GENTA INC DE/
Form 10-K
March 28, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2011
Or
o 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 000-19635

GENTA INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	33-0326866
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
200 Connell Drive Berkeley Heights, New Jersey	07922
(Address of principal executive offices)	(Zip Code)

(908) 286-9800
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:

Title of each class:	Name of each exchange on which registered:
Common Stock, $.001 par value	Over-the-Counter Bulletin Board
Series G Participating Cumulative Preferred Stock Purchase Rights	

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

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 o No x

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 x No o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. o

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

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $43,104,028 as of June 30, 2011 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 28, 2012, the registrant had 2,090,399,725 shares of Common Stock outstanding.

Genta Incorporated
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The statements contained in this Annual Report on Form 10-K that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. The words "potentially", "anticipate", "expect", "could", "calls for" and similar expressions also identify forward-looking statements. We intend that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect our views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Factors that could affect actual results include risks associated with:

- the Company's financial projections;
- the Company's projected cash flow requirements and estimated timing of sufficient cash flow;
- the Company's current and future license agreements, collaboration agreements, and other strategic alliances;
- the Company's ability to obtain necessary regulatory approval for its products from the U.S. Food and Drug Administration, or FDA, or European Medicines Agency, or EMA;
- the safety and efficacy of the Company's products;
- the timing of commencement and completion of clinical trials;
- the Company's ability to develop, manufacture, license and sell its products or product candidates;
- the Company's ability to enter into and successfully execute license and collaborative agreements, if any;
- the adequacy of the Company's capital resources and cash flow projections, and the Company's ability to obtain sufficient financing to maintain the Company's planned operations, or the Company's risk of bankruptcy;
- the adequacy of the Company's patents and proprietary rights;
- the impact of litigation that has been brought against the Company and its officers and directors and any proposed settlement of such litigation; and
- the other risks described under "Certain Risk Factors".

We do not undertake to update any forward-looking statements.

We make available free of charge on our internet website (http://www.genta.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The content on our website is available for informational purposes only. It should not be relied upon for investment purposes, nor is it incorporated by reference into this Form 10-K.

PART I

Item 1. Business

Overview

Genta Incorporated, also referred to herein as “us”, “we”, “our”, “Genta” or “the Company”, was incorporated in Delaware February 4, 1988. Genta is a biopharmaceutical company engaged in pharmaceutical (drug) research and development. We are dedicated to the identification, development and commercialization of novel drugs that are chiefly intended for the treatment of cancer and related diseases.

Our principal goals are to secure marketing approval and to profit from subsequent sales of our products. Our lead compound is tesetaxel, a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types. Clinical trials conducted by us have confirmed that the drug has definite antitumor activity in gastric cancer and breast cancer. Tesetaxel appears to be associated with a substantially lower incidence of side effects, particularly hypersensitivity reactions and peripheral nerve damage, both of which are common side effects of taxanes.

We have initiated and completed a number of clinical trials with tesetaxel, including Phase 2 trials of tesetaxel in patients with advanced gastric cancer, breast cancer, bladder cancer, prostate cancer and melanoma. Our ongoing trials are currently open to enrollment at major cancer centers in the U.S., Europe and Asia.

The FDA granted our request for “Fast Track” designation of tesetaxel for treatment of patients with advanced gastric cancer. Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The designation typically enables a company to submit a New Drug Application, or NDA, on a “rolling” basis with ongoing FDA review during the submission process. NDAs with Fast Track designation are also usually granted priority review by the FDA at the time of submission.

The FDA has also granted our request for designation of tesetaxel as an “Orphan Drug” for treatment of patients with advanced gastric cancer. Orphan Drug designation for tesetaxel in gastric cancer was also granted by the EMA. Orphan Drug designation is designed to facilitate the development of new drugs that are intended to treat diseases that affect a small number of patients. We routinely file requests for both Fast Track and Orphan Drug designation, and similar designations in applicable territories, for diseases that fulfill regulatory requirements for such designation.

Our other pipeline project consists of the development of an orally bioavailable gallium-containing compound. We believe the class of gallium compounds may have broad utility to treat diseases associated with accelerated bone loss. These illnesses include cancer-related hypercalcemia (i.e., life-threatening elevation of blood calcium), bone metastases, Paget’s disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. We have supported research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis who have severe infections.

We completed a single-dose Phase 1 clinical study of one such oral gallium compound, known as G4544a. Since then, we have synthesized additional compounds of this class with the goal of identifying a potential lead compound for further clinical testing. Some of these compounds have been tested in animals to evaluate their oral absorption. If we are able to identify a potentially acceptable formulation of an oral gallium-containing compound, we may evaluate whether an expedited regulatory approval may be possible.

In 2011, we reported results from a Phase 3 randomized trial of Genasense® in advanced melanoma. This trial, known as AGENDA, failed to achieve its primary endpoint of improving overall survival. Given these results, we terminated further internal development of Genasense® and redirected our resources to other programs.

In the U.S. we are currently marketing Ganite®, which is an intravenous formulation of gallium nitrate, for treatment of cancer-related hypercalcemia that is resistant to hydration. Sales of Ganite® have been very low due to our under-investment in its marketing and an inconvenient dosing schedule. Since the relevant patents on Ganite® have expired, we do not plan to substantially increase our investment in the drug. We believe the product may have strategic importance for our franchise of gallium-containing compounds, especially regarding the previously noted oral gallium compounds.

Summary of Business and Research and Development Programs

Our goal is to establish Genta as a biopharmaceutical leader and preferred partner in the oncology market and eventually, as direct marketers of our products in the United States. Our key strategies in this regard are:

- Build on our core competitive strength of oncology development expertise to establish a leadership position in providing biopharmaceutical products for the treatment of cancer;
- Secure a “first-to-market” position for our oral taxane, tesetaxel;
- Develop a first-in-class oral gallium-containing compound for skeletal diseases and other uses;
- Partner with other companies to defer part of the expenses associated with clinical development of our products; and
- Establish a sales and marketing presence in the U.S. oncology market.

Research and Development Programs

Tesetaxel

In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company, Limited. Tesetaxel is a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types. Clinical trials conducted by us have confirmed that the drug has definite antitumor activity in gastric cancer and breast cancer. Tesetaxel appears to be associated with a substantially lower incidence of side effects, particularly hypersensitivity reactions and peripheral nerve damage, both of which are common side effects of taxanes.

We have initiated and completed a number of clinical trials with tesetaxel, including Phase 2 trials of tesetaxel in patients with advanced gastric cancer, breast cancer, bladder cancer, prostate cancer, and melanoma. Our ongoing trials are currently open to enrollment at major cancer centers around the world.

The FDA has granted the Company’s request for “Fast Track” designation of tesetaxel for treatment of patients with advanced gastric cancer. Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The designation typically enables a company to submit a NDA on a “rolling” basis with ongoing FDA review during the submission process. NDAs with Fast Track designation are also usually granted priority review by the FDA at the time of submission.

The FDA has also designated tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Orphan Drug designation for tesetaxel in gastric cancer was also granted by the EMA. Orphan Drug designation is designed to facilitate the development of new drugs that are intended to treat diseases that affect a small number of patients. We routinely file for both Fast Track and Orphan Drug designations, and similar designations in applicable territories, for diseases that fulfill regulatory requirements for such designation.

Tesetaxel Background Information

Tesetaxel is a structurally novel oral semi-synthetic taxane. Taxanes, such as paclitaxel (Taxol®) and docetaxel (Taxotere®), are mainstays of modern anticancer therapy. These drugs are believed to kill cancer cells by disrupting critical proteins that maintain the structure of cancer cells. More recent research suggests that they may also disrupt the blood supply to malignant tumors (i.e., an “antiangiogenic” effect). Because of their antitumor efficacy, taxanes are the most widely used class of drugs for treatment of patients with advanced cancer.

Certain taxanes have been approved by the FDA for the treatment of breast, lung, ovarian, gastric, and prostate cancers. However, all currently approved taxanes require IV infusion under close medical supervision due to a high level of toxicity. For example, both paclitaxel and docetaxel can cause severe, occasionally fatal hypersensitivity reactions, which require pre-medication with corticosteroids and antihistamines to ameliorate their severity. Other serious reactions associated with taxanes include long-lasting damage to peripheral nerves (neuropathy).

With tesetaxel, we hope to provide patients with an oral taxane that retains the broad anticancer activity of the IV drugs, while providing substantially improved safety. Tesetaxel is administered by mouth, which obviates the risk of taxane-related hypersensitivity reactions and the need for associated premedications and extended medical and nursing observation. Oral dosing provides a high level of convenience for patients, physicians and nurses, and increases dosing flexibility.

Tesetaxel Mechanisms of Action and Preclinical Studies

Tesetaxel stabilizes cytoskeletal structures known as microtubules. This effect induces potent cancer killing effects in a wide range of tumor cell types. Microtubule stabilization occurs when tesetaxel binds the beta-tubulin subunit in assembled microtubules, thus “locking” them in place.

Preclinical studies have shown that tesetaxel inhibited tubulin depolymerization, which resulted in the inhibition of mitosis by arresting tumor cells at G2/M phase. The cytotoxic activity of tesetaxel against various types of human tumor cell lines was about 10-fold and 3-fold greater than paclitaxel and docetaxel, respectively. In particular, tesetaxel exhibited much greater cytotoxicity against multidrug-resistant cell lines that constitutively over-expressed a substance known as the P-glycoprotein, or Pgp. Pgp acts as a pump that can rapidly eliminate drugs such as taxanes from inside cancer cells, thereby markedly reducing their effectiveness. Over-expression of Pgp is a major cause of so-called “multidrug resistance”, and high levels of Pgp in cancer cells are linked to a lack of clinical sensitivity to standard taxanes. However, tesetaxel is not susceptible to Pgp, and as such can be used in cancers that are generally considered unresponsive to standard taxanes. Experimentally, the anti-tumor activity of tesetaxel against Pgp-expressing cells was greater than paclitaxel and docetaxel both in vitro and in vivo.

Tesetaxel Clinical Development

Tesetaxel has already been studied in a number of Phase 1 and Phase 2 studies, encompassing more than 400 patients. Preliminary activity has been observed in patients with advanced gastric cancer and advanced breast cancer. In these studies, the most common side-effect was neutropenia, a hematological disorder characterized by a low number of white blood cells. We have identified priority indications for clinical development, including gastric, prostate, breast and bladder cancer, and we have initiated new or confirmatory trials in each of these diseases.

We believe that gastric cancer may represent the best opportunity for regulatory approval. Accordingly, we have designed a prospective, randomized, Phase 3 trial, and we have discussed this trial with regulatory authorities in the United States, Europe, and Japan. Pending completion of these discussions, adequacy of funding, and other matters, we believe this trial can be initiated during 2012. A positive result from this trial that yields regulatory approval may

enable us to commercially launch tesetaxel by 2015.

Ganite®

Ganite® as a Treatment for Cancer-Related Hypercalcemia

On October 6, 2003, we began marketing Ganite® for the treatment of cancer-related hypercalcemia. Ganite® is our first drug to receive marketing approval. The principal patent covering the use of Ganite® for its approved indication, including potential extensions under Hatch-Waxman provisions in the U.S., expired in April 2005.

Hypercalcemia is a life-threatening condition caused by excessive buildup of calcium in the bloodstream, which may occur in up to 20% of cancer patients. Gallium nitrate was originally studied by the National Cancer Institute, or NCI, as a new type of cancer chemotherapy. More than 1,000 patients were treated in Phase 1 and Phase 2 trials, and the drug showed promising antitumor activity against non-Hodgkin's lymphoma, or NHL, bladder cancer and other diseases. In the course of these studies, gallium nitrate was also shown to strongly inhibit bone resorption. Gallium nitrate underwent additional clinical testing and was approved by the FDA in 1991 as a treatment for cancer-related hypercalcemia. Lower doses of Ganite® were also tested in patients with less severe bone loss, including bone metastases, a cancer that has spread to bone, Paget's disease, an affliction of older patients that causes pain and disability, and osteoporosis.

Side effects of Ganite® include nausea, diarrhea and kidney damage. A complete listing of Ganite®'s side effects is contained in the product's Package Insert that has been reviewed and approved by the FDA.

Other Pipeline Products and Technology Platforms

Oral Gallium-Containing Compounds

We have sought to develop novel formulations of gallium-containing compounds that can be taken orally and that will have extended patent protection. Such formulations might be useful for diseases in which long-term low-dose therapy is deemed desirable, such as bone metastases, Paget's disease and osteoporosis. A number of candidate formulations have been developed in this collaboration. In August 2007, we submitted an Investigational New Drug Application, or IND, to the Endocrinologic and Metabolic Drugs Division of the FDA for an experimental compound known as G4544. G4544 is a new tablet formulation that enables oral absorption of the active ingredient contained in Ganite®. We were not satisfied with results obtained with G4544 and have decided to pursue further discovery work. Several patents related to new gallium-containing products have been filed or issued. These patents and filings provide for claims of compositions and uses of gallium compounds that can be taken by mouth over extended periods for treatment of skeletal diseases as well as other indications.

Patents and Proprietary Technology

It is our policy to protect our technology by filing patent applications with respect to technologies important to our business development. To maintain our competitive position, we also rely upon trade secrets, unpatented know-how, continuing technological innovation, licensing opportunities and certain regulatory approvals (such as orphan drug designations).

We own or have licensed patents and applications to numerous aspects of our products and technology, including novel compositions of matter, methods of synthesis and manufacture, methods of controlling gene expression and methods of treating disease.

Tesetaxel, its potential uses, composition, and methods of manufacturing are covered under a variety of patents licensed exclusively from Daiichi Sankyo Company, Limited. We believe that composition-of-matter claims on

tesetaxel extend to at least 2020 in the U.S. and Europe and to 2022 in Japan. Provisions for patent-term extensions beyond 2020 may also be available in the U.S., Europe and Japan that may further their periods of exclusivity once the product is approved for commercialization. A number of other patents have been filed worldwide for this compound. We have also filed several patents on manufacturing methods and compositions of intermediate compounds formed during the manufacturing process of tesetaxel.

The principal patent covering the use of Ganite® for its approved indication, including extensions expired in April 2005. We have filed several applications on novel gallium-containing compounds. At least two of these patents have been issued in the U.S.

The patent positions of biopharmaceutical and biotechnology firms, including Genta, can be uncertain and can involve complex legal and factual questions. Consequently, even though we are currently pursuing our patent applications with the United States and foreign patent offices, we do not know whether any of our applications will result in the issuance of any patents, or if any issued patents will provide significant proprietary protection, or even if successful that these patents will not be circumvented or invalidated. Even if issued, patents may be circumvented or challenged and invalidated in the courts. Because some applications in the United States are kept in secrecy until an actual patent is issued, we cannot be certain that others have not filed patent applications directed at inventions covered by our pending patent applications, or that we were the first to file patent applications for such inventions. Thus, we may become involved in interference proceedings declared by the U.S. Patent and Trademark Office (or comparable foreign office or process) in connection with one or more of our patents or patent applications to determine priority of invention, which could result in substantial costs to us, as well as an adverse decision as to priority of invention of the patent or patent application involved.

Competitors or potential competitors may have filed applications for, or have received patents and may obtain additional patents and proprietary rights relating to, compounds or processes competitive with those of ours. Accordingly, there can be no assurances that our patent applications will result in issued patents or that, if issued, the patents will afford protection against competitors with similar technology. We cannot provide assurance that any patents issued to Genta will not be infringed or circumvented by others, nor can there be any assurance that we will obtain necessary patents or technologies or the rights to use such technologies.

In addition, there may be patents which are unknown to us and which may block our ability to make, use or sell our products. We may be forced to defend ourselves against charges of infringement or we may need to obtain expensive licenses to continue our business. See the Risk Factor below, entitled “We may be unable to obtain or enforce patents, other proprietary rights and licenses to protect our business; we could become involved in litigation relating to our patents or licenses that could cause us to incur additional costs and delay or prevent our introduction of new drugs to market”.

We also rely upon unpatented trade secrets. No assurances can be given as to whether third parties will independently develop substantially equivalent proprietary information and techniques, or gain access to our trade secrets, or disclose such technologies to the public, or that we can meaningfully maintain and protect unpatented trade secrets.

We require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements with us. These agreements generally provide that all confidential information developed or made known to an individual during the course of the individual’s relationship with Genta shall be kept confidential and shall not be disclosed to third parties except in specific circumstances. In the case of employees, the agreement generally provides that all inventions conceived by the individual shall be assigned to, and made the exclusive property of, Genta. There can be no assurance, however, that these agreements will provide meaningful protection for our trade secrets, or guarantee adequate remedies in the event of unauthorized use or disclosure of confidential proprietary information or in the event of an employee’s refusal to assign any patents to Genta in spite of his/her contractual obligation.

License Agreements

Our license agreement for tesetaxel with Daiichi Sankyo Company, Limited, dated March 7, 2008, has a term that continues until when we have no remaining royalty payment obligations to Daiichi Sankyo. Either party may terminate the agreement as a result of a material breach by the other party. The royalty rate that we may be obligated to pay to Daiichi Sankyo ranges in the low to mid teens of aggregate annual net sales, on a sliding scale depending on sales volume. We are required to pay royalties to Daiichi Sankyo on a country-by-country basis until the later of (i) 10 years from the first commercial sale of such product in such country (which has not yet occurred) or (ii) expiration of the last to expire issued patent (or pending patent application) within the Daiichi Sankyo patents with a valid claim covering such product in such country (which is currently scheduled to expire in 2020). We also may be required to pay certain milestone payments in the aggregate of $68 million contingent upon certain clinical thresholds and a number of regulatory approvals. The aggregate payments we made to Daiichi Sankyo under the agreement from the date of execution of the agreement through December 31, 2011 were $3.5 million.

Research and Development

In addition to our current focus in the areas described above, we continually evaluate our programs in light of the latest market information and conditions, the availability of third party funding, technological advances, financial liquidity and other factors. As a result of such evaluations, we change our product development plans from time to time and anticipate that we will continue to do so. We recorded research and development expenses of $12.4 million during the year ended December 31, 2011 and $10.0 million during the year ended December 31, 2010.

Sales and Marketing

Currently, we do not have a sales force. At the present time, we do not contemplate rebuilding a sales and marketing infrastructure in the United States absent favorable regulatory decisions on at least one of our products. For international product sales, we may distribute our products through collaborations with third parties.

On March 6, 2007, we entered into a distribution and supply agreement with IDIS Limited (a privately owned company based in the United Kingdom). The term of the agreement lasts for three years with automatic one-year renewals unless adequate notice of intent not to renew is provided by either party. The agreement will continue on a product-by-product and country-by-country basis until that product has been granted a marketing authorization for an indication within that country of the territory and we have provided written notice of termination for such product in that country. We may terminate this agreement upon notice to IDIS. Either party may terminate the agreement (i) as a result of a material breach by the other party, (ii) upon the other party’s bankruptcy, insolvency, liquidation, or similar events, (iii) upon any distrait, execution or other process levied or enforced against the property of the other party, or (iv) in the event the other party ceases, or threatens to cease to carry on its business. There are no minimum purchase requirements, but we pay IDIS certain scheduled pricing for product that we order. The amount we pay to IDIS is reflected in our results of operations for each respective period.

Manufacturing and Raw Materials

Our ability to conduct clinical trials on a timely basis, to obtain regulatory approvals and to commercialize our products will depend in part upon our ability to manufacture our products, either directly or through third parties, at a competitive cost and in accordance with applicable FDA and other regulatory requirements, including current Good Manufacturing Practice regulations.

We currently rely on third parties to manufacture our products. We have a manufacturing and supply agreement with Johnson Matthey Inc. whereby we will purchase a minimum of 80% of our requirements for quantities of Ganite®;

however, there are no minimum purchase requirements. The agreement renews automatically at the end of each year, unless either party gives one-year notice.

For tesetaxel, we purchased all remaining quantities of bulk drug substance and finished capsules from Daiichi Sankyo Company, Limited. Current inventory totals approximately 6,000 drug doses, an amount that we project will be sufficient for our projected needs for at least the next 2 years. We are currently evaluating new suppliers of both bulk drug substance and finished goods with the intent of completely replacing the supply chain that was previously used to manufacture this compound.

The raw materials that we require to manufacture our drugs are available only from a few suppliers. We believe that we have adequately addressed our needs for suppliers of raw materials to manufacture tesetaxel and Ganite® and to meet future customer demand.

Human Resources

As of December 31, 2011, we had 21 full-time employees, 6 of whom hold doctoral degrees. As of that date, there were 13 employees engaged in research, development and other technical activities and 8 in administration. None of our employees are represented by a union. Most of our management and professional employees have had prior experience and positions with pharmaceutical and biotechnology companies. We believe we maintain satisfactory relations with our employees and have not experienced interruptions of operations due to employee relations issues.

Government Regulation

Regulation by governmental authorities in the United States and foreign countries is a significant factor in our ongoing research and product development activities and in the manufacture and marketing of our proposed products. All of our therapeutic products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and pre-market approval procedures by the FDA and similar authorities in foreign countries. Various federal, and in some cases, state statutes and regulations, also govern or affect the development, testing, manufacturing, safety, labeling, storage, recordkeeping and marketing of such products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable federal and, in some cases, state statutes and regulations, require substantial expenditures. Any failure by us, our collaborators or our licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the marketing of our products and our ability to receive products or royalty revenue.

The activities required before a new pharmaceutical agent may be marketed in the United States begin with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies must be submitted to the FDA as part of an IND. An IND becomes effective within 30 days of filing with the FDA unless the FDA imposes a clinical hold on the IND. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence, as the case may be, without prior FDA authorization, and then only under terms authorized by the FDA.

Clinical trials are generally categorized into four phases.

Phase 1 trials are initial safety trials on a new medicine in which investigators attempt to establish the dose range tolerated by a small group of patients using single or multiple doses, and to determine the pattern of drug distribution and metabolism.

Phase 2 trials are clinical trials to evaluate efficacy and safety in patients afflicted with a specific disease. Typically, Phase 2 trials in oncology comprise 14 to 50 patients. Objectives may focus on dose-response, type of patient, frequency of dosing or any of a number of other issues involved in safety and efficacy.

In the case of products for life-threatening diseases, the initial human testing is generally done in patients rather than in healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such studies may provide results traditionally obtained in Phase 2 trials.

Phase 3 trials are usually multi-center, comparative studies that involve larger populations. These trials are generally intended to be pivotal in importance for the approval of a new drug. In oncology, Phase 3 trials typically involve 100 to 1,000 patients for whom the medicine is eventually intended. Trials are also conducted in special groups of patients or under special conditions dictated by the nature of the particular medicine and/or disease. Phase 3 trials often provide much of the information needed for the package insert and labeling of the medicine. A trial is fully enrolled when it has a sufficient number of patients to provide enough data for the statistical proof of efficacy and safety required by the FDA and others. After a sufficient period of follow-up has elapsed to satisfactorily evaluate safety and efficacy, the trials' results can then be analyzed. Those results are then commonly reported at a scientific meeting, in a medical journal and to the public.

Depending upon the nature of the trial results, a company may then elect to discuss the results with regulatory authorities, such as the FDA. If the company believes the data may warrant consideration for marketing approval of the drug, the results of the preclinical and clinical testing, together with chemistry, manufacturing and control information, are then submitted to the FDA for a pharmaceutical product in the form of a NDA. In responding to a NDA, biologics license application or premarket approval application, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that the approvals that are being sought or may be sought by us in the future will be granted on a timely basis, if at all, or if granted will cover all the clinical indications for which we are seeking approval or will not contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use. Phase 3b trials are conducted after submission of a NDA, but before the product's approval for market launch. Phase 3b trials may supplement or complete earlier trials, or they may seek different kinds of information, such as quality of life or marketing. Phase 3b is the period between submission for approval and receipt of marketing authorization.

After a medicine is marketed, Phase 4 trials provide additional details about the product's safety and efficacy.

In circumstances where a company intends to develop and introduce a novel formulation of an active drug ingredient already approved by the FDA, clinical and preclinical testing requirements may not be as extensive. Limited additional data about the safety and/or effectiveness of the proposed new drug formulation, along with chemistry and manufacturing information and public information about the active ingredient, may be satisfactory for product approval. Consequently, the new product formulation may receive marketing approval more rapidly than a traditional full new drug application; although no assurance can be given that a product will be granted such treatment by the FDA.

Under European Union regulatory systems, we may submit requests for marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

We and our third-party manufacturers are also subject to various foreign, federal, state and local laws and regulations relating to health and safety, laboratory and manufacturing practices, the experimental use of animals and the use, manufacture, storage, handling and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research and development work and manufacturing processes. We currently incur costs to comply with laws and regulations and these costs may become more significant.

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Competition

In many cases, our products under development will be competing with existing therapies for market share. In addition, a number of companies are pursuing the development of antisense technology and controlled-release formulation technology and the development of pharmaceuticals utilizing such technologies. We compete with fully integrated pharmaceutical companies that have substantially more experience, financial and other resources and superior expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and distribution. Smaller companies may also prove to be significant competitors, particularly through their collaborative arrangements with large pharmaceutical companies or academic institutions. Furthermore, academic institutions, governmental agencies and other public and private research organizations have conducted and will continue to conduct research, seek patent protection and establish arrangements for commercializing products. Such products may compete directly with any products that may be offered by us.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. For certain of our potential products, an important factor in competition may be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we 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. We expect that competition among products approved for sale will be based, among other things, on product efficacy, safety, reliability, availability, price, patent position and sales, marketing and distribution capabilities. The development by others of new treatment methods could render our products under development non-competitive or obsolete.

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection, or otherwise develop proprietary products or processes and secure sufficient capital resources for the often-substantial period between technological conception and commercial sales.

Item 1A. Risk Factors

You should carefully consider the following risks and all of the other information set forth in this Form 10-K before deciding to invest in shares of our common stock. The risks described below are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you may lose all or part of your investment.

Risks Related to Our Business

Our business will suffer if we fail to obtain timely funding.

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, preclinical studies and clinical trials, competitive and technological advances, and regulatory activities of the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other regulatory authorities. In order to commercialize our products, seek new product candidates and continue our research and development programs, we will need to raise additional funds. We have historically financed our activities from the sale of shares of common stock, convertible notes, warrants and proceeds from partnerships with other companies.

Presently, with no further financing, we project that we will run out of funds in April 2012. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize o