

ORAMED PHARMACEUTICALS INC.  
Form 424B3  
July 13, 2011

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File Numbers 333-164288, 333-173058, 333-175216  
PROSPECTUS

ORAMED PHARMACEUTICALS INC.

45,521,111 SHARES OF COMMON STOCK

The selling stockholders identified in this prospectus may offer from time to time up to 39,174,923 shares of our common stock and 6,346,188 shares of our common stock issuable upon exercise of warrants and options.

This prospectus describes the general manner in which the shares may be offered and sold by the selling stockholders. If necessary, the specific manner in which the shares may be offered and sold will be described in a supplement to this prospectus.

While we will not receive any proceeds from the sale of the shares by the selling stockholders, we will receive cash proceeds equal to the total exercise price of any warrants or options that are exercised for cash.

Our common stock is quoted on the OTC Bulletin Board, or the OTCBB, under the symbol "ORMP.OB". On June 28, 2011, the last reported bid price per share of our common stock as quoted on the OTCBB was \$0.32 per share.

Investing in the shares involves risks. You should carefully read the "Risk Factors" beginning on page 6 of this prospectus before investing.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 11, 2011.

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You should rely only on the information contained in this prospectus. Neither we nor the selling stockholders have authorized any dealer, salesperson or other person to give any information or to make any representations to you other than the information contained in this prospectus. You must not rely on any information or representations not contained in this prospectus as if we had authorized it. The information contained in this prospectus is current only as of the date on the cover page of this prospectus and may change after that date. We do not imply that there has been no change in the information contained in this prospectus or in our affairs since that date by delivering this prospectus. Neither we nor the selling stockholders are making an offer of these securities in any state where the offer

is not permitted.

As used in this prospectus, the terms “we”, “us”, “our”, the “Company”, “Oramed” and “Oramed Pharmaceuticals” mean Oramed Pharmaceuticals Inc., unless otherwise indicated.

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

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## PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Before making an investment decision, you should read the entire prospectus carefully, including the section entitled “Risk Factors”.

## THE COMPANY

### 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, and the use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

**Oral Insulin:** We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801). Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables its passage in a more physiological manner than current delivery methods of insulin.

Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

**Diabetes:** Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life.

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

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

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

### 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, 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 proteins and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug (“IND”)

application with the U.S. Food and Drug Administration (the “FDA”). 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.

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

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

#### Product Development

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

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). On January 22, 2008, we commenced non-FDA approved Phase 1B clinical trials with our oral insulin capsule (ORMD0801), 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 (ORMD0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On September 14, 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule (ORMD0801) in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This newly completed exploratory study was a proof of concept study for defining a novel indication for ORMD0801. We believe the encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization (CRO), to conduct a toxicology trial on our oral insulin capsules. On March 23, 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule (ORMD0801).

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 (ORMD0801) on type 2 diabetic volunteers. On May 6, 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No

cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

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GLP-1 Analog: On September 16, 2008 we announced the launch of pre-clinical trials of ORMD0901, a GLP-1 analog. The pre-clinical trials include animal studies which suggest that the GLP-1 analog (exenatide -4) when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

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

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

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

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.

#### Recent Business Developments

On December 23, 2010, our wholly owned Israeli subsidiary, Oramed Ltd., was awarded a government grant amounting to a total net amount of NIS 2.9 million (approximately \$807,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel (the "OCS"), which was designated for research and development expenses for the period of July 2010 to June 2011. We used these funds to support further research and development and clinical study of our oral insulin capsule and Oral GLP1-analog.

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

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP 1 analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis.

On March 31, 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera's outstanding share capital on an undiluted basis. We retained 3% of the Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, Oramed received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, to be paid within four months from closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately



\$700,000. In addition, D.N.A invested \$250,000 in our private placement in March 2011, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share.

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

In March, 2011, we consummated a private placement that commenced in November 2010, with a number of accredited investors pursuant to which we agreed to sell to the investors an aggregate of 10,487,500 units at a purchase price of \$0.32 per unit for total consideration of \$3,356,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 shares of common stock at an exercise price of \$0.50 per share. We also issued 196,750 shares of common stock and warrants to purchase 70,863 shares of common stock as finders' fees in connection with the private placement. These amounts include the \$250,000 investment by D.N.A made in connection with our technology transaction which closed on March 31, 2011.

In April 2011, we consummated a private placement with a number of “accredited investors” as defined in Rule 501(a) of Regulation D, pursuant to which we agreed to sell to the investors an aggregate of 1,124,375 units at a purchase price of \$0.32 per unit for total consideration of \$359,800. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per Share.

## THE OFFERING

Issuer	Oramed Pharmaceuticals Inc. Hi-Tech Park 2/5 Givat-Ram, PO Box 39098 Jerusalem 91390, Israel Telephone: 972-2-566-0001
Securities offered by the Selling Stockholders	39,174,923 shares of common stock and 6,346,188 shares of common stock issuable upon exercise of warrants and options.
Trading Market	The common stock offered in this prospectus is quoted on the OTCBB under the symbol "ORMP.OB".
Common stock outstanding (as of June 29, 2011)	70,104,583 shares <sup>1</sup> .
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares of our common stock being offered for sale by the selling stockholders. However, we may receive up to approximately \$3.2 million in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have an average exercise price of \$0.50 per share and are exercisable into 6,346,188 shares of our common stock. These potential proceeds will be used for the research and development of our products and for general working capital purposes. See "Use of Proceeds."
Plan of Distribution	The selling stockholders, and their pledgees, donees, transferees or other successors in interest, may from time to time offer and sell, separately or together, some or all of the common stock covered by this prospectus. Registration of the common stock covered by this prospectus does not mean, however, that those shares necessarily will be offered or sold. See "Plan of Distribution."
Risk Factors	Please read "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the securities offered in this prospectus.

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<sup>1</sup> Does not include 21,469,919 shares of our common stock issuable upon the exercise of outstanding options and warrants.

## RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus before making an investment decision. Our business, prospects, financial condition, and results of operations may be materially and adversely affected as a result of any of the following risks. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in “Risk Factors” are forward looking statements.

### Risks Related to Our Business

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

Our financial statements were prepared on the assumption that we will continue as a going concern. We estimate that our cash reserves will not be sufficient to permit us to continue at our anticipated level of operations for our fiscal year ending August 31, 2012. During 2011, we plan to increase research and development, product development, and administrative expenses relating to our business, including expenses related to research and development related to our oral delivery platform. We intend to use our cash reserves, as well as other funds in the event that they shall become available on commercially reasonable terms, to finance these activities and other activities described herein, although we can provide no assurance that these additional funds will be available in the amounts or at the times we may require. If sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. See “Risk Factors -- We will need substantial additional capital in order to satisfy our business objectives.”

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

To date, we have financed our operations principally through offerings of securities exempt from the registration requirements of the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for a minimum of six months from the date of this prospectus. 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.

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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 February 28, 2011 and August 31, 2010 and 2009, we had working capital of \$3.3 million, \$0.9 million and \$2.8 million, respectively, and stockholders' equity of \$3.2 million, \$0.8 million and \$2.7 million, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through February 28, 2011, the six month period ended February 28, 2011 and the year ended August 31, 2010, we incurred net losses of \$14.2 million, \$1.2 million, and \$3.0 million, 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 and oral administration of exenatides and proteins, and corresponding patent applications filed in Israel, South Africa and India. Further, we intend to rely on a combination of trade secrets and non-disclosure, and other contractual agreements and technical measures to protect our rights in our technology. We intend to depend upon confidentiality agreements with our officers, directors, employees, consultants, and subcontractors, as well as collaborative partners, to maintain the proprietary nature of our technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid our confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. We believe that our technology is not subject to any infringement actions based upon the patents of any third parties; however, our technology may in the future be found to infringe upon the rights of others. Others may assert infringement claims against us, and if we should be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on terms acceptable to us, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition, and results of operations.

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

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

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

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

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

- future clinical trial results may show that the oral insulin capsule is not well tolerated by recipients at its effective doses or is not efficacious as compared to placebo;
- future clinical trial results may be inconsistent with previous preliminary testing results and data from our earlier studies may be inconsistent with clinical data;
- even if our oral insulin capsule is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices;
- our ability to complete the development and commercialization of the oral insulin capsule for our intended use is significantly dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, the oral insulin capsule on a worldwide basis;
- even if our oral insulin capsule is successfully developed, commercially produced and 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 “Our 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.

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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 "Our Business – Governmental Regulation."

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

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

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

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

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

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

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. These industries are highly competitive, and this competition comes both from biotechnology firms and from major pharmaceutical and chemical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our products from universities and other research

institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our products may be subject to competition from products developed using other technologies. See “Our Business – Competition”.

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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,” “Our Business – Strategy” and “Business—Employees.”

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

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

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

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

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

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

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

Entera Bio Ltd. will require additional funding and may not be successful.

As of March 31, 2011, we held approximately 3% of Entera's outstanding shares and are entitled to receive royalties in the amount of 3% of Entera's net revenues (as defined in our patent transfer agreement). Entera will have to raise large amounts of capital to fund its operations, and it may not be able to raise sufficient amounts. Our ownership stake will be diluted if Entera raises funds from third parties. There can be no assurance that Entera's operations will ever result in profits that are distributed to us as shareholders or in net revenues requiring that royalties be paid to us under the terms of our patent transfer agreement.

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Healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may harm our future business.

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators and third-party payors to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for the products that we are developing, or the amounts of reimbursement available for these products from governmental agencies or third-party payors. These limitations could in turn reduce the amount of revenues that we will be able to generate in the future from sales of our products and licenses of our technology.

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

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the U.S. healthcare industry may lower the future revenues for the products we are developing and adversely affect our future business, possibly materially.

#### Risks Related to our Common Stock

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

The price of our common stock is quoted on the Over-the-Counter Bulletin Board, or OTCBB, and constantly changes. In recent years, the stock market in general has experienced extreme price and volume fluctuations. We expect that the market price of our common stock will continue to fluctuate. These fluctuations may result from a variety of factors, many of which are beyond our control. These factors include:

- Clinical trial results and the timing of the release of such results,
- The amount of cash resources and ability to obtain additional funding,
- Announcements of research activities, business developments, technological innovations or new products by companies or their competitors,
- Entering into or terminating strategic relationships,
- Changes in government regulation,
- Departure of key personnel,

- Disputes concerning patents or proprietary rights,
  - Changes in expense level,
- Future sales of our equity or equity-related securities,
- Public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
  - Activities of various interest groups or organizations,
    - Media coverage, and
  - Status of the investment markets.

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

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

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

The Securities and Exchange Commission, or the SEC, has adopted regulations that generally define "penny stock" to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions, such as if the issuer of the security has net tangible assets in excess of \$2,000,000. The market price of our common stock is currently less than \$5.00 per share, and our net tangible assets as of February 28, 2011 were less than \$2,000,000. Therefore, our common stock is currently a "penny stock" according to SEC rules. Designation as a "penny stock" requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser, furnish the customer a document describing the risks of investing in penny stocks and send monthly account statements showing the market value of each penny stock held in the customer's account. These rules may restrict the ability of brokers or dealers to sell penny stocks.

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

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

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

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



The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of June 29, 2011, we had outstanding 70,104,583 shares of common stock. This prospectus relates to 39,174,923 shares of common stock held by the selling stockholders and 6,346,188 shares of common stock issuable upon exercise of warrants and options held by the selling stockholders.

Our issuance of warrants and options to investors, employees and consultants may have a negative effect on the trading prices of our common stock as well as a dilutive effect.

We have issued and may continue to issue warrants, options and convertible notes at, above or below the current market price. As of June 29, 2011, we had outstanding warrants and options exercisable for 21,469,919 shares of common stock (18,552,948 as of February 28, 2011 and 15,584,897 as of August 31, 2010). In addition to the dilutive effect of a large number of shares and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.

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

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

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

Our common stock currently trades on the OTCBB and is not listed for trading on any national securities exchange. Investments in securities trading on the OTCBB are generally less liquid than investments in securities trading on a national securities exchange. The failure of our shares to be approved for trading on a national securities exchange may have the effect of limiting the trading activity of our common stock and reducing the liquidity of an investment in our common stock.

#### Risks Related to Conducting Business in Israel

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

Our operations are located in the State of Israel, and we are directly affected by political, economic, and security conditions in that country. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Since October 2000, there has been a marked increase in hostilities between Israel and the Palestinians, and in 2007, Hamas, an Islamist movement responsible for many attacks against Israelis, took control of the Gaza Strip. Recent political events, including political uprisings and social unrest, in various countries in the Middle East and North Africa have weakened the stability of those countries, which could result in extremists coming to power. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in areas that neighbor Israel, such as Hamas in Gaza and Hezbollah in Lebanon. This situation may potentially escalate in the future to violent events which may affect Israel and us. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

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

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

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

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## FORWARD-LOOKING STATEMENTS

This prospectus and any prospectus supplement may contain forward-looking statements within the meaning of the federal securities laws regarding our business, financial condition, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this prospectus. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this prospectus 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” above, as well as those discussed elsewhere in this prospectus. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. 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 prospectus. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this prospectus which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

## USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares of our common stock being offered for sale by the selling stockholders. However, we may receive up to approximately \$3.2 million in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have an average exercise price of \$0.50 per share and are exercisable into 6,346,188 shares of our common stock. None of the selling stockholders have presently advised us of their intention to exercise any warrants or options at this time. All potential proceeds will be used for the research and development of our products and for general working capital purposes. We will incur all costs associated with this registration statement and prospectus.

## MARKET PRICE AND DIVIDENDS

## Market Price for our Common Stock

Our common stock is quoted on the OTCBB under the symbol "ORMP.OB". We had 70,104,583 shares of common stock issued and outstanding and approximately 73 holders of record of the common stock as of June 28, 2011. 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. 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
<b>Fiscal Year Ending August 31, 2011</b>		
First Quarter	\$0.42	\$0.28
Second Quarter	\$0.37	\$0.27
Third Quarter	\$0.33	\$0.26
Fourth Quarter (through June 28, 2011)	\$0.34	\$0.29
<b>Year Ended August 31, 2010</b>		
First Quarter	\$0.64	\$0.43
Second Quarter	\$0.48	\$0.37
Third Quarter	\$0.55	\$0.41
Fourth Quarter	\$0.51	\$0.36
<b>Year Ended August 31, 2009</b>		
First Quarter	\$0.76	\$0.36
Second Quarter	\$0.52	\$0.25
Third Quarter	\$0.62	\$0.20
Fourth Quarter	\$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. On June 28, 2011, the last reported bid price per share of common stock as quoted on the OTCBB was \$0.32 per share.

## 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and notes thereto that appear elsewhere in this prospectus. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in the section entitled "Risk Factors."

#### Overview of Operations

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, and the use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

#### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug ("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 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.

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

### Other Planned Strategic Activities

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

### Results of Operations

#### 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 February 28, 2011 of \$14.2 million, as well as negative cash flow from operating activities. Based upon our existing spending plans, estimated at \$5.4 million for the twelve months following March 1, 2011, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through February 29, 2012. Accordingly, these factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

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

#### Critical accounting policies

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

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

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

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

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

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

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





Comparison of six month and three month periods ended February 28, 2011 and 2010 and Fiscal Year 2010 to Fiscal Year 2009

The following table summarizes certain statements of operations data for the Company for the six month and three month periods ended February 28, 2011 and 2010:

Operating Data:	Six months ended		Three months ended	
	February 28, 2011	February 28, 2010	February 28, 2011	February 28, 2010
Research and development costs	\$627,816	\$516,057	\$341,328	\$183,572
General and administrative expenses	621,016	493,344	305,887	208,328
Financial (income) expense, net	(3,257 )	(4,397 )	(4,424 )	311
Net loss for the period	1,245,575	1,005,004	\$642,791	\$392,211
Loss per common share – basic and diluted	\$0.02	\$0.02	\$0.01	\$0.01
Weighted average common shares outstanding	60,344,880	57,289,266	62,804,799	57,442,484

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

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

#### Research and development expenses

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

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

organizations are expected to provide services.

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

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

In August 2009, Oramed Ltd., our wholly owned Israeli subsidiary, was awarded a government grant amounting to a total net amount of NIS 3.1 million (approximately \$813,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel, or the OCS. This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and Oral GLP1-analog. In December 2010, Oramed Ltd., was awarded another grant amounting to a total net amount of NIS 2.9 million (approximately \$807,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to June 2011. We used the funds to support further research and development and clinical study of our oral insulin capsule and Oral GLP1-analog. The two grants are subject to repayment according to the terms determined by the OCS and applicable law. See "--Government Grants" below.

During the six months ended February 28, 2011 research and development expenses totaled \$627,816, compared to \$516,057 for the six months ended February 28, 2010. The increase is mainly attributable to an increase in stock based compensation costs due to amortization of options granted in the prior period. At this stage, we do not expect our stock based compensation costs to continue to increase. The research and development costs include stock based compensation costs, which during the six months ended February 28, 2011 totaled \$162,896 as compared to \$42,508 during the six months ended February 28, 2010.

The increase in research and development expenses during the three months ended February 28, 2011 as compared to the three months ended February 28, 2010 is attributable to the same reasons described in the immediate preceding paragraph.

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

#### Government Grants

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

In the six and three months ended February 28, 2011, we recognized research and development grants in an amount of \$208,674 and \$56,698, respectively. As of February 28, 2011, we had no contingent liabilities to the OCS.

In the years ended August 31, 2010 and 2009, we recognized research and development grants in an amount of \$350,198 and \$400,405, respectively. As of August 31, 2010, we had no contingent liabilities to the OCS.

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

Dollar, plus annual interest at LIBOR. The payment of royalties is on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licensed ancillary services.

The R&D Law generally requires that a product developed under a program be manufactured in Israel. However, upon notification to the OCS (and provided that the OCS does not object within 30 days), up to 10% of a company's approved Israeli manufacturing volume, measured on an aggregate basis, may be transferred outside of Israel. In addition, upon the approval of the 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 or the price paid in consideration for the sale of the grant recipient itself, as the case may be (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 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 six months ended February 28, 2011, general and administrative expenses totaled \$621,016 compared to \$493,344 for the six months ended February 28, 2010. Costs incurred related to general and administrative activities during the six months ended February 28, 2011 reflect an increase in professional fee expenses as well as stock options granted to employees and consultants. During the six months ended February 28, 2011, as part of our general and administrative expenses, we incurred \$172,901 related to stock options granted to employees and consultants, as compared to \$113,195 during the six months ended February 28, 2010.

The increase in general and administrative expenses during the three months ended February 28, 2011 as compared to the three months ended February 28, 2010 is attributable to the same reasons described in the immediate preceding paragraph .

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

year ended August 31, 2009.

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#### Financial income/expense, net

During the six month periods ended February 28, 2011 and 2010, we generated interest income on available cash and cash equivalents which was offset by bank charges and imputed interest.

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

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

#### Liquidity and Capital Resources

Since inception through February 28, 2011, we incurred losses in an aggregate amount of \$14.2 million. Since inception through February 28, 2011, we have financed our operations through the private placements of equity and debt financings, raising a total of \$11.1 million, net of transaction costs. We will seek to obtain additional financing through similar sources. As of February 28, 2011, we had \$1.9 million of available cash as well as \$1.8 million in short term interest bearing investments. We anticipate that we will require approximately \$5.4 million to finance our activities during the twelve months following March 1, 2011.

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

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

Our recent financing activities include the following:

- In September 2010 and January 2011, we issued a total of 353,714 shares of our common stock, valued at \$119,800, in the aggregate, to Swiss Caps AG as remuneration for services rendered.
- In March 2011, we completed a private placement with a number of “accredited investors” as defined in Rule 501(a) of Regulation D, pursuant to which we agreed to sell to the investors an aggregate of 10,487,500 units at a purchase price of \$0.32 per unit for total consideration of \$3,356,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per Share. These amounts include the \$250,000 investment by D.N.A made in connection with our technology transaction on March 31, 2011.
- On March 31, 2011, we consummated a transaction with D.N.A for the sale of 781,250 shares of common stock and warrants to purchase up to 273,438 shares of common stock, for a total purchase price of \$250,000 in cash. The shares and warrants were sold in units at a price per unit of \$0.32, each unit consisting of one share of



common stock and a warrant to purchase 0.35 of a share of common stock. The warrants have an exercise price of \$0.50 per share, subject to adjustment, and a term of five years commencing from the closing of the transaction. D.N.A's \$250,000 investment in Oramed is included in the private placement described in the immediately preceding paragraph.

- In April 2011, we completed a private placement with a number of “accredited investors” as defined in Rule 501(a) of Regulation D, pursuant to which we agreed to sell to the investors an aggregate of 1,124,375 units at a purchase price of \$0.32 per unit for total consideration of \$359,800. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per Share.
- In May 2011, we issued 176,923 shares of our common stock, valued at \$47,769, in the aggregate, to Swiss Caps AG as remuneration for services rendered in the past.
- In May 2011, we issued 200,00 shares of our common stock, valued at \$60,000, in the aggregate, to New Castle Consulting, LLC as remuneration for services to be rendered.

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

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

- On November 23, 2009 we granted options under the 2008 Stock Incentive Plan to purchase up to 100,000 shares of our common stock at an exercise price of \$0.76 to a consultant.
- On November 23, 2009 we granted options under the 2008 Stock Incentive Plan to purchase up to 36,000 shares of our common stock at an exercise price of \$0.46 to an employee of our subsidiary.
- On March 16, 2010, 50,000 options were granted to a consultant of our subsidiary at an exercise price of \$0.50 per share. The options vest in three equal annual installments commencing on March 16, 2011 and will expire on March 15, 2015.
- On March 16, 2010, 100,000 options were granted to a consultant of the Company at an exercise price of \$0.43 per share. The options vest in three equal monthly installments commencing on March 30, 2010 and will expire on March 15, 2015.
- On March 16, 2010, 13,200 options were granted to a consultant of the Company at an exercise price of \$0.43 per share. The options vest in six monthly installments commencing on March 30, 2010 and will expire on March 15, 2015.
- On March 25, 2010, 100,000 options were granted to a consultant of the Company at an exercise price of \$0.50 per share. The options vest in four equal quarterly installments commencing on May 17, 2010 and will expire on March 24, 2015.
- On April 21, 2010, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Stock Option Plan at an exercise price of \$0.49 per share, 108,000 of such options vested immediately on the date of grant and the remainder will vest in twenty equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.
- On July 8, 2010, 300,000 options were granted to a director at an exercise price of \$0.48 per share. The options vest in three equal annual installments commencing on July 8, 2011 and will expire on July 7, 2020.

Employee and consultant stock options grant and warrant issuance activities for the fiscal year 2011 include the following:

- On February 15, 2011, 250,000 options were granted to a consultant of the Company at an exercise price of \$0.50 per share. The options vest in five equal quarterly installments commencing on February 16, 2011 and will expire on February 16, 2021.

#### 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 March 1, 2011 are as follows:

Category	Amount
Research and development costs, net of OCS funds	\$ 4,358,000
General and administrative expenses	1,044,000
Financial income, net	1,000
Taxes on income	-
Total	\$ 5,404,000

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.

## OUR 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, and the use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

**Oral Insulin:** We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801) currently in Phase 2 clinical trials. Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables its passage in a more physiological manner than current delivery methods of insulin.

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

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

Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

**Diabetes:** Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life. The cause of diabetes is attributed both to genetics (type 1 diabetes) and, most often, to environmental factors such as obesity and lack of exercise (type 2 diabetes).

According to the International Diabetes Federation ("IDF"), an estimated 285 million people worldwide suffered from diabetes in 2010. In the United States there were approximately 26.8 million people with diabetes, or 8.7% of the United States population in 2010. The IDF predicts that the number of people worldwide with diabetes will exceed 435 million in 2030 if the current rate of growth continues unchecked.

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

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

Each year seven million people develop diabetes. The most dramatic increases in type 2 diabetes have occurred in populations where there have been rapid and major improvements in living standards, demonstrating the important

role played by lifestyle factors and the potential for reversing the global epidemic.

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

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

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

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## Strategy

### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug ("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 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.

### 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 increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

### Other Planned Strategic Activities

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

### Product Development

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

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). 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 (ORMD0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

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On September 14, 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule (ORMD0801) in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This newly completed exploratory study was a proof of concept study for defining a novel indication for ORMD0801. The encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on our oral insulin capsules. On March 23, 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule (ORMD0801). The study was completed under conditions prescribed by the FDA Good Laboratory Practices regulations and is the last study required to be performed before filing an IND filing.

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 (ORMD0801) on type 2 diabetic volunteers. On May 6, 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

GLP-1 Analog: On September 16, 2008 we announced the launch of pre-clinical trials of ORMD0901, a GLP-1-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 are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. We anticipate that the results of these trials will be released in the near future.

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

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

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



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.

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## Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 34 patent applications currently pending with respect to various compositions, methods of production oral administration of proteins and exenatide. Expiration dates for pending patents will fall in 2026 – 2028.

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

Our patent strategy is as follows:

- Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate;
- Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology; and
- Establish comprehensive coverage in the U.S. and in all relevant foreign markets in anticipation of future commercialization opportunities.

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

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

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

### Partnerships and Collaborative Arrangements

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

On February 17, 2006, we entered into an agreement with Hadasit to provide consulting and clinical trial services.

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

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

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

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

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

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

On July 5, 2010, our subsidiary entered into an MSA with sanofi-aventis. According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

### Out-Licensed Technology

On June 1, 2010, our subsidiary, Oramed Ltd., entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd. (formerly Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera"). Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP 1 Analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis. The license was royalty-free unless our ownership interest in Entera decreased to 30% or less of its outstanding share capital, in which case royalties would be payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may have received ownership of the licensed technology, in which case we would have received a license back on the same terms. D.N.A initially invested \$600,000 in Entera, and Entera was initially owned in equal parts by Oramed and D.N.A. Entera's Chief Executive Officer, Dr. Phillip Schwartz, will be granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital, upon full exercise.



On February 22, 2011, Oramed Ltd. entered into a share purchase agreement with D.N.A for the sale of 47% of Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, Oramed received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, to be paid within four months from closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$700,000. In addition, D.N.A agreed to invest \$250,000 in our private placement, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share.

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

The closing of the abovementioned transactions took place on March 31, 2011. On the closing date, Oramed, Entera and D.N.A terminated the joint venture agreement entered into on June 1, 2010 in connection with the formation of Entera.

Government Regulation