

ORAMED PHARMACEUTICALS INC.  
Form 10KSB  
November 26, 2008

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

**FORM 10-KSB**

(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, 2008**

**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**                      **98-0376008**  
(State or other jurisdiction of    (IRS Employer Identification  
incorporation or organization)        No.)

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

**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 Exchange Act: Common Stock, \$0.001 par value

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

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

State issuer's revenues for its most recent fiscal year \$0.00

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. As of November 24, 2008: \$16,905,964 (37,568,808 shares at \$0.45 per share).

State the number of shares outstanding of each of the registrant's classes of common equity, as of the latest practicable date: 56,456,710 shares issued and outstanding as of November 24, 2008.

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## PART I

### ITEM 1 - BUSINESS

*This Annual Report on Form 10-KSB (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-KSB. Additionally, statements concerning future matters are forward-looking statements.*

Although forward-looking statements in this Annual Report on Form 10-KSB 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-KSB. 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-KSB. We file reports with the Securities and Exchange Commission (the "*Commission*"). We make available on our website under "Investor Information/SEC Filings," free of charge, our annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, 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.

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-KSB. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

As used in this Annual Report, the terms "we", "us", "our", the "Company", and "Oramed" mean Oramed Pharmaceuticals Inc. 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 pill to be used for the treatment of individuals with diabetes, rectal application of insulin, use of oral ingestible pills for delivery other polypeptides and use of rectal application for delivery of other polypeptides.

**Oral Insulin:** Oramed is seeking to revolutionize the treatment of diabetes through its proprietary flagship product, an orally ingestible insulin capsule (ORMD-0801) currently in phase 2 clinical trials. The Company's 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 by 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 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.

The Company's research and development team has performed numerous animal studies to optimize the composition and functionality of their oral insulin (ORMD- 0801) modality and to demonstrate its safety and efficacy. The Company's studies have confirmed the feasibility of lowering blood glucose levels within an orally administered form of insulin that is both safe and effective.

The Company's 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 is needed to convert sugar, starches and other food into energy needed for daily life. The cause of diabetes continues to be a mystery, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles.

An estimated 177 million people are suffering from diabetes worldwide. According to the American Diabetes Association, there are 23.6 million children and adults in the United States, or 7.8% of the population, who have diabetes. While an estimated 17.9 million have been diagnosed with diabetes, unfortunately, 5.7 million people (or nearly one quarter) are unaware that they have the disease.

**Intellectual Property:** The Company owns a portfolio of patents and patent applications covering its technologies and is 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. The Company's 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 comprises of Professor Avram Hershko, Dr. Harold Jacob, Dr. Nir Barzilai, Prof. Ele Ferrannini, Dr. Derek LeRoith and Dr. John Ziemniak.

## **Corporate History**

Oramed was incorporated on April 12, 2002, in the State of Nevada under the name “Iguana Ventures Ltd”. Following the incorporation, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. The Company was unsuccessful in implementing its business plan as a mineral exploration company. Accordingly, the Company decided to change the focus of its business by completing a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey private corporation (“ISTI”). On June 4, 2004, the Company changed its name to Integrated Security Technologies by filing a Certificate of Amendment with the Nevada Secretary of State. Effective June 14, 2004 the Company 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, on May 31, 2005, effective as of May 27, 2004 the Company terminated the share exchange agreement with the shareholders of ISTI.

On March 8, 2006, the Company executed an agreement with Hadasit Medical Services and Development Ltd. 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. Effective April 10, 2006, the Company changed its name from “Integrated Security Technologies, Inc.” to “Oramed Pharmaceuticals Inc.”. Based on provisional patent application No. 60/718716, the Company filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for “Methods and Compositions for Oral Administration of Proteins” on August 31, 2006.

## **Strategy**

We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug Application (“IND”) with the U.S. Food and Drug Administration (“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, including an insulin suppository, 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. 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 compliment 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 the 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 II diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

On April 21, 2008, we entered into a service agreement with Encorium Group, Inc. (“Encorium”) pursuant to which Encorium will provide services for the purpose of filing an IND for a Phase 2 study as required by the FDA. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

During 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 I diabetic volunteers. On September 24, 2008, we announced the beginning of this trail.

We plan on conducting two additional non FDA approved Phase 2B study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) on Type II diabetic volunteers, in South Africa and India. The trials are scheduled to commence by the end of 2008 or the beginning of 2009.

***Rectal Application of Insulin and Other Polypeptides:*** We filed two additional provisional patents for a suppository application to our technology portfolio. The first patent focuses on a rectal application for insulin. The second patent focuses on the usage of this rectal application to other polypeptides that at present are only available in injection.



On January 30, 2008, we entered into a master service agreement with OnQ Consulting; a clinical research organization located in Johannesburg, South Africa, to conduct non FDA approved clinical trials for the rectal application of insulin. The trials are expected to begin during the coming months.

On October 23, 2008 we commenced a non FDA approved Phase 1A study to evaluate the safety and efficacy of our insulin suppository (ORMD 0802) on healthy volunteers, in South Africa.

**GLP1 Analog:** On September 16, 2008 we announced the launch of pre-clinical trials of ORMD 0901, a GLP1-analog, the pre-clinical trials includes a animal studies which suggests that the GLP-1analog exenatide -4 when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted surprisingly that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. GLP-1 was found in addition to stimulates insulin release, to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, it slows gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and it increases 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 to be hormone that protects the heart.

**Raw Materials:** Our oral insulin capsule is currently manufactured by Swiss Caps SA, under a Clinical Trial Manufacturing Agreement. The raw materials required for the manufacturing of the capsule are being 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 relationship 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

The following patent applications and provisional patent application are pending:

·PCT/IL2006/001019, "*Methods and Compositions for Oral Administration of Proteins*". The patent application was filed on August 31, 2006.

·11/513,343, "*Methods and Compositions for Oral Administration of Proteins*". The patent application was filed on August 31, 2006.

·60/064,779, "*Methods and Compositions for Oral Administration of Proteins*". The patent application was filed on March 26, 2008.

·PCT/IL2008/000546, "*Methods and Compositions for Rectal Application for Insulin*". The patent application was filed on April 27, 2008.

·PCT/IL2008/000547, “*Methods and Compositions for Rectal Application for Insulin*”. The patent application was filed on April 27, 2008.

·61/071,538, “*Methods and Compositions for Oral Administration of Exenatide*”. The patent application was filed on May 5, 2008.

·61/089,812, “*Methods and Compositions for Oral Administration of Proteins*”. The patent application was filed on August 18, 2008.

Consistent with a strategy to seek protection in key markets worldwide, we have been and will continue to prosecute 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 October 30, 2006, we entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG (“Swiss”), pursuant to which Swiss will manufacture and deliver the oral insulin capsule developed by the Company.

During January and April, 2008, we entered into agreements with OnQ consulting, a clinical research organization (CRO) located in Johannesburg, South Africa, to conduct Phase 1B and 2B clinical trials on our oral insulin capsules and suppository.

On April 21, 2008, we entered into a five year service agreement with Encorium Group, Inc. (“Encorium”) pursuant to which Encorium will provide services for the purpose of filing an Investigational New Drug Application (IND) for a Phase 2 study as required by the US Food and Drug Administration (FDA).

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 will provide 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 September 8, 2008, we entered into Clinical Research Agreement with ETI Karle Clinical Pvt. Ltd. (“ETI”), pursuant to which ETI will be conducting Phase 2A and 2B clinical trials of our oral insulin capsule in India.

We are also currently negotiating a clinical trial agreement with Hadasit to facilitate additional clinical trials to be performed at Hadassah Medical Center in Jerusalem.

## **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 U.S. FDA compliance requirements are considered to be one of the most stringent worldwide following is a description 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 investigational new drug application, or IND, 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.

*Orphan Drug Act.* The Orphan Drug Act provides incentives to develop and market drugs (“*Orphan Drugs*”) for rare disease conditions in the United States. A drug that receives Orphan Drug designation and is the first product to receive FDA marketing approval for its product claim is entitled to a seven-year exclusive marketing period in the United States for that product claim. A drug which is considered by the FDA to be different than such FDA-approved Orphan Drug is not barred from sale in the United States during such exclusive marketing period even if it receives approval for the same claim. We can provide no assurance that the Orphan Drug Act’s provisions will be the same at the time of the approval, if any, of our products.

### ***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. Following are treatment options for type I and II diabetic patients:

· Insulin injections;

· Insulin pumps;

· Insulin inhalers;

· a combination of diet, exercise and oral medication which improve the body's response to insulin or cause the body to produce more insulin, and;

Several entities who are developing oral insulin capsule 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, Bidel (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. Harold Jacob, Dr. Nir Barzilai, Prof. Ele Ferrannini, Dr. Derek LeRoith and Dr. John Ziemniak.



*Professor Avram Hershko, MD PhD* joined the Oramed Scientific Advisory Board in July 2008. He gained his MD (1965) and PhD (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. Prof. 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, as the name suggests, 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. Abnormalities in the ubiquitin system result in diseases such as certain types of cancer. The full range of functions of the ubiquitin system in health and disease has still to be elucidated. Prof. 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* 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.

*Dr. Nir Barzilai* 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.

*Prof. Ele Ferrannini* has published over 350 original papers and 50 book chapters, and he is amongst the "highly cited scientists." (ISIhighlycited.com). One of many great honors achieved for Prof. Ferrannini includes being elected a past President to the EASD, European Association for the Study of Diabetes. The Association is based on individual membership and 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. Prof. 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. Prof. 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.

*Dr. Harold Jacob* has a strong background, both in medical sciences as well as biotechnology and medical devices. 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. Since 1998, Dr. Jacob is 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 it's 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 is CEO of NanoVibronix, a medical device company using surface acoustics to prevent catheter acquired infection as well as other applications. Dr. Jacob is a member of the Board of Directors of the Company.

*Dr. John A, Ziemniak* is currently the director of drugs and biologics product development at Encorium Group Inc. and the co-founder/partner of Gwynedd Pharmaceuticals. Dr. Ziemniak has over 20 years experience in the pharmaceutical industry. He has worked extensively in drug development having been involved in the conception, filing, and approval of over 13 NDAs and greater than 20 INDs covering a wide variety of drugs and indications. Dr. Ziemniak is the co-founder and partner of Gwynedd Pharmaceutical Consultants, a contract organization providing consulting services to the pharmaceutical, medical and dental industries in the area of drug and product development. Dr Ziemniak's areas of specialty include drug delivery, project management, pharmacokinetics, clinical pharmacology and drug development. Dr. Ziemniak has approximately 50 scientific publications and numerous patents on a variety of drug development topics and products.

## **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, 2008, we contracted seven individuals through employment or consulting agreements. Of our staff, two are senior management, two are engaged in research and development work, and the remaining in administration work.

## **Facilities**

Our principal executive offices are located in approximately 117 square meters of office space 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 for this space is \$8,004. 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 1A – RISK FACTORS

*An investment in our common stock 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 before buying shares of our common stock. 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 trading of our common stock could decline as a result of any of these risks. You could lose all or part of your investment in our common stock. Some of the statements in “Risk Factors” are forward looking statements. See “Special Note Regarding 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 ended August 31, 2009. During 2009, 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 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 7 months from the date of this Annual Report. 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 contemplated principal business activity. 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 will 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, 2008 and 2007, we had working capital of \$4,483,940 and \$505,951, respectively, and stockholders' equity of \$4,593,060 and \$513,131, respectively. We generated no revenues to date. For the period from our inception on April 12, 2002 through August 31, 2008, the years ended August 31, 2008 and 2007, we incurred net losses of \$(7,248,204), \$(2,769,271), and \$(3,236,009), 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 and corresponding patent applications filed in certain other countries covering our technology. 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 or the licensed 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 or Canada.

Patent litigation is becoming widespread in the 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 solely on the successful commercialization of the oral insulin capsule.**

The successful commercialization of oral insulin capsule is crucial for our success. Our proposed products and their potential applications are in an early stage of clinical and manufacturing/process development and face 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 no prior experience manufacturing our products.**

We currently lack the resources to manufacture any of our product candidates on a large scale. Our ability to conduct clinical trials and commercialize our product candidates will depend, in part, on our ability to manufacture our products, either directly or, as currently intended, through contract manufacturers, at a competitive cost and in accordance with current Good Manufacturing Practices (“cGMP”) and other regulatory requirements. We anticipate that we will be required to depend on contract manufacturers or collaborative partners for the manufacturing of our product candidates for preclinical studies and clinical trials and intend to use contract manufacturers to produce any products we may eventually commercialize. If we are not able to obtain contract manufacturing on commercially reasonable terms, we may not be able to conduct or complete clinical trials or commercialize our product candidates. We have identified multiple suppliers for most if not all of the components of our drug product candidates, although we can provide no assurance that these components will be available when needed on commercially reasonable terms.

In order to succeed, we ultimately will be required to either develop such manufacturing capabilities or to outsource manufacturing on a long-term basis to third parties. We can provide no assurance that third parties will be interested in manufacturing our products on a timely basis, on commercially reasonable terms, or at all. If we are unable to establish manufacturing capabilities either by developing our own organization or by entering into agreements with others, 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. Further, in the event that we are required to outsource these functions on disadvantageous terms, we may be required to pay a relatively large portion of our net revenue to these organizations, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.



**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 can provide no assurance of the successful and timely development of our new products.**

Our product candidates are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive products on a timely basis. Products that we have developed and may in the future develop are not likely to be commercially available for some time, if at all. The proposed development schedules for our products may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction, or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the nature of technology involved, and the other factors, described elsewhere in "Risk Factors", there can be no assurance that we will be able to complete successfully the development or marketing of any new products.

**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 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 and/or regulatory agencies of other countries. We cannot predict with any certainty the amount of time necessary to obtain such regulatory approvals 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*".

**If our products are commercialized, we may be subject to product liability claims.**

The testing, marketing, and sale of pharmaceutical products entail inherent risks. If we succeed in developing new pharmaceutical products, the sale of such products may expose us to potential liability resulting from the use of such products. Such liability might result from claims made directly by consumers or by pharmaceutical companies or others selling such products. While we may seek to obtain product liability insurance, there can be no assurance that we will be able to obtain such insurance or, if obtained, that such insurance can be acquired in amounts sufficient to protect us against such potential liability or at a reasonable cost. We do not currently maintain product liability insurance.

**As we have no sales, marketing, and distribution capabilities, we will be required to either develop such capabilities or to outsource these activities to third parties.**

We currently have no sales, marketing or distribution capabilities. In order to succeed, we ultimately will be required to either develop such capabilities or to outsource these activities to third parties. We can provide no assurance that third parties will be interested in acting as our outsourced sales, marketing, and distribution arms on a timely basis, on commercially reasonable terms, or at all. If we are unable to establish sales, marketing, or distribution capabilities either by developing our own organization or by entering into agreements with others, we may be unable to successfully sell any products that we are able to begin to commercialize, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations. Further, in the event that we are required to outsource these functions on disadvantageous terms, we may be required to pay a relatively large portion of our net revenue to these organizations, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.

**In the future, we may rely upon our collaborative agreements with large pharmaceutical companies.**

In the future, we may rely heavily on collaborative agreements with large pharmaceutical companies, governments, or other parties for our revenues. Our inability to obtain any one or more of these agreements, on commercially reasonable terms, or at all, or to circumvent the need for any such agreement, could cause significant delays and cost increases and materially affect our ability to develop and commercialize our product candidates. Some of our programs may require the use of multiple proprietary technologies, especially patented drugs. Obtaining licenses for these technologies may require us to make cumulative royalty payments or other payments to several third parties, potentially reducing amounts paid to us or making the cost of our products commercially prohibitive. Manufacturing of drug products may also require licensing technologies and intellectual property from third parties.



We have recently engaged in preliminary discussions with companies outside of the United States to carry out clinical trials of our products. Such agreements could involve us granting exclusive commercialization rights and profit interests in our products derived from certain geographic areas in exchange for payment of the costs of running such clinical trials now. This could have an adverse effect on our ability to market such products to large pharmaceutical companies in the future. There is no guarantee that we will be able to enter into any such agreements or that, if entered into, such agreements would be profitable.

**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. 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. 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 our areas of research and 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.

Our management is required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in this and future annual reports. In addition, we will be required to have our independent public accounting firm attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. Under current rules, we will be subject to this requirement beginning with our annual report on Form 10-K for our fiscal year ending August 31, 2009. If we are unable to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

**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.**

The Company was originally incorporated on April 12, 2002 as an exploration stage company engaged in the acquisition and exploration of mineral properties. The Company was unsuccessful in implementing its business plan as a mineral exploration company and became a public shell company. On May 27, 2004, the Company 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 the Company terminated the share exchange agreement with the shareholders of ISTI, and the Company again became a public shell company. The Company 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 the Company, there can be no assurance that such risks do not occur. The occurrence of any such risk could materially adversely affect the Company's financial condition.

## **Risks Related to our Industry**

**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 actual or proposed 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*”.

**The industry in which we operate is highly competitive.**

Numerous well-known companies, which have substantially greater capital, research and development capabilities and experience than we have, are presently engaged in the research and development efforts with respect to our target indications. By virtue of having or introducing competitive products on the market before us, these entities may gain a competitive advantage. Further future technological developments may render some or all of our current or future products noncompetitive or obsolete, and we may not be able to make the enhancements to our products necessary to compete successfully with newly emerging technologies. If we are unable to successfully compete in our chosen markets, our business prospects, financial condition, and results of operations would be materially adversely affected. See “*Business — Competition*”.

**The government regulatory approval process is time consuming and expensive.**

To date, we have not submitted a marketing application for any product candidate to the FDA or any foreign regulatory agency, and none of our product candidates have been approved for commercialization in any country. Prior to commercialization, each product candidate will be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. We may not be able to obtain regulatory approval for any product candidate we develop or, even if approval is obtained, the labeling for such products may place restrictions on their use that could materially impact the marketability and profitability of the product subject to such restrictions. We have limited experience in designing, conducting and managing the clinical testing necessary to obtain such regulatory approval. Satisfaction of these regulatory requirements, which includes satisfying the FDA and foreign regulatory authorities that the product is both safe and effective for its intended therapeutic uses, typically takes several years depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources.

**Any manufacturer to produce our products will be required to comply with extensive government regulation.**

Before we can begin to commercially manufacture any of our product candidates, we must either secure manufacturing in an approved manufacturing facility or obtain regulatory approval of our own manufacturing facility and processes. In addition, the manufacturing of our product candidates must comply with cGMP and/or other requirements of the FDA and requirements by regulatory agencies in other countries. These requirements govern, among other things, quality control and documentation procedures. We or any third-party manufacturer of our product candidates, may not be able to comply with these requirements, which would prevent us from selling such products. Material changes to the manufacturing processes of our products after approvals have been granted are also subject to

review and approval by the FDA or other regulatory agencies.

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**The commercial success of any newly-introduced pharmaceutical product depends in part upon the ability of patients to obtain adequate reimbursement.**

If we succeed in bringing our product candidates to market, they may not be considered cost-effective, and coverage and adequate payments may not be available or may not be sufficient to allow us to sell our products on a competitive basis. In both the United States and elsewhere, sales of medical products, diagnostics, and therapeutics are dependent, in part, on the availability of reimbursement from third party payors, such as health maintenance organizations and other private insurance plans and governmental programs such as Medicare. Third party payors are increasingly challenging the prices charged for pharmaceutical products and services. We anticipate that our business will be affected by the efforts of government and third party payors to contain or reduce the cost of health care through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. Similar government pricing controls exist in varying degrees in other countries. In addition, the emphasis on managed care in the United States has increased and will continue to increase the pressure on the pricing of pharmaceutical products. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

**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 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:

- quarterly variations in our operating results;
- operating results that vary from the expectations of management, securities analysts and investors;
- changes in expectations as to our business, prospects, financial condition, and results of operations;
- announcements by us, our partners or our competitors regarding material developments;
- the operating and securities price performance of other companies that investors believe are comparable to us;
- future sales of our equity or equity-related securities;



- changes in general conditions in our industry and in the economy, the financial markets and the domestic or international political situation;
- departures of key personnel; and
- regulatory considerations.

As a result of these fluctuations, you may experience difficulty selling shares of our common stock when desired or at acceptable prices.

**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 can make no prediction as to the effect, if any, that future sales of shares of our common stock or equity-related securities, or the availability of shares of common stock for future sale, will have on the trading price of our common stock.

**Our common stock is deemed to be a "penny stock," which may make it more difficult for investors to sell their shares due to suitability requirements.**

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. The market price of our common stock is currently less than \$5.00 per share and therefore is a “penny stock” according to SEC rules. This designation 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 our common stock and may affect the ability of investors hereunder to sell their shares.

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. 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 penny stock market. 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 56,456,710 shares of common stock. Of these shares, 21,132,995 shares, are freely tradable. Giving effect to the exercise in full of all of our outstanding warrants and options, we would have outstanding 73,952,407 shares of common stock.

**Our issuance of warrants and options to investors, employees and consultants and the registration rights for the underlying shares of common stock 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, 2008, we had outstanding 16,611,697 warrants and options (12,033,677 for the year ended August 31, 2007). 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 the board of directors decides is relevant. See “*Dividend Policy*” and “*Description of Securities — Common Stock*”.

**As we have a limited operating history, investors may not have a sufficient history on which to base an investment decision.**

Although we were incorporated in 2002, we commenced our research activities during 2006 and are still in the development stage. Accordingly, we have a limited operating history upon which investors may evaluate our prospects for success. Investors must consider the risks and difficulties frequently encountered by early stage companies, particularly in rapidly evolving markets such as the life science industry. Such risks include, without limitation, the following:

competition;

need for acceptance of products;

ability to anticipate and adapt to a competitive market and rapid technological developments;

amount and timing of operating costs and capital expenditures relating to expansion of our business, operations, and infrastructure; and

dependence upon key personnel.

We cannot be certain our strategy will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected. Information regarding all of our past operations can be found in our reports and registration statements that have been previously filed with the Securities and Exchange Commission.

### **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 military conditions in that country. Since December 1987, the State of Israel has experienced severe civil unrest primarily in the areas that have been under its control since 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 under the age of 51, unless exempt, may be required to perform between 14 and 40 days of 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 the management for misconduct and may not be able to enforce judgment and civil liabilities against our officers, directors, experts and agents.**

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.

**ITEM 2 - PROPERTIES**

Our principal executive offices are located in approximately 117 square meters of office space 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 for this space is \$8,004. 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 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

None

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**PART II****ITEM 5 - MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES****Market Price for our Common Stock**

Our common stock is quoted on the OTC Bulletin Board (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:

	<b>High</b>	<b>Low</b>
<b>Year Ended August 31, 2007</b>		
Three Months Ended November 30, 2006	\$ 1.12	\$ 0.60
Three Months Ended February 28, 2007	\$ 1.16	\$ 0.55
Three Months Ended May 31, 2007	\$ 0.91	\$ 0.56
Three Months Ended August 31, 2007	\$ 0.70	\$ 0.39
<b>Year Ended August 31, 2008</b>		
Three Months Ended November, 2007	\$ 0.48	\$ 0.23
Three Months Ended February, 2008	\$ 0.67	\$ 0.21
Three Months Ended May 31, 2008	\$ 0.66	\$ 0.45
Three Months Ended August 31, 2008	\$ 1.00	\$ 0.60

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 \$0.45 on November 24, 2008. As of such date, we had 56,456,710 shares of common stock outstanding. Based on information available from our registrar and transfer agent, we estimate that we had approximately 61 stockholders of record on November 24, 2008.

**Dividend Policy**

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

**Recent Sales of Unregistered Securities**

On October 17, 2008, the Company issued 203,904 shares of its common stock to Swiss Cap AG as remuneration for the services provided in the amount of \$152,928.

## **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 year ended August 31, 2008.

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

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

On October 15, 2006, the Company's 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. As of August 31, 2008, options with respect to 2,950,000 shares have been granted under the 2006 Stock Option Plan.

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

On May 5, 2008, the Company's board of directors adopted the 2008 Stock Incentive Plan (the "2008 Plan") in order to attract and retain quality personnel. Under the 2008 Stock Option 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, 2008, options exercisable for an aggregate of 1,878,000 shares have been granted.

On August 14, 2007 the Company granted options to purchase up to 3,361,360 shares at an exercise price of \$0.001 for five years to Miriam Kidron. These options are not governed by any of the plans detailed above.

The following table sets forth information with respect to the 2006 Plan and the 2008 Plan as of August 31, 2008:

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PLAN CATEGORY	NUMBER OF SECURITIES TO BE ISSUED UPON WEIGHT-AVERAGE EXERCISE OF EXERCISE PRICE 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	8,189,360	\$ 0.33	2,810,640
<b>TOTAL</b>	<b>8,189,360</b>	<b>\$ 0.33</b>	<b>2,810,640</b>

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## ITEM 6 - MANAGEMENT'S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION

### Overview

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 oral ingestible pills for delivery other polypeptides and use of rectal application for delivery of other polypeptides.

Oramed was incorporated on April 12, 2002, in the State of Nevada under the name "Iguana Ventures Ltd" as an exploration stage company engaged in the acquisition and exploration of mineral properties. The Company was unsuccessful in implementing its business plan as a mineral exploration company. Accordingly, the Company decided to change the focus of its business by completing a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey private corporation ("ISTI") and changed its name to Integrated Security Technologies. Effective June 14, 2004 the Company 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, on May 31, 2005, effective as of May 27, 2004 the Company terminated the share exchange agreement with the shareholders of ISTI.

On March 8, 2006, the Company executed an agreement with Hadasit Medical Services and Development Ltd. 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. Effective April 10, 2006, the Company changed its name from "Integrated Security Technologies, Inc." to "Oramed Pharmaceuticals Inc.". Based on provisional patent application No. 60/718716, the Company filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for "Methods and Compositions for Oral Administration of Proteins" on August 31, 2006.

### Plan of Operation

#### *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 Investigational New Drug Application ("IND") with the U.S. Food and Drug Administration ("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.



***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 the 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 II diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

On April 21, 2008, we entered into a service agreement with Encorium Group, Inc. (“Encorium”) pursuant to which Encorium will provide services for the purpose of filing an IND for a Phase 2 study as required by the FDA. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

During 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 I diabetic volunteers. On September 24, 2008, we announced the beginning of this trial.

We plan on conducting two additional non FDA approved Phase 2B study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) on Type II diabetic volunteers, in South Africa and India. The trials are scheduled to commence by the end of 2008 or the beginning of 2009.

***Rectal Application of Insulin and Other Polypeptides:*** We filed two additional provisional patents for a suppository application to our technology portfolio. The first patent focuses on a rectal application for insulin. The second patent focuses on the usage of this rectal application to other polypeptides that at present are only available in injection.

On January 30, 2008, we entered into a master service agreement with OnQ Consulting; a clinical research organization located in Johannesburg, South Africa, to conduct non FDA approved clinical trials for the rectal application of insulin. The trials are expected to begin during the coming months.

On October 23, 2008 we commenced a non FDA approved Phase 1A study to evaluate the safety and efficacy of our insulin suppository (ORMD 0802) on healthy volunteers, in South Africa.

**GLP1 Analog:** On September 16, 2008 we announced the launch of pre-clinical trials of ORMD 0901, a GLP1-analog, the pre-clinical trials includes a dog trial which suggests that the GLP-1analog exenatide -4 when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted surprisingly that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. GLP-1 was found in addition to stimulates insulin release, to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, it slows gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and it increases 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 to be hormone that protects the heart.

We have recently engaged in preliminary discussions with potential partners outside of the United States regarding their management of clinical trials of our oral insulin capsules. Such agreements could involve us granting exclusive commercialization rights and profit interests in our products derived from certain geographic areas outside the United States in exchange for payment of the costs of running such clinical trials now. These discussions are in a very early stage, however, and may not result in our being able to enter into any such partnerships.

### ***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. 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, 2008 of \$7,248,204, as well as negative cash flow from operating activities. Based upon our existing spending commitments, estimated at \$5,000,000 for the twelve months following September 1, 2008, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through August 31, 2009. 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*

**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.

Effective March 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), “*Share-based Payment*” (“*FAS 123(R)*”). FAS 123(R) 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 expense over the requisite service period, net of estimated forfeitures. The Company estimated forfeitures based on historical experience and anticipated future conditions.

In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (“*SAB 107*”). SAB 107 provides supplemental implementation guidance on FAS 123(R), including guidance on valuation methods, inventory capitalization of share-based compensation cost, income statement effects, disclosures and other issues. SAB 107 requires share-based payment to be classified in the same expense line items as cash compensation. The Company has applied the provisions of SAB 107 in its adoption of FAS 123(R).

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 multiple option award approach.

The Company elected to adopt the modified prospective application transition method, as permitted by FAS 123(R). Under such transition method, upon the adoption of FAS 123(R), the Company’s financial statements for periods prior to the effective date of the Statement are not restated.

In December 2007, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 110 (“*SAB 110*”) relating to the use of a “simplified” method in developing an estimate of the expected term of “plain vanilla” share options. SAB 107 previously allowed the use of the simplified method until December 31, 2007. SAB 110 allows, under certain circumstances, to continue to accept the use of the simplified method beyond December 31, 2007. The Company has applied the provisions of SAB 110 in its financial statement.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value based on an option-pricing model or when more reliability is based on the fair value of the services

received, pursuant to the guidance in EITF 96-18 “*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*”. The fair value of the options granted is revalued over the related service periods and recognized using the accelerated 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. The Company has provided a full valuation allowance with respect to its deferred tax assets.

Regarding the Subsidiary, paragraph 9(f) of FAS 109, “*Accounting for Income Taxes*”, 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.

As of September 1, 2007, the Company adopted FASB Interpretation No. 48, “*Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109*” (“FIN 48”). FIN 48 specifies how tax benefits for uncertain tax positions are to be recognized, measured and derecognized in financial statements; requires certain disclosures of uncertain tax positions; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim-period guidance, among other provisions. On May 2, 2007, the FASB issued FASB Staff Position No. FIN 48-1, “*Definition of Settlement in FASB Interpretation No. 48-1*” (“FSP FIN 48-1”). FSP FIN 48-1 provides guidance regarding how an entity should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits.

**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 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.

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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.

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

The following table summarizes certain statements of operations data for the Company for the nine months period ended May 31, 2008 and 2007:

Operating Data:	Year ended	
	August 31, 2008	August 31, 2007
Research and development costs	\$ 1,175,657	\$ 2,214,429
General and administrative expenses	1,504,354	918,477
Financial (income) expense, net	(72,904)	103,103
Loss before taxes on income	(2,607,107)	(3,236,009)
Taxes on income	162,164	
Net loss for the period	(2,769,271)	(3,236,009)
Loss per common share – basic and diluted	\$ (0.06)	\$ (0.08)
Weighted average common shares outstanding	48,604,889	42,298,080

### ***Research and development costs***

Research and development expenses are the costs incurred in the process of our pre-clinical and our clinical trials. Clinical trial and pre-clinical 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.

During the year ended August 31, 2008 research and development expenses totaled \$1,175,657, compared to \$2,214,429 for the year ended August 31, 2007. The increase is mainly attributable to increased clinical trials activities, materials and patent related costs. The research and development costs include stock based compensation costs, which during the year ended August 31, 2008 totaled \$285,336 as compared to \$1,666,466 during the year ended August 31, 2007.

### ***General and administrative expenses***

General and administrative expense includes 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, 2008, general and administrative expenses totaled \$1,504,354 compared to \$918,477 for the year ended August 31, 2007. Costs incurred related to general and administrative activities during the year

ended August 31, 2008 reflect an increase of professional, legal and consulting expenses and an increase in general expenses such as office and maintenance expenses. During the year ended August 31, 2008, as part of our general and administrative expenses, we incurred \$378,113 related to stock options granted to employees and consultants, as compared to \$479,863 during the year ended August 31, 2007.

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

During the year ended August 31, 2008 we generated interest income on available cash and cash equivalents balance which were offset by bank charges. During the year ended August 31, 2007, we incurred imputed interest expenses on convertible notes issued as well as bank charges.

***Liquidity and Capital Resources***

Through August 31, 2008, we incurred losses in an aggregate amount of \$7,248,204. We have financed our operations through the private placements of equity and debt financing. Since inception through August 31, 2008, we raised a total of \$8,308,785, net of transaction costs, through private placements of equity and debt financing. We anticipate that we will obtain additional financing through similar sources. As of August 31, 2008 we had \$2,267,320 of available cash as well as \$2,728,000 in short term interest bearing investments. The Company anticipates it will require approximately \$5.0 million to finance its activities during the twelve months following September 1, 2008.

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.

Our recent financing activities include the following:

- On August 3, 2007, we completed a private placement for the sale of 510,000 units at a purchase price of \$0.50 per unit for a total consideration of \$255,000. Each unit consisted of one share of common stock and one share purchase warrant. Each share purchase warrant entitles the holder to purchase one additional share of common stock for a period of 3 years at an exercise price of \$0.75.
- On September 7, 2007, we issued 283,025 shares of common stock valued at \$113,210 to a third party, for services rendered in the prior year.
  - On November 8, 2007, we issued 10,000 shares as a finder's fee to a placement agent valued at \$2,900.
- On July 14, 2008 we completed a private placement to twenty-nine accredited investors pursuant to which we sold to the investors an aggregate of 8,524,669 shares of common stock at a purchase price of \$0.60 per share. The investors also received three year warrants to purchase an aggregate of 4,262,337 shares of common stock at an exercise price of \$0.90 per share. The Company paid \$85,000 to a director as a finders fee and issued an aggregate of 143,333 shares of common stock to four other individuals as finders fees in connection with the private placement.
- On October 17, 2008, Oramed issued 203,904 shares of common stock valued at \$152,928 to a third party, for services rendered in the prior year.

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

Employee and consultant stock options grants and warrant issuance activities for the year ending August 31, 2008 include the following:

- On September 4, 2007, we granted options to purchase up to 300,000 shares of our common stock at an exercise price of \$0.45 to two consultants.
- On October 30, 2007, we granted options to purchase up to 100,000 shares of our common stock at an exercise price of \$0.76 to Dr. John Ziemniak, a new member of our Scientific Advisory Board.
- On April 27, 2008, the Board of Directors of the Company adopted the Oramed Pharmaceuticals Inc. 2008 Stock Incentive Plan (the "2008 Plan"). The Board has reserved 8,000,000 shares of the Company's common stock for issuance, in the aggregate, under the Plan.
  - On May 7, 2008, we granted options under the 2008 Plan to purchase up to 864,000 shares of our common stock at an exercise price of \$0.54 to each of Nadav Kidron and Miriam Kidron.
- On July 17, 2008, we granted options under the 2008 Plan to purchase up to 100,000 shares of our common stock at an exercise price of \$0.62 to Professor Avram Hershko a new member of our Scientific Advisory Board.
- On August 4, 2008, we granted options under the 2008 Plan to purchase up to 50,000 shares of our common stock at an exercise price of \$0.9 to an outside consultant.
- On October 12, 2008 we granted options under the 2008 Plan to purchase up to 828,000 shares of our common stock at an exercise price of \$0.47 to Chaime Orlev our Chief Financial Officer.
- On October 12, 2008 we granted options under the 2008 Plan to purchase up to 56,000 shares of our common stock at an exercise price of \$0.47 to an employee of our subsidiary.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

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## 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, 2008 are as follows:

Category	Amount
Research & Development	\$ 3,562,000
General & Administrative Expenses	1,424,000
Finance income, net	(55,000)
Taxes on income	30,000
Total	\$ 4,961,000

As previously indicated we are planning to conduct further clinical studies as well as file an IND 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.

## Employment and Consulting Agreements

On May 1, 2008 we entered into an employment agreement with Chaime Orlev (the "Employment Agreement"), pursuant to which Mr. Orlev was appointed as Chief Financial Officer ("CFO"), Treasurer and Secretary of Oramed. Mr. Orlev's responsibilities include oversight of Oramed's financial reporting and controls. The Employment Agreement provides that for the period through July 31, 2008 (the "First Term"), Mr. Orlev will be employed to work on a part-time basis and will be compensated a gross monthly amount of NIS 20,000. Beginning on September 1, 2008 and continuing until the Employment Agreement is terminated by either party pursuant to the Employment Agreement (the "Second Term"), Mr. Orlev will serve Oramed in a full-time capacity and will be compensated a gross monthly amount of NIS 30,000. Mr. Orlev has also agreed that during the term of his employment with Oramed and for a 12 month period thereafter, he will not compete with Oramed nor solicit employees of Oramed.

On May 1, 2008 we entered into a consulting agreement with a Dr. Ehud Arbit ("Dr. Arbit") which agreement was amended and restated, effective May 1, 2008. The consulting agreement provides for a consultancy period of twelve months, pursuant to which Dr. Arbit will assist our efforts to complete the FDA approval process for its oral insulin capsule. Dr. Arbit is entitled to a fixed monthly fee of \$8,333 effective from May 1, 2008, and reimbursement of pre-approved out of pocket expenses. On October 3, 2008, we amended the consulting agreement with Dr. Arbit. Pursuant to the amendment, Dr. Arbit will perform his work under the contract on a full time basis and his compensation will be \$16,666 per month, effective as of July 1, 2008.

On July 1, 2008, we entered into a consulting agreement with KNRV Ltd. ("KNRV"), an Israeli company owned by Nadav Kidron, whereby Nadav Kidron, through KNRV, will provide services as President and Chief Executive Officer of the Company (the "Nadav Kidron Consulting Agreement"). Additionally, on July 1, 2008, we entered into a consulting agreement with KNRV whereby Dr. Miriam Kidron, through KNRV, will provide services as Chief Medical and Technology Officer of both the Company (the "Miriam Kidron Consulting Agreement" and together with the Nadav Kidron Consulting Agreement, the "Consulting Agreements").

The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNR Y (i) will be paid, under each of the Consulting Agreements, in New Israeli Shekels (“NIS”) a gross amount of NIS50,400 + Value-Added-Tax per month and (ii) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements.

**ITEM 7 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of Oramed Pharmaceuticals Inc. (A Development Stage Company) and its subsidiary (the “*Company*”) as of August 31, 2008, and the related consolidated statements of operations, changes in stockholders’ equity and cash flows for the year then ended and cumulatively, for the period from September 1, 2007 to August 31, 2008 (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, 2008, and the consolidated results of their operations and their cash flows for the year then ended and cumulatively, for the period from September 1, 2007 to August 31, 2008 (not separately presented herein), in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1a to the financial statements, the Company has recurring losses for the period from inception (April 12, 2002) through August 31, 2008 and presently the Company does not have sufficient cash resources to meet its requirements in the following twelve months. These reasons raise substantial doubt about 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Kesselman & Kesselman

Tel Aviv, Israel  
November 26, 2008

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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 accompanying consolidated balance sheet of Oramed Pharmaceuticals, Inc. as of August 31, 2007, and the related consolidated statements of expenses, changes in stockholders' deficit, and cash flows for the year then ended and 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 audits 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 provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oramed, as of August 31, 2007, and 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.

The accompanying financial statements have been prepared assuming that Oramed will continue as a going concern. As discussed in Note 1 to the financial statements, Oramed suffered recurring losses from operations which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

December 10, 2007

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

CONSOLIDATED BALANCE SHEETS  
U.S. dollars

	<b>August 31</b>	
	<b>2008</b>	<b>2007</b>
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 2,267,320	\$ 1,918,229
Short term investments (note 2)	2,728,000	
Prepaid expenses	402,574	11,906
Total current assets	5,397,894	1,930,135
<b>LONG TERM DEPOSITS</b> (Note 7b)	10,824	5,444
<b>PROPERTY AND EQUIPMENT, NET</b> (Note 4)	98,296	1,736
Total assets	\$ 5,507,014	\$ 1,937,315
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses (note 10)	\$ 866,702	\$ 340,872
Account payable with former shareholder	47,252	47,252
Convertible notes payable (Note 5)		275,000
Receipts on account of shares issuance (Note 6)		761,060
Total current liabilities	913,954	1,424,184
<b>COMMITMENTS</b> (Note 7)		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$ 0.001 par value (200,000,000 authorized shares; 56,252,806 and 45,231,779 shares issued and outstanding as of August 31, 2008 and 2007, respectively)	56,252	45,231
Additional paid-in capital	11,785,012	4,946,833
Deficit accumulated during the development stage	(7,248,204)	(4,478,933)
Total stockholders' equity	4,593,060	513,131
Total liabilities and stockholders' equity	\$ 5,507,014	\$ 1,937,315

**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

	2008	Year ended August 31 2007	Period from April 12, 2002 (inception) through August 31, 2008
<b>RESEARCH AND DEVELOPMENT EXPENSES</b> (Note 11)	\$ 1,175,657	\$ 2,214,429	\$ 3,587,834
<b>IMPAIRMENT OF INVESTMENT</b>			434,876
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b> (note 12)	1,504,354	918,477	3,030,458
<b>OPERATING LOSS</b>	2,680,011	3,132,906	7,053,168
<b>INTEREST INCOME</b>	(83,185)	(12,321)	(97,506)
<b>INTEREST EXPENSE</b>	10,281	115,424	130,378
<b>LOSS BEFORE TAXES ON INCOME</b>	2,607,107	3,236,009	7,086,040
<b>TAXES ON INCOME</b> (note 13)	162,164		162,164
<b>NET LOSS FOR THE PERIOD</b>	\$ 2,769,271	\$ 3,236,009	\$ 7,248,204
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	\$ (0.06)	\$ (0.08)	
<b>WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK</b>	48,604,889	42,298,080	

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 (DEFICIT)

U.S. dollars

	Common Stock Shares	\$	Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
<b>BALANCE AS OF APRIL 12, 2002</b> (inception)	34,828,200	\$ 34,828	\$ 18,872		\$ 53,700
<b>CHANGES DURING THE PERIOD FROM APRIL 12, 2002 THROUGH AUGUST 31, 2006</b> (audited):					
<b>SHARES CANCELLED</b>	(19,800,000)	(19,800)	19,800		-
<b>SHARES ISSUED FOR INVESTMENT IN ISTI-NJ</b>	1,144,410	1,144	433,732		434,876
<b>SHARES ISSUED FOR OFFERING COSTS</b>	1,752,941	1,753	(1,753)		-
<b>SHARES ISSUED FOR CASH</b>	2,3531,228	23,531	274,450		297,981
<b>CONTRIBUTIONS TO PAID IN CAPITAL</b>			18,991		18,991
<b>COMPREHENSIVE LOSS</b>				(16)	(16)
<b>IMPUTED INTEREST</b>			4,657		4,657
<b>NET LOSS</b>				(1,242,908)	(1,242,908)
<b>BALANCE AS OF AUGUST 31, 2006</b>	41,456,779	41,456	768,749	(1,242,924)	(432,719)
<b>SHARES AND WARRANTS ISSUED FOR CASH</b>	3,650,000	3,650	1,821,350		1,825,000
<b>SHARES ISSUED FOR SERVICES</b>	125,000	125	98,625		98,750
<b>STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS</b>			1,968,547		1,968,547
<b>STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS</b>			177,782		177,782
<b>DISCOUNT ON CONVERTIBLE NOTE RELATED TO BENEFICIAL CONVERSION FEATURE</b>			108,000		108,000
<b>IMPUTED INTEREST</b>			3,780		3,780
<b>NET LOSS</b>				(3,236,009)	(3,236,009)



<b>BALANCE AS OF AUGUST 31, 2007</b>	45,231,779	45,231	4,946,833	(4,478,933)	513,131
<b>RECEIPTS ON ACCOUNT OF SHARES AND WARRANTS</b>			6,061		6,061
<b>SHARES ISSUED FOR CONVERSION OF CONVERTIBLE NOTE</b>	550,000	550	274,450		275,000
<b>SHARES AND WARRANTS ISSUED FOR CASH – NET OF ISSUANCE EXPENSES</b>	10,178,002	10,178	5,774,622		5,784,800
<b>SHARES ISSUED FOR SERVICES</b>	293,025	293	115,817		116,110
<b>STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS</b>			459,467		459,467
<b>STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS</b>			203,982		203,982
<b>IMPUTED INTEREST</b>			3,780		3,780
<b>NET LOSS</b>				(2,769,271)	(2,769,271)
<b>BALANCE AS OF AUGUST 31, 2008</b>	56,252,806	\$ 56,252	\$ 11,785,012	\$ (7,248,204)	\$ 4,593,060

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

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended August 31		Period from April 12, 2002 (inception date) through August 31, 2008
	2008	2007	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (2,769,271)	\$ (3,236,009)	\$ (7,248,204)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	15,454		15,454
Amortization of debt discount		108,000	108,000
Exchange differences on long term deposits	(1,642)		(1,642)
Stock based compensation	663,449	2,146,329	2,809,778
Common stock issued for services	116,110	98,750	214,860
Impairment of investment			434,876
Imputed interest	3,780	3,780	12,217
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(390,668)	*(11,906)	(402,574)
Accounts payable and accrued expenses	525,830	287,220	866,702
Total net cash used in operating activities	(1,836,958)	(603,836)	(3,190,533)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(112,014)	(1,736)	(113,750)
Short term investments	(2,728,000)		(2,728,000)
Lease deposits	(3,738)	*(5,444)	(9,182)
Total net cash used in investing activities	(2,843,752)	(7,180)	(2,850,932)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from sales of common stocks and warrants - net of issuance expenses	5,029,801	1,823,056	7,961,481
Receipts on account of shares issuances		255,000	6,061
Proceeds from convertible notes		275,000	275,000
Proceeds from short term note payable		20,000	120,000
Payments of short term note payable		(20,000)	(120,000)
Shareholder advances			66,243
Net cash provided by financing activities	5,029,801	2,353,056	8,308,785
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>			
	349,091	1,742,040	2,267,320
	1,918,229	176,189	

**CASH AND CASH EQUIVALENTS AT  
BEGINNING OF PERIOD**

<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	\$ 2,267,320	\$ 1,918,229	\$ 2,267,320
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**Non cash investing and financing activities:**

Receipts on account of shares issuance - reclassified from liability to shareholder's equity	6,061		
Stock issued for receipts on account of shares issuance and convertible notes	\$ 1,030,000	\$ 1,944	
Discount on convertible note related to beneficial conversion feature		\$ 108,000	\$ 108,000
Shares issued for offering costs			\$ 1,753
Contribution to paid in capital			\$ 18,991

\* Reclassified

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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:**

**a. General:**

Oramed Pharmaceuticals, Inc. (a development stage company) (the “Company”) was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd. to acquire the provisional patent related to orally ingestible insulin pill to be used for the treatment of individuals with diabetes. The Company has been in the development stage since its formation and has not yet realized 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*”).

The Company is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with Statement of financial Accounting Standard (“*SFAS*”) No. 7 “*Accounting and Reporting by Development Stage Enterprises*”.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (April 12, 2002) through August 31, 2008 of \$7,248,204, as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following September 1, 2008. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as the Company 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 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 and existing shareholders.

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”).

**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.

**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 Company’s research and development costs are incurred in dollars. A significant part of the Company’s capital expenditures and most of their financing is 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.

**e. Principles of consolidation**

The consolidated financial statements include the accounts of Oramed Pharmaceuticals Inc. and its Israeli subsidiary Oramed Ltd. All material inter-company transactions and balances have been eliminated in consolidation.

**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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

**g. 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, paragraph 9(f) of FAS 109, “*Accounting for Income Taxes*”, 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

**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, payroll taxes, 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.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company’s clinical trials are performed primarily by contract research organizations (“CROs”). CROs typically perform most of the start-up activities for the Company’s trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

**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.





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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

**j. Comprehensive loss**

The Company has no other comprehensive loss components other than net loss for the fiscal years of 2007 and 2008.

**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 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, warrants and convertible notes excluded from the calculation of diluted net loss was 16,611,697 for the year ended August 31, 2008 (12,033,677 for the year ended August 31, 2007).

**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**

Effective March 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), “*Share-based Payment*” (“*FAS 123(R)*”). FAS 123(R) 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 expense over the requisite service period, net of estimated forfeitures. The Company estimated forfeitures based on historical experience and anticipated future conditions.

In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (“*SAB 107*”). SAB 107 provides supplemental implementation guidance on FAS 123(R), including guidance on valuation methods, inventory capitalization of share-based compensation cost, income statement effects, disclosures and other issues. SAB 107 requires share-based payment to be classified in the same expense line items as cash compensation. The Company has applied the provisions of SAB 107 in its adoption of FAS 123(R).

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 multiple option award approach.

FAS 123(R) applies to all awards granted or modified after the Statement’s effective date. In addition, compensation cost for the unvested portion of previously granted awards that remain outstanding on the Statement’s effective date shall be recognized on or after the effective date, as the related services are rendered, based on the awards’ grant-date fair value as previously calculated for the pro-forma disclosure under FAS 123.



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

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

The Company elected to adopt the modified prospective application transition method, as permitted by FAS 123(R). Under such transition method, upon the adoption of FAS 123(R), the Company's financial statements for periods prior to the effective date of the Statement are not restated.

In December 2007, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 110 ("SAB 110") relating to the use of a "simplified" method in developing an estimate of the expected term of "plain vanilla" share options. SAB 107 previously allowed the use of the simplified method until December 31, 2007. SAB 110 allows, under certain circumstances, to continue to accept the use of the simplified method beyond December 31, 2007. The Company has applied the provisions of SAB 110 in its financial statement.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value based on an option-pricing model or when more reliability is based on the fair value of the services received, pursuant to the guidance in EITF 96-18 "*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*". The fair value of the options granted is revalued over the related service periods and recognized using the accelerated method.

**n. Uncertainty in income tax**

As of September 1, 2007, the Company adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 specifies how tax benefits for uncertain tax positions are to be recognized, measured and derecognized in financial statements; requires certain disclosures of uncertain tax positions; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim-period guidance, among other provisions. On May 2, 2007, the FASB issued FASB Staff Position No. FIN 48-1, "Definition of Settlement in FASB Interpretation No. 48-1" ("FSP FIN 48-1"). FSP FIN 48-1 provides guidance regarding how an entity should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits.

**o. Concentration of credit risks**

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

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

1) In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "*Fair Value Measurements*" ("*SFAS 157*"). SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years (September 1, 2009, for the Company). The Company is currently assessing the impact that SFAS 157 may have on its results of operations and financial position.

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

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

- 2) In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115"* ("SFAS 159"). SFAS 159 is expected to expand the use of fair value accounting but does not affect existing standards which require certain assets or liabilities to be carried at fair value. The objective of SFAS 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS 159, a company may choose, at its initial application or at other specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years (September 1, 2009, for the Company). If the company is to elect the fair value option for its existing assets and liabilities, the effect as of the adoption date, shall be reported as a cumulative-effect adjustment to the opening balance of retained earnings. The Company is currently assessing the impact that SFAS 159 may have on its financial position.
- 3) In June 2007, the Emerging Issues Task Force (EITF) reached Issue No. 07-03, *"Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities"* (EITF No. 07-03). EITF No. 07-03 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. The provisions of EITF 07-03 will be effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years (September 1, 2009, for the Company). The provisions of this EITF are applicable for new contracts entered into on or after the effective date. Earlier application is not permitted.
- 4) In December 2007, the FASB ratified EITF Issue No. 07-01, *"Accounting for Collaborative Arrangements"* ("EITF 07-01"). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008 (September 1, 2009, for the Company). EITF 07-01 shall be applied using modified version of retrospective transition for those arrangements in place at the effective date. An entity should report the effects of applying this Issue as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects the change retrospectively. The Company is currently assessing the impact that EITF 07-01 may have on its results of operations and financial position.

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

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

- 5) In May 2008, the FASB issued SFAS No. 162, *"The Hierarchy of Generally Accepted Accounting Principles"* ("FAS 162"). FAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with GAAP for nongovernmental entities. FAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles." We do not expect the adoption of this statement to have a material impact on our results of operations, financial position or cash flows.
- 6) In June 2007, the Emerging Issues Task Force (EITF) reached Issue No. 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities" (EITF No. 07-03). EITF No. 07-03 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. The provisions of EITF 07-03 will be effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years (September 1, 2008, for the Company). The provisions of this EITF are applicable for new contracts entered into on or after the effective date. Earlier application is not permitted.

**q. Reclassifications**

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

**NOTE 2 – SHORT TERM INVESTMENTS:**

Amount represents bank deposits with an original maturity of more than three months but less than one year. The bank deposits are in US Dollars and bear interest at 2.56% – 2.66% per annum.

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

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

The fair value of the financial instruments included in the working capital of the Group is identical or close to their carrying value (refer to note 1o).

**NOTE 4 - PROPERTY AND EQUIPMENT, Net:**

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

	August 31	
	2008	2007
Cost:		
Leasehold improvements	\$ 76,029	

Office furniture and equipment	17,684		
Computers and peripheral equipment	20,037	\$	1,736
	113,750		1,736
Less - accumulated depreciation	15,454		-
	\$ 98,296	\$	1,736

- b.** Depreciation expense totaled \$15,454 and \$0 in the years ended August 31, 2008 and 2007, respectively.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 5 - CONVERTIBLE NOTES**

In February 2007, the Company borrowed \$125,000 on a convertible note without interest, due on demand and unsecured. The note is convertible at \$0.50 per share. The Company analyzed the note under EITF 98-5 and EITF 00-27 to determine if it contained a beneficial conversion feature. It was determined the note did contain a beneficial conversion feature with an intrinsic value of \$60,000. Because the note is due on demand, the entire amount of the beneficial conversion feature was amortized immediately to interest expense.

In May 2007, the Company borrowed \$150,000 on a convertible note without interest, due on demand and unsecured. The note is convertible at \$0.50 per share. The Company analyzed the note under EITF 98-5 and EITF 00-27 to determine if it contained a beneficial conversion feature. It was determined the note did contain a beneficial conversion feature with an intrinsic value of \$48,000. Because the note is due on demand, the entire amount of the beneficial conversion feature was amortized immediately to interest expense.

The Company analyzed the conversion option of both notes and determined it did not require derivative treatment under FAS 133 and EITF 00 - 19.

During the year ended August 31, 2008, the Company received conversion notices regarding the above mentioned convertible notes. The common stock underlying the convertible notes were issued on July 1, 2008.

**NOTE 6 - RECEIPTS ON ACCOUNT OF SHARES ISSUANCE**

The balance of the Receipts on account of shares issuance as of August 31, 2007 represent 1,012,317 shares of common stock sold during fiscal year 2006, for \$506,061, of which 1,000,000 were issued on July 1, 2008, and 510,000 shares of common stock sold during fiscal year 2007, for \$255,000, which were issued on November 8, 2007. As of August 31, 2008 the balance of unissued shares is 12,317. The Company has included the shares as outstanding for the calculation of the annual loss per share.

**NOTE 7 - COMMITMENTS:**

- a. On March 8, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd (“Hadasit”) to acquire provisional patent application No. 60/718716, including related intellectual property. The provisional patent application No. 60/718716 related to a method of preparing insulin so that it may be taken orally for the use in the treatment of individuals with diabetes.

Under the terms of the agreement, the Company agreed to contract Hadasit to provide consulting services relating to the completion of clinical trials on provisional patent application No. 60/718716. As remuneration for the services provided under the agreement Hadasit is entitled to \$200,000, of which \$163,000 was expensed through August 31, 2008.

Hadasit is a 7% shareholder of the Company. The primary researcher for Hadasit is Dr. Miriam Kidron, a director of the Company. As part of the above agreement, the Company entered into an employment agreement with Dr. Kidron that included the grant of 3,361,360 options exercisable at \$0.001 per share for a period of five years (See note 8g). On July 1, 2008, the employment agreement was replaced by a consulting agreement (See note 14c).





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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 7 - COMMITMENTS** (continued):

**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 year ended August 31, 2008 were \$20,325. The future lease payments under the lease agreement are \$30,748, \$30,748 and \$9,851 for the years ending August 31, 2009, 2010 and 2011 respectively.

As security for its obligation under the lease agreements the Subsidiary paid \$10,824, which are classified as long term deposits.

**c.** On September 19, 2007 the Subsidiary entered into a new lease agreement for its new office facilities, in Israel. The new lease agreement is for a period of 51 months. The monthly lease payment is 2,396 NIS and is linked to the increase in the Israeli consumer price index (As of August 31, 2008 the monthly payment in the Company's functional currency is \$667), the future lease payments under the lease are \$8,004 for the years ending August 31, 2009, 2010 and 2011 and \$2,668 for the year ending August 31, 2012.

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.** During January and April 2008 the Company entered into agreements with OnQ consulting, a clinical research organization (CRO) located in Johannesburg, South Africa, to conduct Phase 1B and 2B clinical trials on its oral insulin capsules. The total cost estimated for the studies is \$262,595 of which \$15,325 was expensed through August 31, 2008.

**e.** On April 21, 2008, the Company entered into a five year service agreement with Encorium Group, Inc. ("Encorium") pursuant to which Encorium will provide services for the purpose of filing an Investigational New Drug Application (IND) for a phase 2 study as required by the US Food and Drug Administration (FDA). The total cost under the agreement is estimated at \$1,455,143 of which \$171,000 was paid through August 31, 2008, and included in prepaid expenses.

**f.** During April 2008, the Company entered into a five years master services agreement with SAFC, an operating division of Sigma-Aldrich, Inc. ("SAFC"), pursuant to which SAFC will provide 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, in accordance with mutually agreed upon work orders. The total cost under the agreement is estimated at \$605,159 of which \$266,403 was paid through August 31, 2008, of which \$82,431 was expensed and the remaining was included in prepaid expenses.

**g.** On May 1, 2008, the Company entered into a consulting agreement with a third party ("the Consultant") for a period of twelve months, pursuant to which the Consultant will assist Oramed's efforts to complete the FDA approval process for its oral insulin capsule. On October 3, 2008 the Company and the Consultant agreed to amend the agreement effective July 1, 2008. The Consultant is entitled to a fixed monthly fee of \$16,666 (for the period from May 1, 2008 through June 30, 2008 the monthly fee was \$8,333) and reimbursement of pre-approved out of pocket

expenses.

- h.** As to a Clinical Trial Manufacturing Agreement with Swiss Caps AG, see note 9a.

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

**NOTE 8 - 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, 2008 and 2007:

**a.** On January 3, 2007, the Company entered into a subscription agreement for the sale of 50,000 units at a purchase price of \$0.50 per unit for total consideration of \$25,000. 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 one share of common stock exercisable for two years at an exercise price of at \$0.75 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to the warrants estimated by using the Black Scholes option-pricing model is \$8,630 and was based on the following assumptions: dividend yield of 0%; expected volatility of 135.2%; risk-free interest rates of 4.76%; and expected lives of 2 years.

**b.** On June 15, 2007, the Company entered into a subscription agreement for the sale of 3,600,000 units at a purchase price of \$0.50 per unit for total consideration of \$1,800,000. 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 one share of common stock exercisable for three years at an exercise price of \$0.75 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to all warrants estimated by using the Black Scholes option-pricing model is \$620,569 and was based on the following assumptions: dividend yield of 0%; expected volatility of 121.5%; risk-free interest rates of 5.07%; and expected lives of 3 years.

**c.** On August 2, 2007, the Company entered into a subscription agreement for the sale of 510,000 units at a purchase price of \$0.50 per unit for total consideration of \$255,000. 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 one share of common stock exercisable for three years at an exercise price of \$0.75 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to all warrants estimated by using the Black Scholes option-pricing model is \$93,847 and was based on the following assumptions: dividend yield of 0%; expected volatility of 121.9%; risk-free interest rates of 4.57%; and expected lives of 3 years.

In connection with the subscription agreement the Company issued, to third parties who assisted in securing the agreement, 10,000 shares of the Company's common stock.

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

**NOTE 8 - STOCK HOLDERS' EQUITY** (continued):

d. On July 14, 2008, the Company entered into a Securities Purchase Agreement with twenty-nine accredited investors for the sale of 8,524,669 units at a purchase price of \$0.60 per unit for total consideration of \$5,114,799. 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 half a share of common stock exercisable for three years at an exercise price of \$0.90 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to the warrants was estimated by using the Black Scholes option-pricing model at \$1,124,564 and was based on the following assumptions: dividend yield of 0%; expected volatility of 117.9%; risk-free interest rates of 2.8%; and expected lives of 3 years.

As finders fee, in connection with the securities purchase agreement, the Company paid \$85,000 cash fee to a director (see note 13b), as well as issued 143,333 shares of the Company's common stock for other individuals.

e. As to shares issued as part of stock based compensation plan see Note 8.

**NOTE 9 - 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.

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

**NOTE 9 - STOCK BASED COMPENSATION** (continued):

The following are stock options and warrants transactions made during the years ended August 31, 2008 and 2007, (See Note 15 as to grants of stock options subsequent to August 31, 2008):

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 was issued. The Company accounted the transaction with Swiss according to FAS 150 *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*”.

On December 27, 2006 and September 10, 2007, respectively, the Company issued 125,000 and 283,025, shares of its common stock to Swiss as remuneration for the services provided. The shares of common stock issued for service rendered at \$98,750 and \$113,210, respectively. As for shares issued following August 31, 2008 see note 15c.

b. On November 23, 2006, 500,000 options were granted to an employee under the 2006 Stock Option Plan at an exercise price of \$0.76 per share (equivalent to the traded market price on the date of grant), the options vest in twelve equal monthly installments over the first year and expire on November 23, 2009. The fair value of these options on the date of grant was \$214,431 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 115%; risk-free interest rates of 4.7%; and expected lives of 1.77 years.

c. On November 23, 2006, 250,000 options were granted to an outside consultant under the 2006 Stock Option Plan at an exercise price of \$0.76 per share (equivalent to the traded market price on the date of grant), the options vest in twelve equal monthly installments over the first year and expire on November 23, 2009. The fair value of these options on November 30, 2007 (the date when the option were fully vested) was \$33,075 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 119%; risk-free interest rates of 3.0%; and the remaining contractual life of 1.98 years.

d. On December 31, 2006, 400,000 options were granted to four then new member of the Scientific Advisory Board, an outside parties, under the 2006 Stock Option Plan. at an exercise price of \$0.76 per share (less then the traded market price on the date of grant), the options vest in twelve equal monthly installments over the first year and expired on June 30, 2008. The fair value of these options on December 31, 2007 (the date when the option were fully vested) was \$7,262 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 120%; risk-free interest rates of 3.5%; and the remaining contractual life of 0.5 years. These options expired on June 30, 2008.

e. On March 18, 2007, 100,000 options were granted to a then new member of the Scientific Advisory Board, an outside party under the 2006 Stock Option Plan at an exercise price of \$0.76 per share (over the traded market price on the date of grant), the options vest in twelve equal monthly installments over the first year and expire on March 18, 2010. The fair value of these options on March 17, 2008 (the date when the option were fully vested) was \$27,939 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 122%; risk-free interest

rates of 3.5%; and the remaining contractual life of 2.00 years.

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

**NOTE 9 - STOCK BASED COMPENSATION** (continued):

- f.** On August 2, 2007, 1,700,000 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, under the 2006 Stock Option Plan at an exercise price of \$0.45 per share (over the traded market price on the date of grant), the options vested immediately and expire on August 2, 2012. The fair value of these options on the date of grant was \$450,449 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 105%; risk-free interest rates of 4.6%; and expected lives of 3.0 years.
- g.** On August 14, 2007, 3,361,630 stock options were granted to Miriam Kidron, the Company's Chief Medical and Technology Officer and director, at an exercise price of \$0.001 per share, the options vested immediately and expire on August 14, 2012. The fair value of these options on the date of grant was \$1,348,340 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 105%; risk-free interest rates of 4.6%; and expected lives of 3.0 years.
- h.** On September 4, 2007, 300,000 options were granted to two outside consultants, at an exercise price of \$0.45 per share (equivalent to the traded market price on the date of grant), the options vest in twelve equal monthly installments over the first year and expire on September 4, 2009. The fair value of these options as of August 31, 2008 was \$125,440, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 118%; risk-free interest rates of 2.17%; and the remaining contractual life of 1.01 years.
- i.** On October 30, 2007, 100,000 options were granted to an advisory board member, at an exercise price of \$0.76 per share (over the traded market price on the date of grant), the options vest in eighteen equal monthly installments from the date of grant and expire on October 30, 2010. The fair value of these options as of August 31, 2008 was \$39,615, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 118%; risk-free interest rates of 2.17%; and the remaining contractual life of 1.66 years.
- j.** On May 7, 2008, 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 \$0.54 per share (equivalent to the traded market price on the date of grant), 288,000 of the options vested immediately on the date of grant and the remainder will vest in twenty equal monthly installments. These options expire on May 7, 2018. The fair value of these options on the date of grant was \$784,430, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 116%; risk-free interest rates of 3.41%; and expected lives of 5.44 years.
- k.** On July 17, 2008, 100,000 options were granted to an advisory board member, at an exercise price of \$0.62 per share (equivalent to the traded market price on the date of grant), the options vest in four equal quarterly installments commencing on September 17, 2008 and expire on July 17, 2011. The fair value of these options as of August 31, 2008 was \$51,624, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 118%; risk-free interest rates of 2.36%; and the remaining contractual life of 2.88 years.





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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 9 - STOCK BASED COMPENSATION** (continued):

I. On August 4, 2008, 50,000 options were granted to an outside consultant, at an exercise price of \$0.90 per share (equivalent to the traded market price on the date of grant), the options vest in four equal quarterly installments commencing on October 1, 2008 and expire on August 4, 2011. The fair value of these options as of August 31, 2008 was \$23,873, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 118%; risk-free interest rates of 2.36%; and the remaining contractual life of 2.93 years.

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 year ended August 31</b>	
	<b>2008</b>	<b>2007</b>
Expected option life (years)	1.0-5.4	1.5-3.0
Expected stock price volatility (%)	116.3-118.0	105.4-117.4
Risk free interest rate (%)	2.2-3.4	4.4-4.7
Expected dividend yield (%)	0.0	0.0

A summary of the status of the stock options granted to employees and directors as of August 31, 2008 and 2007, and changes during the year ended on this date, is presented below:

	<b>Year ended August 31,</b>			
	<b>2008</b>		<b>2007</b>	
	<b>Number of options</b>	<b>Weighted average exercise price \$</b>	<b>Number of options</b>	<b>Weighted average exercise price \$</b>
Options outstanding at beginning of year	5,561,360	0.21	-	
Changes during the year:				
Granted – at market price	1,728,000	0.54		
Granted – at an exercise price above market				
Price			2,200,000	0.52
Granted – at an exercise price below market				
price			3,361,360	0.001
Options outstanding at end of year	7,289,360	0.29	5,561,360	0.21

Options exercisable at end of year	6,137,360	5,436,360
Weighted average fair value of options granted during the year	\$ 0.45	\$ 0.35

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**ORAMED PHARMACEUTICALS INC.**

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 9 - STOCK BASED COMPENSATION** (continued):

Costs incurred in respect of stock based compensation for employees and directors, for year ended August 31, 2008, 2007 were \$459,467 and \$1,968,547, respectively.

The following table presents summary information concerning the options outstanding as of August 31, 2008:

Range of exercise prices \$	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.001	3,361,360	3.95	0.001	2,416,818
0.45 to 0.62	3,428,000	6.83	0.50	770,040
0.76 to 0.90	500,000	1.23	0.76	-
	7,289,360	5.12	0.29	3,186,858

The following table presents summary information concerning the options exercisable as of August 31, 2008:

Range of exercise prices \$	Number exercisable	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.001	3,361,360	3.95	0.001	2,416,818
0.45 to 0.62	2,276,000	5.38	0.47	562,680
0.76 to 0.90	500,000	1.23	0.76	-
	6,137,360	4.26	0.24	2,979,498

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 9 - STOCK BASED COMPENSATION** (continued):

A summary of the status of the stock options granted to non-employees as of August 31, 2008, and changes during the year ended on this date, is presented below:

	Year ended August 31			
	2008	Weighted average exercise price \$	2007	Weighted average exercise price \$
	Number of options		Number of options	
Options outstanding at beginning of year	750,000	0.76	-	
Changes during the year:				
Granted – at market price	150,000	0.71		
Granted – at an exercise price above market Price	400,000	0.53	350,000	0.76
Granted – at an exercise price below market price			400,000	0.76
Expired	400,000	0.76		
Options outstanding at end of year	900,000	0.65	750,000	0.76
Options exercisable at end of year	733,333		495,833	

The Company recorded stock compensation of \$203,982 and \$177,782 during the year ended August 31, 2008 and 2007 respectively, related to consulting services.

The following table presents summary information concerning the options outstanding as of August 31, 2008:

Range of exercise prices \$	Number outstanding	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.45 to 0.62	400,000	1.48	0.49	91,000
0.76 to 0.90	500,000	1.55	0.77	-
	900,000	1.52	0.65	91,000

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 9 - STOCK BASED COMPENSATION** (continued):

The following table presents summary information concerning the options exercisable as of August 31, 2008:

Range of exercise prices \$	Number exercisable	Weighted Average Remaining Contractual Life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.45 to 0.62	300,000	1.01	0.45	81,000
0.76 to 0.90	433,333	1.38	0.76	-
	733,333	1.23	0.63	81,000

Unrecognized compensation as determined under FAS 123R as of August 31, 2008 totaled \$670,698, to be recorded over the next 17 months.

**NOTE 10 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES:**

	Year ended August 31,	
	2008	2007
Service providers	\$ 635,762	\$ 275,465
Tax provisions	162,164	
Related parties	28,062	65,407
Payroll and related expenses	40,714	
	\$ 866,702	\$ 340,872

**NOTE 11 - RESEARCH AND DEVELOPMENT EXPENSES:**

	Year ended August 31,		Period from April 12, 2002 (inception) through August 31, 2008
	2008	2007	
Clinical trials	\$ 538,056	\$ 417,045	\$ 1,063,326
Consulting fees	205,372	93,731	388,625
Costs for registration of patents	89,645	11,045	100,690
	285,336	1,664,666	1,951,802

Compensation costs  
in respect of warrants  
granted to employees,  
directors and  
consultants

Other	57,248	26,142	83,391
	\$ 1,175,657	\$ 2,214,429	\$ 3,587,834

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**NOTE 12 - GENERAL AND ADMINISTRATIVE EXPENSES**

	<b>Year ended August 31</b>		<b>Period from April 12, 2002 (inception) through August 31, 2008</b>
	<b>2008</b>	<b>2007</b>	
Compensation costs in respect of warrants granted to employees, directors and consultants	\$ 378,113	\$ 479,863	\$ 857,976
Professional services	391,309	120,018	771,279
Consulting fees	151,037	146,756	325,319
Travel costs	141,862	122,412	278,173
Write off of debt			275,000
Business development	154,357		154,357
Payroll and related expenses	130,081		130,081
Insurance	23,630		23,630
Other	133,965	49,428	214,643
	\$ 1,504,354	\$ 918,477	\$ 3,030,458

**NOTE 13 - TAXES ON INCOME:****a. Corporate taxation in the U.S.**

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

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

As of August 31, 2008, the Company has an accumulated tax loss carryforward of approximately \$3,425,168 (August 31, 2007 approximately - \$1,317,244). 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 2027.

**b. Corporate taxation in Israel:**

The Subsidiary is taxed in accordance with Israeli tax laws. The regular corporate tax rate in Israel for 2008 is 27%. The corporate tax rates for 2009 and thereafter are as follows: 2009 - 26% and for 2010 and thereafter - 25%.

**NOTE 13 - TAXES ON INCOME** (continued):**c. Deferred income taxes:**

	<b>August 31</b>	
	<b>2008</b>	<b>2007</b>
In respect of:		
Net operating loss carryforward	\$ 1,194,401	\$ 480,353
Less - Valuation allowance	(1,194,401)	(480,353)
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:**

	<b>Year ended August 31</b>		<b>Period from April 12, 2002 (inception) through August 31, 2008</b>
	<b>2008</b>	<b>2007</b>	
Loss before taxes on income:			
U.S.	\$ 2,315,686	\$ 3,164,462	\$ 6,885,236
Outside U.S.	291,421	71,547	362,968
	2,607,107	3,236,009	7,248,204
Taxes on income:			
Current:			
U.S.	39,799		39,799
Outside U.S.	122,365		122,365
	\$ 162,164		\$ 162,164

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**NOTE 13 - 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:

	<b>Year ended August 31</b>		<b>Period from April 12, 2002 (inception) through August 31, 2008</b>
	<b>2008</b>	<b>2007</b>	
Loss before income taxes as reported in the consolidated statement of operations	\$ (2,607,107)	\$ (3,236,009)	\$ (7,086,040)
Computed "expected" tax benefit	(912,487)	(1,132,603)	(2,480,114)
Increase (decrease) in income taxes resulting from:			
Change in the balance of the valuation allowance for deferred tax losses	714,048	336,541	1,194,401
Disallowable deductions	200,916	790,338	1,282,466
Increase in taxes resulting from different tax rates applicable to non			
U.S. subsidiary	29,037	5,724	34,761
Uncertain tax position	130,650		130,650
Taxes on income for the reported year	\$ 162,164	-;-	\$ 162,164

**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 do 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, 2008 the Company recorded \$37,469 of penalties related to tax contingencies.

**Year ended  
December 31, 2008**

Balance at September 1, 2007	-
Increase in tax positions for current year	130,650
Net deferred tax assets	\$ 130,650

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

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**NOTE 13 - TAXES ON INCOME (continued):**

As of September 1, 2007, the Company is subject to Israeli income tax examinations and to U.S. Federal income tax examinations for the tax years of 2002 through 2007. As of August 31, 2008, the Company did not record any change to its unrecognized tax benefits.

**NOTE 14 - RELATED PARTIES - TRANSACTIONS:**

- a. On March 8, 2006, the Company entered into a research and license agreement with Hadasit, a 9% shareholder of the Company. The primary researcher for Hadasit is Miriam Kidron the Company's Chief Medical and Technology Officer and director.
- b. On January 18, 2008, Oramed entered into an agreement with a director that will provide managerial services, pursuant to which the director will be entitled to an annual payment of \$15,000, as a reimbursement of expenses. . In connection with the Company's private placement on July 14, 2008, the director received \$85,000 as a finders fee.
- c. On July 1, 2008, the Subsidiary entered into a consulting agreement with KNR Y Ltd. ("KNRY"), an Israeli company owned by Nadav Kidron, whereby Mr. Nadav Kidron, through KNR Y, 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 KNR Y whereby Dr. Miriam Kidron, through KNR Y, 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 replace the existing employment agreements entered into between the Company and KNR Y, dated as of August 1, 2007, pursuant to which Nadav Kidron and Miriam Kidron, respectively, provide 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 KNR Y (i) will be paid, under each of the Consulting Agreements, in New Israeli Shekels ("NIS") a gross amount of NIS50,400 + Value-Added-Tax per month (as of August 31, 2008 the monthly payment in the Company's functional currency is \$14,030+VAT) and (ii) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements.

**NOTE 15 – SUBSEQUENT EVENTS:**

- a. On September 8, 2008, the Company entered into Clinical Research agreement with ETI Karle Clinical Pvt. Ltd. ("ETI"), pursuant to the agreement ETI will be conducting clinical trials for the Company in India. In consideration for the services provided under the agreement ETI will be entitled to an estimated cash compensation of \$227,604.
- b. On October 12, 2008, an aggregate of 884,000 options were granted to two employees of the subsidiary at an exercise price of \$0.47 per share. The options vest in three equal annual installments commencing on May 1, 2009 and will expire on October 12, 2018.
- c. On October 17, 2008, the Company issued 203,904 shares of its common stock to Swiss as remuneration for the services provided, in the amount of \$152,928.

## **ITEM 8 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None

### **ITEM 8A – CONTROLS AND PROCEDURES**

(a) 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, 2008. 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) 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, 2008 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 there is no reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and that the Company's internal controls over financial reporting were not effective as of August 31, 2008.

Subsequent to August 31, 2008, management, including our principal executive officer and principal financial officer, has started an extensive process, of documenting all process related to the financial reporting, in order to strengthen our internal controls over financial reporting in order to reasonably ensure that 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.

To improve our internal control over financial reporting, subsequent to year-end, we have launched a comprehensive program designed to strengthen our internal controls over financial reporting. Among other things, the program provides for the engagement of an outside consulting accounting firm (separate from our independent auditing firm) to review the Company's financial reports on a quarterly basis and the implementation of an improved documentation system underlying financial reports

(c) There were no changes in our internal controls over financial reporting identified with the evaluation thereof that occurred during the quarter ended August 31, 2008 that have materially affected, or are reasonable likely to materially affect our internal control over financial reporting.

#### **ITEM 8B – OTHER INFORMATION**

None

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**PART III****ITEM 9 - DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS, CONTROL PERSONS AND CORPORATE GOVERNANCE; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

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

<b>Name</b>	<b>Age</b>	<b>Position</b>
Nadav Kidron	34	President, Chief Executive Officer and Director
Miriam Kidron	67	Chief Medical and Technology Officer and Director
Leonard Sank	43	Director
Harold Jacob	54	Director and member of the Scientific Advisory Board
Chaime Orlev	38	Chief Financial Officer and Treasurer

**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. Mr. Kidron is an entrepreneur whose expertise includes senior executive roles in a wide range of industries. From 2003 – 2006 he was the managing director at the Institute of Advanced Jewish Studies – Bar Ilan University. From 2001 - 2003, he was a lawyer intern at with Wine Mishaiker and Erenstov Law Offices in Jerusalem, Israel. Mr. Kidron obtained his LLB from the Bar – Ilan University and is currently enrolled in the International MBA program at the Bar - Ilan University.

**Dr. Miriam Kidron** was appointed as Chief Medical and Technology Officer and Director on 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 specializes in the developed 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 during 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 where he has played an important leadership role in developing businesses. During the past two years Mr. Sank has disposed of his holdings in Eastvaal Motor Group a diversified retail motor business and resigned as a director in 2007 He also sold his investment in Vecto Finance a credit lending business and resigned his directorship in 2007. Mr. Sank has since acquired property and various other investments as well as his stake in Oramed. Mr. Sank maintains a directorship on the board of South Africa's biggest private company Macsteel Service Centers SA Pty Ltd as well as serves on the board of local non profit charity organizations in Cape Town where he resides.





**Mr. Chaime Orlev** joined our Company in May 2008, he has many years of experience of financial management experience in publicly traded companies, specializing in the high technology sector. Mr. Orlev served as Chief Financial Officer of Gammacan International Inc., a life science company focused on the development of immunotherapy and related approaches to treat cancer, from October 2005 through February 2008. From September 2004 to September 2005, Mr. Orlev acted as Chief Financial Officer for Solel Solar Systems, an Israeli-based company specializing in the development, manufacturing and marketing of solar energy systems and related equipment, as well as coatings for different substrates. From April 2001 to August 2004 Mr. Orlev was the Vice President, Finance and Chief Financial Officer of Huntleigh, a provider of airport services to carriers. Mr. Orlev holds an MBA from the Leon Recanati Graduate School of Business Administration at the Tel Aviv University and a BA in Business Administration from the College of Business in Israel. Mr. Orlev is a certified public accountant in Israel.

**Dr. Harold Jacob** has a strong background, both in medical sciences as well as biotechnology and medical devices. 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. Since 1998, Dr. Jacob is 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 is CEO of NanoVibronix, a medical device company using surface acoustics to prevent catheter acquired infection as well as other applications.

### **Board of Directors and Officers**

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.

There have been no events under any bankruptcy act, no criminal proceedings and no judgments, injunctions, orders or decrees material to the evaluation of the ability and integrity of any director, executive officer, or control person of the Company during the past five years.

### **Board Meeting Attendance**

During the year ended August 31, 2008, our board held 3 meetings and took actions by written consent on 16 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, 2008 the Board has not established any committees. The Board is intending to establish an Audit and Compensation committee during the year ending August 31, 2009.

## **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 2008, we believe that during fiscal year 2008, other than as set forth below, 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. The Form 3 of one of our directors, Harold Jacob, was not timely filed.

## **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 10 - EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table sets forth the compensation earned during the years ended August 31 2007 and 2008 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 (1)	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Award (\$)	Non-Equity Incentive Compensation		All Other Compensation (\$)	Total (\$)
						Nonqualified Compensation (\$)	Deferred Compensation (\$)		
Nadav Kidron President and CEO and director (8)	2008	151,037	Nil	Nil	216,504	Nil	Nil	14,511	382,053
	2007	84,900	Nil	Nil	225,225	Nil	Nil	Nil	310,125
Miriam Kidron Chief Medical and Technology Officer and director (9)	2008	145,405	Nil	Nil	216,504	Nil	Nil	10,774	372,683
	2007	62,500	Nil	Nil	1,573,564	Nil	Nil	Nil	1,636,064
Chaime Orlev CFO and Secretary(10)	2008	23,484	Nil	Nil	Nil	Nil	Nil	7,981	31,466
	2007	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Alex Werber CFO and Secretary(11)	2008	36,129	Nil	Nil	Nil	Nil	Nil	Nil	36,129
	2007	4,000	Nil	Nil	Nil	Nil	Nil	Nil	4,000

- 1 The information is provided for each fiscal year which begins on September 1 and ends on August 31.
- 2 No bonus awards were made to the Named Executive Officers in the fiscal years ended August 31, 2008 and 2007.
- 3 No stock awards were granted to the Named Executive Officers in the fiscal years ended August 31, 2008 and 2007.
- 4 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, 2008 and 2007 are set forth in the notes to of our audited consolidated financial statements included in our Form 10-KSB for fiscal year ended August 31, 2008. 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.
- 5 We do not have a non-equity incentive compensation plan.
- 6 We do not have a deferred non-qualified compensation plan.

- 7 See All Other Compensation Table below.
- 8 Mr. Kidron was appointed as our President, CEO and Director on March 8, 2006.
- 9 Ms. Kidron was appointed as our Chief Medical and Technology Officer and Director on March 8, 2006.
- 10 Mr. Orlev was appointed as our CFO and Secretary on May 1, 2008.
- 11 Mr. Werber served as our CFO and Secretary from August 1, 2007 thorough April 30, 2008.

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**All Other Compensation Table**

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

<b>Name</b>	<b>Year</b>	<b>Automobile Related Expenses (\$)</b>	<b>Manager's Insurance * (\$)</b>	<b>Education Fund* (\$)</b>	<b>Total (\$)</b>
Nadav Kidron	2008	14,511	Nil	Nil	14,511
Miriam Kidron	2008	10,774	Nil	Nil	10,774
Chaime Orlev	2008	3,218	3,379	1,384	7,981

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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, 2008.

Name	Option Awards				Stock Awards					
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards Number of Securities Underlying Unexercised Options (#)	Equity Incentive Plan Awards Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock Held That Have Not Vested (#)	Value of Shares or Units of Stock Held That Have Not Vested (\$)	Market Value of Unearned Shares, Units or Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested (\$)
Nadav		(1)								
Kidron	850,000	-	-	0.45	08/01/12	-	-	-	-	-
	288,000 <sup>(2)</sup>	576,000 <sup>(2)</sup>	-	0.54	05/06/18	-	-	-	-	-
Miriam	3,361,360 <sup>(3)</sup>	-	-	0.001	08/13/12	-	-	-	-	-
Kidron	850,000 <sup>(1)</sup>	-	-	0.45	08/01/12	-	-	-	-	-
	288,000 <sup>(2)</sup>	576,000 <sup>(2)</sup>	-	0.54	05/06/18	-	-	-	-	-

(1) On August 2, 2007, 1,700,000 options were granted to 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, 1,728,000 options were granted to Nadav Kidron and Miriam Kidron under the 2008 Stock Option Plan at an exercise price of \$0.54 per share, 288,000 of the 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.

**Stock Option Plans****2006 Stock Option Plan**

On October 15, 2006, the Company's 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. As of August 31, 2008, options with respect to 2,950,000 shares have been granted under the 2006 Plan.



## **2008 Stock Incentive Plan**

On May 5, 2008, the Company's 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 employees of the Company or a parent or subsidiary of the Company. 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, 2008, options exercisable for an aggregate of 1,878,000 shares have been granted.

On August 14, 2007 the Company granted to 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.

## **Employment and Consulting Agreements**

Effective August 1, 2007 we entered into employment agreements with KNRY Ltd. ("KNRY"), 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, KNRY 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 KNRY, whereby Mr. Nadav Kidron, through KNRY, 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 KNRY whereby Dr. Miriam Kidron, through KNRY, 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 KNRY, 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 KNRY (i) will be paid, under each of the Consulting Agreements, in New Israeli Shekels ("NIS") a gross amount of NIS50,400 + Value-Added-Tax 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.

The Company, through its Israeli subsidiary, Oramed Ltd., has entered into an employment agreement with Chaime Orlev (the "Orlev Employment Agreement") as of May 1, 2008, pursuant to which Mr. Orlev was appointed as Chief Financial Officer ("CFO"), Treasurer and Secretary of Oramed. Mr. Orlev's responsibilities include oversight of Oramed's financial reporting and controls.

The Orlev Employment Agreement provides that for the period through July 31, 2008 (the "First Term"), Mr. Orlev was employed to work on a part-time basis and was compensated a gross monthly amount of NIS 20,000. Beginning on September 1, 2008 and continuing until the Orlev Employment Agreement is terminated by either party pursuant to the Orlev Employment Agreement (the "Second Term"), Mr. Orlev will serve Oramed in a full-time capacity and will be compensated a gross monthly amount of NIS 30,000. Mr. Orlev has also agreed that during the term of his employment with Oramed and for a 12 month period thereafter, he will not compete with Oramed nor solicit employees of Oramed.

On May 1, 2008 Oramed entered into a consulting agreement with a Dr. Ehud Arbit ("Dr. Arbit") for a period of twelve months, pursuant to which the Consultant will assist our efforts to complete the FDA approval process for its oral insulin capsule. Dr. Arbit is entitled to a fixed monthly fee of \$8,333 effective from May 1, 2008, and reimbursement of pre-approved out of pocket expenses. On October 3, 2008, the Company amended a consulting agreement with Dr. Arbit, pursuant to the amendment the Consultant will perform his work under the contract on a full time basis and his compensation will be \$16,666 per month commencing on July 1, 2008.

On November 2, 2008, we entered into indemnification agreements with our directors and 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.

### 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 September 1, 2008, each independent director is entitled to receive as remuneration for his or her service as a member of the board a sum equal to US\$8,000 per annum, to be paid quarterly and shortly after the close of each quarter. Leonard Sank and Harold Jacob are the only independent members of the board of directors. 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, 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, 2008.

Name of Director	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive			Total (\$)
				Plan Compensation (\$)	Nonqualified Deferred Compensation (\$)	All Other Compensation (\$)	
Nadav Kidron <sup>(2)</sup>							
Miriam Kidron <sup>(2)</sup>							
Leonard Sank	100,000 <sup>(3)</sup>	Nil	Nil	Nil	Nil	Nil	100,000
Harold Jacob	Nil	Nil	7,567	Nil	Nil	Nil	7,567

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-KSB. 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.
  - 3 The Compensation includes \$85,000 received as finders fee in connection with the July 2008 private placement as well as \$15,000 as reimbursement of expense pursuant to an agreement dated January 18, 2008.

## ITEM 11- 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, 2008 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 (iv) by all our directors and executive officers as a group. On such date, we had 56,456,710 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, 2008.

Name an address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Nadav Kidron †‡ 10 Itamar Ben Avi St. Jerusalem, Israel	11,581,735 <sup>(1)</sup>	20.08%
Zeev Bronfeld 6 Uri St. Tel-Aviv, Israel	6,158,517	10.91%
Miriam Kidron †‡ 2 Elza St. Jerusalem, Israel	4,571,360 <sup>(2)</sup>	7.49%
Apollo Nominees Inc One Financial Place Suite 100 Lower Collymore Rock St. Michael, Barbados	4,517,501 <sup>(3)</sup>	7.78%
Hadassit Medical Research Services & Development Ltd P.O. Box 12000 Jerusalem, Israel	4,141,532	7.34%
Leonard Sank † 3 Blair Rd Camps Bay Cape Town, South Africa	3,982,650 <sup>(4)</sup>	6.88%
Harold Jacob † Haadmur Mebuyon 26 Jerusalem, Israel	100,000 <sup>(5)</sup>	*
Chaime Orlev ‡ 10 Hameyasdim St. Kiryat Ono, Israel	Nil	Nil
All current Executive Officers and Directors as a group (five persons)	12,729,385 <sup>(6)</sup>	26.37%

\* Less than 1%

† Indicates Director

‡ Indicates Officer

- (1) Includes 1,210,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (2) Includes 4,571,360 shares of common stock issuable upon the exercise of outstanding stock options.
- (3) Includes 1,645,834 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (4) Includes 1,625,000 shares of common stock issuable upon the exercise of warrants beneficially owned by such individual.
- (5) Consists of 100,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (6) Includes 2,935,000 shares of common stock issuable upon the exercise of outstanding stock options.

**ITEM 12 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

Except as otherwise indicated below, we have not been a party to any transaction, proposed transaction, or series of transactions in which the amount involved exceeds \$60,000, and in which, to its knowledge, any of its 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.

Leonard Sank, one of our directors, was paid a finders fee of \$85,000 in connection with our private placement of shares of our common stock and warrants on July 14, 2008.

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.

The Board has determined that Leonard Sank and Harold Jacob 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 13 – EXHIBITS**

**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)
- 4.3 Convertible Debenture issued by the Registrant to Epsom Investment Services, dated February 12, 2007 (incorporated by reference from our Quarterly Report on Form 10-QSB filed on April 14, 2008)
- 4.4 Convertible Debenture issued by the Registrant to Epsom Investment Services, dated May 31, 2007 (incorporated by reference from our Quarterly Report on Form 10-QSB filed on April 14, 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 our company 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 our company and Dr. Miriam Kidron (incorporated by reference from our current report on Form 8-K filed February 17, 2006).
- 10.4 Agreement between our company 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 Service Agreement, dated April 21, 2008, between Oramed Pharmaceuticals Inc. and Encorium Group, Inc.
- 10.9 Employment Agreement dated August 1, 2007 between Oramed Pharmaceuticals Inc. and Alex Werber (incorporated by reference from our current report on Form 8-K filed on August 3, 2007)

10.10 Form of Shares for Services agreement (incorporated by reference from our current report on Form 8-K filed on August 3, 2007)

10.11 Employment Agreement dated August 1, 2007 between Oramed Pharmaceuticals Inc. and Nadav Kidron (incorporated by reference from our current report on Form 8-K filed on August 28, 2007)

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10.12 Employment Agreement dated August 1, 2007 between Oramed Pharmaceuticals Inc. and Dr. Miriam Kidron (incorporated by reference from our current report on Form 8-K filed on August 28, 2007)

10.13 Investor Relations Agreement dated August 27, 2007 between Oramed Pharmaceuticals Inc. and The Investor Relations Group Inc. (incorporated by reference from our current report on Form 8-K filed on September 10, 2007)

10.14 Master Services Agreement dated January 29, 2008 between Oramed Pharmaceuticals Inc. and OnQ Consulting (incorporated by reference from our current report on Form 8-K filed on February 1, 2008)

10.15 Expense Agreement dated January 18, 2008 between Oramed Pharmaceuticals Inc. and Leonard Sank (incorporated by reference from our current report on Form 8-K filed on February 1, 2008)

10.16 Employment Agreement by and between Oramed Ltd. and Chaime Orlev entered into as of May 1, 2008 (incorporated by reference from our current report on Form 8-K filed on May 7, 2008)

10.17 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)

10.18 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)

10.19 Oramed Pharmaceuticals Inc. 2008 Stock Incentive Plan (incorporated by reference from our current report on Form 8-K filed on July 2, 2008)

10.20 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).

10.21 Form of Stock Purchase Agreement (incorporated by reference from our current report on Form 8-K filed on July 15, 2008)

10.22\* Consulting Agreement, dated May 1, 2008, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit

10.23\* Amended and Restated Consulting Agreement, dated as of May 1, 2008, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit

10.24\* Amended to Consulting Agreement, dated as of October 3, 2008, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit

14.1 Code of Ethics (incorporated by reference from our current report on Form 8-K filed on November 29, 2007)

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

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

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

\* Filed herewith

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**ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES**

We incurred the following fees to Kesselman & Kesselman, certified public accountants (Isr.), a member of PricewaterhouseCoopers International Limited, for services rendered during the fiscal year ended August 31, 2008. For the year ending August 31, 2007 the fees are in connection with services provided by Malone & Bailey, PC, certified public accountants (US):

<b>Summary:</b>	<b>2008</b>	<b>2007</b>
Audit fees <sup>(1)</sup>	\$ 105,965	\$ 31,500
Audit related fees <sup>(2)</sup>	—	—
Tax fees <sup>(3)</sup>	\$ 32,630	—
Other fees	—	—

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(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 assurance and related services by our accountants that are reasonably related to the performance of the audit or review of our financial statements and are not reported under item (1).

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

**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/ CHAIME ORLEV  
Chaime Orlev,  
Chief Financial Officer  
(principal accounting officer)

Date: November 26, 2008

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 in the capacities as on November 26, 2008.

/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