ORAMED PHARMACEUTICALS INC.
Form S-1
March 25, 2011

As filed with the Securities and Exchange Commission on March 24, 2011

Registration No. 333

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ORAMED PHARMACEUTICALS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	2834	98-0376008
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Hi-Tech Park 2/5
Givat-Ram
PO Box 39098
Jerusalem 91390, Israel
Telephone: 972-2-566-0001
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Vcorp Services, LLC
1811 Silverside Road
Wilmington, Delaware 19810
Telephone: (888) 528 2677
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement, as determined by market and other conditions.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount To Be Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee (3)
Common Stock, $0.001 par value (4)	13,993,217	$ 0.27	$ 3,778,168	$ 438.65

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the "Act"), this registration statement shall be deemed to cover any additional number of shares of common stock as may be issued from time to time upon exercise of the warrants or options to prevent dilution as a result of stock splits, stock dividends or similar transactions. No additional consideration will be received for the common stock, and therefore no registration fee is required pursuant to Rule 457(i) under the Act.

(2) Estimated in accordance with Rule 457(c) under the Act, solely for the purpose of calculating the registration fee, based on the average of the high and low prices of our common stock on March 21, 2011, as reported on the OTC Bulletin Board.

(3) Pursuant to Rule 429 under the Securities Act of 1933, the prospectus constituting a part of this registration statement also relates to 30,444,550 shares of Registrant's securities registered under Registration Statement 333-164288, for which a filing fee in the amount of $2,672.73 has previously been paid.

(4) Represents 10,028,000 shares of common stock of Oramed Pharmaceuticals Inc. being registered for resale that have been issued to the selling stockholders and 3,965,217 shares of common stock of Oramed Pharmaceuticals Inc. issuable upon exercise of warrants and options that have been issued to the selling stockholders.

Pursuant to Rule 429(a) under the Securities Act of 1933, the prospectus included in this registration statement is a combined prospectus and also relates to 30,444,550 shares registered and remaining unsold under Registrant's Registration Statement on Form S-1 (No. 333-164288) and amendments thereto. Pursuant to Rule 429(b), this registration statement, upon effectiveness, also constitutes a Post-Effective Amendment to Registration Statement No. 333-164288, which post-effective amendment shall hereafter become effective concurrently with the effectiveness of this registration statement and in accordance with Section 8(c) of the Securities Act of 1933. If securities previously registered under that registration statement are offered and sold before the effective date of this registration statement, the amount of previously registered securities so sold will not be included in the prospectus hereunder.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion. Dated March 24, 2011.

PROSPECTUS

ORAMED PHARMACEUTICALS INC.

44,437,767 SHARES OF COMMON STOCK

The selling stockholders identified in this prospectus may offer from time to time up to 37,269,298 shares of our common stock and 7,168,469 shares of our common stock issuable upon exercise of warrants and options.

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

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

Our common stock is quoted on the OTC Bulletin Board, or the OTCBB, under the symbol “ORMP.OB”. On March 23, 2011, the last reported bid price per share of our common stock as quoted on the OTCBB was $0.27 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 _____.

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You should rely only on the information contained in this prospectus. Neither we nor the selling stockholders have authorized any dealer, salesperson or other person to give any information or to make any representations to you other than the information contained in this prospectus. You must not rely on any information or representations not

contained in this prospectus as if we had authorized it. The information contained in this prospectus is current only as of the date on the cover page of this prospectus and may change after that date. We do not imply that there has been no change in the information contained in this prospectus or in our affairs since that date by delivering this prospectus. Neither we nor the selling stockholders are making an offer of these securities in any state where the offer is not permitted.

As used in this prospectus, the terms “we”, “us”, “our”, the “Company”, “Oramed” and “Oramed Pharmaceuticals” mean Ora Pharmaceuticals Inc., 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 section entitled “Risk Factors”.

THE COMPANY

General

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

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

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

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

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

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

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

Strategy

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

pharmaceutical products.

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

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

Product Development

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

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD 0801). On January 22, 2008, we commenced non-FDA approved Phase 1B clinical trials with our oral insulin capsule (ORMD 0801), in healthy human volunteers with the intent of dose optimization. On March 11, 2008, we successfully completed our Phase 1B clinical trials.

On April 13, 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

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

On March 23, 2011, we reported that we successfully completed a comprehensive toxicity study for our oral insulin capsule (ORMD0801). On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD 0801) on type 2 diabetic volunteers. On May 6, 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

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

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

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

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

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

The raw materials required for the manufacturing of the capsule are purchased from third parties, under separate agreements. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

Out-Licensed Technology

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

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-license 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. D.N.A invested $600,000 in Entera, and Entera was owned in equal parts by Oramed and D.N.A, subject to dilution by future issuances of shares.

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

As part of the transaction, we entered into a patent transfer agreement (to replace the original license agreement upon closing) according to which, Oramed will assign to Entera all of its right, title and interest in and to the patent

application that it has licensed to Entera since August 2010. Under this agreement, Oramed Ltd. is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza.

The closing of the abovementioned transactions will take place concurrently on the first business day following the satisfaction of all the closing conditions. If the closing does not occur by March 31, 2011, Oramed will have the right to terminate the agreements. Upon the closing, Oramed, Entera and D.N.A will terminate the jointventure agreement, entered into on June 1, 2010 in connection with the formation of Entera.

Mr. Zeev Bronfeld, one of D.N.A's directors and controlling shareholders, holds more than 5% of our outstanding common stock. Accordingly, pursuant to Israeli law, the closing of the transactions is subject to the approval of D.N.A's shareholders at its extraordinary general meeting to be held on March 28, 2011.

Recent Business Developments

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

In March, 2011, we consummated a private placement that commenced in November 2010, with a number of accredited investors pursuant to which we agreed to sell to the investors an aggregate of 9,706,250 units at a purchase price of $0.32 per unit for total consideration of $3,106,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of $0.50 per share. We also issued 196,750 shares of common stock and warrants to purchase 70,863 shares of common stock as finders' fees in connection with the private placement.

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	37,269,298 shares of common stock and 7,168,469 shares of common stock issuable upon exercise of warrants and options.
Trading Market	The common stock offered in this prospectus is quoted on the OTCBB under the symbol "ORMP.OB".
Common stock outstanding (as of March 22, 2011)	67,822,035 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 $4.2 million in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have an average exercise price of $0.58 per share and are exercisable into 7,168,469 shares of our common stock. These potential proceeds will be used for the research and development of our products and for general working capital purposes. See "Use of Proceeds."
Plan of Distribution	The selling stockholders, and their pledgees, donees, transferees or other successors in interest, may from time to time offer and sell, separately or together, some or all of the common stock covered by this prospectus. Registration of the common stock covered by this prospectus does not mean, however, that those shares necessarily will be offered or sold. See "Plan of Distribution."
Risk Factors	Please read "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the securities offered in this prospectus.

1 Does not include 20,552,948 shares of our common stock issuable upon the exercise of outstanding options and warrants.

RISK FACTORS

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

Risks Related to Our Business

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

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

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

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

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- effects of commercialization activities and facility expansions if and as required.

If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize

ourselves. In such event, our business, prospects, financial condition, and results of operations may be adversely affected as we may be required to scale-back, eliminate, or delay development efforts or product introductions or enter into royalty, sales or other agreements with third parties in order to commercialize our products.

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, 2010 and August 31, 2010 and 2009, we had working capital of $927,555, $938,225 and $2.8 million, respectively, and stockholders' equity of $814,071, $830,272 and $2.7 million, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through November 30, 2010, the three month period ended November 30, 2010 and the year ended August 31, 2010, we incurred net losses of $13.6 million, $602,784, and $3.0 million, respectively. We may never achieve profitability and expect to incur net losses in the foreseeable future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

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

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