

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

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended August 31, 2009

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 000-50298

ORAMED PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	98-0376008
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

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

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

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

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

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

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

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

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

(Do not check if a smaller reporting company)

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

None.

ORAMED PHARMACEUTICALS, INC.

FORM 10-K

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PART I

ITEM 1 - BUSINESS

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

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

We file reports with the Securities and Exchange Commission (the “SEC” or the “Commission”). We make available on our website under “Investor Information/SEC Filings,” free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Our website address is www.oramed.com. You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

As used in this Annual Report on Form 10-K, the terms “we”, “us”, “our”, the “Company”, and “Oramed” mean Oramed Pharmaceuticals Inc., unless otherwise indicated.

DESCRIPTION OF BUSINESS

General

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

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

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

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

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

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

An estimated 177 million people are suffering from diabetes worldwide. According to the American Diabetes Association, there are 23.6 million children and adults in the United States, or 7.8% of the population, who have diabetes. While an estimated 17.9 million have been diagnosed with diabetes, unfortunately, 5.7 million people (or nearly one quarter) are unaware that they have the disease.

Intellectual Property: The Company owns a portfolio of patents and patent applications covering its technologies and is aggressively protecting these technology developments on a worldwide basis.

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

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

Strategy

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

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

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

Product Development

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

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

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

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

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

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

Rectal Application of Insulin and Other Polypeptides: We filed two additional provisional patents for a suppository application to our technology portfolio. The first patent focuses on a rectal application for insulin. The second patent focuses on the usage of this rectal application to other polypeptides that at present are only available in injection.

On January 30, 2008, we entered into a master service agreement with OnQ Consulting; a clinical research organization located in Johannesburg, South Africa, to conduct non FDA approved clinical trials for the rectal application of insulin. On February 4, 2009, we announced that we had concluded a proof of concept study of the insulin suppositories.

On October 23, 2008 we commenced a non-FDA approved Phase 1A study to evaluate the safety and efficacy of our insulin suppository (ORMD 0802) on healthy volunteers, in South Africa.

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

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

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

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

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

Patents and Licenses

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

- PCT/IL2006/001019, "Methods and Compositions for Oral Administration of Proteins". The patent application was filed on August 31, 2006.
- 11/513,343, "Methods and Compositions for Oral Administration of Proteins". The patent application was filed on August 31, 2006.
- 60/064,779, "Methods and Compositions for Oral Administration of Proteins". The patent application was filed on March 26, 2008.
- PCT/IL2008/000546, "Methods and Compositions for Rectal Application for Insulin". The patent application was filed on April 27, 2008.
- PCT/IL2008/000547, "Methods and Compositions for Rectal Application for Insulin". The patent application was filed on April 27, 2008.
- 61/071,538, "Methods and Compositions for Oral Administration of Exenatide". The patent application was filed on May 5, 2008.

- 61/089,812, “Methods and Compositions for Oral Administration of Proteins”. The patent application was filed on August 18, 2008.

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

Our patent strategy is as follows:

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

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

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

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

Partnerships and Collaborative Arrangements

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

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

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

During January and April 2008, we entered into agreements with OnQ consulting, a clinical research organization (“CRO”) located in Johannesburg, South Africa, to conduct non-FDA Phase 1B and 2B clinical trials on our oral insulin capsules and suppository in South Africa.

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

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

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

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

Government Regulation

The Drug Development Process

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

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

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

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

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

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

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

- **Phase I.** Phase I studies involve testing a drug or product on a limited number of healthy participants, typically 24 to 100 people at a time. Phase I studies determine a product's basic safety and how the product is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year.
- **Phase II.** Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to review the substance in Phase III studies.
- **Phase III.** Phase III studies involve testing large numbers of participants, typically several hundred to several thousand persons. The purpose is to verify effectiveness and long-term safety on a large scale. These studies generally last two to three years. Phase III studies are conducted at multiple locations or sites. Like the other phases, Phase III requires the site to keep detailed records of data collected and procedures performed.

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

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

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

Other Regulations

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

Competition

Competition in General

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

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

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