ORAMED PHARMACEUTICALS INC.
Form 424B3
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Registration Nos. 333-164288, 333-173058, 333-175216, 333-186375

PROSPECTUS

6,037,483 SHARES OF COMMON STOCK

The selling stockholders identified in this prospectus may offer from time to time up to 4,191,459 shares of our common stock and 1,846,024 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, or approximately $8,500,000 based on a weighted average exercise price of $4.59 per share.

Our common stock is quoted on the Nasdaq Capital Market, or Nasdaq, under the symbol “ORMP.” On February 19, 2013, the closing price of our common stock on Nasdaq was $9.60 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 February 20, 2013.

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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”, and “Oramed” mean Oramed Pharmaceuticals Inc. and our wholly-owned Israeli subsidiary, Oramed Ltd., unless otherwise indicated.

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

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 sections entitled “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements.”

On January 22, 2013, we effected a one-for-twelve reverse split of our shares of common stock, and accordingly the par value of our common stock was changed from $.001 to $.012 per share. On January 23, 2013, our shares of common stock began to trade on a reverse split-adjusted basis. Unless indicated otherwise by the context, all common stock, option, warrant and per share amounts in this prospectus have been adjusted to give retroactive effect to the reverse stock split for all periods presented.

THE COMPANY

General

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

Oral Insulin: We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801). 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.

GLP-1 Analog: Our second pipeline product is an orally ingestible exenatide (GLP-1 analog) capsule, which aids in the balance of blood-sugar levels and decreases appetite. Glucagon-like peptide-1, or 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.

Combination of Oral Insulin and GLP-1 Analog: Our third pipeline product is a combination of our two primary products, oral insulin and oral exenatide. Preliminary results of this trial were announced in June 2012. The results showed that our two main products have greater positive effects when given together, as a combination therapy, above the administration of each product alone. A human clinical trial on healthy volunteers is expected to commence in the first quarter of calendar year 2013.

Strategy

We plan to conduct further research and development on the technology covered by the patent application

"Methods and Composition for Oral Administration of Proteins," which we acquired from Hadasit Medical Research Services and Development Ltd., or Hadasit, in 2006 and which is pending in various foreign jurisdictions, as well as the other patents we have filed in various foreign jurisdictions since then, as discussed below under "Our Business—Patents and Licenses" and "Risk Factors." Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin or other proteins, such as exenatide, for the treatment of diabetes. The enzymes and vehicles that are added to the proteins in the formulation process must not modify the proteins chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. On December 31, 2012, we filed an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, to begin a Phase 2 clinical trial of our orally ingested insulin capsule, in order to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. We have been communicating with the FDA regarding our IND, and, according to FDA requirements, intend to conduct a sub study before we begin the main clinical trial. We began conducting a clinical trial of our orally ingested exenatide in January 2013, and plan to conduct a trial of the combination of the two proteins in the first quarter of calendar year 2013. Clinical trials are planned in order to substantiate our results as well as for purposes of making future filings for drug approval. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

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

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.

Recent Product Developments

Orally Ingestible Insulin

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

In December 2012, we filed an IND application with the FDA for a Phase 2 clinical trial of our orally ingested insulin candidate, ORMD0801. We have been communicating with the FDA regarding our IND, and, according to FDA requirements, intend to conduct a sub study before we begin the main clinical trial.

GLP-1 Analog

In December 2009, we successfully completed our first-in-humans clinical trial which tested the safety and efficacy of the exenatide capsule ORMD0901. The trial was conducted on healthy males and monitored their responses to a single dose delivered 60 minutes before a glucose load. ORMD0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

A further clinical trial for our exenatide capsule on healthy volunteers and type 2 diabetic patients began in

January 2013. We expect to receive results from such trial in the first quarter of calendar year 2013.

Combination Therapy

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

We plan to commence a first human clinical trial on healthy volunteers with the combination therapy in the first quarter of calendar year 2013.

Recent Other Business Developments and Financing Activities

In September 2012, we entered into a Master Services Agreement with Medpace, Inc., or Medpace, to retain Medpace as a contract research organization, or CRO, for our upcoming Phase 2 clinical trial for an oral insulin capsule that is expected to start in the first calendar quarter of 2013 in the United States, and is expected to be completed in December 2013. As consideration for its services, we will pay Medpace a total amount of approximately $3,500,000 during the term of the engagement, based on the achievement of certain milestones.

In October 2012, we entered into a Securities Purchase Agreement with D.N.A Biomedical Solutions Ltd., or D.N.A, an Israeli company listed on the Tel Aviv Stock Exchange, or TASE, according to which, we issued to D.N.A 199,172 shares of our common stock in consideration for a warrant to purchase up to 21,637,611 ordinary shares of D.N.A, or the D.N.A Warrant. We had previously acquired 8,404,667 ordinary shares of D.N.A issued in March 2011. In February 2013, following receipt by D.N.A of TASE approval to list the ordinary shares of D.N.A issuable upon exercise of the D.N.A Warrant, we sent to D.N.A an exercise notice to exercise the D.N.A Warrant. In addition, in February 2013 we sold 3,500,000 of the D.N.A shares that were issued to us in March 2011. The shares were sold in a private transaction for a total of NIS 420,000 (or approximately $114,000, based on the exchange rate between the NIS and the U.S. dollar, as quoted by the Bank of Israel on the date of sale), before brokerage fees. As of February 19, 2013 we own approximately 2.6% of D.N.A's outstanding ordinary shares, and, following the exercise of the D.N.A Warrant, own approximately 12.8% of D.N.A's ordinary shares.

Between September and November 2012, we completed private placements pursuant to which we sold to certain investors an aggregate of 335,477 "units" at a purchase price of $4.44 per unit for total consideration of $1,489,518. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.50 of a share of common stock at an exercise price of $6.00 per share. In connection with such private placements, we paid cash compensation of $12,885 as a finder's fee. We also issued 1,127 shares of common stock and warrants to purchase 564 shares of common stock as a finder's fee to a third-party in connection with the private placements and issued 12,745 shares of common stock and warrants to purchase 6,373 shares of common stock as a finder's fee to one of our directors, Leonard Sank. The shares and warrant shares issued in these private placements are included in this prospectus for resale. See "Selling Stockholders."

In November 2012, we entered into a letter agreement, or the Agreement, with Regals Fund LP, or Regals, in connection with (1) the warrant originally issued in January 2011, as amended in August 2012 and November 2012, to purchase up to 290,459 shares of our common stock, (2) the warrant dated August 28, 2012, to purchase up to 112,613 shares of our common stock and (3) the warrant dated November 5, 2012, to purchase up to 16,892

shares of our common stock , or together, the Warrants. Pursuant to the Agreement, we and Regals agreed to amend the Warrants to provide that the anti-dilution protection of the Warrants shall be deleted in its entirety. In addition, as to the warrants issued in August and November 2012, the parties agreed to reduce the exercise price to $3.7656 per share, the current exercise price per share of the warrants originally issued in January 2011. At such time, we also issued to Regals a warrant, or the New Warrant, pursuant to which Regals shall have the right to purchase up to 137,311 shares of our common stock over a period of four years at an exercise price of $7.20 per share. All such warrant shares issued to Regals are included in this prospectus for resale. See “Selling Stockholders.”

In December 2012, we were issued a patent by the South African Patent Office, which covers part of our technology with respect to oral delivery of peptides.

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	4,191,459 shares of our common stock and 1,846,024 shares of our common stock issuable upon the exercise of warrants and options.
Trading Market	The common stock offered in this prospectus is traded on Nasdaq under the symbol “ORMP.”
Common Stock Outstanding (as of February 19, 2013)	7,222,397 shares1.
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 $8,500,000 in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have a weighted average exercise price of $4.59 per share and are exercisable into 1,846,024 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 such 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.

1 Does not include 2,272,949 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. The following risk factors are not the only risk factors facing our Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, prospects, financial condition, and results of operations.

Risks Related to Our Business

We continue and expect to incur losses in the future.

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

Based on our current cash resources and commitments, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that we will not need additional funds prior to such time. If there are unexpected increases in our operating expenses, we may need to seek additional financing during the next 12 months.

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

To date, we have financed our operations principally through offerings of securities exempt from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for at least the next 12 months from the date of this prospectus. 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 patentprosecutions,
- Competing technological and market developments,
- Our ability to establish additional collaborative relationships, and
- Effects of commercialization activities and facility expansions if and as required.

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

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

We are a development stage company with no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which could generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of November 30, 2012, August 31, 2012 and August 31, 2011, we had working capital of $6,473,335, $4,439,438 and $3,842,790, respectively, and stockholders' equity of $6,249,867, $3,778,013 and $3,723,916, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through November 30, 2012, the three month period ended November 30, 2012, and the year ended August 31, 2012, we incurred net losses of $18,850,530, $958,753 and $3,344,478, 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.

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

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

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

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

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

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

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

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

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

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

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

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

- Even if our oral insulin capsule is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance of our product, and

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

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

We have limited experience in conducting clinical trials.

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

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

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

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

The testing, marketing and manufacturing of any of our products will require the approval of the FDA or regulatory agencies of other countries. We have completed certain non-FDA clinical trials and pre-clinical trials for our products but have yet to conduct any FDA approved trials. We have filed an IND application with the FDA in December 2012 to conduct an FDA approved Phase 2 study on our oral insulin capsule product and we intend to conduct a sub study before we begin the main clinical trial, in accordance with FDA requirements.

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—Government Regulation."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Healthcare policy changes, including pending legislation recently adopted and further proposals still pending to reform the U.S. healthcare system, may harm our future business.

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

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

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

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

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

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

Risks Related to our Common Stock

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

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

We have effected a reverse stock split of our shares of common stock.

Our board of directors, or our Board, and our stockholders have approved a reverse stock split at a ratio of one-for-twelve, effective January 22, 2013. While our Board believes that the potential advantages of a reverse stock split, including meeting Nasdaq listing requirements, outweigh the risks, there can be no assurance that:

- Our shares of common stock will trade at a price in proportion to the reduction in the number of outstanding shares resulting from the reverse stock split,

- The reverse stock split will result in a per share price high enough to attract and retain employees and strategic partners,

- The bid price of our shares of common stock after a reverse stock split can be maintained at or above the minimum bid price requirement,

- Our shares of common stock will not be delisted from Nasdaq for other reasons,

- The liquidity of our shares of common stock will not be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split,

- Engaging in a reverse stock split will not be perceived in a negative manner by investors, analysts or other stock market participants, or

- The reverse stock split will not result in some stockholders owning “odd-lots” of less than 100 shares of common stock, potentially resulting in higher brokerage commissions and other transaction costs than the commissions and costs of transactions in “round-lots” of even multiples of 100 shares.

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

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

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

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

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 February 19, 2013, we had outstanding 7,222,397 shares of common stock, a large majority of which are freely tradeable. Giving effect to the exercise in full of all of our outstanding warrants and options, we would have outstanding 9,495,346 shares of common stock. This prospectus relates to 4,191,459 shares of common stock held by the selling stockholders and 1,846,024 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 February 19, 2013, we had outstanding warrants and options exercisable for 2,272,949 shares of common stock (2,241,872 as of November 30, 2012, and 1,892,142 as of August 31, 2012). In addition to the dilutive effect of a large number of shares and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.

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

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

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

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

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

As of February 19, 2013, our directors, executive officers and principal affiliated stockholders beneficially own 35.4% of our outstanding shares of common stock. As a result, these stockholders, should they act together, may have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, should they act together, may have the ability to control our management and affairs. Accordingly, this concentration of ownership might harm the market price of our common stock by:

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

Risks Related to Conducting Business in Israel

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

Our operations are located in the State of Israel, and we are directly affected by political, economic, and security conditions in that country. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Since October 2000, there has been a high level of violence between Israel and the Palestinians. In addition, acts of terrorism, armed conflicts or political instability in the region could negatively affect local business conditions and harm our results of operations. We cannot predict the effect on the region of any diplomatic initiatives or political developments involving Israel or the Palestinians or other countries in the Middle East. Recent political events, including political uprisings, social unrest and regime change, in various countries in the Middle East and North Africa have weakened the stability of those countries, which could result in extremists coming to power. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. This situation may potentially escalate in the future to violent events which may affect Israel and us. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

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

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) and any prospectus supplement contains forward-looking statements within the meaning of the federal securities laws regarding our business, clinical trials, financial condition, expenditures, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estima 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 "Risk Factors" 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. Except as required by law, we undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this 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 $8,500,000 in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have a weighted average exercise price of $4.59 per share and are exercisable into 1,846,024 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 the preparation and filing of the registration statement of which this prospectus is a part. Brokerage fees, commissions and similar expenses, if any, attributable to the sale of shares offered hereby will be borne by the applicable selling stockholders.

MARKET PRICE AND DIVIDENDS

Market Price for our Common Stock

Our common stock was quoted on the OTCQB through February 8, 2013. Effective February 11, 2013, our common stock is listed on Nasdaq under the symbol "ORMP." The quarterly high and low reported bid prices for our common stock as quoted on the OTCQB for the periods indicated are as follows:

	High	Low
Year Ended August 31, 2011		
Three Months Ended November 30, 2010	$5.04	$3.36
Three Months Ended February 28, 2011	$4.44	$3.24
Three Months Ended May 31, 2011	$4.20	$2.76
Three Months Ended August 31, 2011	$4.08	$2.40
Year Ended August 31, 2012		
Three Months Ended November 30, 2011	$5.28	$3.00
Three Months Ended February 29, 2012	$4.56	$3.24
Three Months Ended May 31, 2012	$4.32	$3.24
Three Months Ended August 31, 2012	$4.32	$2.76
Year Ended August 31, 2013		
Three Months Ended November 30, 2012	$4.08	$3.24

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 February 19, 2013, the closing price of our common stock on Nasdaq was $9.60 per share.

Holders

As of February 19, 2013, there were 7,222,397 shares of our common stock issued and outstanding held of record by approximately 96 registered stockholders. We believe that a significant number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories and are therefore not included in the number of stockholders of record.

Dividend Policy

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

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

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

Overview of Operations

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

Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins," which we acquired from Hadasit in 2006 and which is pending in various foreign jurisdictions, as well as the other patents we have filed in various foreign jurisdictions since then, as discussed below under "Our Business—Patents and Licenses" and above under "Risk Factors." Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin or other proteins, such as exenatide, for the treatment of diabetes. The enzymes and vehicles that are added to the proteins in the formulation process must not modify the proteins chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. On December 31, 2012, we filed an IND application with the FDA, to begin a Phase 2 clinical trial of our orally ingested insulin capsule, in order to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. We have been communicating with the FDA regarding our IND, and, according to FDA requirements, intend to conduct a sub study before we begin the main clinical trial. We began conducting a clinical trial of our orally ingested exenatide in January 2013, and plan to conduct a trial of the combination of the two proteins in the first quarter of calendar year 2013. Clinical trials are planned in order to substantiate our results as well as for purposes of making future filings for drug approval. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

Long Term Business Strategy

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

studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

Other Planned Strategic Activities

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

Results of Operations

Critical accounting policies

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

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

Marketable securities: Consist mainly of ordinary shares and a warrant to purchase ordinary shares of D.N.A, which are classified as available-for-sale and are recorded at fair value. As of October 1, 2011, the ordinary shares are not restricted and the fair value of the ordinary shares is measured based on the quoted prices of the ordinary shares on an active market. Changes in fair value, net of taxes, are reflected in other comprehensive income (loss). The ordinary shares that will be received upon exercising the warrant will be restricted for a period of six months from the exercise date. The fair value of the restricted ordinary shares receivable upon exercise of the warrant was measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market.

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

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

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

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

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

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

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

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

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

Comparison of Three Month Period Ended November 30, 2012 to 2011 and Fiscal Year 2012 to Fiscal Year 2011

The following table summarizes certain statements of operations data for us for the three month periods ended November 30, 2012 and 2011:

	Three months ended	
Operations Data:	November 30, 2012	November 30, 2011
Research and development costs, net	$392,626	$184,016
General and administrative expenses	339,213	281,901
Financial expenses, net	226,914	12,602
Net loss for the period	$958,753	$478,519
Total other comprehensive income	(235,868)	(4,205)
Total comprehensive loss for the period	$722,885	$474,314
Loss per common share – basic and diluted	$(0.14)	$(0.08)
Weighted average common shares outstanding	6,826,896	5,842,803

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

Operations Data:	Year ended August 31, 2012	August 31, 2011
Research and development expenses, net	$1,680,845	$1,159,309
General and administrative expenses	1,203,164	1,275,960
Gain on sale of investment	-	(1,033,004)
Impairment of available for sale securities	184,254	197,412
Financial expenses (income), net	185,997	(14,452)
Loss before taxes on income	(3,254,260)	(1,585,225)
Taxes on income	90,218	(23,980)
Net loss for the period	$(3,344,478)	$(1,561,245)
Loss per common share – basic and diluted	$(0.57)	$(0.29)
Weighted average common shares outstanding	5,884,595	5,417,278

Research and development expenses

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

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

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

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

In August 2009, Oramed Ltd. was awarded a government grant amounting to a total net amount of NIS 3.1 million (approximately $813,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel, or OCS. This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and oral GLP-1-analog. In December 2010, Oramed Ltd. was awarded a second grant, or the Second Grant, amounting to a total net amount of NIS 2.9 million (approximately $720,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to November 2011. As a result of a delay in the research and development plan, as of November 30, 2011, Oramed Ltd. had used only NIS 1,473,000

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

During the three months ended November 30, 2012, research and development expenses totaled $392,626, compared to $184,016 for the three months ended November 30, 2011. The increase is mainly attributed to the preparation for the FDA approved Phase 2 study that will be conducted during fiscal year 2013. The research and development costs include stock based compensation costs, which during the three months ended November 30, 2012 totaled $78,438 as compared to $24,605 during the three months ended November 30, 2011.

During the year ended August 31, 2012, research and development expenses totaled $1,680,845, compared to $1,159,309 for the year ended August 31, 2011. The increase is mainly attributed to the preparation for the FDA approved Phase 2 study that will be conducted during fiscal year 2013. The research and development costs include stock based compensation costs, which during the year ended August 31, 2012 totaled $98,688, as compared to $265,327 during the year ended August 31, 2011. The decrease is mainly attributable to the end of the vesting period at January 31, 2012 of the 72,000 options granted to Dr. Miriam Kidron in April 2010.

Government grants

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

In May 2012, Oramed Ltd. was granted a third grant amounting to a total net amount of NIS 595,000 (approximately $148,000) from the OCS, which was designated for research and development expenses for the period of September 2012 to December 2012. We used the funds to support further research and development and clinical studies of our oral insulin capsule and oral GLP-1 analog.

In the three months ended November 30, 2012, we recognized research and development grants in an amount of $10,058 from the OCS, and in the three months ended November 30, 2011, we recognized research and development grants in an amount of $41,257 from OCS. As of November 30, 2012, we had no contingent liabilities to the OCS.

In the years ended August 31, 2012 and 2011, we recognized research and development grants in an amount of $372,959 and $354,906, respectively. As of August 31, 2012, we did not incur any royalty liability to the OCS.

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

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

in such cases.

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred to another person or entity 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 research committee, under special circumstances, may approve the transfer of OCS-funded know-how outside of Israel if: (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, which portion will not exceed six times the amount of the grants received by the grant recipient plus interest (or three times the amount of the grants received plus interest, in the event that the recipient of the know-how has committed to retain the R&D activities of the grant recipient in Israel after the transfer); (b) the grant recipient receives know-how from a third party in exchange for its OCS-funded know-how; (c) such transfer of OCS-funded know-how arises in connection with certain types of cooperation in research and development activities; or (d) such transfer of OCS-funded know-how arises in connection with a liquidation by reason of insolvency or receivership of the grant recipient.

The R&D Law imposes reporting requirements with respect to certain changes in the ownership of a grant recipient. The R&D Law requires the grant recipient and its controlling shareholders and foreign interested parties to notify the OCS of any change in control of the recipient or a change in the holdings of the means of control of the recipient that results in a non-Israeli becoming an interested party in the recipient, and requires the new interested party to undertake to the OCS to comply with the R&D Law. In addition, the rules of the OCS may require additional information or representations in respect of certain such events. For this purpose, "control" is defined as the ability to direct the activities of a company other than any ability arising solely from serving as an officer or director of the company. A person is presumed to have control if such person holds 50% or more of the means of control of a company. "Means of control" refers to voting rights or the right to appoint directors or the chief executive officer. An "interested party" of a company includes a holder of 5% or more of its outstanding share capital or voting rights, its chief executive officer and directors, someone who has the right to appoint its chief executive officer or at least one director, and a company with respect to which any of the foregoing interested parties owns 25% or more of the outstanding share capital or voting rights or has the right to appoint 25% or more of the directors. Accordingly, any non-Israeli who acquires 5% or more of our common stock will be required to notify the OCS that it has become an interested party and to sign an undertaking to comply with the R&D Law.

Failure to meet the R&D Law's requirements may subject us to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings. In addition, the Israeli government may from time to time audit sales of products which it claims incorporate technology funded through OCS programs which may lead to additional royalties being payable on additional products.

Grants from the Bio-Jerusalem fund

The Bio-Jerusalem fund was founded by the Jerusalem Development Authority in order to support the biomed industry in Jerusalem. We are committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grants received by the Company (Israeli CPI linked) in the total amount of $65,053 as of November 30, 2012. For the three month periods ended November 30, 2012 and 2011, we received $12,320 and $0, respectively, from the Bio-Jerusalem fund. For the year ended August 31, 2012 there were no grants received from the Bio-Jerusalem fund, and in the year ended August 31, 2011, we received $20,950 from said fund. As of November 30, 2012, we had not yet realized any revenues since inception and thus did not incur any royalty liability to the Bio-Jerusalem fund.

General and administrative expenses

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

For the three months ended November 30, 2012, general and administrative expenses totaled $339,213 compared to $281,901 for the three months ended November 30, 2011. The increase in costs incurred related to general and administrative activities during the three months ended November 30, 2012, reflect an increase in stock options granted to employees and consultants of $113,079. The increase in general and administrative expenses was partially offset by a decrease in investor relations costs, most of which were paid in the three months ended November 30, 2011 with our common stock and warrants to purchase common stock. During the three months ended November 30, 2012, as part of our general and administrative expenses, we incurred $139,770 related to stock options granted to employees and consultants, as compared to $26,691 during the three months ended November 30, 2011.

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

Financial income/expense, net

Financial expenses for the three months ended November 30, 2012 includes an expense of $296,982 resulting mainly from the removal of the anti-dilution protections from warrant liabilities and the grant of new warrants.

In the three months ended November 30, 2012, we incurred revenues from exchange rate differences as well as interest income on available cash and cash equivalents that were partially offset by bank charges. In the three months ended November 30, 2011, we received a higher amount of interest income on available cash and cash equivalents which was offset by bank charges.

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

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

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

In March 2011, we consummated a transaction with D.N.A whereby we sold to D.N.A 47% of Entera Bio Ltd.'s, or Entera's, outstanding share capital on an undiluted basis, as discussed below under "Our Business—Out-Licensed Technology." As a result of the transaction, we recognized a gain on sale of investment of $1,033,004 for the year ended August 31, 2011. Also as a result of the transaction, we received 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately $581,977 as of March 31, 2011, the closing date of the Entera sale. The D.N.A shares were recorded at fair value as discussed above under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Marketable securities." As of November 30, 2012 and August 31, 2012, these ordinary shares of D.N.A had an aggregate market value of approximately $317,657 and $200,311, respectively. Pursuant to the Israel Securities Law, the ordinary shares of D.N.A that we own are subject to certain restrictions on sale. In addition, even if such restrictions are no longer applicable, the market price for D.N.A's ordinary shares may decline, which could result in a loss to us if we sell such shares at a price below the value on the date we acquired such shares. The ordinary shares of D.N.A have historically experienced low trading volume; as a

result there is no guarantee that we will be able to resell the ordinary shares of D.N.A at the prevailing market prices. Changes in fair value, net of taxes, are discussed in Note 3 to our accompanying consolidated financial statements for the three months ended November 30, 2012 and 2011 and for the years ended August 31, 2012 and 2011. See "—Liquidity and capital resources" for a discussion of the February 2013 sale of certain of our ordinary shares of D.N.A.

Liquidity and capital resources

From inception through November 30, 2012, we incurred losses in an aggregate amount of $18,850,530. We have financed our operations through the private placements of equity financing, raising a total of $16,603,071, net of transaction costs. We will seek to obtain additional financing through similar sources in the future as needed. As of November 30, 2012, we had $5,531,075 of available cash. We anticipate that we will require approximately $4.9 million to finance our activities during the 12 months following November 30, 2012.

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

Effective February 11, 2013, our common stock is listed on Nasdaq under the symbol “ORMP.” As a result of our shares of common stock being listed on Nasdaq, we may experience increased trading volume in our shares of common stock and increases in our share price resulting from the heightened market exposure. However, there can be no assurance that the aforementioned benefits will result.

During the three month period ended November 30, 2012, cash and cash equivalents increased by $1,100,335 from the $4,430,740 reported as of August 31, 2012, which is due to the reasons described below. During the year ended August 31, 2012, cash and cash equivalents increased by $2,917,375 from the $1,513,365 reported as of August 31, 2011, which is primarily due to proceeds from the issuance of common stock and warrants and proceeds from the sale of our investment in Entera.

Operating activities used cash of $792,826 in the three months ended November 30, 2012, as compared to $484,070 in the three months ended November 30, 2011. Cash used for operating activities in the three months ended November 30, 2012 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments and common stock issuances, while cash used by operating activities in the three months ended November 30, 2011 primarily consisted of net loss resulting from research and development and general and administrative expenses. Operating activities used cash of $2,301,608 in the year ended August 31, 2012 and $1,705,844 in the year ended August 31, 2011. Cash used for operating activities in the year ended August 31, 2012 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments, common stock issued for services and increases in accounts payable and accrued expenses. The increase in cash used by operating activities in the year ended August 31, 2012, as compared to the year ended August 31, 2011, is mainly due to the gain on sale of investment of $1,033,004 from our sale of Entera’s shares as discussed below under “Our Business—Out-Licensed Technology,” that was recognized in the year ended August 31, 2011.

Investing activities provided cash of $454,227 in the three months ended November 30, 2012, as compared to $448,939 in the three months ended November 30, 2011. Cash provided by investing activities in the three months ended November 30, 2012 consisted primarily of proceeds from short-term bank deposits. Cash provided by investing activities in the three months ended November 30, 2011 consisted primarily of proceeds from the sale of our investment in Entera. Investing activities provided cash of $1,768,898 in the year ended August 31, 2012, as compared to $1,703,430 used in investing activities in the year ended August 31, 2011. Cash provided by investing activities in the year ended August 31, 2012 consisted primarily of proceeds from short-term bank deposits and proceeds from the sale of our investment in Entera. In the year ended August 31, 2011, cash used in investing activities consisted primarily of purchasing short term investments.

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Financing activities provided cash of $1,458,436 in the three months ended November 30, 2012, as compared to $0 for the three months ended November 30, 2011. Cash provided by financing activities during the three months ended November 30, 2012 consisted of proceeds from our issuance of common stock and warrants as further discussed below. Financing activities provided cash of $3,488,942 in the year ended August 31, 2012 and $3,694,212 in the year ended August 31, 2011. Cash provided by financing activities during both periods consisted of proceeds from our issuance of common stock and warrants.

During the three months period ended November 30, 2012, of the $10,058 OCS grants we recognized during such period, we received none towards our research and development expenses, as was also the case in the three months ended November 30, 2011. The amounts that were recognized but not received during the three months ended November 30, 2012 are expected to be received from the OCS following the submission of periodic and final reports by Oramed Ltd., and their examination by the OCS. The OCS has supported our activity in the past three years.

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

During fiscal years 2012 and 2011 we issued a total of 89,970 shares of common stock to various third party vendors for services rendered. The aggregate value of those shares was approximately $335,429. We also consummated three private placements by selling 967,662 and 801,852 “units” at a purchase price of $3.84 and $4.44 per unit, respectively, for total consideration of $3,715,800 and $3,560,192, respectively. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 and 0.50, respectively, of a share of common stock at an exercise price of $6.00 per share.

Our recent financing activities include the following:

- In January 2011, we issued a total of 8,334 shares of our common stock, valued at $30,000, in the aggregate, to a third party as remuneration for services rendered.

- In February 2011, we granted options to purchase up to 20,834 shares of our common stock, at an exercise price of $6.00 per share, to a consultant for services rendered. The options vest in five annual installments commencing in February 2012 and expiring in February 2021. The initial fair value of the options on the date of grant was $62,185, calculated using the Black-Scholes option-pricing model, and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 78.65%; risk-free interest rates of 3.42%; and the remaining contractual life of 10 years. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

- In March 2011, we completed a private placement pursuant to which we sold to the investors an aggregate of 873,961 “units” at a purchase price of $3.84 per unit for total consideration of $3,356,000. Each unit consisted of one share of our common stock and a five-year warrant to purchase 0.35 of a share of our common stock at an exercise price of $6.00 per share. We also issued 16,397 shares of our common stock and warrants to purchase 5,906 shares of our common stock as finders’ fees in connection with the private placement. These amounts include the $250,000 investment by D.N.A in connection with our technology transaction on March 31, 2011.

- In April 2011, we granted 3,584 options to a third-party as remuneration for services rendered at an exercise price of $6.00 per share (higher than the traded market price on the date of grant). The options vested immediately on the date of grant and will expire in April 2016. The fair value of these options on the date of grant was $10,000, calculated using the Black-Scholes option-pricing model, and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 79.24%; risk-free interest rates of 2.06%; and the remaining contractual life of five years.

- In April 2011, we completed a private placement pursuant to which we sold to the investors an aggregate of 93,701 "units" at a purchase price of $3.84 per unit for total consideration of $359,800. Each unit consisted of one share of our common stock and a five-year warrant to purchase 0.35 of a share of our common stock at an exercise price of $6.00 per share. We also issued five year warrants to purchase 5,622 shares of our common stock at an exercise price of $6.00 per share and paid $21,588 as finders' fees in connection with the private placement.

- In May 2011, we issued 14,744 shares of our common stock, valued at $47,769, in the aggregate, to a third party as remuneration for services rendered.

- In May 2011, we issued 16,667 shares of our common stock, valued at $60,000, in the aggregate, to a third party as remuneration for services to be rendered.

- In July 2011, we issued warrants to purchase 2,667 shares of our common stock at an exercise price of $6.00 per share to a third-party as remuneration for services rendered during the 12 month period commencing in May 2011. The warrants vest in twelve equal annual installments commencing in October 2011 and will expire in July 2016. The fair value of these warrants on the date of grant was $5,057, calculated using the Black-Scholes option-pricing model, and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 77.39%; risk-free interest rates of 1.55%; and the remaining contractual life of five years.

- In December 2011, we issued 6,917 shares of our common stock, valued at $24,900, in the aggregate, to an advisor as remuneration for services rendered.

- In February 2012, we issued warrants to purchase 62,500 shares of our common stock at an exercise price of $6.00 per share to an advisor as remuneration for services to be rendered during the 12 month period commencing in February 2012. The warrants vest in 12 equal monthly installments commencing in February 2012 and will expire in February 2017. The fair value of these warrants on the date of grant was $171,236, calculated using the Black-Scholes option-pricing model, and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 76.82%; risk-free interest rates of 0.81%; and the remaining contractual life of five years.

- In March 2012, we issued 11,084 shares in the aggregate of our common stock, valued at $38,570, to two advisory companies as remuneration for services rendered.

- In May 2012, we issued 6,917 shares of our common stock, valued at $24,900, in the aggregate, to an advisor as remuneration for services rendered.

- In July 2012, we issued 4,167 shares of our common stock, valued at $16,000, in the aggregate, to an advisor as remuneration for services rendered.

- Between August and November 2012, we completed private placements pursuant to which we sold to the investors an aggregate of 1,137,336 "units" at a purchase price of $4.44 per unit for total consideration of $5,049,710. Each unit consisted of one share of our common stock and a five-year warrant to purchase 0.50 of a share of our common stock at an exercise price of $6.00 per share. We paid cash compensation of $84,135 as a finder's fee. We also issued 1,127 shares of our common stock and warrants to purchase 564 shares of our common stock as a finder's fee to a third party in connection with the private placements and issued 12,745 shares of our common stock and warrants to purchase 6,373 shares of our common stock as a finder's fee to Mr. Leonard Sank, one of our directors. The units issued in these private placements, except 11,261 of such units, are included in this prospectus for resale. See "Selling Stockholders." Most of the selling stockholders were granted customary registration rights with respect to resales of shares, including the shares underlying the warrants. Regals participated in such private placements and received certain special rights, including preemptive rights as long as they hold at least 5% of our outstanding common stock. With respect to Regals' participation in the August 2012 private placement, we

undertook to file a registration statement to register their shares and the shares underlying their warrants, by December 27, 2012. Since such registration statement was not timely filed, we may be required to pay liquidated damages of $10,000 or, at Regals' discretion, 27,027 shares of common stock. Such liquidated damages may increase if we do not meet the Effectiveness Deadline as defined in Regals' agreement. The liquidated damages may not exceed, in the aggregate, $100,000. Regals has not notified us that they plan to request such payment, and such damages may be waived by Regals.

• Ιν Οχτοβερ 2012, ωε εντερεδ ιντο α Σεχυριτιεσ Πυρχηασε Αγρεεμεντ ωιτη Δ.Ν.Α, αχχορδινγ το ωηιχη, ωε ισσυεδ το Δ.Ν.Α 199,172 σηαρεσ οφ ουρ χομμον στοχκ ιν χονσιδερατιον φορ τηε Δ.Ν.Α Ωαρραντ. Μρ. Ζεεϖ Βρονφελδ, α χοντρολλινγ σηαρεηολδερ οφ Δ.Ν.Α, βενεφιχιαλλψ οωνεδ 7.1% οφ ουρ ουτστανδινγ χομμον στοχκ πριορ το τηε τρανσαχτιον. Ασ α ρεσυλτ οφ τηε ηολδινγσ οφ Μρ. Βρονφελδ, τηε Ισραελι Σεχυριτιεσ Αυτηοριτψ, ορ τηε ΙΣΑ, ινφορμεδ Δ.Ν.Α τηατ ιν ιτσ οπινιον τηε προχεδυρε οφ αππροϖινγ τηε τρανσαχτιον βψ Δ.Ν.Α ωασ νοτ ιν αχχορδανχε ωιτη αππλιχαβλε λαω. Ωε, βασεδ ον α λεγαλ οπινιον ωε ρεχειϖεδ φρομ χουνσελ, αρε οφ τηε οπινιον τηατ τηε προχεδυρε ωασ ιν ορδερ, βασεδ ον πρεχεδεντσ ανδ χουνσελ σ εξπεριενχε ωιτη σιμιλαρ χασεσ. Ωε ηαδ πρεϖιουσλψ αχθυιρεδ 8,404,667 ορδιναρψ σηαρεσ οφ Δ.Ν.Α ισσυεδ ιν Μαρχη 2011 ασ φυρτηερ δισχυσσεδ ιν Ουρ Βυσινεσσ Ουτ−Λιχενσεδ Τεχηνολογψ. Ιν Φεβρυαρψ 2013, φολλοωινγ ρεχειπτ βψ Δ.Ν.Α οφ ΤΑΣΕ αππροϖαλ το λιστ τηε ορδιναρψ σηαρεσ οφ Δ.Ν.Α ισσυαβλε υπον εξερχισε οφ τηε Δ.Ν.Α Ωαρραντ, ωε σεντ το Δ.Ν.Α αν εξερχισε νοτιχε το εξερχισε τηε Δ.Ν.Α Ωαρραντ. Ιν αδδιτιον, ιν Φεβρυαρψ 2013 ωε σολδ 3,500,000 οφ τηε Δ.Ν.Α σηαρεσ τηατ ωερε ισσυεδ το υσ ιν Μαρχη 2011. Τηε σηαρεσ ωερε σολδ ιν α πριϖατε τρανσαχτιον φορ α τοταλ οφ ΝΙΣ 420,000 (ορ αππροξιματελψ ∃114,000, βασεδ ον τηε εξχηανγε ρατε βετωεεν τηε ΝΙΣ ανδ τηε Υ.Σ. δολλαρ, ασ θυοτεδ βψ τηε Βανκ οφ Ισραελ ον τηε δατε οφ σαλε), βεφορε βροκεραγε φεεσ. Ασ οφ Φεβρυαρψ 19, 2013 ωε οων αππροξιματελψ 2.6% οφ Δ.Ν.Α σ ουτστανδινγ ορδιναρψ σηαρεσ, ανδ, φολλοωινγ τηε εξερχισε οφ τηε Δ.Ν.Α Ωαρραντ, οων αππροξιματελψ 12.8% οφ Δ.Ν.Α σ ορδιναρψ σηαρεσ. Πυρσυαντ το τηε Ισραελ Σεχυριτιεσ Λαω, τηε ρεμαινινγ ορδιναρψ σηαρεσ οφ Δ.Ν.Α τηατ ωε οων αρε συβφεχτ το χερταιν ρεστριχτιονσ ον σαλε. Ιν αδδιτιον, εϖεν ιφ συχη ρεστριχτιονσ αρε νο λονγερ αππλιχαβλε, τηε μαρκετ πριχε φορ Δ.Ν.Α σ ορδιναρψ σηαρεσ μαψ δεχλινε, ωηιχη χουλδ ρεσυλτ ιν α λοσσ το υσ ιφ ωε σελλ συχη σηαρεσ ατ α πριχε βελοω τηε ϖαλυε ον τηε δατε ωε αχθυιρεδ συχη σηαρεσ. Τηε ορδιναρψ σηαρεσ οφ Δ.Ν.Α ηαϖε ηιστοριχαλλψ εξπεριενχεδ λοω τραδινγ ϖολυμε; ασ α ρεσυλτ τηερε ισ νο γυαραντεε τηατ ωε ωιλλ βε αβλε το ρεσελλ ουρ ρεμαινινγ ορδιναρψ σηαρεσ οφ Δ.Ν.Α ατ τηε πρεϖαιλινγ μαρκετ πριχεσ.

• In November 2012, we entered into the Agreement with Regals in connection with the Warrants. Pursuant to the Agreement, we and Regals agreed to amend the Warrants to provide that the anti-dilution protection of the Warrants shall be deleted in its entirety. In addition, as to the warrants issued in August and November 2012, the parties agreed to reduce the exercise price to $3.7656 per share, the current exercise price per share of the warrants originally issued in January 2011. At such time, we also issued to Regals the New Warrant. All such warrant shares issued to Regals are included in this prospectus for resale. See “Selling Stockholders.”

• In connection with the New Warrant, Nadav Kidron, our President, Chief Executive Officer and a director, in his personal capacity as one of our stockholders, agreed that following the execution and delivery of the Agreement, in the event that an adjustment pursuant to the anti-dilution protection of the Warrants (had they not been amended by the Agreement) would have been triggered and the number of shares of our common stock that Regals would have been able to purchase under the Warrants would have increased by an aggregate number in excess of 137,311 common shares, then Regals shall have the right to purchase from Mr. Kidron such number of shares of our common stock owned by Mr. Kidron, up to a maximum of 112,690 shares of our common stock. This right shall survive until the termination of the Warrants.

Off-Balance Sheet Arrangements

As of August 31, 2012 and November 30, 2012, we had no off balance sheet arrangements that have had or that we expect would be reasonably likely to have a future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

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 February 1, 2013 are as follows:

Category	Amount
Research and development, net of OCS funds	$ 3,616,000
General and administrative expenses	1,026,000
Financial income, net	(12,000)
Total	$ 4,630,000

As indicated above, in December 2012 we filed an IND application with the FDA for our orally ingested insulin and we are conducting, or planning to conduct, further clinical studies with our exenatide capsule and the combination therapy, respectively, and others. We expect to have a significant increase in research and development expenses during the term of the FDA approved Phase 2 study that will be conducted during fiscal year 2013. Our ability to complete these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us and receiving additional grants from the OCS.

OUR BUSINESS

General

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

Oral Insulin: We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801). 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.

GLP-1 Analog: Our second pipeline product is orally ingestible exenatide (GLP-1 analog) capsule, which aids in the balance of blood-sugar levels and decreases appetite. Results of a trial on healthy volunteers and type 2 diabetic patients are expected in the first quarter of calendar year 2013.

Combination of Oral Insulin and GLP-1 Analog: Our third pipeline product is a combination of our two primary products, oral insulin and oral exenatide. Preliminary results of this trial were announced in June 2012. The results showed that our two main products have greater positive effects when given together, as a combination therapy, above the administration of each product alone. A human clinical trial on healthy volunteers is expected to commence in the first quarter of calendar year 2013.

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, an estimated 371 million people worldwide suffered from diabetes in 2012. In 2012, an estimated 4.8 million people died from consequences of high blood sugar. According to the American Diabetes Association, or ADA, in the United States there were approximately 25.8 million people with diabetes, or 8.3% of the U.S. population in 2010. Diabetes is a leading cause of blindness, kidney failure, heart attack, stroke and amputation.

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

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

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

Strategy

Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins," which we acquired from Hadasit in 2006 and which is pending in various foreign jurisdictions, as well as the other patents we have filed in various foreign jurisdictions since then, as discussed below under "—Patents and Licenses" and above under "Risk Factors." Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin or other proteins, such as exenatide, for the treatment of diabetes. The enzymes and vehicles that are added to the proteins in the formulation process must not modify the proteins chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. On December 31, 2012, we filed an IND application with the FDA to begin a Phase 2 clinical trial of our orally ingested insulin capsule, in order to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. We have been communicating with the FDA regarding our IND, and, according to FDA requirements, intend to conduct a sub study before we begin the main clinical trial. We began conducting a clinical trial of our orally ingested exenatide in January 2013, and plan to conduct a trial of the combination of the two proteins in the first quarter of calendar year 2013. Clinical trials are planned in order to substantiate our results as well as for purposes of making future filings for drug approval. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

Long Term Business Strategy

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

Other Planned Strategic Activities

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

Product Development

Orally Ingestible Insulin

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

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

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

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

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

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

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

In September 2012, we entered into a Master Services Agreement with Medpace to retain Medpace as a CRO for our upcoming Phase 2 clinical trial for an oral insulin capsule that is expected to start in the first calendar quarter of 2013 in the United States, and is expected to be completed in December 2013. As consideration for its services, we will pay Medpace a total amount of approximately $3,500,000 during the term of the engagement, based on the achievement of certain milestones.

In December 2012, we filed an IND application with the FDA for a Phase 2 clinical trial of our orally ingested insulin candidate, ORMD0801. We have been communicating with the FDA regarding our IND, and, according to FDA requirements, intend to conduct a sub study before we begin the main clinical trial.

GLP-1 Analog

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

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

In September 2009, we received approval from the IRB to commence human clinical trials of an oral GLP-1 analog. The approval was granted after successful pre-clinical results were reported. The trials were conducted on healthy

male volunteers at Hadassah University Medical Center in Jerusalem. These first-in-humans clinical trials were testing the safety and efficacy of ORMD0901, an encapsulated oral GLP-1 analog formulation. The study monitored the responses of healthy males to a single dose delivered 60 minutes before a glucose load and was completed in December 2009. ORMD0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

A further clinical trial for our exenatide capsule on healthy volunteers and type 2 diabetic patients began in January 2013. We expect to receive results from such trial in the first quarter of calendar year 2013.

Combination Therapy

In June 2012, we presented an abstract, which reported on the impact of our oral insulin capsule ORMD0801 delivered in combination with our oral exenatide capsule ORMD0901. The work that was presented assessed the safety and effectiveness of a combination of oral insulin and oral exenatide treatments delivered to pigs prior to food intake. The drug combination resulted in significantly improved blood glucose regulation when compared to administration of each drug separately. A clinical trial is expected to commence in the first quarter of calendar year 2013.

Raw Materials

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

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

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

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

Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 35 patent applications currently pending, with respect to various compositions, methods of production and oral administration of proteins and exenatide. Expiration dates for pending patents, if granted, will fall between 2026 and 2032.

In January 2012, we received the approval for a key patent by the Australian Patent Office. The patent covers an important part of our core technology which allows for the oral delivery of peptides.

In January 2012, we filed a provisional patent application with the U.S. Patent and Trademark Office for a combination therapy of our lead compound, ORMD0801, in combination with our oral GLP-1 analog formulation, ORMD0901.

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

In May 2012, we were issued a patent by each of the Israeli Patent Office, which covers part of our technology with respect to oral delivery of peptides, and the New Zealand Patent Office, which covers part of our technology with

respect to oral exenatide compositions.

In December 2012, we were issued a patent by the South African Patent Office, which covers part of our technology with respect to oral delivery of peptides.

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

Our patent strategy is as follows:

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

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

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

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

Partnerships and Collaborative Arrangements

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

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

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

In February 2012, we entered into an advisory agreement with a third party advisor for a period of one year, pursuant to which the advisor agreed to provide investor relations services for share based compensation as follows: 25,000

shares of our common stock will be issued in six installments over the engagement period, commencing as of February 15, 2012, and a warrant to purchase 62,500 shares of our common stock. The warrant has a term of five years and an exercise price of $6.00 per share and vests in 12 monthly installments over the first year of the agreement. In July 2012, we and the advisor entered into an amendment to the agreement, according to which the original agreement was extended until July 3, 2013 (unless terminated earlier by one of the parties), and a new payment and vesting schedule was determined as of such date for the remaining share based compensation and unvested warrant shares, respectively, until the end of the new term of the agreement. As of November 30, 2012, 8,334 shares of our common stock had been issued to the advisor, and 33,334 of the warrant shares had vested.

In September 2012, we entered into a Master Services Agreement with Medpace to retain Medpace as a CRO for our upcoming Phase 2 clinical trial for an oral insulin capsule that is expected to start in the first calendar quarter of 2013 in the United States, and is expected to be completed in December 2013. As consideration for its services, we will pay Medpace a total amount of approximately $3,500,000 during the term of the engagement, based on the achievement of certain milestones.

Out-Licensed Technology

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

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

In March 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, we received a promissory note issued by D.N.A in the principal amount of $450,000, with an annual interest rate of 0.45%, to be paid within four months after closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately $581,977 as of March 31, 2011 ($200,311 as of November 30, 2012). The promissory note was secured by a personal guarantee of the D.N.A majority shareholders and its term was extended in August 2011. D.N.A paid off the promissory note in November 2011. The ordinary shares of D.N.A were restricted for six months from the closing. In February 2013 we sold 3,500,000 of the D.N.A shares that were issued to us in March 2011. The shares were sold in a private transaction for a total of NIS 420,000 (or approximately $114,000, based on the exchange rate between the NIS and the U.S. dollar, as quoted by the Bank of Israel on the date of sale), before brokerage fees. Pursuant to the Israel Securities Law, the remaining ordinary shares of D.N.A that we own are subject to certain additional restrictions on sale through the market, which will expire on March 31, 2013. Following that date, the market price for D.N.A's ordinary shares may decline, which could result in a loss to us if we sell such shares at a price below the value on the date we acquired such shares. The ordinary shares of D.N.A have historically experienced low trading volume; as a result there is no guarantee that we will be able to resell our remaining ordinary shares of D.N.A at the prevailing market prices. In addition, D.N.A invested $250,000 in our private placement investment round, which closed in March 2011, for which it received 65,105 shares of our common stock and a five-year warrant to purchase 22,787 shares of our common stock at an exercise price of $6.00 per share.

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

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

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

Government Regulation

The Drug Development Process

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

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

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

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

- Who must be recruited as qualified participants,
- How often to administer the drug or product,
- What tests to perform on the participants, and
- What dosage of the drug or amount of the product to give to the participants.

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

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

Phase 1. Phase 1 studies involve testing a drug or product on a limited number of healthy participants, typically 24 to 100 people at a time. Phase 1 studies determine a product's basic safety and how the product is absorbed by, and

eliminated from, the body. This phase lasts an average of six months to a year.

Phase 2. Phase 2 trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase 2 testing typically lasts an average of one to two years. In Phase 2, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase 2 testing also involves determining acceptable dosage levels of the drug. If Phase 2 studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will generally continue to review the substance in Phase 3 studies.

Phase 3. Phase 3 studies involve testing large numbers of participants, typically several hundred to several thousand persons. The purpose is to verify effectiveness and long-term safety on a large scale. These studies generally last two to three years. Phase 3 studies are conducted at multiple locations or sites. Like the other phases, Phase 3 requires the site to keep detailed records of data collected and procedures performed.

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

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

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