analog:** On September 16, 2008 we announced the launch of pre-clinical trials of ORMD 0901, a GLP-1 analog. 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.

On September 9, 2009, we received approval from the Institutional Review Board (IRB) in Israel 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. We anticipate that the results of these trials will be released in the near future.

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 surprisingly 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.

**Raw Materials:** Our oral insulin capsule is currently manufactured by Swiss Caps AG, under a Clinical Trial Manufacturing Agreement.

On July 5, 2010, our subsidiary entered into a Manufacturing Supply Agreement (MSA) with Sanofi-Aventis Deutschland GmbH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the USA.

The raw materials required for the manufacturing of the capsule are purchased from third parties, under separate agreements. 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 in changing 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 materially adversely affect 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 34 patent applications currently pending with respect to various compositions, methods of production oral administration of proteins and exenatide. Expiration dates for pending patents will in 2026 – 2028.

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 U.S. and in all relevant foreign markets in anticipation of future commercialization opportunities.



The validity, enforceability, written supports, and breadth of claims in our patent applications involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications filed by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid or enforceable if subsequently challenged, or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us. Since patent applications in the United States are maintained in secrecy for the initial period of time following filing, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

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, board of directors, 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.

Our success will also depend in part on our ability to commercialize our technology without infringing the proprietary rights of others. No assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and commercialization of our technology.

#### **Partnerships and Collaborative Arrangements**

We believe that working together with strategic partners will expedite product formulation, production and approval.

On March 8, 2006, we entered into an agreement with Hadasit to provide consulting and clinical trial services.

On October 30, 2006, we entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG ("Swiss"), pursuant to which Swiss currently manufactures the oral insulin capsule developed by us.

During April 2008, we entered into a five year master services agreement with SAFC, an operating division of Sigma-Aldrich, Inc., pursuant to which SAFC is providing services for individual projects, which may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, clerical, project management, central laboratory services, pre-clinical services, pharmaceutical sciences services, and other research and development services.

On April 21, 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. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

On July 8, 2009 we entered into an additional agreement with Hadasit, to facilitate additional clinical trials to be performed at Hadassah Medical Center in Jerusalem.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization (CRO), to conduct a toxicology trial on our oral insulin capsules.

On May 2, 2010, we entered into an additional agreement with SAFC Pharma, a division of the Sigma-Aldrich Corporation, to develop a process to produce one of our oral capsule ingredients.

On July 5, 2010, our subsidiary entered into a Manufacturing Supply Agreement (MSA) with Sanofi-Aventis Deutschland GMBH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the USA.

### **Out-Licensed Technology**

On June 1, 2010, our subsidiary, Oramed Ltd., entered into an agreement with D.N.A Biomedical Solutions Ltd (formerly, Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera").

Under the terms of a license agreement that was entered into between Oramed and Entera, we will out-license 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 will be an oral formulation for the treatment of osteoporosis. The license will be royalty-free unless our ownership interest in Entera decreases to 30% or less of its outstanding share capital, in which case royalties will be payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may receive ownership of the licensed technology, in which case we would receive a license back on the same terms.

D.N.A invested \$600,000 in Entera in two parts of \$400,000 in August 2010 and \$200,000 in November 2010, and Entera is owned in equal parts by Oramed and D.N.A, subject to dilution by future issuances of shares. Entera's Chief Executive Officer, Dr. Phillip Schwartz, will be granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital, upon full exercise. In the event that Entera has not obtained third-party financing by June 1, 2011, or such other date mutually agreed upon by the parties, each of Oramed and D.N.A will be required to make a capital contribution to Entera in the amount of \$150,000.

Mr. Zeev Bronfeld, who is one of D.N.A.'s controlling shareholders, holds approximately 10.71% of our outstanding common stock (see "Securities Ownership of Certain Beneficial Owners and Management").

## 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. The FDA compliance requirements are considered to be one of the most stringent worldwide. 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.

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 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 contract research organization conducting the study proposes to use to recruit participants, and the form of consent which the participants will be required to sign prior to their participation in the clinical studies.

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

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

· *Phase II.* Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to review the substance in Phase III studies.

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

*New Drug Approval.* The results of the clinical trials are submitted to the FDA as part of a new drug application ("NDA"). Following the completion of Phase III studies, assuming the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of its product, it submits 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 IV.* The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug. For example, large-scale trials may also be used to prove effectiveness and safety of new forms of drug delivery for approved drugs. Examples may be using an inhalation spray versus taking tablets or a sustained-release form of medication versus capsules taken multiple times per day.

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 and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, 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 United States 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 extent of governmental regulation which might result from future legislation or administrative action cannot be accurately predicted.

## **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 affect 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: Diabetology (UK, Phase 2), Emisphere Technologies (US, Phase 2), Biocon (India), Apollo Life Sciences (Australia, Phase 1), Generex (Canada, Phase 3) – Buccal delivery, Biodel (US, Phase 3) – Sublingual delivery and MannKind (US) -Inhaled delivery

### **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 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, Dr. Nir Barzilai, Professor Ele Ferrannini, Dr. Derek LeRoith and Dr. John Amatruda.

*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, a period which included service as a physician in the Israel Defense Forces (1965-67). 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 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. Hershko and his colleagues showed that cellular proteins are degraded by a highly selective proteolytic system. This system tags proteins for destruction by linkage a protein called ubiquitin, which had previously been identified in many tissues, but whose function was previously unknown. Subsequent work in Hershko's 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). Hershko is a member of the Israel Academy of Sciences (2000) and a Foreign Associate of the US Academy of Sciences (2003).

*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, NY. Dr. LeRoith has worked at the NIH since 1979 in the field of Endocrinology and Diabetes and rose to be Diabetes Branch at the National Institutes of Health in Bethesda MD, a position he held until 2005. His main interests have focused on the role of insulin and the insulin-like growth factors 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 the insulin-like growth factors. Dr. 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 world expert on these topics. In recognition of his contributions he has received many lectureships 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 that deal with the education of endocrinologist and primary care physicians.

*Professor Ele Ferrannini* joined the Oramed Scientific Advisory Board in February 2007. He is a past President to the EASD, European Association for the Study of Diabetes, which embraces scientists, physicians, laboratory workers, nurses and students from all over the world who are interested in diabetes and related subjects for Europe, such that the ADA, American Diabetes Association does in America. Professor Ferrannini has worked with various institutions including the Department of Internal Medicine, University of Pisa School of Medicine, and CNR (National Research Council) Institute of Clinical Physiology, Pisa, Italy; Diabetes Division, Department of Medicine, University of Texas Health Science Center at San Antonio, Texas, USA. He has also had extensive training focused on microbiology, immunology, 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 from the University of Torino. He has published over 350 original papers and 50 book chapters and he is among the "highly cited scientists", according to the Institute for Scientific Information.

*Dr. Nir Barzilai* 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. 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. He has spent over 20 years in assisting patients internationally and training in vast fields from Medicine, Geriatrics, Endocrinology and Molecular Genetics. Dr. Barzilai has had a strong career in diabetes studies between Israel, London and the United States. He has worked for such esteemed institutions as Hadassah Research Hospital, NIH (National Institute of Health), and many esteemed US based university hospitals including Cornell and Yale.

*Dr. John Amatruda* 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. 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 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, including Vice President and Therapeutic Area Head for Metabolism and Atherosclerosis and acting Therapeutic Area head for Cardiovascular. These groups filed NDAs for Vytolin, 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 on 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 the experienced personnel involved in our research and development program. In addition, we believe we have successfully recruited 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, 2010, we contracted eight individuals through employment or consulting agreements. Of our staff, two are senior management, four are engaged in research and development work, and the remaining are involved in administration work.

## **Facilities**

Our principal executive offices are comprised of approximately 117 square meters of office space located in Givat-Ram, Jerusalem, Israel. The lease commenced on October 1, 2007 and is for a period of 51 months. The aggregate annual base rental fee for this space is \$7,532. 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.

## **Corporate History**

Oramed was incorporated on April 12, 2002, in the State of Nevada under the name Iguana Ventures Ltd. Following the incorporation, we were an exploration stage company engaged in the acquisition and exploration of mineral properties. We were unsuccessful in implementing its business plan as a mineral exploration company. Accordingly, we decided to change the focus of our business by completing a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey private corporation ("ISTI"). On June 4, 2004, we changed our name to Integrated Security Technologies by filing a Certificate of Amendment with the Nevada Secretary of State. Effective June 14, 2004 we effected a 3.3:1 forward stock split, increasing the amount of authorized capital to 200,000,000 shares of common stock with the par value of \$.001 per share. However, due to disappointing results, we terminated the share exchange agreement with the shareholders of ISTI.

On March 8, 2006, we executed an agreement with Hadasit Medical Services and Development Ltd. ("Hadasit") to acquire provisional patent application No. 60/718716 and related intellectual property. The provisional patent application No. 60/718716 relates to a method of preparing insulin so that it may be taken orally to be used in the treatment for the treatment of individuals with diabetes. On April 10, 2006, we changed our name from Integrated Security Technologies, Inc. to Oramed Pharmaceuticals Inc. On August 31, 2006, based on provisional patent application No. 60/718716, we filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for "Methods and Compositions for Oral Administration of Proteins."



## 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 “Risk Factors” are forward looking statements.*

### Risks Related to Our Business

#### **There is substantial doubt as to our ability to continue as a going concern.**

Our financial statements were prepared on the assumption that we will continue as a going concern. We estimate that our cash reserves will not be sufficient to permit us to continue at our anticipated level of operations for our fiscal year ending August 31, 2011. During 2011, we plan to increase research and development, product development, and administrative expenses relating to our business, including expenses related to research and development related to our oral delivery platform. We intend to use our cash reserves, as well as other funds in the event that they shall become available on commercially reasonable terms, to finance these activities and other activities described herein, although we can provide no assurance that these additional funds will be available in the amounts or at the times we may require. If sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. See “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. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for a minimum of six months from the date of this Annual Report on Form 10-K. We estimate that 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, 2010 and August 31, 2009, we had working capital of \$938,225 and \$2,805,733, respectively, and stockholders' equity of \$830,272 and \$2,746,192, respectively. We generated no revenues to date. For the period from our inception on April 12, 2002 through August 31, 2010, the year ended August 31, 2010 and the year ended August 31, 2009, we incurred net losses of \$(12,986,054), \$(2,977,376), and \$(2,760,474), respectively. We may never achieve profitability and expect to incur net losses in the foreseeable future. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations.*"

**We rely upon patents to protect our technology. 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, rectal application for insulin, and oral administration of exenatides and proteins, and corresponding patent applications filed in Israel, South Africa and India. 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.

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.

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 "*Business—Patents and Licenses.*"

**At present, our success depends primarily on the successful commercialization of the 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 receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance of the products; 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 Medical Center, ETI Karle Clinical Pvt, Ltd., and OnQ Consulting to assist us in designing, conducting and managing our various clinical trials in Israel, South Africa, and India, respectively, as more fully described in “Description Business – Partnerships and Collaborative Agreements.” Any failure of such consultants to fulfill their obligations could result in significant additional costs as well as delays in designing, consulting and completing clinical trials on our products.

Notwithstanding the assistance of such consultants, 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 "*Business – Governmental 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 III) and sales and marketing of our oral insulin capsule and other products. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere.

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

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

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

**We depend upon our senior management and skilled personnel and their loss or unavailability could put us at a competitive disadvantage.**

We currently depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants and other key personnel, including Dr. Miriam Kidron, our Chief 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 “keyman” 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 and the related rules and regulations of the SEC, requires us to implement additional 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.

**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 its 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 private corporation (“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.

**Entera Ltd., our new joint venture with D.N.A, may not be successful**

Our transaction with D.N.A, Entera Ltd., may not realize all of its intended benefits. In connection with Entera

- we may be required to contribute additional funds to Entera to enable its continued operations;
- we may have difficulties in retaining key employees who are necessary to manage the new company; and
- there can be no assurance that Entera’s operations will ever result in profits that are distributed to us as shareholders.

Moreover, because Entera is a 50% held company, we do not have complete control over its operations, including business decisions which may impact Entera’s profitability.

**Healthcare policy changes, including pending proposals 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.

Recently, the United States 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.

### **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 quoted on the over-the-counter bulletin board ("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. 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 ability to obtain additional funding,
- Announcements of research activities, business developments, technological innovations or new products by companies or their competitors,
- Entering into or terminating strategic relationships,
- Changes in government regulation,
- Departure of key personnel,
- Disputes concerning patents or proprietary rights,
- Changes in expense level,
- Future sales of our equity or equity-related securities,
- Public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
- Activities of various interest groups or organizations,
- Media coverage, and
- Status of the investment markets.



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

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

**If our common stock is deemed to be a “penny stock,” it 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 Securities and Exchange Commission, or 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, subject to specific exemptions, such as if the issuer of the security has net tangible assets in excess of \$2,000,000. The market price of our common stock is currently less than \$5.00 per share and our net tangible assets as of August 31, 2009 are less than \$2,000,000. 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 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. These 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 loss.

We are aware of the abuses that have occurred in the market for low-priced stocks. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, we will strive within the confines of practical limitations to prevent such abuses with respect to our common stock.

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

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Currently, we have outstanding 58,756,535 shares of common stock. Of these shares, 35,741,879 shares, are freely tradable. Giving effect to the exercise in full of all of our outstanding warrants and options, we would have outstanding 72,650,218 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, 2010, we had outstanding 15,584,897 warrants and options (18,017,697 as of August 31, 2009). 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.

**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 of directors and will be dependent upon our financial condition, results of operations, capital requirements, and any other factors that our board of directors decides is relevant. See “*Market Price and Dividends*” and “*Description of Common Stock*”.

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

Our common stock currently 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. In addition, since December 1987, the State of Israel has experienced severe civil unrest primarily in the areas that came under its control in 1967. No prediction can be made as to whether these problems will be resolved. 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 all of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against our management for misconduct.**

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 any of our 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. federal 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 office space located in Givat-Ram, Jerusalem, Israel. The lease commenced on October 1, 2007 and is for a period of 51 months. The aggregate annual base rental fee for this space is \$7,532. We believe that our existing facilities are suitable and adequate to meet our current business requirements. In the event that we should require additional or alternative facilities, we believe that such facilities can be obtained on short notice at competitive rates.

**ITEM 3 - LEGAL PROCEEDINGS**

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

**ITEM 4 - [REMOVED AND RESERVED]**

## 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.OB". The quarterly high and low reported bid prices for our common stock as quoted on the OTCBB for the periods indicated are as follows:

	<u>High</u>	<u>Low</u>
<b>Year Ended August 31, 2009</b>		
Three Months Ended November 30, 2008	\$ 0.76	\$ 0.36
Three Months Ended February 28, 2009	\$ 0.52	\$ 0.25
Three Months Ended May 31, 2009	\$ 0.62	\$ 0.20
Three Months Ended August 31, 2009	\$ 0.59	\$ 0.40
<b>Year Ended August 31, 2010</b>		
Three Months Ended November 30, 2009	\$ 0.64	\$ 0.43
Three Months Ended February 28, 2010	\$ 0.48	\$ 0.37
Three Months Ended May 31, 2010	\$ 0.55	\$ 0.41
Three Months Ended August 31, 2010	\$ 0.51	\$ 0.36

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 \$0.32 on November 22, 2010.

#### Holder

As of November 23, 2010, there were 58,565,535 shares of our common stock issued and outstanding that are held of record by 59 registered stockholders. We believe that a number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories.

#### 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 of directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our board deems relevant.

## **Recent Sales of Unregistered Securities**

On November 9, 2010, we issued 253,714 shares of our common stock to Swiss Cap AG as remuneration for services rendered during 2010, in the amount of \$88,880. The shares were sold in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act. No underwriters were involved in the transaction or received any commissions or other compensation.

On November 16, 2010, we consummated a private placement by selling 937,500 units at a purchase price of \$0.32 per unit for a total consideration of \$300,000. Each unit consisted of one share of common stock and 0.35 share purchase warrant. Each share purchase warrant entitles the holder to purchase one share of common stock for a period of 5 years at an exercise price of \$0.50. The private placement was exempt from registration pursuant to Section 4(2) of the Securities Act.

## **Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

We did not purchase any of our shares of common stock or other securities during the fiscal year ended August 31, 2010.

## **Securities Authorized for Issuance under Equity Compensation Plans**

### ***2006 Stock Option Plan***

On October 15, 2006, our board of directors adopted the 2006 Stock Option Plan (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. As of August 31, 2010, options with respect to 1,700,000 shares were outstanding under the 2006 Plan, which amount reflects the aggregate grant of options with respect to 3,350,000 shares, of which 1,650,000 expired through August 31, 2010.

### ***2008 Stock Incentive Plan***

On May 5, 2008, our board of directors adopted the 2008 Stock Incentive Plan (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 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 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 have been reserved for the grant of options, which may be issued at the discretion of our board of directors from time to time. As of August 31, 2010, options with respect to 6,739,200 shares have been granted under the 2008 Plan, 978,000 of which have been forfeited.

### ***Other***

On August 14, 2007 we granted Dr. Miriam Kidron options to purchase up to 3,361,360 shares at an exercise price of \$0.001; the options vested immediately and have an expiration date of August 14, 2012. These options are not governed by any of the plans detailed above.

The following table sets forth information with respect to our equity compensation plans as of August 31, 2010:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weight-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (A))
	(A)	(B)	(C)
Equity compensation plans approved by security holders	—	—	—
Equity compensation plans not approved by security holders	10,822,560	\$ 0.25	3,538,000
<b>Total</b>	10,822,560	\$ 0.25	3,538,800

## ITEM 6 – SELECTED FINANCIAL DATA

As a smaller reporting company, we are not required to provide the information required by this Item.

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

The following discussion and analysis should be read in conjunction with our audited Financial Statements and Notes thereto for the years ended August 31, 2010 and 2009.

### Overview of Operations

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin pill to be used for the treatment of individuals with diabetes, rectal application of insulin, flu vaccines, use of orally ingestible pills for delivery of other polypeptides and use of rectal application 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 Medical Services and Development Ltd., as well as the other patents we have filed since. 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 or 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 chemically or biologically the insulin 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 other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of making future filings for drug approval in these countries. 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, including an insulin suppository and use of rectal application for delivery of other polypeptides.

#### *Long Term Business Strategy*

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to ensure 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 compliment our existing drug portfolio.

## **Results of Operations**

### ***Going concern assumption***

The accompanying financial statements have been prepared assuming that we will continue as a going concern. We have net losses for the period from inception (April 12, 2002) through August 31, 2010 of \$12,986,054, as well as negative cash flow from operating activities. Based upon our existing spending commitments, estimated at \$5.2 million for the twelve months following September 1, 2010, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through August 31, 2011. Accordingly, these factors raise substantial doubt about our ability to continue as a going concern. 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 shareholders.

The financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability.

### ***Critical accounting policies***

Our significant accounting policies are more fully described in the notes to our 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 financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these 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 financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

**Valuation of options and warrants:** We granted options to purchase shares of our common stock to employees and consultants and issued warrants in connection with fund raising.

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 estimated 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 a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

**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 its deferred tax assets.

Regarding our subsidiary, Oramed Ltd., the 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 abovementioned differences were not reflected in the computation of deferred tax assets and liabilities.

The following table summarizes certain statements of operations data for us for the twelve months period ended August 31, 2010 and 2009:

	Year ended	
Operating Data:	August 31, 2010	August 31, 2009
Research and development expenses, net	\$ 1,463,886	\$ 1,574,074
General and administrative expenses	1,508,667	1,210,044
Financial income, net	(10,148)	(21,047)
Loss before taxes on income	(2,962,405)	(2,763,071)
Taxes on income	14,971	(2,597)
Net loss for the period	\$ (2,977,376)	\$ (2,760,474)
Loss per common share – basic and diluted	\$ (0.05)	\$ (0.05)
Weighted average common shares outstanding	57,389,991	56,645,820

## ***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 contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations, or 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., our wholly owned Israeli subsidiary, 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 the OCS. This grant was used for research and development expenses for the period of February 2009 to June 2010. The grant is subject to repayment according to the terms determined by the OCS and applicable law. See "—Government Grants" below. The funds were designated and used by Oramed Ltd. to support further R&D and clinical study of its oral insulin capsule and Oral GLP1-Analog.

During the year ended August 31, 2010, research and development expenses totaled \$1,463,886, compared to \$1,574,074 for the year ended August 31, 2009. The decrease is mainly attributable to a decrease in purchase of clinical materials. The research and development costs include stock based compensation costs, which during the year ended August 31, 2010, totaled \$341,203 as compared to \$264,861 during the year ended August 31, 2009.

## **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, commonly referred to as 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, 2010 and 2009, we recognized research and development grants in an amount of \$350,198 and \$400,405, respectively. As of August 31, 2010, 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 licenses. 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, up to 10% of a company's approved Israeli manufacturing volume, measured on an aggregate basis, may be transferred out of Israel. In addition, upon the approval of the Chief Scientist, 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 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 the 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 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, except in certain special circumstances and subject to the OCS' prior approval. The OCS may approve the transfer of OCS-funded know-how outside Israel, generally 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 (according to certain formulas), or (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 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 directly 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 ordinary shares 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.

#### ***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, 2010, general and administrative expenses totaled \$1,508,667 compared to \$1,210,044 for the year ended August 31, 2009. Costs incurred related to general and administrative activities during the year ended August 31, 2010 reflect an increase of professional, legal and consulting expenses and an increase in business development costs. During the year ended August 31, 2010, as part of our general and administrative expenses, we incurred \$466,623 related to stock options granted to employees and consultants, as compared to \$288,338 during the year ended August 31, 2009.

#### ***Financial income/expense, net***

During the year ended August 31, 2010, we generated interest income on available cash and cash equivalents balance which were offset by bank charges. During the year ended August 31, 2009, we incurred imputed interest expenses on convertible notes issued as well as bank charges.

The decrease in the interest income for the year ending August 31, 2010 as compared with the year ended August 31, 2009 is attributable to the decrease in interest rates in both the United States and the State of Israel, and to decrease in cash and cash equivalents.

#### **Liquidity and Capital Resources**

Since inception through August 31, 2010, we incurred losses in an aggregate amount of \$12,986,054. We have financed our operations through the private placements of equity and debt financing, raising a total of \$8,308,785, net of transaction costs. We will seek to obtain additional financing through similar sources. As of August 31, 2010, we had \$1,199,638 of available cash as well as \$100,000 in short term interest bearing investments. We anticipate that we will require approximately \$5.2 million to finance our activities during the twelve months following September 1, 2010.

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 shareholders as well as receive additional funding from the OCS.

During our fiscal years 2009 and 2010 we issued 1,312,515 common shares to various third party vendors for services rendered. The aggregate value of those shares was approximately \$589,000. Subsequent to our year-ended August 31, 2010, we issued an addition 253,714 shares of common stock valued at \$88,880 to a third party for services rendered. We also consummated a private placement by selling 937,500 units at a purchase price of \$0.32 per unit for a total consideration of \$300,000. Each unit consisted of one share of common stock and 0.35 share purchase warrant. Each share purchase warrant entitles the holder to purchase one share of common stock for a period of 5 years at an exercise price of \$0.50.

#### ***Employee's and Consultant's Stock Options and Warrants***

Employee and consultant stock options grant and warrant issuance activities for the fiscal year 2010 include the following:

- On November 23, 2009 we granted options under the 2008 Stock Incentive Plan to purchase up to 100,000 shares of our common stock at an exercise price of \$0.76 to a consultant.

- On November 23, 2009 we granted options under the 2008 Stock Incentive Plan to purchase up to 36,000 shares of our common stock at an exercise price of \$0.46 to an employee of our subsidiary.

- On March 16, 2010, 50,000 options were granted to a consultant of our subsidiary at an exercise price of \$0.50 per share. The options vest in three equal annual installments commencing on March 16, 2011 and will expire on March 15, 2015.

- On March 16, 2010, 100,000 options were granted to a consultant of the Company at an exercise price of \$0.43 per share. The options vest in three equal monthly installments commencing on March 30, 2010 and will expire on March 15, 2015.

- On March 16, 2010, 13,200 options were granted to a consultant of the Company at an exercise price of \$0.43 per share. The options vest in six monthly installments commencing on March 30, 2010 and will expire on March 15, 2015.

- On March 25, 2010, 100,000 options were granted to a consultant of the Company at an exercise price of \$0.50 per share. The options vest in four equal quarterly installments commencing on May 17, 2010 and will expire on March 24, 2015.

- On April 21, 2010, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Stock Option 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 will vest in twenty equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.

On July 8, 2010, 300,000 options were granted to a director at an exercise price of \$0.48 per share. The options vest in three equal annual installments commencing on July 8, 2011 and will expire on July 7, 2020.

#### **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, 2010 are as follows:

<b>Category</b>	<b>Amount</b>
Research & Development, net of OCS funds	\$ 4,033,000
General & Administrative expenses	1,204,000
Finance income, net	2,000
Total	<u>\$ 5,239,000</u>

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. Our ability to proceed with these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us.

#### **ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As a smaller reporting company, we are not required to provide the information required by this Item.

#### **ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

See Item 15.

#### **ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## ITEM 9A – CONTROLS AND PROCEDURES

### (a) Disclosure Controls and Procedures

Our management, including our chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of August 31, 2010. 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, 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, is accumulated and communicated to our management, including our principal executive and principal 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 Commission's rules and forms.

### (b) 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) of the Securities Exchange Act of 1934, as amended. 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 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 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 principal executive officer and principal financial officer, we evaluated the effectiveness of our internal control over financial reporting as of August 31, 2010 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, 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 CFO 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.

Based on this evaluation, our management concluded that the Company's internal controls over financial reporting were not effective as of August 31, 2010 at a reasonable assurance level.



During the year ended August 31, 2010, management started an extensive program of documenting all processes related to the financial reporting, in order to strengthen our internal controls over financial reporting in order to reasonably ensure the reliability of financial reporting and the preparation of financial statements.

This management report on internal control over financial reporting shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or otherwise subject to the liabilities of that Section.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Commission that permit us to provide only management's report in this Annual Report.

**(c) Changes in Internal Control over Financial Reporting**

There were no changes in our internal controls over financial reporting identified with the evaluation thereof that occurred during the quarter ended August 31, 2010 that have materially affected, or are reasonable likely to materially affect our internal control over financial reporting.

**ITEM 9B – OTHER INFORMATION**

None.

## 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, executive officers and significant employees.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Nadav Kidron	36	President, Chief Executive Officer and Director
Miriam Kidron	69	Chief Medical and Technology Officer and Director
Leonard Sank	45	Director
Harold Jacob	56	Director and member of the Scientific Advisory Board
Michael Berelowitz	66	Director
Yifat Zommer	36	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, executive officer and significant employee, 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 as President, Chief Executive Officer and director in March 2006. From 2003 to 2006, he was the managing director at the Institute of Advanced Jewish Studies – Bar Ilan University. From 2001 to 2003, he was a legal intern at Wine Mishaiker and Erenstov Law Offices in Jerusalem, Israel. Mr. Kidron holds an LLB from Bar – Ilan University and is currently enrolled in the International MBA program at Bar – Ilan University.

**Dr. Miriam Kidron** was appointed as Chief Medical and Technology Officer and director in March 2006. Dr. Kidron is a pharmacologist and a biochemist with a PhD in biochemistry. From 1990 to 2007, Dr. Kidron has been 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.

**Mr. Leonard Sank** was appointed as a director in October 2007. Mr. Sank is a South African entrepreneur and business man who is devoted to entrepreneurial endeavors and initiatives. He has over 20 years of experience playing important leadership roles in developing businesses. He was a director in Eastvaal Motor Group, a diversified retail motor business. He was also a director in Vecto Finance, a credit lending business. He has also served as a director of Macsteel Service Centres SA Pty Ltd., South Africa's largest private company. He also serves on the board of local non-profit charity organizations in Cape Town, where he resides.

**Dr. Harold Jacob** was appointed as a director in July 2008. Since 1998, Dr. Jacob has served as the president of Medical Instrument, 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., during the years 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 Ballard. Since 2003, Dr. Jacob has served as the CEO of NanoVibronix, 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 in the years 1986-1995, and was a Clinical Assistant Professor of Medicine at SUNY during the years 1983-1990. Dr. Jacob founded and served as Editor in Chief of Endoscopy Review and has authored numerous publications in the field of gastroenterology.

**Dr. Michael Berelowitz** was appointed as a director on June 1, 2010. Since 2009, Dr. Berelowitz has 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 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 American Diabetes Association, 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.

**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 PricewaterhouseCoopers (PwC), where she served for five years. Ms. Zommer holds a Bachelor of Accounting and Economics degree from the Hebrew University and Business Administration (MBA) from Tel-Aviv University. 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 of directors 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 of directors has determined that Leonard Sank, Harold Jacob and Michael Berelowitz are independent as defined under the rules promulgated by the NASDAQ Stock Market. For the past three years, we have not held an annual meeting of stockholders. We intend to hold an annual meeting of stockholders during fiscal year 2011.

## Board Meeting Attendance

During the year ended August 31, 2010, our board held six meetings and took actions by written consent on 13 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.

## Committees

As of August 31, 2010 the Board has not established any committees. The Board intends to establish an audit and compensation committee during the year ending August 31, 2011. The Board has not established a nominating committee because it believes that the Board, of which three of its five members are independent directors, is qualified to fulfill that function.

## 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 2010, we believe that during fiscal year 2010, our executive officers, directors and all persons who own more than ten percent of a registered class of our equity securities complied with all Section 16(a) filing requirements.

## Code of Ethics

We have adopted a Code of Ethics for our officers, directors and employees. A copy of the Code of Ethics 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 years ended August 31 2009 and 2010 by our President and Chief Executive Officer, our Chief Medical and Technology Officer, our Chief Financial Officer and former Chief Financial Officer (the "Named Executive Officers"):

Name and Principal Position	Year	Salary	Option Awards	All Other Compensation	Total
	(1)	(\$)	(\$) (2)	(\$) (3)	(\$)
Nadav Kidron President and CEO and director (4)	2010	159,919	236,344	10,783	407,046
	2009	155,359	153,855	15,474	324,688
Miriam Kidron Chief Medical and Technology Officer and director (5)(6)	2010	160,092	236,344	7,727	404,163
	2009	154,983	153,855	11,539	320,377
Yifat Zommer CFO, Treasurer and Secretary (7)	2010	76,896	81,803	26,979	185,678
	2009	20,468	19,946	11,245	51,659
Chaime Orlev CFO and Secretary(8)	2009	59,300	Nil	25,544	84,844

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

2 The amounts reflect the compensation expense in accordance with FAS 123(R) of these option awards. The assumptions used to determine the fair value of the option awards for fiscal years ended August 31, 2010 and 2009 are set forth in the notes to of our audited consolidated financial statements included in our Form 10-K for fiscal year ended August 31, 2010. 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 was appointed as our President, CEO and Director on March 8, 2006 and receives compensation from our subsidiary through KNRY, an Israeli entity owned by Mr. Kidron. See "Employment and Consulting Agreements."

5 Dr. Kidron was appointed as our Chief Medical and Technology Officer and Director on March 8, 2006 and receives compensation from our subsidiary through KNRY, an Israeli entity owned by Mr. Kidron. See "Employment and Consulting Agreements."

6 See "Certain Relationships and Related Transactions and Director Independence" for a description of management fees received by Dr. Kidron from Hadasit.

7 Ms. Zommer was appointed as our CFO, Treasurer and Secretary on April 19, 2009.

8 Mr. Orlev served as our CFO and Secretary from May 1, 2008 through March 31, 2009.

### All Other Compensation Table

All Other Compensation amounts in the Summary Compensation Table consist of the following:

Name	Year	Automobile Related Expenses	Manager's Insurance *	Education Fund*	Total (\$)
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		(\$)				
Nadav Kidron	2010	10,783	Nil	Nil	10,783	
Miriam Kidron	2010	7,727	Nil	Nil	7,727	
Yifat Zommer	2010	9,814	11,466	5,699	26,979	

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\* 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, 2010.

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	850,000 <sup>(1)</sup>	-	0.45	08/01/12
	720,000 <sup>(2)</sup>	144,000 <sup>(2)</sup>	0.54	05/06/18
	864,000 <sup>(5)</sup>	612,000 <sup>(2)</sup>	0.49	04/20/20
Miriam Kidron	3,361,360 <sup>(3)</sup>	-	0.001	08/13/12
	850,000 <sup>(1)</sup>	-	0.45	08/01/12
	720,000 <sup>(2)</sup>	144,000 <sup>(2)</sup>	0.54	05/06/18
	864,000 <sup>(5)</sup>	612,000 <sup>(2)</sup>	0.49	04/20/20
Yifat Zommer	-	400,000 <sup>(4)</sup>	0.47	10/19/19

- (1) On August 2, 2007, 850,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2006 Stock Option Plan at an exercise price of \$0.45 per share; the options vested immediately and have an expiration date of August 2, 2012.
- (2) On May 7, 2008, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Stock Option 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 will vest in twenty equal monthly installments, commencing on June 7, 2008. The options have an expiration date of May 7, 2018.
- (3) On August 14, 2007 3,361,630 stock options were granted to Miriam Kidron, at an exercise price of \$0.001 per share; the options vested immediately and have an expiration date of August 14, 2012. These options were not issued pursuant to any outstanding award plans.
- (4) On June 3, 2009, 400,000 options were granted to Yifat Zommer under the 2008 Stock Option 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.
- (5) On April 21, 2010, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Stock Option 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 will vest in twenty one equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.

## Stock Option Plans

### 2006 Stock Option Plan

On October 15, 2006, our board of directors adopted the 2006 Stock Option Plan (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. As of August 31, 2010, options with respect to 1,700,000 shares were outstanding under the 2006 Plan, which amount reflects the aggregate grant of options with respect to 3,350,000 shares, of which 1,650,000 expired through August 31, 2010.

## **2008 Stock Incentive Plan**

On May 5, 2008, our board of directors adopted the 2008 Stock Incentive Plan (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 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 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 have been reserved for the grant of options, which may be issued at the discretion of our board of directors from time to time. As of August 31, 2010, options with respect to 6,739,200 shares have been granted under the 2008 Plan, 978,000 of which have been forfeited.

### **Other**

On August 14, 2007 we granted Dr. Miriam Kidron options to purchase up to 3,361,360 shares at an exercise price of \$0.001; the options vested immediately and have an expiration date of August 14, 2012. These options are not governed by any of the plans detailed above.

### **Stock Options Grants**

We made the following stock options grants to the Named Executive Officers and directors during the year ending August 31, 2010:

- On April 21, 2010, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Stock Option 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 will vest in twenty equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.

- On July 8, 2010, 300,000 options were granted to a director at an exercise price of \$0.48 per share. The options vest in three equal annual installments commencing on July 8, 2011 and will expire on July 7, 2020.

### **Employment and Consulting Agreements**

Effective August 1, 2007, we entered into employment agreements with KNRV Ltd. (“KNRV”), pursuant to which Nadav Kidron and Dr. Miriam Kidron provided employment services to our company. Based on the agreements, Nadav Kidron served as the President and Chief Executive officer and Miriam Kidron served as the Chief Medical and Technology Officer of the Company. As remuneration for such services, KNRV was paid \$20,000 per month, commencing on August 1, 2007.

On July 1, 2008, Oramed Ltd., our Israeli subsidiary, entered into a consulting agreement with KNRV, whereby Mr. Nadav Kidron, through KNRV, provides services as President and Chief Executive Officer of both the Company and Oramed Ltd. (the “Nadav Kidron Consulting Agreement”). Additionally, on July 1, 2008, Oramed Ltd. entered into a consulting agreement with KNRV whereby Dr. Miriam Kidron, through KNRV, provides services as Chief Medical and Technology Officer of both the Company and Oramed Ltd. (the “Miriam Kidron Consulting Agreement” and together with the Nadav Kidron Consulting Agreement, the “Consulting Agreements”). The Consulting Agreements replace the employment agreements entered into between the Company and KNRV, dated as of August 1, 2007 referenced above.

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 New Israeli Shekels 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 November 2, 2008, we entered into 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 law.

The Company, through its Israeli subsidiary, Oramed Ltd., has 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 Oramed. On August 31, 2009, the agreement was amended, pursuant to which Ms. Zommer's gross monthly salary will be NIS 22,000 (\$5,764). In accordance with the employment agreement, as amended, as of October 19, 2009, Ms. Zommer's gross monthly salary was increased to NIS 24,200 (\$6,340).

On April 19, 2009, Oramed and Ms. Zommer also entered into an indemnification agreement, pursuant to which Oramed agrees to indemnify Ms. Zommer for any liability she may incur by reason of the fact that she serves as Oramed's CFO, to the maximum extent permitted by law.

## Director Compensation

Directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors. 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 (for the period from September 1, 2008 to May 31, 2010 - \$8,000 per annum). The board of directors may award special remuneration to any director undertaking any special services on behalf of us other than services ordinarily required of a director.

Other than 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.

The following table sets forth director compensation for the year ended August 31, 2010.

Name of Director	Fees Earned or Paid in Cash (\$)	Option Awards (1) (\$)	Total (\$)
Nadav Kidron <sup>(2)</sup>			
Miriam Kidron <sup>(2)</sup>			
Leonard Sank	8,500	45,218	53,718
Harold Jacob	8,500	45,218	53,718
Michael Berelowitz	2,500	11,201	13,701

1 The amounts reflect the compensation expense in accordance with FAS 123(R) of these option awards. The assumptions used to determine the fair value of the option awards are set forth in Note 8 of our audited consolidated financial statements included in this 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.



2 Please refer to the summary compensation table for executive compensation with respect to the named individual.

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of August 31, 2010 by (i) by each person who is known by us to own beneficially more than 5% of the Common Stock, (ii) by each of the Named Executive Officers and (iii) by all our directors and executive officers as a group. On such date, we had 57,565,321 shares of Common Stock outstanding.

As used in the table below and elsewhere in this form, the term “*beneficial ownership*” with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following August 31, 2010.

Name and Address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Nadav Kidron †‡ 10 Itamar Ben Avi St. Jerusalem, Israel	12,373,735 <sup>(1)</sup>	20.77%
Zeev Bronfeld 6 Uri St. Tel-Aviv, Israel	6,158,517	10.70%
Miriam Kidron †‡ 2 Elza St. Jerusalem, Israel	5,363,360 <sup>(2)</sup>	8.52%
Apollo Nominees Inc One Financial Place Suite 100 Lower Collymore Rock St. Michael, Barbados	3,577,501 <sup>(3)</sup>	6.09%
Hadasit Medical Research Services & Development Ltd. P.O. Box 12000 Jerusalem, Israel	4,141,532	7.19%
Leonard Sank † 3 Blair Rd Camps Bay Cape Town, South Africa	2,582,650 <sup>(4)</sup>	4.47%
Harold Jacob † Haadmur Mebuyon 26 Jerusalem, Israel	100,000 <sup>(5)</sup>	*
Michael Berelowitz † 415 East 37 <sup>th</sup> Street New York, NY, USA	—	—
Yifat Zommer ‡ P.O. Box 39098, Jerusalem, Israel	133,333 <sup>(6)</sup>	*
All current executive officers and directors, as a group (six persons)	20,553,078 <sup>(7)</sup>	34.17%

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\* Less than 1%

† Indicates Director

‡ Indicates Officer

- (1) Includes 2,002,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (2) Includes 5,363,360 shares of common stock issuable upon the exercise of outstanding stock options.
- (3) Includes 1,145,834 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (4) Includes 225,000 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (5) Consists of 100,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (6) Consists of 133,333 shares of common stock issuable upon the exercise of outstanding stock options.
- (7) Includes 7,863,693 shares of common stock issuable upon the exercise of outstanding stock options.

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

Except as otherwise indicated below, during the fiscal year 2010 we have not been a party to any transaction, 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 holder, or any member of the immediate family of the foregoing persons has had or will have a direct or indirect material interest.

Our policy is to enter into transactions with related parties 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 parties transactions are approved by our board of directors.

On June 1, 2010, our subsidiary Oramed Ltd., entered into an agreement with D.N.A Biomedical Solutions Ltd (formerly, Laser Detect Systems Ltd) ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera"). Under the terms of a license agreement that was entered into between Oramed and Entera, Oramed will out-license 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 a different patent application. Entera's initial development effort will be an oral formulation for the treatment of osteoporosis. Mr. Zeev Bronfeld, who is one of D.N.A's controlling shareholders, holds approximately 10.71% of our outstanding common stock (see "Securities Ownership of Certain Beneficial Owners and Management"). See "Item 1 – Business – Description of Business – Out-Licensed Technology" for further information.

The board of directors has determined that Leonard Sank, Harold Jacob and Michael Berelowitz are independent as defined under the rules promulgated by the NASDAQ Stock Market.

See "Employment and Consulting Agreements" above for information as to the agreements with our employees and consultants.

### ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES

We incurred the following fees to Kesselman & Kesselman, certified public accountants in Israel, a member of PricewaterhouseCoopers International Limited, for services rendered during the fiscal years ended August 31, 2010 and 2009:

<b>Summary:</b>	<b>2010</b>	<b>2009</b>
Audit fees <sup>(1)</sup>	\$ 65,880	\$ 60,000
Tax fees <sup>(2)</sup>		\$ 15,000

(1) Amount represents fees paid for professional services for the audit of our consolidated annual financial statements and review of our interim consolidated financial statements included in quarterly reports and services that are normally provided by our accountants in connection with statutory and regulatory filings or engagements.

(2) Amount represents fees paid for professional services for tax compliance and tax advice.

We do not have an Audit Committee. As such, our entire Board of Directors acts as our audit committee. No formal pre-approval process has been adopted.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

**(a)(1) Financial Statements**

The following financial statements are filed as part of this report:

	<b>Page</b>
<b>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - Report of Kesselman &amp; Kesselman</b>	F-1
<b>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - Report of Malone &amp; Bailey, PC</b>	F-2
<b>CONSOLIDATED FINANCIAL STATEMENTS:</b>	
Balance sheets	F-3
Statements of operations	F-4
Statements of changes in stockholders' equity	F-5
Statements of cash flows	F-6
Notes to financial statements	F-7-F-29

## 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, 2010 and 2009, 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, 2010 (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, 2010 and 2009, 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, 2010 (not separately presented herein), in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1a to the financial statements, the Company has suffered recurring losses for the period from inception (April 12, 2002) through August 31, 2010 and presently the Company does not have sufficient cash and other resources to meet its requirements in the following twelve months. These factors raise substantial doubts as to the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1a. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty

Kesselman & Kesselman

Tel Aviv, Israel  
November 29, 2010

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.

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

	<b>August 31</b>	
	<b>2010</b>	<b>2009</b>
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,199,638	\$ 1,716,866
Short term investments (note 2)	100,000	1,000,000
Restricted cash (note 1n)	16,008	16,000
Accounts receivable - other	59,175	36,939
Prepaid expenses	1,859	4,119
Related parties (note 13)	7,689	
Grants receivable from the Chief Scientist	12,438	400,405
Total current assets	<u>1,396,807</u>	<u>3,174,329</u>
<b>LONG TERM DEPOSITS</b> (note 6b)	<u>10,582</u>	<u>12,161</u>
<b>PROPERTY AND EQUIPMENT, NET</b> (note 5)	<u>43,499</u>	<u>75,361</u>
Total assets	<u>\$ 1,450,888</u>	<u>\$ 3,261,851</u>
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses (note 9)	\$ 411,330	\$ 321,344
Account payable with former shareholder	47,252	47,252
Total current liabilities	<u>458,582</u>	<u>368,596</u>
<b>PROVISION FOR UNCERTAIN TAX POSITION</b> (note 12f)	<u>162,034</u>	<u>147,063</u>
<b>COMMITMENTS</b> (note 6)		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$ 0.001 par value (200,000,000 authorized shares; 57,565,321 and 56,456,710 shares issued and outstanding as of August 31, 2010 and 2009, respectively)	57,565	56,456
Additional paid-in capital	13,758,761	12,698,414
Deficit accumulated during the development stage	(12,986,054)	(10,008,678)
Total stockholders' equity	<u>830,272</u>	<u>2,746,192</u>
Total liabilities and stockholders' equity	<u>\$ 1,450,888</u>	<u>\$ 3,261,851</u>

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



**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, 2010
	2010	2009	
<b>RESEARCH AND DEVELOPMENT EXPENSES, NET</b> (note 10)	\$ 1,463,886	\$ 1,574,074	\$ 6,692,540
<b>IMPAIRMENT OF INVESTMENT</b>			434,876
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b> (note 11)	1,508,667	1,210,044	5,682,423
<b>OPERATING LOSS</b>	2,972,553	2,784,118	12,809,839
<b>FINANCIAL INCOME</b>	(24,692)	(38,602)	(160,800)
<b>FINANCIAL EXPENSE</b>	14,544	17,555	162,477
<b>LOSS BEFORE TAXES ON INCOME</b>	2,962,405	2,763,071	12,811,516
<b>TAXES ON INCOME</b> (note 12)	14,971	(2,597)	174,538
<b>NET LOSS FOR THE PERIOD</b>	<u>\$ 2,977,376</u>	<u>\$ 2,760,474</u>	<u>\$ 12,986,054</u>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>	
<b>WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK</b>	<u>57,389,991</u>	<u>56,645,820</u>	

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		Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	\$			
<b>BALANCE AS OF APRIL 12, 2002 (inception)</b>	34,828,200	\$ 34,828	\$ 18,872		\$ 53,700
<b>CHANGES DURING THE PERIOD FROM APRIL 12, 2002 THROUGH AUGUST 31, 2008:</b>					
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 ISSUED FOR CASH- NET OF ISSUANCE EXPENSES	37,359,230	37,359	7,870,422		7,907,781
SHARES ISSUED FOR SERVICES	418,025	418	214,442		214,860
CONTRIBUTIONS TO PAID IN CAPITAL			18,991		18,991
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
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			2,428,014		2,428,014
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			381,764		381,764
DISCOUNT ON CONVERTIBLE NOTE RELATED TO BENEFICIAL CONVERSION FEATURE			108,000		108,000
COMPREHENSIVE LOSS				(16)	(16)
IMPUTED INTEREST			12,217		12,217
NET LOSS				(7,248,188)	(7,248,188)
<b>BALANCE AS OF AUGUST 31, 2008</b>	<b>56,252,806</b>	<b>56,252</b>	<b>11,785,012</b>	<b>(7,248,204)</b>	<b>4,593,060</b>
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)
<b>BALANCE AS OF AUGUST 31, 2009</b>	<b>56,456,710</b>	<b>56,456</b>	<b>12,698,414</b>	<b>(10,008,678)</b>	<b>2,746,192</b>
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)
<b>BALANCE AS OF AUGUST 31, 2010</b>	<b>57,565,321</b>	<b>\$ 57,565</b>	<b>\$ 13,758,761</b>	<b>\$ (12,986,054)</b>	<b>\$ 830,272</b>

The accompanying notes are an integral part of the consolidated 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 March 8, 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 6a.

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

The Company has suffered recurring losses for the period from inception (April 12, 2002) through August 31, 2010 amounting to \$12,986,054, as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash and other resources to meet its requirements in the twelve months following September 1, 2010. These factors raise substantial doubts as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. Management is in the process of evaluating various financing alternatives through fund raising in the public or private equity markets, as the Company will need to finance future research and development activities and general and administrative expenses. Although there is no assurance that the Company 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, existing shareholders, as well as on going funding from the Office of the Chief Scientist ("OCS"), (see note 6h).

These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

**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"). In June 2009, the Financial Accounting Standards Board ("FASB") issued the FASB Accounting Standards Codification ("Codification" or "ASC"). The Codification became the single authoritative source for U.S. GAAP and changed the way in which the accounting literature is organized. The Codification does not change U.S. GAAP and accordingly its adoption did not have a material impact on the Company's consolidated financial statements

**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 statement 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.

**d. Functional currency**

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

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

For the year ended August 31, 2010, the group recorded \$10,650 as financial income derived from exchange rate differences.

**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 a 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

**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.

**ORAMED PHARMACEUTICALS INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

**h. Research and development**

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, employee benefits, 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, 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. 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, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Grants received from the OCS are recognized 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. See also note 6h.

**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 2009 and 2010.

**k. Loss per share**

Basic and diluted net losses per share of common stock 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, warrants and convertible notes 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 15,584,897 for the year ended August 31, 2010 (18,017,697 for the year ended August 31, 2009).

**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.



**ORAMED PHARMACEUTICALS INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

**n. Fair value measurement:**

On September 1, 2008, the Company adopted the methods of fair value as described in the authoritative guidance issued by the FASB, which defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosure about fair value measurements to value its financial assets and liabilities. As defined in the guidance, 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, 2009 the only assets or liabilities measured at fair value comprise of derivatives, which have a negligible fair value, measured based on observable prices (level 2).

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.

**o. 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 in the opinion the credit risk in respect of these balances is remote.

**p. Newly issued and recently adopted accounting pronouncements:**

In June 2009, the FASB updated accounting guidance relating to variable interest entities. As applicable to the Company, this will become effective as of the first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. As applicable to the Company, the adoption of the new guidance is not expected to have a material impact on the consolidated financial statements.

**ORAMED PHARMACEUTICALS INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

**q. Reclassifications**

Certain figures in respect of prior year 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. The bank deposits are in US Dollars and bear interest of 0.4% and 1.4% per annum as of August 31, 2010 and 2009, respectively.

**NOTE 3 - FAIR VALUE OF FINANCIAL INSTRUMENTS:**

The financial instruments of the Group consist mainly of cash and cash equivalents, current receivables and accounts payable and accruals.

The fair value of the financial instruments included in the working capital of the Group is identical or close to their carrying value.

**NOTE 4 - INVESTMENT IN A JOINT VENTURE**

- a. On June 1, 2010, the subsidiary of the Company entered into an agreement with D.N.A Biomedical Solutions Ltd (formerly, Laser Detect Systems Ltd) ("D.N.A"), an Israeli company, for the establishment of a new company, Entera Bio Ltd. ("Entera"), ("the JV Agreement"). According to the JV Agreement, D.N.A will invest \$600,000 in Entera, and Entera will be owned in equal parts by the subsidiary and D.N.A. In consideration for 50% of Entera's shares, the Subsidiary of the Company will enter into a Patent License Agreement with Entera, according to which, the subsidiary of the Company will out-license to Entera a technology for the development of oral delivery drugs for certain actions. The out-licensed technology differs from Oramed's main delivery technology that is used for oral insulin and is subject to a different patent application. Entera's initial development effort will be an oral formulation for the treatment of osteoporosis. Entera's Chief Executive Officer will be granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital. In the event that Entera has not obtained third-party financing by June 1, 2011, or such other date mutually agreed upon by the parties, each of the subsidiary and D.N.A will be required to make a capital contribution to Entera in the amount of \$150,000. The agreement also contains customary provisions with respect to preemptive rights, rights of first refusal, drag-along rights, veto rights and information rights. Mr. Zeev Bronfeld, who is one of D.N.A 's controlling shareholders, is also an affiliated shareholder of the Company. On August 19, 2010, the closing of the transaction took place and the subsidiary of the Company and Entera entered into the Patent License Agreement. On August 31, 2010, D.N.A. invested \$400,000 in Entera.

As of August 31, 2010, the Group holds 50% of the issued and outstanding share capital of Entera (45% - on fully diluted basis). As the Group did not obtain control in Entera, these consolidated financial statements do not include Entera's financial statement.

**ORAMED PHARMACEUTICALS INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 4 - INVESTMENT IN A JOINT VENTURE** (continued)

The Group recognized deferred income at the amount of \$200,000 (50% of \$400,000) that is presented as a provision and deducted from investment account at the same amount. As of August 31, 2010, Entera's losses from operations are at the amount of \$134,049.

Entera continued activities as a going concern are subject to additional financing until the completion of the development activities and the commencement of profit generating sales.

The Company has concluded Entera is a variable interest entity according to of the terms of the JV Agreement. The Company reviewed several factors to determine whether the Company is the primary beneficiary of Entera, including the nature of Entera's financing, its management structure, the nature of day-to-day operations and certain other factors. Based on those factors, the Company determined that it is not the primary beneficiary of Entera. The Company recognized its share of losses from this entity under the equity method, offset with a corresponding amount of revenue recognition on the out-license agreement.

- b. The investment in Entera is composed at follows:

	<b>August 31</b>
	<b>2010</b>
Share in Entera's shareholders	\$ 200,000
Currency translation adjustment	(176)
Less - equity losses	<u>(67,025)</u>
	132,799
Less - deferred income	<u>(132,799)</u>
Net investment	<u><u>-,</u></u>

**NOTE 5 - PROPERTY AND EQUIPMENT, Net:**

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

	<b>August 31</b>	
	<b>2010</b>	<b>2009</b>
<b>Cost:</b>		
Leasehold improvements	\$ 76,029	\$ 76,029
Office furniture and equipment	19,941	19,941
Computers and peripheral equipment	25,333	25,333
	<u>121,303</u>	<u>121,303</u>
Less - accumulated depreciation and amortization	77,804	45,942
	<u>\$ 43,499</u>	<u>\$ 75,361</u>

- b. Depreciation expenses totaled \$31,862 and \$30,488 in the years ended August 31, 2010 and 2009, respectively.

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

**NOTE 6 - 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.

On January 7, 2009, the Company entered into a second agreement with Hadasit (the "Second Agreement") to provide for the closing referenced in the First Agreement. In the Second Agreement, Hadasit confirms that it 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.

On July 8, 2009 the Company entered into a third agreement with Hadasit, Prof. Itamar Raz and Dr. Miriam Kidron ("the Third Agreement"), to provide consulting and clinical trial services. According to the Third Agreement, Hadasit will be entitled to a 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 will be paid in accordance with the actual progress of the study. The total amount that was paid through August 31, 2010 was \$359,255.

- 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, 2010 and 2009 were \$37,583 and \$44,092, respectively. The future lease payments under the lease agreement are \$39,292, \$22,945 and \$13,047 for the years ending August 31, 2011, 2012 and 2013, respectively.

As security for its obligation under the lease agreements the Subsidiary deposited \$9,010, which are classified as long term deposits.

- c. On September 19, 2007 the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement is for a period of 51 months, and will end on December 31, 2011. The monthly lease payment is 2,396 NIS and is linked to the increase in the Israeli consumer price index, (as of August 31, 2010 the monthly payment in the Company's functional currency is \$628, the future annual lease payments under the agreement for the years ending August 31, 2011 and 2012 are \$7,532 and \$2,512, respectively).

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. As to a Clinical Trial Manufacturing Agreement with Swiss Caps AG, see note 8a.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

- e. On April 21, 2009, the subsidiary entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. ("ADRES") 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. IND according to FDA regulations. In consideration for the services provided under the agreement, ADRES will be entitled to a total cash compensation of \$211,000, of which the amount \$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 August 31, 2010, of that \$30,000 were paid for completing the three first milestones.
- f. On February 10, 2010, the subsidiary entered into an agreement with Vetgenerics Research G. Ziv Ltd, a clinical research organization (CRO), to conduct a toxicology trial on its oral insulin capsules. The total cost estimated for the studies is €107,100 (\$133,040) of which €12,195 (\$16,806) was paid through August 31, 2010 and additional \$38,147 are presented as accounts payables.
- g. On May 2, 2010, the subsidiary entered into an agreement with SAFC Pharma, a division of the Sigma-Aldrich Corporation, to develop a process to produce one of its oral capsule ingredients, for a total estimated consideration of \$269,600, of which \$35,589 are presented as accounts payables.
- h. On July 5, 2010, the subsidiary of the Company entered into a Manufacturing Supply Agreement (MSA) with Sanofi-Aventis Deutschland GMBH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply the subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the USA.
- i. Grants from the Chief Scientist Office ("OCS")

The subsidiary is committed to pay royalties to the Government of Israel on proceeds from sales of products in the research and development of which the Government participates by way of grants.

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.

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.

On August 31, 2010, the subsidiary has not yet realized any revenues from the said project and did not incur any royalty liability. For the years ended August 31, 2010, and 2009, and for the period from inception on April 12, 2002 through August 31, 2010, the research and development expenses are presented net of OCS Grants, in the total amount of \$350,198 and \$400,405 and \$750,603, respectively.

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

**NOTE 7 - 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, 2010 and 2009:

- a. As to shares issued as part of stock based compensation plan see Note 8.
- b. As to a Clinical Trial Manufacturing Agreement with Swiss Caps AG, see note 8a.

**NOTE 8 - STOCK BASED COMPENSATION:**

On October 15, 2006, the Company's Board of Directors adopted the 2006 Stock Option Plan (the "2006 Stock Option Plan").

On May 5, 2008, the Company's Board of Directors adopted the 2008 Stock Option Plan (the "2008 Stock Option Plan").

Under both plans 11,000,000 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 these plans, 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

The following are stock options and warrants transactions made during the years ended August 31, 2009 and 2010:

- a. On October 30, 2006 the Company entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG (“Swiss”), pursuant to which Swiss would manufacture and deliver the oral insulin capsule developed by the Company. In consideration for the services being provided to the Company by Swiss, the Company agreed to pay a certain predetermined amounts which are to be paid in common stocks of the Company, the number of stocks to be issued is based on the invoice received from Swiss, and the stock market price 10 days after the invoice is issued. During the years ended on August 31 2010 and 2009, the Company issued 388,724 and 203,904 shares of its common stock, respectively, to Swiss as remuneration for the services provided in the amount of \$198,850 and \$113,210, respectively.
- b. On October 12, 2008, 828,000 options were granted to an employee of the subsidiary, at an exercise price of \$0.47 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual installments commencing on November 1, 2009 and expire on October 11, 2018. On March 31, 2009 the employee ended his services with the Company and the options were forfeited before they had vested. The Company recognized an expense of \$71,406 during the six months ended February 28, 2009 and reversed that expense in the three months ended May 31, 2009.
- c. On October 12, 2008, 56,000 options were granted to an employee of the subsidiary, at an exercise price of \$0.47 per share (equivalent to the traded market price on the date of grant). The options vest in two equal annual installments commencing on May 1, 2009 and expire on October 11, 2018.
- d. On January 11, 2009, an aggregate of 600,000 options were granted to two Board of Directors members and 150,000 options were granted to an employee of the subsidiary. All 750,000 options were granted at an exercise price of \$0.43 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual installments commencing on January 1, 2010 and expire on January 10, 2019. On May 31, 2009 the employee ended his services with the Company and the options were forfeited before they had vested. During the year ended August 31, 2009, the Company recognized an expense of \$4,354 related to the options granted to the employee and reversed that expense during the same year.
- e. On January 11, 2009, an aggregate of 300,000 options were granted to three Scientific Advisory Board members, at an exercise price of \$0.76 per share (higher than the traded market price on the date of grant). The options vest in four equal quarterly installments commencing on April 1, 2009 and expire on January 10, 2019.
- f. On June 3, 2009, 400,000 options were granted to an employee of the subsidiary, at an exercise price of \$0.47 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual installments, commencing October 19, 2010, and expire on October 19, 2019.
- g. On August 20, 2009, 100,000 options were granted to an employee of the subsidiary, at an exercise price of \$0.42 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual installments commencing August 20, 2010, and expire on August 20, 2019.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

- h. On November 23, 2009, 100,000 options were granted to a consultant, at an exercise price of \$0.76 per share (higher than the traded market price on the date of grant), the options vest in three equal annual installments commencing November 23, 2010 and expire on November 23, 2014. The engagement with the consultant has ended during the nine months period ended May 31, 2010. The fair value of these options on the date of grant, was \$36,662, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 123.30%; risk-free interest rates of 2.20%; and the remaining contractual life of 5 years. The Company recorded all expenses in respect of these options during that period.
- i. On November 23, 2009, 36,000 options were granted to an employee of the Subsidiary, at an exercise price of \$0.46 per share (equivalent to the traded market price on the date of grant), the options vest in three equal annual installments commencing November 23, 2010, and expire on November 23, 2019. The fair value of these options on the date of grant was \$14,565, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 123.55%; risk-free interest rates of 2.55%; and the remaining contractual life of 6 years.
- j. On December 29, 2009, the Company issued 100,000 shares of its common stock to a third party as remuneration for services rendered and to be rendered during the six month period commencing December 15, 2009. The fair value of these shares on the date of issuance was \$37,000.
- k. On March 16, 2010, 13,200 options were granted to a consultant, at an exercise price of \$0.43 per share (equivalent to the traded market price on the date of grant), the options vest in six monthly installments commencing March 30, 2010 and expire on March 15, 2015. The fair value of these options on the date of grant, was \$4,747, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 121.61%; risk-free interest rates of 2.37%; and the remaining contractual life of 5 years.
- l. On March 16, 2010, 100,000 options were granted to a consultant, at an exercise price of \$0.43 per share (equivalent to the traded market price on the date of grant), the options vest in three equal monthly installments commencing March 30, 2010 and expire on March 15, 2015. The fair value of these options on the date of grant, was \$35,960, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 121.61%; risk-free interest rates of 2.37%; and the remaining contractual life of 5 years.
- m. On March 16, 2010, 50,000 options were granted to a consultant, at an exercise price of \$0.50 per share (higher than the traded market price on the date of grant), the options vest in three equal annual installments commencing March 16, 2011 and expire on March 15, 2015. The fair value of these options on the date of grant, was \$17,702, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 121.61%; risk-free interest rates of 2.37%; and the remaining contractual life of 5 years.
- n. On March 25, 2010, 100,000 options were granted to a consultant, at an exercise price of \$0.50 per share (higher than the traded market price on the date of grant), the options vest in four equal quarterly installments commencing May 17, 2010 and expire on March 24, 2015. The fair value of these options on the date of grant, was \$39,051, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 121.21%; risk-free interest rates of 2.65%; and the remaining contractual life of 5 years.



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

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

- o. On April 21, 2010, an aggregate of 1,728,000 options were 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 are related parties, at an exercise price of \$0.49 per share (equivalent to the traded market price on the date of grant), 216,000 of the options vested immediately on the date of grant and the remainder will vest in twenty one equal monthly installments. These options expire on April 20, 2020. The fair value of these options on the date of grant was \$807,392, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 120.69%; risk-free interest rates of 3.77%; and expected lives of 10 years.
- p. On July 8, 2010, 300,000 options were granted to a director at an exercise price of \$0.48 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual installments commencing on July 8, 2011 and will expire on July 7, 2020. The fair value of these options on the date of grant, was \$123,890, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 117.82%; risk-free interest rates of 2.14%; and the remaining contractual life of 6 years.
- q. On August 2, 2010, the Company issued 50,000 shares of its common stock to a third party as remuneration for services to be rendered during the six month period commencing July 14, 2010. The fair value of these shares on the date of issuance was \$21,000.

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:

	<b>For options granted in the year ended August 31</b>	
	<b>2010</b>	<b>2009</b>
Expected option life (years)	4.5-10.0	1.0-9.8
Expected stock price volatility (%)	113.1-130.5	113.1-130.5
Risk free interest rate (%)	1.3-3.9	0.7-3.6
Expected dividend yield (%)	0.0	0.0

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

A summary of the status of the stock options granted to employees and directors as of August 31, 2010 and 2009, and changes during the years ended on those dates, is presented below:

	Year ended August 31,			
	2010		2009	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	8,445,360	0.31	7,289,360	0.29
Changes during the year:				
Granted - at market price	2,064,000	0.49	2,134,000	0.45
Expired	(500,000)	0.76		
Forfeited			(978,000)	0.46
Options outstanding at end of year	<u>10,009,360</u>	0.32	<u>8,445,360</u>	0.31
Options exercisable at end of year	<u>7,549,360</u>		<u>7,001,360</u>	
Weighted average fair value of options granted during the year	<u>\$ 0.46</u>		<u>\$ 0.45</u>	

Costs incurred in respect of stock based compensation for employees and directors, for the years ended August 31, 2010 and 2009 were \$690,882 and \$436,025, respectively.

The following table presents summary information concerning the options outstanding as of August 31, 2010:

Range of exercise prices \$	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.001	3,361,360	1.95	0.001	1,307,569
0.40 to 0.62	6,648,000	5.31	0.32	-
	<u>10,009,360</u>	<u>4.18</u>	<u>0.21</u>	<u>1,307,569</u>

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

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

The following table presents summary information concerning the options exercisable as of August 31, 2010:

Range of exercise prices	Number exercisable	Weighted Average Remaining Contractual Life	Weighted average exercise price	Aggregate intrinsic value
\$		Years	\$	\$
0.001	3,361,360	1.95	0.001	1,307,569
0.40 to 0.62	4,188,000	3.99	0.49	-
	<u>7,549,360</u>	<u>3.08</u>	<u>0.27</u>	<u>1,307,569</u>

As of August 31, 2010, there were \$601,523 unrecognized compensation costs related to non-vested employees and directors ,to be recorded over the next 35 months.

A summary of the status of the stock options granted to non-employees as of August 31, 2010, and changes during the years ended on this date, is presented below:

	Year ended August 31			
	2010		2009	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Options outstanding at beginning of year	1,200,000	0.68	900,000	0.65
Changes during the year:				
Granted - at market price	113,200	0.43		
Granted - at an exercise price above market price	250,000	0.60	300,000	0.76
Expired	(750,000)	(0.64)		
Options outstanding at end of year	<u>813,200</u>	0.63	<u>1,200,000</u>	0.68
Options exercisable at end of year	<u>313,200</u>		<u>900,000</u>	

The Company recorded stock compensation of \$116,944 and \$117,174 during the years ended August 31, 2010 and 2009 respectively, related to consulting services.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

The following table presents summary information concerning the options granted to non-employees outstanding as of August 31, 2010:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life	Weighted average exercise price	Aggregate intrinsic value
\$		Years	\$	\$
0.40 to 0.62	363,200	3.54	0.78	-
0.76 to 0.90	450,000	6.18	0.51	-
	<u>813,200</u>	<u>5.00</u>	<u>0.63</u>	<u>-</u>

The following table presents summary information concerning the options exercisable as of August 31, 2010:

Range of exercise prices	Number exercisable	Weighted Average Remaining Contractual Life	Weighted average exercise price	Aggregate intrinsic value
\$		Years	\$	\$
0.40 to 0.62	263,200	3.15	0.52	-
0.76 to 0.90	50,000	0.92	0.90	-
	<u>313,200</u>	<u>2.80</u>	<u>0.58</u>	<u>-</u>

As of August 31, 2010 there were \$29,884 unrecognized compensation costs related to non-vested non-employees, to be recorded over the next 31 months.

**NOTE 9 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:**

	Year ended August 31,	
	2010	2009
Service providers	\$ 381,522	\$ 274,291
Tax provisions		12,504
Payroll and related expenses	29,808	34,549
	<u>\$ 411,330</u>	<u>\$ 321,344</u>

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

**NOTE 10 - RESEARCH AND DEVELOPMENT EXPENSES:**

	Year ended		Period
	August 31,		from April
	2010	2009	12, 2002
			(inception)
			through
			August 31,
			2010
Clinical trials	\$ 905,206	\$ 1,304,779	\$ 3,273,311
Payroll and consulting fees	402,145	286,315	1,122,696
Costs for registration of patents	32,992	17,775	151,457
Compensation costs in respect of warrants granted to employees, directors and consultants	341,203	264,861	2,557,866
Other	132,538	100,749	337,814
Less - grants from the OCS	<u>(350,198)</u>	<u>(400,405)</u>	<u>(750,603)</u>
	<u>\$ 1,463,886</u>	<u>\$ 1,574,074</u>	<u>\$ 6,692,540</u>

**NOTE 11 - GENERAL AND ADMINISTRATIVE EXPENSES**

	Year ended		Period
	August 31		from April
	2010	2009	12, 2002
			(inception)
			through
			August 31,
			2010
Compensation costs in respect of warrants granted to employees, directors and consultants	\$ 466,623	\$ 288,338	\$ 1,612,937
Professional services	322,447	240,523	1,334,249
Consulting fees	159,919	155,359	640,597
Travel costs	67,543	94,844	419,425
Write off of debt			275,000
Business development	151,517	73,286	379,160
Payroll and related expenses	159,485	190,923	434,878
Insurance	23,958	25,068	72,656
Other	157,175	141,703	513,521
	<u>\$ 1,508,667</u>	<u>\$ 1,210,044</u>	<u>\$ 5,682,423</u>

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

**NOTE 12 - TAXES ON INCOME:**

Taxes on income included in the consolidated statements of operations represent current taxes due to taxable income of the US 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, 2010, the Company has an accumulated tax loss carryforward of approximately \$3,979,276 (August 31, 2009 approximately \$3,606,510). Under USA tax laws, carryforward tax losses expire 20 years after the year in which it incurred, in the case of the Company the net loss carryforward will expire in the years 2025 through 2028.

**b. Corporate taxation in Israel:**

The Subsidiary is taxed in accordance with Israeli tax laws. The regular corporate tax rate in Israel for 2010 is 25%.

On July 23, 2009, the Economic Efficiency (Legislation Amendments to the Implementation of the Economic Plan for the Years 2009 and 2010) Law, 2009 (hereinafter – the 2009 Amendment) was published in the Official Gazette. Inter alia, the 2009 Amendment provides for a further gradual reduction of the corporate tax rate in tax years 2011 and thereafter, as follows: 2010 -25%, 2011 - 24%, 2012 - 23%, 2013 - 22%, 2014 - 21%, 2015 - 20% and 2016 and thereafter - 18%.

As of August 31, 2010, the Subsidiary has an accumulated tax loss carryforward of approximately \$2,664,091(August 31, 2009 approximately \$1,115,041).

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

**NOTE 12 - TAXES ON INCOME** (continued):

**c. Deferred income taxes:**

	August 31	
	2010	2009
In respect of:		
Net operating loss carryforward	\$ 1,978,850	\$ 1,507,587
Less - Valuation allowance	(1,978,850)	(1,507,587)
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.

**d. Income loss before taxes on income and income taxes included in the income statements:**

	Year ended August 31		Period from April 12, 2002 (inception) through August 31, 2010
	2010	2009	2010
Loss before taxes on income:			
U.S.	\$ 453,676	\$ 248,890	\$ 7,587,802
Outside U.S.	2,508,729	2,514,181	5,385,876
	2,962,405	2,763,071	12,973,678
Taxes on income:			
Current:			
U.S.	13,107	16,664	69,570
Outside U.S.	1,864	(19,261)	104,968
	\$ 14,971	\$ (2,597)	\$ 174,538

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

**NOTE 12 - TAXES ON INCOME** (continued):

**e. Reconciliation of the theoretical tax expense to actual 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 U.S., and the actual tax expense:

	Year ended August 31		Period from April 12, 2002 (inception) through August 31, 2010
	2010	2009	2010
Loss before income taxes as reported in the consolidated statement of operations	\$(2,962,405)	\$(2,763,071)	\$(12,811,516)
Computed "expected" tax benefit	(1,036,842)	(967,075)	(4,484,031)
Increase (decrease) in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax losses	576,939	528,143	2,229,483
Disallowable deductions	211,304	149,043	1,642,813
Increase in taxes resulting from different tax rates applicable to non U.S. subsidiary	248,599	270,879	554,239
Uncertain tax position	14,971	16,413	162,034
Taxes on income for the reported year	<u>\$ 14,971</u>	<u>\$ (2,597)</u>	<u>\$ 174,538</u>

**f. Uncertainty in Income Taxes**

The Company adopted FIN 48 effective September 1, 2007. FIN 48 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 had no unrecognized tax benefits as of September 1, 2007. As a result of the implementation of FIN 48 the Company recorded an additional provision for income taxes in the amount of \$130,650 due to uncertainty in its tax position. The Company recognizes interest and penalties related to its tax contingencies as income tax expense. As of August 31, 2010 and 2009, the Company recorded \$65,151 and \$47,881, respectively, of penalties related to tax contingencies.

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

	Year ended August 31	
	2010	2009
Balance at Beginning of Year	\$ 147,063	\$ 130,650
Increase (decrease) in tax positions for prior years	14,971	8,844
Increase in tax positions for current year		7,569
Balance at End of Year	<u>\$ 162,034</u>	<u>\$ 147,063</u>



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

**NOTE 12 - TAXES ON INCOME** (continued):

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

The Company is subject to Israeli income tax examinations and to U.S. Federal income tax examinations for the tax years of 2002 through 2008. As of August 31, 2009, the Company did not record any change to its unrecognized tax benefits.

**NOTE 13 - RELATED PARTIES - TRANSACTIONS:**

- a. During the fiscal years of 2010 and 2009 the Company paid to directors \$19,500 and \$16,000, respectively, for managerial services.
- b. As to the agreements with Hadassit, see note 6a.
- c. On July 1, 2008, the subsidiary entered into a consulting agreement with KNRY Ltd. ("KNRY"), an Israeli company owned by Nadav Kidron, whereby Mr. Nadav Kidron, through KNRY, 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 KNRY whereby Dr. Miriam Kidron, through KNRY, 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 KNRY, dated as of August 1, 2007, pursuant to which Nadav Kidron and Miriam Kidron, respectively, provided services to Oramed and the subsidiary. 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 New Israeli Shekels ("NIS") a gross amount of NIS50,400 per month (as of August 31, 2010 the monthly payment in the Company's functional currency is \$13,204) 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 8o.
- e. As to the establishment of the Joint Venture Entera, see note 4.
- f. According to the JV agreement (note 4), Entera will rent office space and services from the subsidiary of the Company 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. It was acknowledged that the rental period may be less than 24 months if Oramed vacates such premises before the end of such 24-month period.
- g. According to the JV agreement (note 4), the subsidiary of the Company shall provide accounting services to Entera at a monthly fee in the amount of NIS 3,500 (\$917).
- h. Balances with related parties:

	<b>August 31</b>	
	<b>2010</b>	<b>2009</b>
Current assets - related parties - Entera	<u>7,689</u>	<u>-</u>
Accounts payable and accrued expenses - KNRY	<u>22,773</u>	<u>26,450</u>

**ORAMED PHARMACEUTICALS INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 14 - SUBSEQUENT EVENTS**

- a. On November 9, 2010, the Company issued 253,714 shares of its common stock to Swiss as remuneration for the services provided, in the amount of \$88,880.
- b. On November 16, 2010, the Company entered into a Securities Purchase Agreement with an accredited investor for the sale of 937,500 units at a purchase price of \$0.32 per unit for total consideration of \$300,000. 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.

**(a)(2) Financial Statements Schedules**

We do not have any financial statement schedules required to be supplied under this Item.

**(a)(3) Exhibits**

Refer to (b) below.

**(b) Exhibits:**

- 3.1 Articles of Incorporation (incorporated by reference from our Registration Statement on Form SB-2, filed on November 29, 2002).
- 3.2 Bylaws (incorporated by reference from our Current Report on Form 8-K filed on April 10, 2006).
- 3.3 Articles of Merger filed with the Nevada Secretary of State on March 29, 2006 (incorporated by reference to our Current Report on Form 8-K filed on April 10, 2006).
- 4.1 Specimen Stock Certificate (incorporated by reference from our Registration Statement on Form SB-2, filed on November 29, 2002).
- 4.2 Form of Warrant Certificate (incorporated by reference from our current report on Form 8-K filed July 15, 2008)
- 10.1 Form of Securities Purchase Agreement for February 6, 2006 private placement (incorporated by reference from our current report on Form 8-K filed February 6, 2006).
- 10.2 Agreement between us and Hadasit Medical Services and Development Ltd. dated February 17, 2006 concerning the acquisition of U.S. patent application 60/718716 (incorporated by reference from our current report on Form 8-K filed February 17, 2006).

- 10.3 Consulting Agreement between us and Dr. Miriam Kidron (incorporated by reference from our current report on Form 8-K filed February 17, 2006).
- 10.4 Agreement between us and Swiss Caps Ag dated October 30, 2006 (incorporated by reference from our current report on Form 8-K filed October 26, 2006).
- 10.5 Stock Option Plan dated October 15, 2006 (incorporated by reference from our current report on Form 8-K filed on November 28, 2006).
- 10.6 Stock Option Agreement dated November 23, 2006 (incorporated by reference from our current report on Form 8-K filed on November 28, 2006).
- 10.7 Form of Subscription Agreement and Warrant Certificate (incorporated by reference from our current report on Form 8-K filed on June 18, 2007).
- 10.8 Form of Shares for Services Agreement (incorporated by reference from our current report on Form 8-K filed on August 3, 2007).
- 10.12 Master Services Agreement dated January 29, 2008 between us and OnQ Consulting (incorporated by reference from our current report on Form 8-K filed on February 1, 2008).
- 10.13 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).
- 10.14 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).
- 10.15 Oramed Pharmaceuticals Inc. 2008 Stock Incentive Plan (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.16 Form of Notice of Stock Option Award and Stock Option Award Agreement (incorporated by reference from our current report on Form 8-K filed on July 2, 2008).
- 10.17 Form of Stock Purchase Agreement (incorporated by reference from our current report on Form 8-K filed on July 15, 2008).
- 10.18 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).
- 10.18 Indemnification 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).
- 10.19 Agreement dated April 22, 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).
- 10.20 Agreement dated July 8, 2009, between our company and Hadasit Medical Services and Development Ltd. (incorporated by reference from our current report on Form 8-K filed July 9, 2009).
- 10.21 Agreement dated January 7, 2009, between our company and Hadasit Medical Services and Development Ltd. (incorporated by reference from our current report on Form 8-K filed January 7, 2009).
- 10.22 Form of Indemnification Agreements dated November 2, 2008, between our company and each of our directors and officers (incorporated by reference from our current report on Form 8-K filed November 6, 2009).
- 10.23 Agreement dated June 1, 2010, between Oramed Ltd. and Laser Detect Systems Ltd. (incorporated by reference from our quarterly report on Form 10-Q filed July 14, 2010).
- 10.22 Manufacturing 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).
- 23.1\* Consent of Kesselman & Kesselman

23.2\* Consent of Malone & Bailey

31.1\* Certification Statement of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2\* Certification Statement of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1\* Certification Statement of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002.

\* Filed herewith

## SIGNATURES

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

### **ORAMED PHARMACEUTICALS INC.**

/s/ NADAV KIDRON

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

/s/ YIFAT ZOMMER

Yifat Zommer,  
Chief Financial Officer  
(principal accounting officer)

Date: November 26, 2010

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 indicated on November 26, 2010.

/s/ NADAV KIDRON

Nadav Kidron,  
President and Chief Executive Officer and Director

/s/ MIRIAM KIDRON

Miriam Kidron,  
Chief Medical and Technology Officer and Director

/s/ LEONARD SANK

Leonard Sank,  
Director

/s/ HAROLD JACOB

Harold Jacob,  
Director

/s/ MICHAEL BERELOWITZ

Michael Berelowitz,  
Director

**Kesselman & Kesselman**  
Certified Public Accountants  
Trade Tower, 25 Hamered Street  
Tel Aviv 68125 Israel  
P.O Box 452 Tel Aviv 61003  
Telephone +972-3-7954555  
Facsimile +972-3-7954556

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference of our report dated November 29, 2010 relating to the financial statements of Oramed Pharmaceuticals, Inc.'s which appears in the Annual Report on Form 10K for the year ended August 31, 2010, in the Registration Statement on Form S-8 (333-164288).

/s/ Kesselman & Kesselman,

Tel Aviv, Israel  
November 29, 2010

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference of our report dated December 10, 2007 relating to the inception through August 31, 2007 audited financial statements of Oramed Pharmaceuticals, Inc. which appears in this Annual Report on Form 10-K for that period in the Registration Statement on Form S-8 (333-164288).

*/s/ MaloneBailey, LLP*

MaloneBailey, LLP  
[www.malone-bailey.com](http://www.malone-bailey.com)  
Houston, Texas

November 29, 2010

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[www.malonebailey.com](http://www.malonebailey.com)



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Registered Public Company Accounting Oversight Board • AICPA

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## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Nadav Kidron, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oramed Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal controls over financial reporting as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting, to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. the registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 26, 2010

By: /s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

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## CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Yifat Zommer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oramed Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal controls over financial reporting as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting, to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 26, 2010

By: /s/ Yifat Zommer  
\_\_\_\_\_  
Yifat Zommer  
Chief Financial Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
AND PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
(SUBSECTIONS (A) AND (B) OF SECTION 1350, CHAPTER 63 OF TITLE 18,  
UNITED STATES CODE)**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers Oramed Pharmaceuticals Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that the Annual Report for the fiscal year ended August 31, 2010 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 26, 2010

/s/ Nadav Kidron

Nadav Kidron, President and Chief Executive Officer

Dated: November 26, 2010

/s/ Yifat Zommer

Yifat Zommer, Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided by the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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