ORAMED PHARMACEUTICALS INC.
Form 10-K
November 25, 2009

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

FORM 10-K

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

For the Fiscal Year Ended August 31, 2009

¨ 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 incorporation or organization)	(IRS Employer Identification No.)

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

972 2 566 0001
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.
Yes ¨ No ¨

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x
(Do not check if a smaller reporting company)	

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. $9,534,674 based on a price of $0.25, being the last price at which the shares of the Registrant's common stock were sold on the OTC Bulletin Board prior to the end of the most recently completed second fiscal quarter.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 57,026,597 shares issued and outstanding as of November 23, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

None.

ORAMED PHARMACEUTICALS, INC.

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PART I

ITEM 1 - BUSINESS

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “se “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements.

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

We file reports with the Securities and Exchange Commission (the “SEC” or the “Commission”). We make available on our website under “Investor Information/SEC Filings,” free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Our website address is www.oramed.com. 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) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

As used in this Annual Report on Form 10-K, the terms “we”, “us”, “our”, the “Company”, and “Oramed” mean Oram 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 capsule or tablet to be used for the treatment of individuals with diabetes, rectal application of insulin, use of oral ingestible capsules or tablets 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 (ORMD0801) 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 proteins and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically, and the insulin and the dosage form must be safe to ingest.

The Company's research and development team has performed numerous animal studies to optimize the composition and functionality of their oral insulin (ORMD0801) modality and to demonstrate its safety and efficacy. 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 causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life. The cause of diabetes is attributed both to genetics 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 Dr. Nir Barzilai, Professor Ele Ferrannini, Professor Avram Hershko, and Dr. Derek LeRoith.

Strategy

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

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to ensure regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. We have not yet engaged in any meaningful discussions with potential partners and no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

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

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) on Type I diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. ("ADRES"), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD 0801) on Type II diabetic volunteers. We are considering whether and when to conduct an additional non-FDA approved Phase 2B study in India.

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. On February 4, 2009, we announced that we had concluded a proof of concept study of the insulin suppositories.

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.

As we believe that the potential commercial market for our oral insulin products are significantly greater than the potential commercial market for our rectal application products, we have determined to use our limited resources to research and develop our oral insulin capsules and tablets and have temporarily suspended our development of our recital application products.

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

On September 9, 2009, we received approval from the Institutional Review Board (IRB) in Israel to commence human clinical trials of an oral GLP-1 Analog. The approval was granted after successful pre-clinical results were reported. The trials will be conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem.

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

Raw Materials: Our oral insulin capsule is currently manufactured by Swiss Caps AG, under a Clinical Trail Manufacturing Agreement. The raw materials required for the manufacturing of the capsule are purchased from third parties, under separate agreements. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

Patents and Licenses

The following patent applications and provisional patent application are pending with the United States Patent and Trademark Office (PTO):

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

Our patent strategy is as follows:

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

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

- Establish comprehensive coverage in the U.S. and in all relevant foreign markets in anticipation of future commercialization opportunities.

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

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

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

Partnerships and Collaborative Arrangements

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

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

On October 30, 2006, we entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG (“Swiss”), pursuant to which Swiss currently manufactures the oral insulin capsule developed by 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 non-FDA Phase 1B and 2B clinical trials on our oral insulin capsules and suppository in South Africa.

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

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

On April 21, 2009, we entered into a consulting service agreement with ADRES, pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study in accordance with FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

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

Government Regulation

The Drug Development Process

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

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

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

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

- who must be recruited as qualified participants;
- how often to administer the drug or product;
- what tests to perform on the participants; and
- what dosage of the drug or amount of the product to give to the participants.

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

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

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

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

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

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

Phase IV. The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug. For example, large-scale trials may also be used to prove effectiveness and safety of new forms of drug delivery for approved drugs. Examples may be using an inhalation spray versus taking tablets or a sustained-release form of medication versus capsules taken multiple times per day.

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

Other Regulations

Various Federal and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research are applicable to our activities. They include, among others, the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation. The extent of governmental regulation which might result from future legislation or administrative action cannot be accurately predicted.

Competition

Competition in General

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

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

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

Competition for our Oral Insulin Capsule

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

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

Several entities who are developing oral insulin capsules and other alternative oral insulin as well as the development stage are thought to be: Diabetology (UK, Phase 2), Emisphere Technologies (US, Phase 2), Biocon (India), Apollo Life Sciences (Australia, Phase 1), Generex (Canada, Phase 3) – Buccal delivery, Biodel (US, Phase 3) – Sublingual delivery and MannKind (US) -Inhaled delivery

Scientific Advisory Board

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

Professor Avram Hershko, MD PhD joined the Oramed Scientific Advisory Board in July 2008. He earned his MD degree (1965) and PhD degree (1969) from the Hebrew University- Hadassah Medical School of Jerusalem, a period which included service as a physician in the Israel Defense Forces (1965-67). After a post-doctoral fellowship with Gordon Tomkins at the University of San Francisco (1969-72), he joined the faculty of the Haifa Technion becoming professor in 1980. He is now Distinguished Professor in the Unit of Biochemistry in the B. Rappaport Faculty of Medicine of the Technion. Professor Hershko's main research interests concern the mechanisms by which cellular proteins are degraded, a formerly neglected field of study. Hershko and his colleagues showed that cellular proteins are degraded by a highly selective proteolytic system. This system tags proteins for destruction by linkage a protein called ubiquitin, which had previously been identified in many tissues, but whose function was previously unknown. Subsequent work in Hershko's and many other laboratories has shown that the ubiquitin system has a vital role in controlling a wide range of cellular processes, such as the regulation of cell division, signal transduction and DNA repair. Professor Hershko was awarded the Nobel Prize in Chemistry (2004) jointly with his former PhD student Aaron Ciechanover and their colleague Irwin Rose. His many honors include the Israel Prize for Biochemistry (1994), the Gardner Award (1999), the Lasker Prize for Basic Medical Research (2000), the Wolf Prize for Medicine (2001) and the Louisa Gross Horwitz Award (2001). Hershko is a member of the Israel Academy of Sciences (2000) and a Foreign Associate of the US Academy of Sciences (2003).

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

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

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

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, 2009, we contracted eight individuals through employment or consulting agreements. Of our staff, two are senior management, four are engaged in research and development work, and the remaining 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 $7,548. We believe that our existing facilities are suitable and adequate to meet our current business requirements. In the event that we should require additional or alternative facilities, we believe that such facilities can be obtained on short notice at competitive rates.

Corporate History

Oramed was incorporated on April 12, 2002, in the State of Nevada under the name Iguana Ventures Ltd. Following the incorporation, 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, 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. ("Hadasit") to acquire provisional patent application No. 60/718716 and related intellectual property. The provisional patent application No. 60/718716 relates to a method of preparing insulin so that it may be taken orally to be used in the treatment for the treatment of individuals with diabetes. On April 10, 2006, the Company changed its name from Integrated Security Technologies, Inc. to Oramed Pharmaceuticals Inc. On August 31, 2006, 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."

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 on Form 10-K 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.

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, 2010. During 2010, we plan to increase research and development, product development, and administrative expenses relating to our business, including expenses related to research and development related to our oral delivery platform. We intend to use our cash reserves, as well as other funds in the event that they shall become available on commercially reasonable terms, to finance these activities and other activities described herein, although we can provide no assurance that these additional funds will be available in the amounts or at the times we may require. If sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. See "Risk Factors — We will need substantial additional capital in order to satisfy our business objectives."

We will need substantial additional capital in order to satisfy our business objectives.

To date, we have financed our operations principally through offerings of securities exempt from the registration requirements of the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for a minimum of 7 months from the date of this Annual Report on Form 10-K. We estimate that we will require substantial additional financing at various intervals in order to continue our research and development programs, including significant requirements for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals, and for commercialization of our products. We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. In the event that we are unable to obtain such financing, we will not be able to fully develop and commercialize our technology. Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and

- effects of commercialization activities and facility expansions if and as required.

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

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

We are a development stage company with no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which could generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of August 31, 2009 and 2008, we had working capital of $2,805,733 and $4,483,940, respectively, and stockholders' equity of $2,746,192 and $4,593,060, respectively. We generated no revenues to date. For the period from our inception on April 12, 2002 through August 31, 2009, the years ended August 31, 2009 and 2008, we incurred net losses of $(10,008,678), $(2,760,474), and $(2,769,271), respectively We may never achieve profitability and expect to incur net losses in the foreseeable future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies. We currently hold several pending patent applications in the United States for our technologies covering oral administration of insulin and other proteins, rectal application for insulin, and oral administration of exenatides and proteins, and corresponding patent applications filed in Israel, South Africa and India. Further, we intend to rely on a combination of trade secrets and non-disclosure, and other contractual agreements and technical measures to protect our rights in our technology. We intend to depend upon confidentiality agreements with our officers, directors, employees, consultants, and subcontractors, as well as collaborative partners, to maintain the proprietary nature of our technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid our confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. We believe that our technology is not subject to any infringement actions based upon the patents of any third parties; however, our technology may in the future be found to infringe upon the rights of others. Others may assert infringement claims against us, and if we should be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on terms acceptable to us, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition, and results of operations.

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

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

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

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

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

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

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

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

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

- even if our oral insulin capsule is successfully developed, commercially produced and receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance of the products; and

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

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

We have limited experience in conducting clinical trials.

Clinical trials must meet FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We have entered into agreements with Hadasit Medical Center, ETI Karle Clinical Pvt, Ltd., and OnQ Consulting to assist us in designing, conducting and managing our various clinical trials in Israel, South Africa, and India, respectively, as more fully described in "Description Business – Partnerships and Collaborative Agreements." Any failure of such consultants to fulfill their obligations could result in significant additional costs as well as delays in designing, consulting and completing clinical trials on our products.

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

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

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

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

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

We are dependent on outside vendors for our entire supply of the oral insulin capsule. While we believe that there are numerous sources of supply available, if the third party suppliers were to cease production or otherwise fail to supply us with quality raw materials in sufficient quantities on a timely basis and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct testing and clinical trials would be materially adversely affected

We are highly dependant upon our ability to enter into agreements with collaborative partners to develop, commercialize, and market our products.

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

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

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

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

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

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

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

We currently depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants and other key personnel, including Dr. Miriam Kidron, our Chief Medical and Technology Officer. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition, and results of operations. We do not maintain "keyman" life insurance policies for any of our senior executives. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. There is currently a shortage of employees with expertise in developing, manufacturing and commercialization of products and related clinical and regulatory affairs, and this shortage is likely to continue. Competition for skilled personnel is intense and turnover rates are high. Our ability to attract and retain qualified personnel may be limited. Our inability to attract and retain qualified skilled personnel would have a material adverse effect on our business, prospects, financial condition,

and results of operations.

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

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

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

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 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:

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

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

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

Our 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 58,026,597 shares of common stock. Of these shares, 28,543,347 shares, are freely tradable. Giving effect to the exercise in full of all of our outstanding warrants and options, we would have outstanding 75,744,294 shares of common stock.

Our issuance of warrants and options to investors, employees and consultants and 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, 2009, we had outstanding 18,017,697 warrants and options (16,611,697 for the year ended August 31, 2008). In addition to the dilutive effect of a large number of shares and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.

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

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements which we may enter into with institutional lenders or otherwise may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, and any other factors that our board of directors decides is relevant. See "Dividend Policy" and "Description of Securities — Common Stock".

Risks Related to conducting Business in Israel

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

Our operations are located in the State of Israel, and we are directly affected by political, economic, and security conditions in that country. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. In addition, since December 1987, the State of Israel has experienced severe civil unrest primarily in the areas that came under its control in 1967. No prediction can be made as to whether these problems will be resolved. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

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

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

All of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against any of our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state. Additionally, it may be difficult to enforce civil liabilities under U.S. federal securities law in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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 $7,548. 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

PART II

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

Market Price for our Common Stock

Our common stock is quoted on the 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:

	High	Low
Year Ended August 31, 2008		
Three Months Ended November 30, 2007	$ 0.48	$ 0.23
Three Months Ended February 29, 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
Year Ended August 31, 2009		
Three Months Ended November 30, 2008	$ 0.76	$ 0.36
Three Months Ended February 28, 2009	$ 0.52	$ 0.25
Three Months Ended May 31, 2009	$ 0.62	$ 0.20
Three Months Ended August 31, 2009	$ 0.59	$ 0.40

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 $0.46 on November 24, 2009.

Holders

As of November 23, 2009, there were 57,026,597 shares of our common stock issued and outstanding that are held of record by 61 registered stockholders. We believe that a number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories.

Dividend Policy

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

Recent Sales of Unregistered Securities

On September 11, 2009, we issued 569,887 shares of our common stock to Swiss Cap AG as remuneration for services rendered during 2009, in the amount of $203,699. The shares were sold in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act. No underwriters were involved in the transaction or received any commissions or other compensation.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our shares of common stock or other securities during the fiscal year ended August 31, 2009.

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. In addition, under the terms of the 2006 Plan, options that have expired or been terminated for any reason prior to being exercised may be reissued. As of August 31, 2009, options with respect to 2,950,000 shares were outstanding under the 2006 Plan, which amount reflects the aggregate grant of options with respect to 3,350,000 shares, of which 400,000 have been forfeited through August 31, 2009.

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, 2009, options exercisable for an aggregate of 4,312,000 shares have been granted, 978,000 of which have been forfeited.

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, 2009:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (A)	Weight-average exercise price of outstanding options, warrants and rights (B)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (A)) (C)
Equity compensation plans approved by security holders	—	—	—
Equity compensation plans not approved by security holders	9,645,360	$ 0.35	3,738,000

Total	9,645,360	$	0.35	3,738, 000

ITEM 6 – Selected Financial Data

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

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

The following discussion and analysis should be read in conjunction with our audited Financial Statements and Notes thereto for the years ended August 31, 2009 and 2008.

Overview of Operations

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin pill to be used for the treatment of individuals with diabetes, rectal application of insulin, flu vaccines, use of oral ingestible pills for delivery other polypeptides and use of rectal application for delivery of other polypeptides.

Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit Medical Services and Development Ltd., as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an IND application with the FDA. Additional clinical trials are planned in other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of making future filings for drug approval in these countries. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products, including an insulin suppository and use of rectal application for delivery of other polypeptides.

Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to ensure regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. We have not yet engaged in any meaningful discussions with potential partners and no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

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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, 2009 of $10,008,678 , as well as negative cash flow from operating activities. Based upon our existing spending commitments, estimated at $5.8 million for the twelve months following September 1, 2009, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through August 31, 2010. 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.

We account for share based payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), “Share-based Payment” (“SFAS 123R”). SFAS 123R requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. We estimated forfeitures based on historical experience and anticipated future conditions.

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

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance in Emerging Issues Task Force ("EITF") 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" (ËITF 96-18"). The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

Taxes on income: Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to its deferred tax assets.

Regarding 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, we 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.

The following table summarizes certain statements of operations data for us for the twelve months period ended August 31, 2009 and 2008:

	Year ended	
Operating Data:	August 31, 2009	August 31, 2008
Research and development expenses	$ 1,522,188	$ 1,210,494
General and administrative expenses	1,261,930	1,469,517
Financial income, net	(21,047)	(72,904)
Loss before taxes on income	(2,763,071)	(2,607,107)
Taxes on income	(2,597)	162,164
Net loss for the period	$ (2,760,474)	$ (2,769,271)
Loss per common share – basic and diluted	$ (0.05)	$ (0.06)
Weighted average common shares outstanding	56,645,820	48,604,889

Research and development expenses

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

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

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

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

During the year ended August 31, 2009, research and development expenses totaled $1,522,188, compared to $1,210,494 for the year ended August 31, 2008. The increase is mainly attributable to increased clinical trial activities, materials and consulting costs. In August 2009, Oramed Ltd., our wholly owned Israeli subsidiary, was awarded a government grant amounting to a total net amount of NIS 3.1 million (approximately $813,000), from the Office of the Chief Scientist (OCS) of the Ministry of Industry, Trade and Labor of Israel. This grant will be used for research and development expenses for the period of February 2009 to January 2010. The grant is subject to repayment according to the terms determined by the OCS and applicable law. See "—Government Grants" below. The funds will be designated and used by Oramed Ltd. to support further R&D and clinical study of its oral insulin capsule and Oral GLP1-Analog.. The research and development expenses for the year ended August 31, 2009 are presented less a participation amount of $400,405 which was incurred from February 1, 2009 to August 31, 2009. The research and development costs include stock based compensation costs, which during the year ended August 31, 2009 totaled $264,861 as compared to $285,336 during the year ended August 31, 2008.

Government Grants

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

In the year ended August 31, 2009, we recognized research and development grants in an amount of $400,405. As of August 31, 2009, we had no contingent liabilities to the OCS.

Under the terms of the grants we received from the OCS, we are obligated to pay royalties of 3% to 3.5% on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licenses. Royalties are payable up to 100% of the amount of such grants, or up to 300% as detailed below, linked to the U.S. Dollar, plus annual interest at LIBOR.

The R&D Law generally requires that a product developed under a program be manufactured in Israel. However, upon notification to the OCS, up to 10% of a company's approved Israeli manufacturing volume, measured on an aggregate basis, may be transferred out of Israel. In addition, upon the approval of the Chief Scientist, a greater portion of the manufacturing volume may be performed outside of Israel, provided that the grant recipient pays royalties at an increased rate, which may be substantial, and the aggregate repayment amount is increased up to 300% of the grant, depending on the portion of the total manufacturing volume that is performed outside of Israel. The R&D Law further permits the OCS, among other things, to approve the transfer of manufacturing rights outside Israel in exchange for an import of different manufacturing into Israel as a substitute, in lieu of the increased royalties. The R&D Law also allows for the approval of grants in cases in which the applicant declares that part of the manufacturing will be performed outside of Israel or by non-Israeli residents and the research committee is convinced that doing so is essential for the execution of the program. This declaration will be a significant factor in the determination of the OCS whether to approve a program and the amount and other terms of benefits to be granted. For example, an increased royalty rate and repayment amount might be required in such cases.

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred to third parties in Israel without the approval of the research committee. Such approval is not required for the sale or export of any products resulting from such research or development. The R&D Law further provides that the know-how developed under an approved research and development program may not be transferred to any third parties outside Israel, except in certain special circumstances and subject to the OCS' prior approval. The OCS may approve the transfer of OCS-funded know-how outside Israel, generally in the following cases: (a) the grant recipient pays to the OCS a portion of the sale price paid in consideration for such OCS-funded know-how (according to certain formulas), or (b) the grant recipient receives know-how from a third party in exchange for its OCS-funded know-how, or (c) such transfer of OCS-funded know-how arises in connection with certain types of cooperation in research and development activities.

The R&D Law imposes reporting requirements with respect to certain changes in the ownership of a grant recipient. The law requires the grant recipient and its controlling shareholders and foreign interested parties to notify the OCS of any change in control of the recipient or a change in the holdings of the means of control of the recipient that results in a non-Israeli becoming an interested party directly in the recipient, and requires the new interested party to undertake to the OCS to comply with the R&D Law. In addition, the rules of the OCS may require additional information or representations in respect of certain such events. For this purpose, "control" is defined as the ability to direct the activities of a company other than any ability arising solely from serving as an officer or director of the company. A person is presumed to have control if such person holds 50% or more of the means of control of a

company. "Means of control" refers to voting rights or the right to appoint directors or the chief executive officer. An "interested party" of a company includes a holder of 5% or more of its outstanding share capital or voting rights, its chief executive officer and directors, someone who has the right to appoint its chief executive officer or at least one director, and a company with respect to which any of the foregoing interested parties owns 25% or more of the outstanding share capital or voting rights or has the right to appoint 25% or more of the directors. Accordingly, any non-Israeli who acquires 5% or more of our ordinary shares will be required to notify the OCS that it has become an interested party and to sign an undertaking to comply with the R&D Law.

General and administrative expenses

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

For the year ended August 31, 2009, general and administrative expenses totaled $1,261,930 compared to $1,469,517 for the year ended August 31, 2008. Costs incurred related to general and administrative activities during the year ended August 31, 2009 reflect a decrease of professional, legal and consulting expenses and a decrease in investor relations and public relations expenses. During the year ended August 31, 2009, as part of our general and administrative expenses, we incurred $288,338 related to stock options granted to employees and consultants, as compared to $378,113 during the year ended August 31, 2008.

Financial income/expense, net

During the year ended August 31, 2009, we generated interest income on available cash and cash equivalents balance which were offset by bank charges. During the year ended August 31, 2008, we incurred imputed interest expenses on convertible notes issued as well as bank charges.

The decrease in the interest income for the year ending August 31, 2009 as compared with the year ended August 31, 2008 is attributable to the decrease in interest rates in both the United States and the state of Israel.

Liquidity and Capital Resources

Through August 31, 2009, we incurred losses in an aggregate amount of $10,008,678. We have financed our operations through the private placements of equity and debt financing. Since inception through August 31, 2009, we have financed our operations through the private placements of equity and debt financings, raising a total of $8,308,785, net of transaction costs. We will seek to obtain additional financing through similar sources. As of August 31, 2009, we had $1,716,866 of available cash as well as $1,000,000 in short term interest bearing investments. The Company anticipates it will require approximately $5.8 million to finance its activities during the twelve months following September 1, 2009.

Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders as well as receive additional funding from the OCS.

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 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, we issued 203,904 shares of common stock valued at $152,928 to a third party, for services rendered in the prior year.

- On September 11, 2009, we issued 569,887 shares of common stock valued at $203,699 to a third party, for services rendered in the prior year.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning September 1, 2009 are as follows:

Category		Amount
Research & Development, net of OCS funds	$	4,259,000
General & Administrative expenses		1,511,000
Finance income, net		10,000
Taxes on income		13,000
Total	$	5,793,000

As previously indicated we are planning to conduct further clinical studies as well as file an IND application with the FDA for our orally ingested insulin. Our ability to proceed with these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TABLE OF CONTENTS

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, 2009 and 2008, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended and cumulatively, for the period from September 1, 2007 to August 31, 2009 (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, 2009 and 2008, and the consolidated results of their operations and their cash flows for the years then ended and cumulatively, for the period from September 1, 2007 to August 31, 2009 (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, 2009 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 25, 2009

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

We conducted our audit in accordance with standards of the Public Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Comapny is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

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

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

December 10, 2007

ORAMED PHARMACEUTICALS, INC.

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars

	August 31	
	2009	2008
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,716,866	$ 2,267,320
Short term investments (Note 2)	1,000,000	2,728,000
Restricted cash (Note 1n)	16,000	
Accounts receivable - other	36,939	38,822
Prepaid expenses	4,119	363,752
Grants receivable from the Chief Scientist	400,405	
Total current assets	3,174,329	5,397,894
LONG TERM DEPOSITS (Note 6b)	12,161	10,824
PROPERTY AND EQUIPMENT, NET (Note 4)	75,361	98,296
Total assets	$ 3,261,851	$ 5,507,014
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses (note 9)	$ 321,344	$ 736,052
Account payable with former shareholder	47,252	47,252
Total current liabilities	368,596	783,304
PROVISION FOR UNCERTAIN TAX POSITION (Note 12f)	147,063	130,650
COMMITMENTS (Note 6)		
STOCKHOLDERS’ EQUITY:		
Common stock, $ 0.001 par value (200,000,000 authorized shares; 56,456,710 and 56,252,806 shares issued and outstanding as of August 31, 2009 and 2008, respectively)	56,456	56,252
Additional paid-in capital	12,698,414	11,785,012
Deficit accumulated during the development stage	(10,008,678)	(7,248,204)
Total stockholders' equity	2,746,192	4,593,060
Total liabilities and stockholders’ equity	$ 3,261,851	$ 5,507,014

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

ORAMED PHARMACEUTICALS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. dollars

	Year ended August 31		Period from April 12, 2002 (inception) through August 31,
	2009	2008	2009
RESEARCH AND DEVELOPMENT EXPENSES, NET (Note 10)	$ 1,522,188	$ 1,210,494	$ 5,144,859
IMPAIRMENT OF INVESTMENT			434,876
GENERAL AND ADMINISTRATIVE EXPENSES (note 11)	1,261,930	1,469,517	4,257,551
OPERATING LOSS	2,784,118	2,680,011	9,837,286
FINANCIAL INCOME	(38,602)	(83,185)	(136,108)
FINANCIAL EXPENSE	17,555	10,281	147,933
LOSS BEFORE TAXES ON INCOME	2,763,071	2,607,107	9,849,111
TAXES ON INCOME (note 12)	(2,597)	162,164	159,567
NET LOSS FOR THE PERIOD	$ 2,760,474	$ 2,769,271	$ 10,008,678
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.05)	$ (0.06)	
WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	56,645,820	48,604,889	

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

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

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

SHARES ISSUED FOR CONVERSION OF CONVERTIBLE NOTE	550,000	550	274,450		275,000
SHARES AND WARRANTS ISSUED FOR CASH – NET OF ISSUANCE EXPENSES	10,178,002	10,178	5,774,622		5,784,800
SHARES ISSUED FOR SERVICES	293,025	293	115,817		116,110
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			459,467		459,467
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			203,982		203,982
IMPUTED INTEREST			3,780		3,780
NET LOSS				(2,769,271)	(2,769,271)
BALANCE AS OF AUGUST 31, 2008	56,252,806	56,252	11,785,012	(7,248,204)	4,593,060
SHARES ISSUED FOR SERVICES RENDERED	203,904	204	152,724		152,928
SHARES TO BE ISSUED FOR SERVICES RENDERED			203,699		203,699
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			436,025		436,025
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			117,174		117,174
IMPUTED INTEREST			3,780		3,780
NET LOSS				(2,760,474)	(2,760,474)
BALANCE AS OF AUGUST 31, 2009	56,456,710	$ 56,456	$ 12,698,414	$ (10,008,678)	$ 2,746,192

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,
	2009	2008	2009
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (2,760,474)	$ (2,769,271)	$ (10,008,678)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	30,488	15,454	45,942
Amortization of debt discount			108,000
Exchange differences on long term deposits	641	(1,642)	(1,001)
Stock based compensation	553,199	663,449	3,362,977
Common stock issued for services	152,928	116,110	367,788
Common stock to be issued for services	203,699		203,699
Impairment of investment			434,876
Imputed interest	3,780	3,780	15,997
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(38,889)	(390,668)	(441,463)
Restricted cash	(16,000)		(16,000)
Accounts payable and accrued expenses	(414,708)	395,180	321,344
Provision for uncertain tax position	16,413	130,650	147,063
Total net cash used in operating activities	(2,268,923)	(1,836,958)	(5,459,456)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(7,553)	(112,014)	(121,303)
Short term investments	(1,000,000)	(2,728,000)	(3,728,000)
Proceeds from sale of short term investments	2,728,000		2,728,000
Lease deposits, net	(1,978)	(3,738)	(11,160)
Total net cash provided by (used in) investing activities	1,718,469	(2,843,752)	(1,132,463)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from sales of common stocks and warrants - net of issuance expenses		5,029,801	7,961,481
Receipts on account of shares issuances			6,061
Proceeds from convertible notes			275,000
Proceeds from short term note payable			120,000
Payments of short term note payable			(120,000)
Shareholder advances			66,243
Net cash provided by financing activities		5,029,801	8,308,785
	(550,454)	349,091	(550,454)

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS			
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,267,320	1,918,229	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 1,716,866	$ 2,267,320	$ 1,716,866
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	
Discount on convertible note related to beneficial conversion feature			$ 108,000
Shares issued for offering costs			$ 1,753
Contribution to paid in capital			$ 18,991

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

ORAMED PHARMACEUTICALS INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General:

Oramed Pharmaceuticals Inc. (the "Company") was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. On March 8, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd ("Hadasit") (the "First Agreement") to acquire the provisional patent related to orally ingestible insulin pill to be used for the treatment of individuals with diabetes, see also note 6a.

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