

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

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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.

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## PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Before making an investment decision, you should read the entire prospectus carefully, including the 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 shares <sup>1</sup> .
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares of our common stock being offered for sale by the selling stockholders. However, we may receive up to approximately \$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.

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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 patent prosecutions,
- Competing technological and market developments,
- Our ability to establish additional collaborative relationships, and
- Effects of commercialization activities and facility expansions if and as required.

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

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

We are a development stage company with no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which could generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of 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
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