

RECD S.E.O.  
MAY 11 2007  
1086

  
07054587

2006 Annual Report



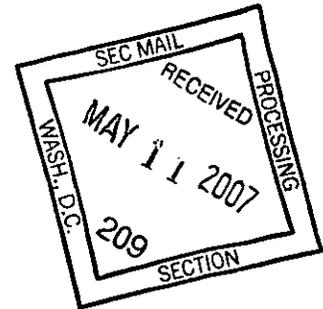
PROCESSED  
MAY 18 2007  
D THOMSON  
FINANCIAL



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

Form 10-KSB

- ANNUAL REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2006
- TRANSITION REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_



Commission File Number: 333-112754

**OSTEOLOGIX, INC.**

(Name of small business issuer in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

425 Market Street, Suite 2230,  
San Francisco, CA

(Address of principal executive offices)

32-0104570

(I.R.S. Employer  
Identification No.)

94105

(Zip Code)

Issuer's telephone number (415) 955-2726

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

Securities registered under Section 12(g) of the Exchange Act:  
Common Stock, \$0.0001 par value

Check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

The registrant is in the development stage and did not report any revenue for the fiscal year ended December 31, 2006.

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was \$6,715,000 as of March 15, 2007. The aggregate market value is based on 21,050,987 shares outstanding less 14,655,451 shares deemed to be held by affiliates.

There were 21,050,987 shares of the issuer's common stock outstanding on March 15, 2007.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement for its 2007 Annual Meeting of Shareholders are incorporated by reference into Part III (Items 9, 10, 11, 12, and 14) hereof.

Transitional Small Business Disclosure Format (check one): YES  NO

## PART I

### Item 1. *Description of Business.*

#### Overview and Company Background

We are in the business of developing pharmaceuticals for the treatment and prevention of diseases of bone and joint tissues. Our lead product candidate, NB S101, is in clinical development for treatment of osteoporosis.

We were initially formed on June 16, 2003 in Denmark as Nordic Bone A/S, based on intellectual property rights for a product to treat osteoporosis. In October 2004, Nordic Bone A/S incorporated a wholly-owned subsidiary in the United States, and in November 2004 Nordic Bone A/S changed its name to Osteologix A/S. From the formation of Osteologix until May 24, 2006, we were 100%-owned by Nordic Biotech K/S, a Copenhagen, Denmark based venture capital firm. On May 24, 2006, Osteologix A/S completed a "reverse merger" transaction with Castle & Morgan Holdings, Inc., a U.S. public company incorporated in Delaware and traded on the Over-the-Counter Bulletin Board. In the merger, Castle and Morgan Holdings, Inc. issued new shares of common stock in exchange for 100% of the issued common stock of Osteologix A/S. Also on May 24, 2006, a subsidiary of Osteologix A/S completed a private placement transaction, raising \$10 million in gross proceeds by issuing new shares of its common stock. Immediately following the merger, Castle & Morgan Holdings, Inc. changed its name to Osteologix, Inc. and the newly issued shares in the subsidiary of Osteologix A/S were exchanged for Osteologix, Inc. shares. As a result of these transactions, the stock in Osteologix A/S previously held by Nordic Biotech K/S exchanged into a 50.0% ownership of Osteologix, Inc., the investors buying stock in the private placement exchanged their shares for 36.4% of Osteologix, Inc., and the previous stockholders of Castle & Morgan Holdings, Inc. owned 13.6% of Osteologix, Inc. Because Nordic Biotech K/S participated in the private placement financing, immediately following the transactions of May 24, 2006 they owned 60.1% of Osteologix, Inc.

After our initial formation in 2003, Osteologix began operating activities in early 2004 with chemistry and *in vitro* studies for the selection and development of NB S101, our lead product candidate for the treatment of osteoporosis. Later in 2004 we established a United States subsidiary and opened an office in San Francisco. In 2005 we expanded our operational capabilities to enter human clinical studies and completed our first phase I clinical trial. In 2006 we initiated our first phase II clinical trial.

Currently, our primary goal is to obtain FDA and European approval for NB S101 for the treatment of osteoporosis. NB S101 contains strontium malonate as its active ingredient and is a once-daily oral tablet. A European company has received approval in Europe for another form of strontium as a treatment for osteoporosis, and has published the results of studies it conducted on its form of strontium that demonstrated its ability to increase formation of new bone while simultaneously decreasing resorption, or loss, of existing bone. In preclinical studies with NB S101 we have also demonstrated this positive impact on bone activity. No product currently approved (or, to our knowledge, under investigation) for the treatment of osteoporosis in the U.S. has the ability to increase bone formation and decrease resorption. Our recently completed phase I studies of the pharmacokinetic, or PK, properties of NB S101 revealed that a one gram tablet dose of NB S101 resulted in the same level of strontium in human serum as the European company's approved product containing over two grams of strontium ranelate in sachet formulation, which must be mixed with water before ingestion. Thus, at a significantly lower dose our tablet formulation of strontium is bioequivalent to a marketed sachet product that has been proven safe and effective in osteoporotic patients in Europe. These data, combined with the results of our recent phase I study, form the basis for our phase II program and the pursuit of approval for NB S101 for the treatment of osteoporosis in the U.S., Europe and elsewhere.

#### Development of NB S101 for Osteoporosis

We have conducted various studies of NB S101 in animal species and has conducted phase I clinical trials in humans. The phase I pharmacokinetic and bioequivalence study was conducted in healthy human volunteers in order to determine the blood levels of strontium at various points in time following administration of a single dose of NB S101. In addition, we have initiated long term toxicology and safety studies in rodents and non-rodents.

Based on the results of various studies in animals and data from the phase I human clinical trial, in November 2006, Osteologix received approval from the Danish Medical Authority and the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, as well as from the ethics committees in the two countries, to initiate its first planned phase II trial. The phase II clinical trial is designed to evaluate the safety and efficacy of NB S101 in postmenopausal women with low bone mineral density, or BMD. The primary endpoint in the study is the change in patients' bone resorption, as measured by the biochemical marker CTX-1. We also plan to capture data regarding the effect of NB S101 on bone formation, bone mineral density and a marker of cartilage degradation. During the course of the clinical trial we will also measure the levels of strontium in patients' serum and assess side effects. We are comparing three different doses of NB S101 to placebo and to Protelos (strontium ranelate), a drug which is approved for osteoporosis in Europe and contains a different strontium salt as its active ingredient. We anticipate enrolling approximately 275 women in the study, and will treat them for three months.

We anticipate that the current phase II study will most likely be followed by a larger phase IIb study with BMD measurements as the primary endpoint. Subsequently, to receive approval in the United States and in Europe, we expect the phase III program would consist of at least one fracture prevention study. We have designed our development plan for NB S101 for osteoporosis to comply with both U.S. and European guidelines.

### **Development of NB S101 for Other Indications**

We intend to explore the possibility of developing a strontium product for non-osteoporosis indications in which the uncoupling action of strontium on bone metabolism would be expected to provide substantial therapeutic benefit. The pharmacodynamic action of strontium on bone simultaneously provides an anabolic and an antiresorptive effect. We believe this dual action may stimulate formation and in-growth of new bone, while at the same time allowing normal bone remodeling and removal of damaged, or necrotic, bone from specific skeletal sites that need bone rejuvenation. Thus, we expect that new clinical indications may include orthopedics, secondary osteoporosis (including glucocorticoid-induced osteoporosis), osteonecrosis, and osteoarthritis.

Commercial products for these indications could be developed as different indications for NB S101, or, alternatively, we could develop other strontium product(s) covered by our intellectual property portfolio for these other indications. We are currently conducting feasibility studies and evaluations to assess commercial potential, clinical opportunity and possible regulatory and development strategies. We plan to conduct more preclinical studies for one or more of these opportunities in the near future. Additionally, we may enlist strategic partners to develop NB S101 or other products in our portfolio for indications that we choose not to pursue ourselves. Development plans for the orthopedic and other indications are still under consideration. We also intend to expand our current product pipeline by internal development, acquisitions and/or in licensing of additional product candidates, which may include pharmaceutical projects within the field of bone and joint-related disorders. We may look to major pharmaceutical companies as prospective partners to assist in the developing and eventual marketing of certain of our products.

### **Osteoporosis Overview**

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and increased susceptibility to fractures. In initial stages, the disease predominantly affects trabecular bone, and skeletal sites (such as spine, hip and wrist) that are rich in trabecular bone are particularly subject to increased risk of osteoporotic fracture. Osteoporosis is defined according to BMD measurements, and a woman is diagnosed with osteoporosis when BMD is at least 2½ standard deviations below the healthy premenopausal mean. A woman is diagnosed with osteopenia, a precursor to osteoporosis, when her BMD is between 1 and 2½ standard deviations below the healthy premenopausal mean.

Osteoporosis is often called the "silent disease" because bone loss occurs without symptoms. People may not know that they have osteoporosis until their bones become so weak that a sudden strain, bump or fall causes a fracture, or a vertebra to collapse. Collapsed vertebrae may initially be felt or seen in the form of severe back pain, loss of height, or spinal deformities such as kyphosis or stooped posture. Assessment methods for evaluating skeletal strength, integrity and turnover rate are key in diagnosing and treating osteoporosis. BMD measurement is the currently-recommended primary clinical diagnosis tool. Reliable equipment exists for quantitative assessment

of BMD at various anatomical sites, the most important of which is the lower part of the spine, which is very susceptible to the deleterious effects of osteoporosis because it is made up almost exclusively of trabecular bone. In the last decade, other tools, including imaging techniques such as MRI, ultrasound and very specific biochemical markers of bone resorption and formation have been used to accurately quantify bone status and rapidly demonstrate therapeutic effects of medical interventions on bone metabolism.

According to the National Osteoporosis Foundation, or NOF, osteoporosis is a major public health threat for an estimated 44 million Americans, or 55% of people 50 and older. In the U.S. today, 10 million people are estimated to already have osteoporosis and almost 34 million more are estimated to have osteopenia, which places them at increased risk for osteoporosis. Approximately 80% of those with osteoporosis in the U.S. are women. Osteoporosis is similarly widespread in Europe, and epidemiological studies in China and India point to similar prevalence there. Extensive scientific literature documents osteoporosis prevalence in both sexes. Depending on the skeletal sites and populations studied, most studies show an osteoporosis prevalence of 15% to 25% among postmenopausal women; prevalence of osteopenia is substantially higher. Although the prevalence of osteoporosis is lower among men, studies show that by age 70, most men lose bone at a rate equivalent to women. Studies in both the U.S. and in Europe estimate that approximately five percent of men over 50 have osteoporosis.

The most severe consequence of osteoporosis is skeletal fracture. According to the NOF, one in two women and one in four men over age 50 can be expected to have an osteoporosis-related fracture at some time. Osteoporosis is responsible for more than 1.5 million fractures in the U.S. annually, including more than 300,000 hip fractures, approximately 700,000 fractures of vertebrae, 250,000 of wrist, and 300,000 at other skeletal sites. While hip fractures are two to three times more frequent in women than men, the one year mortality is nearly twice as high for men, indicating the seriousness of osteoporosis in men.

Also according to the NOF, currently an average of only 20% of people with osteoporosis are diagnosed, and of those diagnosed, less than half are treated with medication to prevent further bone loss or to increase bone density. In men particularly, osteoporosis awareness is very low. Attempts to close this gap are expected to be a major driver for future growth of the osteoporosis market. As Western populations age in the coming decades, we and others believe that osteoporosis prevalence will increase substantially. We also believe that better treatments will lead to a higher percentage of patients on medication.

### Current Osteoporosis Treatments

Several classes of compounds are currently used in routine clinical practice for treatment and prevention of osteoporosis, including bisphosphonates, Selective Estrogen Receptor Modulators, or SERMs, Hormone Replacement Therapy, or HRT, and parathyroid hormone, or PTH. There is also one strontium compound approved in Europe, Protelos(R), which is from the same class of pharmaceuticals as our product NB S101. Calcitonin products are also used in osteoporosis. A summary of the reported magnitude of skeletal effects and commonly reported side effects associated with each class is briefly outlined below.

<u>Pharmaceutical Class</u>	<u>Magnitude of Fracture Prevention</u>	<u>Market Leader(s)</u>	<u>Known Side Effects</u>	<u>Mechanism of Action</u>
Bisphosphonates	41 to 49% overall reduction in vertebral fracture risk after 3 years.	Fosamax (Alendronate), Merck. Actonel (Risedronate), Procter & Gamble and GlaxoSmithKline. Boniva (Roche and GSK).	Gastrointestinal side effects such as esophagitis, esophageal ulcers and esophageal erosions. Possible association with osteonecrosis of the jaw.	Potent Antiresorptive
SERMs	35% overall risk reduction in vertebral fracture after 3 years.	Evista (Raloxifene), Eli Lilly	Certain estrogen-related effects such as hot flashes and leg cramps.	Antiresorptive

<u>Pharmaceutical Class</u>	<u>Magnitude of Fracture Prevention</u>	<u>Market Leader(s)</u>	<u>Known Side Effects</u>	<u>Mechanism of Action</u>
HRT	Varying reports of 25 to 50% risk reduction.	Premarin, Wyeth.	Increased risk of certain cancers and possibly cardiovascular disease.	Antiresorptive
PTH	65% reduction in relative risk of vertebral fracture after 19 months.	Forteo, Eli Lilly. Preos, NPS pharmaceuticals (Europe only).	Few and minor in clinical trials (dizziness, leg cramps). Osteosarcoma seen in animals.	Anabolic hormone
Strontium	49% reduction in vertebral fracture risk after 12 months. 41% overall reduction after 3 years.	Protelos (strontium ranelate), Servier.	Diarrhea (usually transient). Slight increase in venous thromboembolism.	Both an antiresorptive and an anabolic effect
Calcitonin	Limited clinical documentation for significant fracture reduction.	Miacalcin, (salmon Calcitonin) Novartis. Fortical (Unigene Laboratories).	Nasal irritation. More rare: Bloody urine, breathing difficulty, dizziness	Antiresorptive. Calcium regulating hormone

Calcium and vitamin D are common and widespread interventions for promoting bone health, and both play a vital role in the maintenance of skeletal integrity. Although they also serve a useful role in correcting dietary deficiencies, calcium and vitamin D treatment does not alter current bone turnover or reverse established osteoporosis. Calcium and vitamin D, however, are useful supplements to other osteoporosis therapies.

#### Development History of NB S101 and Overview of Development Strategy

Early in the development of NB S101, during 2003 and 2004, we performed studies of chemical and physical properties of a selected range of physiologically acceptable strontium salts. Based on the outcome of these studies we selected certain salts for further *in vivo* pharmacokinetic and pharmacodynamic testing. Based on these studies, we chose strontium malonate as our lead product candidate for further clinical development. We also refer to the pharmaceutical formulation of strontium malonate that we are developing as NB S101.

The clinical development of NB S101 was initiated in 2004 with preclinical safety, toxicology and pharmacodynamic studies, in addition to work on formulation. During 2005, we conducted human phase I studies to obtain pharmacokinetic data. In 2006 we initiated a phase II human clinical trial to obtain evidence of the efficacy by measuring biochemical markers of bone resorption and bone formation. Our preclinical and clinical studies have been and are being conducted according to International Conference on Harmonization, or ICH, guidelines. Future clinical trials are anticipated to include an additional phase II human clinical trial, measuring the effect of NB S101 on bone mineral density. When we reach phase III development we expect the central study to be a placebo-controlled vertebral fracture prevention trial in osteoporotic women.

Our clinical development plan for NB S101 contemplates pursuing multiple registration pathways and clinical indications with the main emphasis being on filing a New Drug Application, or NDA, with the U.S Food and Drug Administration, or FDA, for NB S101 for prevention and treatment of osteoporosis. We anticipate that approval of our NDA will require a full development program complying with FDA guidelines, including its "Clinical evaluation of agents used in the prevention and treatment of postmenopausal osteoporosis," published in 1994. We also believe we will need to submit a full safety and toxicology package for NB S101. The European Agency for Evaluation of Medicinal Products, or EMEA, has published guidelines similar to the FDA's for development of products for osteoporosis, and we have designed our program to also comply with these requirements. We plan to use the preclinical package, phase I studies, phase II studies and phase III studies for registration in both the U.S. and Europe. Because strontium ranelate has been approved by EMEA we are able to include strontium ranelate treatment for comparison purposes in clinical trials performed in Europe. We may also be able to use efficacy and

safety data from published studies on strontium ranelate to a somewhat lesser extent, although this will have to be discussed with the regulatory authorities. We may also use other published literature on strontium toxicology to a limited extent.

As we continue development of NB S101, we plan to retain the internal core competency required for design, planning, supervision and interpretation of the studies, although we expect all the clinical studies will be performed externally in collaboration with suitable Clinical Research Organizations, or CROs, and that preclinical studies will be conducted in collaboration with academic research institutions and CROs. We have outsourced all manufacturing of the active pharmaceutical ingredient, or API, and the finished medical product, which is also called the investigational medical product, or IMP, to contract manufacturers who produce, package and supply the required materials according to our specifications.

### **Preclinical Experience with NB S101**

In addition to the preclinical studies with NB S101 we carried out, comprehensive documentation on the safety and toxicological properties of strontium salts is available from reference literature. A number of studies to assess possible health effects of various strontium salts suggest strontium itself is considered safe. Based primarily on rat studies, the U.S. Department of Human and Health Services has established a lowest observed adverse effects level of 550 mg/kg/day. For comparison purposes, the highest strontium malonate dose in our current phase II clinical is approximately 40 mg/kg/day, corresponding to about 20 mg/kg/day ionic strontium.

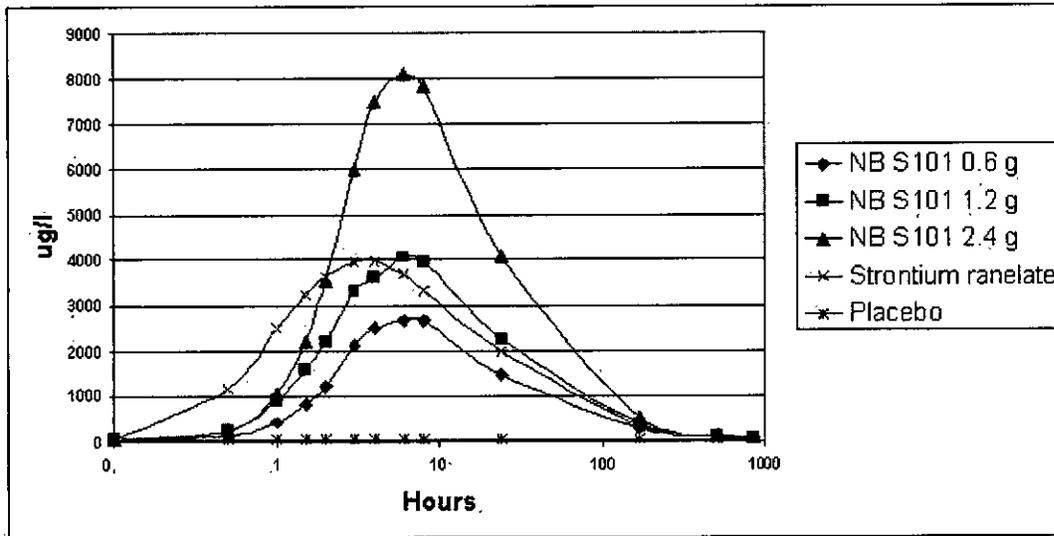
We have compiled a documentation package containing data from preclinical and phase I safety, toxicology and pharmacokinetic studies for NB S101 that we submitted to drug regulatory authorities in the United Kingdom and Denmark with our phase II clinical trial applications prior to their approval. This package contained data on strontium malonate regarding

- pharmacokinetics
- genotoxicity
- maximum tolerated dose, and
- long-term safety and toxicology.

We have designed the preclinical program to comply with regulatory requirements and relevant ICH guidelines. In compliance with the requirements, we carried out toxicological studies in rodents and in non-rodent species. We are continuing additional safety and toxicology work as NB S101 advances in clinical development, and expect to continue to accrue additional data throughout the development timeline of NB S101. To assess the effects of NB S101 on skeletal metabolism and bone strength, we have also conducted various pharmacodynamic studies, including pre-clinical efficacy studies in an animal model of osteoporosis.

**Phase I Studies**

In September 2005, we completed a phase I randomized, semi-blinded pharmacokinetic and bioequivalence study of NB S101 in 60 healthy male volunteers divided into five different groups. The study's primary objective was to obtain pharmacokinetic data (Area under the curve, or AUC, and plasma concentration at the peak, or Cmax) on strontium uptake and elimination from oral administration of NB S101. Secondary objectives included identification of the dose of NB S101 bioequivalent to 2.0 grams Protelos(R), obtaining data on markers of calcium balance and assessment of the dynamic effects of NB S101 on biochemical markers of bone turnover. The chart below shows the mean plasma strontium concentrations measured in the five study groups (3 different doses of NB S101 — 0.6 grams, 1.2 grams, and 2.4 grams, the approved dose of Protelos, and placebo) over the five-week observation period of the phase I trial on a logarithmic time scale.



The table below shows the mean maximum plasma strontium concentrations observed in the phase I clinical trial (ITT analysis set).

<u>Cmax</u> <u>(ng/ml)</u>	<u>NB S101 0.6g</u> <u>N=12</u>	<u>NB S101 1.2g</u> <u>N=12</u>	<u>NB S101 2.4g</u> <u>N=12</u>	<u>Protelos 2.0g</u> <u>N=12</u>
Mean . . . . .	2924	4553	8697	4181
Standard Error . . . . .	275.0	432.5	1054.4	406.9
Range . . . . .	1027 - 4434	1396 - 7611	1703 - 16510	2639 - 7880

In the phase I clinical trial, NB S101 was well tolerated in the 36 subjects treated with the product. During the trial two cases of diarrhea were reported among the 12 subjects treated with Protelos (diarrhea is reported as the most frequent gastrointestinal adverse effect of Protelos), but no cases of diarrhea were reported among the 36 subjects treated with NB S101.

From the phase I clinical trial, we learned that 0.99 grams of NB S101 was bioequivalent to 2 grams of Protelos(R), and based on this finding we currently believe that we may seek approval for a 1.0 gram dose of NB S101, administered in a single tablet once a day. Our 1.0 gram tablet contains 465 mg of strontium, as compared to 680 mg of strontium contained in the approved dosage of Protelos. We believe that our product can deliver the same levels of strontium in the blood at a much lower dose than Protelos because of its improved bioavailability. This is likely to be related to the different anion (ranelate versus malonate), because the ranelate ion appears to bind to the strontium ion stronger than the malonate ion, thus impairing the uptake of free strontium from the intestinal lumen.

We plan to carry out an additional phase I study addressing and quantifying the effect of food and calcium intake on absorption of NB S101. Calcium is known to affect strontium absorption, probably because strontium and calcium are taken up in the intestine by the same transport mechanisms, resulting in reduced absorption of strontium

when calcium is present. Our study plan currently calls for the food and calcium interaction study to be carried out as a controlled, randomized, cross-over study with four interventions, comprising single dose administrations. We estimate that the study population will comprise approximately 15 to 20 postmenopausal women. While this study does not need to be completed prior to initiating our planned phase IIb and phase III trials, we believe it does need to be completed prior to our submitting an NDA to the FDA.

Our complete phase I program and the package of preclinical safety and toxicology experiments has been designed to be compatible with pursuit of clinical development of NB S101 in osteoporosis and in other clinical indications.

### **Phase II Studies**

The primary goals of our phase II studies are to document the efficacy of NB S101 and to establish an effective and tolerable dose of NB S101 that will enable us or a pharmaceutical collaborator to initiate phase III clinical trials that would be designed to obtain approval of NB S101. We currently plan to conduct two phase II studies. The first of our two phase II studies, which we sometimes refer to as a phase IIa trial, was initiated in November 2006. This trial is a randomized, double-blind, placebo-controlled, parallel-group three month safety and efficacy trial with an overall objective of assessing the effects of NB S101 on bone metabolism and the safety, tolerability and pharmacokinetics of NB S101 in postmenopausal women. We plan to enroll approximately 275 women with low bone mineral density in this study. There are five treatment groups in the study, three of which receive NB S101 (0.75 grams, 1.0 gram and 2.0 grams, which are below, at, and above the currently-estimated therapeutic dose), one which receives placebo, and one which receives Protelos(R) to enable reference comparison. While the study is double-blind with respect to the groups receiving NB S101 or placebo, the study is not blinded with respect to the Protelos(R) group because of its unusual dosing regimen. The primary endpoint of the study is the effect of NB S101 on CTX-1, which is a biochemical marker of bone resorption. In addition, we plan to evaluate the effect of NB S101 on strontium levels, bone mineral density and markers of bone formation and cartilage degradation. Responses in the NB S101 treated groups will be compared with the responses seen in the placebo and Protelos(R) groups. Side effects will also be assessed. We expect to have preliminary results from the phase IIa trial in late 2007 or early 2008.

We expect that, following completion of the phase IIa trial, we will conduct a larger double-blind, placebo-controlled phase II study, which we sometimes refer to as a phase IIb trial, that includes more study subjects followed for a longer time period, with bone mineral density as the primary endpoint. The overall objective of this second phase II study will be to obtain efficacy data for NB S101 in comparison with placebo, and to obtain safety, tolerability and pharmacokinetic data in osteoporotic postmenopausal women. We plan to conduct this second phase II trial as a multicenter international study. In this trial, NB S101 or placebo will be administered once daily over a twelve-month period. We currently plan to start the phase IIb trial in 2008.

The patient group we plan to enroll in the phase IIb study is compatible with the patient group needed to obtain a treatment of osteoporosis indication. We anticipate that each arm of the study would include approximately 250 women, resulting in a total study population of approximately 500 subjects if we choose to evaluate one dose of NB S101, or 750 subjects if we choose to evaluate two doses of NB S101 in this trial. The final number of study subjects needed for a statistically powerful study will be calculated based on statistical analysis of the phase IIa study as well as other available documentation. We are currently exploring whether this study, with a 12 to 24 month open-label extension, may form one of the pivotal studies required for registration.

### **Phase III Studies**

The FDA and EMEA require positive results from phase III studies before they will approve an NDA. In order to obtain approval for a new drug for the treatment of osteoporosis, current U.S. and European regulatory guidelines require placebo-controlled double-blind studies with fracture reduction as the primary endpoint. An adequate fracture-prevention trial represents a significant time and resource investment, as the treatment duration is usually three years. These trials raise ethical questions concerning the use of placebo groups when approved drugs are available to treat osteoporosis, and both European and U.S. regulatory authorities are currently debating whether continued use of such trials can be recommended. If future guidelines prevent or limit the use of placebo control in such studies, we plan to alternatively conduct a non-inferiority study against an established osteoporosis treatment or otherwise modify our plans based on any new guidelines established for approval of drugs to treat or prevent osteoporosis.

Based on the current FDA and EMEA guidelines, we anticipate the primary objective of a phase III study will be to evaluate the ability of NB S101 to prevent incident vertebral fracture. We also anticipate that we would collect data on non-vertebral fractures, spine, hip and forearm BMD, and biochemical markers of bone and cartilage turnover. We estimate that the phase III study may enroll up to 3,000 osteoporotic women, comparing one dose of NB S101 to placebo over a three-year treatment period, with a possible two-year extension. Based on results of the phase II studies and additional data, we plan to conduct further statistical assessments prior to finalizing any phase III clinical trial design or finally determining the number of patients needed.

Our clinical development plans are based on the current profile of NB S101, our experience with preclinical and phase I testing of NB S101, our understanding of current FDA and EMEA guidelines, and our review of publicly available data on potentially competing products. We expect that the results of phase II trials and the continuing studies of NB S101 in animals will increase our knowledge regarding NB S101, and may lead to our modifying our current development strategy. In addition, changes in market conditions or regulatory requirements may also require us to modify our development plans.

### **Osteoporosis Market**

We believe that osteoporosis and other diseases of skeletal deterioration remain underserved medical needs, despite recent medical advances in the area and the progress of other drugs in development. For this reason, the American Society for Bone and Mineral Research, or ASBMR, and the International Osteoporosis Foundation, or IOF, have actively promoted osteoporosis awareness among medical professionals, legislators and the public.

The worldwide market for prescription osteoporosis products is estimated by Datamonitor at \$8.7 billion in product sales in 2007. The market is expected to grow at a compound annual growth rate of 10% through 2015, reaching estimated sales of \$17.8 billion. We believe that the market for osteoporosis treatments will continue to grow as the population grows older and lives longer. We also believe that the market potential is even greater because many patients with osteoporosis do not comply with their prescribed therapies due to the side effects of current therapies and other unsatisfactory therapeutic effects. We believe that our product NB S101 offers benefits compared to the current therapies and thus has the potential to be a leading treatment for osteoporosis, if approved.

### **Our Strategy**

Our goal is to become a leading pharmaceutical development company by continuing to develop and commercialize new medications for bone disease and/or women's health that offer advantages over existing treatments. Our development program for NB S101 is an example of our progress in executing upon this goal. We are also seeking to develop or acquire other new treatments for bone disease or women's health. Our strategy is to:

- Focus on unmet and underserved needs;
- Efficiently select product candidates to minimize development risk and maximize commercialization opportunities;
- Structure attractive co-development and commercialization agreements to maximize up-front guaranteed and milestone payments; and
- Identify business opportunities and product candidates for attractive indications.

We plan to use external collaborators, contract and clinical research organizations, and scientific and business contacts and consultants during our product evaluation and development efforts in order to access the most relevant expertise and identify the most appropriate potential development programs and partners.

### **Sales and Marketing**

To commercialize NB S101, we intend to collaborate with a major global pharmaceutical company with experience marketing products to physicians that commonly prescribe treatments for osteoporosis, such as general practitioners, with especially broad sales, marketing, and distribution capabilities. However, we also plan to evaluate granting licenses to large, regional pharmaceutical companies (such as one license for North America, another for Europe and another for Japan and Asia) that have capability to market the product adequately in their respective territories.

## Competition

The success of NB S101 will depend in part on our ability to achieve market share at the expense of existing, established products, to leverage favorably with future products in development and to grow new or existing markets. Currently, there are five classes of compounds approved for sale in the U.S. which we see as competition for the treatment and prevention of osteoporosis: Hormone replacement therapy, or HRT, Selective Estrogen Receptor Modulators, or SERMs, bisphosphonates, parathyroid hormone, or PTH, and Calcitonin. The following is a summary of these treatments:

- HRT was a common therapy among postmenopausal women for many years, as estrogen offers relief of many menopausal inconveniences in addition to its bone protecting effect. However, recent large studies, such as the Women's Health Initiative, show that HRT use is associated with increased risk of breast cancer, cardiovascular disorders and other side effects. Since these studies have been published, there have been significant declines in the usage of HRT, and we believe it will play a much smaller role in the treatment and prevention of osteoporosis in the future. The class is dominated by Premarin, made by Wyeth.
- SERMs were developed to preserve beneficial effects of estrogen while minimizing potential side effects. Currently, only one SERM is approved (raloxifene, Evista, by Eli Lilly), but additional SERMs are currently in development or being evaluated by the FDA for approval. SERM action on bone is mainly anti-resorptive, with less potency than the bisphosphonates, but SERMs still significantly reduce fractures in large clinical trials. A primary concern is the SERMs potential ability to affect tissues other than bone, due to the widespread occurrence and pleiotrophic effects of sex steroid receptors. Endometrial safety and CNS related effects (e.g. hot flash occurrence) also remain issues with SERMs.
- Bisphosphonates are potent anti-resorptive agents with well established fracture reduction efficacy. Bisphosphonates are the leading treatments for osteoporosis, dominated by alendronate (Fosamax, Merck), and risedronate (Actonel, Procter&Gamble). Newer bisphosphonates have been introduced by Roche (ibandronate, Bonviva) and Novartis (zoledronate, Zometa). Unlike HRT and SERMs, bisphosphonates may be taken by men. New formulations for parenteral administration (i.e., intravenous or subcutaneous) are also being introduced. Major side effects include irritation of the gastrointestinal system, which require the patients to stand upright for a period after administration. Furthermore, the poor bioavailability of bisphosphonates limit oral intake (they are generally taken in the morning, and require fasting before and after intake). Osteonecrosis of the jaw bone is being reported in some bisphosphonate users.
- PTH takes a central role in the body's regulation of calcium homeostasis and bone turnover. It has a potent anabolic effect on bone tissues, stimulating the formation and maturation of bone-forming osteoblasts which in turn causes significant increases in new bone formation. To date, only one PTH product, Forteo (Eli Lilly), is marketed in the United States. PTH products, given as daily injections, are approved for severe osteoporosis, where build-up of new bone is key in preventing further deterioration. However, PTH is not recommended for prophylactic or longer term therapy. Typically, treatment duration is limited to two years because of the risk of osteosarcoma revealed in preclinical testing. Moreover, treatment with PTH is inconvenient because it is administered by daily subcutaneous injections.
- Calcitonin: Calcitonin is a natural hormone involved in the physiological maintenance of calcium homeostasis and regulation of skeletal metabolism. It decreases release of calcium by down-regulating the activity of the bone resorbing osteoclasts. Calcitonin is available in a nasal spray, but it is currently used in a relatively small proportion of the osteoporotic population. Although the effect of calcitonin on BMD is lower than those seen with HRT, SERMs, PTH and bisphosphonates, calcitonin has been reported to have some analgesic effects, which may be useful in patients with painful symptoms. Calcitonin has one of the best side effect profiles among currently approved treatments for osteoporosis, which probably is among the key rationale for its use in osteoporosis therapy. Widespread use in osteoporosis is hampered by the lack of clinical proof for fracture prevention.

One osteoporosis product containing strontium has been developed by the French pharmaceutical company Servier, SA. Their product contains strontium ranelate as the active ingredient and is sold under the tradename Protelos(R) in Europe. Protelos was approved for sale by the Committee for Medicinal Products for Human Use, or

CHMP, of the EMEA in late 2004, and Servier began marketing Protelos in most European countries in 2005. Protelos is formulated in daily 2.0 gram sachets, which are packets of powdered drug substance that must be reconstituted in water prior to ingestion. The phase III program conducted by Servier prior to receiving approval of Protelos consisted of two double-blind placebo controlled clinical trials, the Spinal Osteoporosis Therapeutic Intervention, or SOTI, trial for assessing the ability of strontium ranelate to reduce the risk of vertebral (spinal) fractures and the Treatment Of Peripheral Osteoporosis study, or TROPOS, for assessing the ability of Protelos to reduce the risk of peripheral (non-spinal) fractures. Almost 7,000 osteoporotic women in total completed these two three-year studies. In these trials, strontium ranelate demonstrated statistically significant reductions in both vertebral and non-vertebral fractures. Strontium ranelate treatment also increased patients' BMD and showed concomitant decreases in bone resorption and increases in bone formation. One adverse effects of the use of strontium ranelate was an increase in venous thromboembolism (25 cases among 3,352 strontium ranelate treated women compared to 14 cases among 3,317 placebo treated women). In addition, transient mild diarrhea was also seen among some of the strontium-ranelate treated women. Other side-effects were generally few. To our knowledge, Protelos(R) is currently the only pharmaceutical product containing ionic non-radioactive strontium, and thus is a relevant competitor for NB S101. We believe that our product is in a superior dosage form (tablet vs. sachet) and that it may have a superior side-effect profile compared to Protelos, while having similar efficacy on the skeletal system. Since its introduction, quarterly sales of Protelos have increased at over 36% per quarter over the past five quarters, and have reached a rate in excess of \$100 million per year based on the most recent quarter reported (third quarter 2006, as reported by IMS, an organization that tracks sales of prescription pharmaceutical products).

Most major pharmaceutical companies have established an osteoporosis franchise or are in late-stage clinical development with osteoporosis products. Furthermore, several biotechnology companies are pursuing new osteoporosis drugs. One new approach is based on Osteoprotegerin, or OPG, a circulating 'decoy-receptor' for the RANK-L hormone (receptor activator of nuclear factor-kappaB-ligand). RANK-L up-regulates formation of osteoclasts and thus increases bone degradation, and a RANK-L-specific monoclonal antibody (AMG-162, or denosumab, Amgen) that inhibits osteoclast activity is currently in late stage clinical development. Other drug targets currently being investigated include: matrix metallo-proteinases, or MMPs, such as cathepsin K; ion channels of importance for osteoclast function such as CLC-7, developed by Nordic Bioscience; and other endocrine factors involved in physiological regulation of bone turnover (e.g. Calcitonin, marketed by Novartis and GLP-2 developed by Sanos Bioscience). An important goal for future therapies is to evoke a long-lasting skeletal benefit to enable a build-up of lost bone mass. We believe that one possible way to achieve net bone growth is by positively uncoupling bone resorption and formation as has been observed in long-duration strontium therapy. Thus, we anticipate that the strontium class of pharmaceuticals provides a valuable alternative to existing prophylactic and therapeutic treatment options for osteoporosis.

### **Intellectual Property**

Our goal is to (a) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (b) preserve our trade secrets, and (c) operate without infringing on the proprietary rights of other parties, worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

We have filed more than 25 individual patent applications that are pending worldwide. Three international patent applications filed on May 6, 2004 form the foundation of our patent portfolio, and the first of these patents was issued in Europe on October 18, 2006. These three patent applications claim water soluble strontium salts, controlled release strontium salt compositions, and combinations of strontium salts and other agents. The three key patent applications and their primary claims are as follows:

- PCT/DK2004/000328: "Water Soluble Strontium Salts for Use in the Treatment of Cartilage and/or Bone Conditions." Claims are generally directed to water soluble strontium salts and the use of such formulations to treat metabolic bone diseases. The most notable clinical indication claimed in this application is osteoporosis, but several other metabolic bone diseases are also claimed. This application has been granted

in Europe on October 18, 2006 and is pending elsewhere. A divisional application in Europe containing broader claims is still pending.

- PCT/DK2004/000327: "Combination Treatment with Strontium for the Prophylaxis and/or Treatment of Cartilage and/or Bone Conditions." This application is generally directed to compositions containing strontium salts and one or more other active substances for the treatment of bone and/or cartilage disorders such as osteoporosis. The application has entered the national/regional phases in the U.S., Japan, Australia, Canada and before the EPO. However, prosecution by the patent authorities in the respective countries has only recently been initiated.
- PCT/DK2004/000326: "Controlled Release Composition Containing a Strontium Salt." This application is generally directed to controlled release formulations of strontium salts and uses for treating a broad variety of cartilage and/or bone diseases, including osteoporosis. The application has entered the national/regional phases in the U.S., Japan, Australia, Canada and before the EPO. However, prosecution by the patent authorities in the respective countries has not been initiated yet.

We have received international search reports (performed by the European Patent Office) for the patent applications listed above. The International Searching Authorities of the European Patent Organization identified some prior art, which might have potential impact on the patentability and/or allowable scope of the claims of these applications. As is typical in patent prosecution, certain limitations to the claims may have to be introduced during the prosecution of the patent applications before their actual grant. However, it is difficult to predict the ultimate scope of the patent claims we will be granted by the patent authorities.

In addition to the above, we have filed a number of additional applications in order to protect relevant new developments and scientific and clinical knowledge that we have gained. These additional patent applications are for specific methods of manufacturing strontium salts and for other clinical indications, such as treatment of osteonecrosis. All international patent applications which we have filed designate all countries which are party to the Patent Cooperation Treaty, or PCT, which is effectively all major industrialized countries. Our current strategy is to file applications as PCT applications seeking worldwide coverage, and then file applications nationally in the U.S., Europe, Canada, Japan, and Australia.

### **Third party patent rights**

We believe we will have freedom to develop our strontium salts for the treatment of metabolic bone diseases such as osteoporosis. However, there are other patents for the use of strontium. Within the class of strontium-based pharmaceutical products, Servier has several patents. These include U.S. Patent No. 5,128,367, which is directed to strontium ranelate and other metal ranelates, as well as methods and compositions for treating osteoporosis. In addition, Servier's U.S. Patent No. 4,939,164 is directed to a specific strontium salt of pentanedioic acid, as well as methods and compositions for treating osseous diseases using this salt. Also, Servier's U.S. Patent No. 5,075,336 describes specific types of carboxylic acid salts, including strontium salts as well as methods and compositions for treating osseous diseases using these salts. Servier's U.S. Patent No. 5,856,356 (European equivalent: EP813862) describes the use of strontium salts, including strontium ranelate, for treatment of arthrosis. Servier has also filed additional U.S. patent applications that have published as U.S. Publication Nos. 2004/0059134, 2004/0059135 and 2004/0063972, directed to methods of manufacturing strontium salts. Due to prior art restrictions, Servier's European patent EP813862 has been limited to one claim, the use of strontium ranelate for treatment of osteoarthritis.

In addition to the patents held by Servier, there are other issued patents describing the use of strontium salts for treatment of human subjects. U.S. Patent No. 5,851,556 issued to the French company L'Oreal describes the use of various alkaline earth metal salts such as strontium salts for the treatment of skin conditions, bronchopulmonary conditions, pain, gastrointestinal conditions, central nervous system disorders, disorders associated with the release of TNF alpha and disorders associated with the release of substance P. The Norwegian company Santosolve has one issued patent — EP 1429792, which generally describes strontium salts, and compositions and methods using such salts for treating sub-dermal soft tissue pain and herpetic infections, and one published patent application — WO 04084920, which is generally directed to methods for treating inflammation with a strontium compound. There

may be other patents or patent applications of which we are not aware that may represent a dominate position to ours.

In November 2005, we entered into a patent license agreement with Aditech AB, or Aditech. Aditech is 100% owned by Nordic Biotech, and at the time of the agreement Nordic Biotech owned 100% of Osteologix. The agreement provides Aditech with rights to develop pharmaceutical products for certain non-osteoporosis indications contained in our patent portfolio, in exchange for Aditech's obligation to pay us a royalty on product revenues generated from products developed under the Agreement. Also the agreement, Aditech has an exclusive worldwide license to Osteologix's patents containing certain compounds other than strontium compounds, which are outside the core focus of the Company's business, for which we are also entitled to receive a royalty on product revenues. Osteologix, in turn, has an exclusive worldwide license to Aditech's patents for strontium compounds. In exchange for the rights granted, Aditech paid us \$750,000 in February 2006. We are also entitled to a 2.5% royalty on future net sales of products developed by Aditech under the agreement. Aditech is entitled to a 1.5% royalty on future net sales of products containing strontium compounds that we develop. We currently believe that it is unlikely that Aditech will develop products that are licensed from Osteologix.

To supplement our patent portfolio, we also depend on the skills, knowledge, and experience of our scientific and technical personnel, as well as that of our advisors, consultants, and other contractors. To help protect our patentable proprietary know-how, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. We require all employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit disclosure of confidential information and, where applicable, require disclosure and assignment to us of ideas, developments, discoveries and inventions important to our business.

### **Government Regulation**

The FDA, comparable foreign regulators and state and local pharmacy regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products.

The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act generally involves:

- Preclinical laboratory and animal tests;
- Submission of an Investigational New Drug Application, or IND, prior to commencing human clinical trials;
- Adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;
- Submission to the FDA of a New Drug Application, or NDA; and
- FDA review and approval of a NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

We plan to submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials in the United States. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, we must resolve the matters with the FDA before beginning clinical trials. It is possible that our submission may not result in FDA authorization to commence clinical trials.

Clinical trials must be supervised by a qualified investigator in accordance with good clinical practice regulations, which include informed consent requirements. An independent Institutional Review Board, or IRB, at each medical center reviews and approves and monitors the study, and is periodically informed of the study's progress, adverse events and changes in research. Progress reports are submitted annually to the FDA, and more frequently if adverse events occur.

Human clinical trials typically have three sequential phases that may overlap:

- Phase I: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion.
- Phase II: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage.
- Phase III: When phase II evaluations demonstrate that a dosage range is effective with an acceptable safety profile, phase III trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites.

We cannot be certain that we will successfully complete phase II, or phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time for various reasons, including a finding that subjects or patients are exposed to an unacceptable health risk.

Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with good manufacturing practice, or GMP, requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. While Osteologix does not own manufacturing facilities, we contract with qualified third parties who must comply with manufacturing practices and procedures established by the FDA for the manufacture of bulk active pharmaceutical ingredients and finished products.

Results of preclinical and clinical trials, and manufacturing specifications are submitted to the FDA, along with other data on the product, as part of a NDA for approval. Once the FDA accepts an NDA for filing, it begins an in-depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted. The process may be significantly extended by requests for additional information or clarification regarding information already provided. As part of this review, the FDA may also refer the application to an appropriate advisory committee, which is typically a panel of clinicians. Manufacturing establishments often are inspected prior to NDA approval to assure compliance with GMP requirements and with manufacturing commitments made in the application.

Submission of an NDA to the FDA typically requires payment of a fee, which we estimate may exceed \$1 million at the time an application for NB S101 may be ready, if at all. Currently, the FDA generally assigns a goal of ten months for issuing its "complete response," in which the FDA may approve the NDA, deny the NDA, or require additional information before coming to a decision on approval or denial of the NDA. The FDA can always decide the NDA does not warrant approval. If the FDA does approve the NDA, the product can become available for physicians to prescribe to patients. However, product approval may be withdrawn at any time if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and may also require surveillance programs to monitor products that have been approved. The FDA has the power to require changes in product labeling or prohibit further marketing based on its discretion.

Satisfaction of the FDA's regulatory requirements typically takes a number of years, but the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in

later-stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if one of our products receives regulatory approval, the approval may be significantly limited to specific indications or uses. Also, after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are also subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We will likely incur significant costs to comply with these laws and regulations now or in the future.

In addition, the FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide could result in new government regulations materially adverse to our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The U.S. Federal Trade Commission and the Office of the Inspector General of the U.S. Department of Health and Human Services, or HHS, also regulate certain pharmaceutical marketing practices. Government reimbursement practices and policies with respect to our products are also important to our success.

We are subject to numerous federal, state and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. The regulatory framework under which we operate will inevitably change in light of scientific, economic, demographic and policy developments, and such changes may have a material adverse effect on our business.

### **European Regulation**

Similar to requirements in the U.S., in Europe prior regulatory approval is required for phase I clinical trials. Thereafter, data from successful phase I studies are submitted to regulatory authorities to support applications for phase II studies. European authorities typically have one to three months, which often may be extended in their discretion, to raise objections to proposed studies. One or more independent ethics committees also review relevant ethical issues, similar to reviews performed by IRBs.

For European marketing approval, we submit to the relevant authority for review a Marketing Authorization Application, or MAA, providing information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as non-clinical and clinical data.

The European Union provides two different, elective authorization routes for approval: centralized and decentralized. For NB S101 we have selected the centralized route, which, if successful, leads to approval for the entire European Union. Under this procedure our application will be reviewed by members of the Committee for

Proprietary Medicinal Products, or CPMP, on behalf of EMEA. Based on that review, the CPMP will provide an opinion on safety, quality and efficacy to the European Commission, which makes the decision to grant or refuse authorization.

Approval in Europe can take several months to several years, and can be denied. Regulatory authorities conduct facilities inspections and review manufacturing procedures, operating systems and personnel qualifications. In many cases, each drug manufacturing facility must be approved, and further inspections may occur over the product's life. The regulatory agency may require additional studies prior to approval and may also require post-marketing studies or additional product surveillance to monitor for adverse effects. Further clinical studies are usually necessary for approval of additional indications. As in the U.S., the terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

Failure to comply with ongoing requirements can result in suspension of regulatory approval and civil and criminal sanctions. European regulatory authorities have the authority to revoke, suspend or withdraw approvals, prevent companies and individuals from participating in the drug approval process, require product recalls, seize products, obtain injunctions to close non-compliant manufacturing plants and stop shipments of products.

### **Pricing Controls**

Pricing for products that are approved is also subject to regulation. Requirements vary widely between countries and can be implemented differently in each country. Even if our drug candidates are approved, we may not be able to obtain favorable pricing arrangements for our products.

### **Third-Party Reimbursements**

In the U.S., the European Union and elsewhere, pharmaceutical sales are dependent in part on the availability and adequacy of reimbursement from third party payers such as governments and private insurance plans. Third party payers are increasingly challenging established prices, and new products may have difficulty finding ready acceptance unless there is a clear therapeutic benefit.

### **Employees**

As of December 31, 2006, other than our Chief Executive Officer and Chief Financial Officer who are located in San Francisco, California, and our Chief Operating Officer who is located in Copenhagen, Denmark, we had two employees involved in research and development and located in Copenhagen, Denmark. None of our employees are represented by any collective bargaining agreements.

### ***Item 2. Description of Property.***

Osteologix has locations in San Francisco, California and Copenhagen, Denmark. We have an operating lease for our corporate headquarters in San Francisco that requires monthly payments of approximately \$7,000, in addition to certain operating expenses, and expires in October 2007. We have an operating lease for our research and development operations in Copenhagen that requires monthly payments of approximately \$3,000, in addition to certain operating expenses, and expires in March 2008, although this lease may be canceled by us at any time upon providing six months advance notice. For both of our operating leases, we believe that suitable substitute space is readily available should we decide or be unable to renew.

### ***Item 3. Legal Proceedings.***

Not applicable.

### ***Item 4. Submission of Matters to a Vote of Security Holders***

Not applicable.

## PART II

### Item 5. *Market for Common Equity and Related Stockholder Matters.*

Our Common Stock trades on the OTC Bulletin Board under the symbol "OLGX". Some quotation systems require the symbol to be entered as "OLGX.OB". Prior to May 24, 2006, the Company was a non-operating shell company that traded under the symbol "CSMH" on the OTC Bulletin Board. No shares of the Company's Common Stock traded between January 1, 2005 and June 30, 2006. The following table sets forth, for the periods indicated, the quarterly high and low trading prices of our common stock as reported on the OTC Bulletin Board for the past two fiscal years. The trading prices reflect the prices prior to and after the merger transaction on May 24, 2006. The trading prices prior to April 13, 2006 have been adjusted to reflect a 1-for-three reverse split which occurred on April 13, 2006.

	<u>High</u>	<u>Low</u>
Fourth Quarter 2006.....	\$1.45	\$0.85
Third Quarter 2006 .....	\$1.60	\$1.20
Second Quarter 2006 .....	\$1.05*	\$1.05*
First Quarter 2006 .....	\$1.05*	\$1.05*
Fourth Quarter 2005.....	\$1.05*	\$1.05*
Third Quarter 2005 .....	\$1.05*	\$1.05*
Second Quarter 2005 .....	\$1.05*	\$1.05*
First Quarter 2005 .....	\$1.05*	\$1.05*

\* These prices represent the most recent trade, which was for 5,000 shares at \$0.35 per share on December 31, 2004 (before the reverse split, after the reverse split the trade would be adjusted to 1,667 shares at \$1.05).

As of March 15, 2007, there were 66 holders of record of Osteologix common stock.

### Item 6. *Management's Discussion and Analysis or Plan of Operation*

#### **PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The statements contained in this Form 10-KSB that are not purely 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. These include statements about the Company's expectations, beliefs, intentions or strategies for the future, which are indicated by words or phrases such as "anticipate," "believe," "design," "expect," "intend," "may," "plan," "will," and similar words or phrases. The forward-looking statements are based on the Company's current expectations and are subject to certain risks, uncertainties and assumptions. The Company's actual results could differ materially from results anticipated in these forward-looking statements. All forward-looking statements included in this document are based on information available to the Company on the date hereof, and the Company assumes no obligation to update any such forward-looking statements. References in this filing to the "Company", "we", "us", "our", or "Osteologix" refer to Osteologix, Inc. and its subsidiary after the merger, and to Osteologix A/S and its subsidiary prior to the merger.

Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis or Plan of Operations," and elsewhere in this report are forward-looking statements that involve risks and uncertainties. The factors listed in the section captioned "Risk Factors" contained at the end of this Item 6 and all cautionary language in this report provide examples of risks, uncertainties and events that may cause our actual results to differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

#### **Company Information and Background**

We are in the business of developing pharmaceuticals for the treatment and prevention of diseases of bone and joint tissues. Our lead product candidate, NB S101, is in clinical development for treatment of osteoporosis.

We were initially formed on June 16, 2003 in Denmark as Nordic Bone A/S, based on intellectual property rights for a product to treat osteoporosis. In October 2004, Nordic Bone A/S incorporated a wholly-owned subsidiary in the United States, and in November 2004 Nordic Bone A/S changed its name to Osteologix A/S. From the formation of Osteologix until May 24, 2006, we were 100%-owned by Nordic Biotech K/S, a Copenhagen, Denmark based venture capital firm. On May 24, 2006, Osteologix A/S completed a "reverse merger" transaction with Castle & Morgan Holdings, Inc., a U.S. public company incorporated in Delaware and traded on the Over-the-Counter Bulletin Board. In the merger, Castle and Morgan Holdings, Inc. issued new shares of common stock in exchange for 100% of the issued common stock of Osteologix A/S. Also on May 24, 2006, a subsidiary of Osteologix A/S completed a private placement transaction, raising \$10 million in gross proceeds by issuing new shares of its common stock. Immediately following the merger, Castle & Morgan Holdings, Inc. changed its name to Osteologix, Inc. and the newly issued shares in the subsidiary of Osteologix A/S were exchanged for Osteologix, Inc. shares. As a result of these transactions, the stock in Osteologix A/S previously held by Nordic Biotech K/S exchanged into a 50.0% ownership of Osteologix, Inc., the investors buying stock in the private placement exchanged their shares for 36.4% of Osteologix, Inc., and the previous stockholders of Castle & Morgan Holdings, Inc. owned 13.6% of Osteologix, Inc. Because Nordic Biotech K/S participated in the private placement financing, immediately following the transactions of May 24, 2006 they owned 60.1% of Osteologix, Inc.

After our initial formation in 2003, Osteologix began operating activities in early 2004 with chemistry and *in vitro* studies for the selection and development of NB S101, our lead product candidate for the treatment of osteoporosis. Later in 2004 we established a United States subsidiary and opened an office in San Francisco. In 2005 we expanded our operational capabilities to enter human clinical studies and completed our first phase I clinical trial. In 2006 we initiated our first phase II clinical trial.

Currently, our primary goal is to obtain FDA and European approval for NB S101 for the treatment of osteoporosis. NB S101 contains strontium malonate as its active ingredient and is a once-daily oral tablet. A European company has received approval in Europe for another form of strontium as a treatment for osteoporosis, and has published the results of studies it conducted on its form of strontium that demonstrated its ability to increase formation of new bone while simultaneously decreasing resorption, or loss, of existing bone. In preclinical studies with NB S101 we have also demonstrated this positive impact on bone activity. No product currently approved (or, to our knowledge, under investigation) for the treatment of osteoporosis in the U.S. has the ability to increase bone formation and decrease resorption. Our recently completed phase I studies of the pharmacokinetic, or PK, properties of NB S101 revealed that a one gram tablet dose of NB S101 resulted in the same level of strontium in human serum as the European company's approved product containing over two grams of strontium ranelate in sachet formulation, which must be mixed with water before ingestion. Thus, at a significantly lower dose our tablet formulation of strontium is bioequivalent to a marketed sachet product that has been proven safe and effective in osteoporotic patients in Europe. These data, combined with the results of our recent phase I study, form the basis for our phase II program and the pursuit of approval for NB S101 for the treatment of osteoporosis in the U.S., Europe and elsewhere.

### **Critical Accounting Policies and Use of Estimates**

The preparation of our financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenue and expense, and the disclosure of contingent assets and liabilities. We evaluate our estimates and assumptions on an ongoing basis. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our consolidated financial statements require significant estimates and judgments:

*Accounting for stock options.* On January 1, 2006 we adopted the requirements of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," or SFAS 123R, which requires the expensing of the estimated fair value of stock options issued to employees and members of our board of directors. We adopted this standard utilizing the prospective transition method, under which prior periods were not restated to reflect the impact of SFAS 123R for comparative purposes. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the effective date and subsequently

modified. Estimated compensation expense for existing awards that were outstanding on the effective date is now recognized in the statement of operations over the remaining vesting periods using the expense as calculated for pro forma disclosure purposes under the previous stock-based compensation requirements. Prior to January 1, 2006, we used the intrinsic-value method of accounting for stock-based awards granted to employees and members of our board of directors and we did not recognize compensation cost in our financial statements because all these stock options had exercise prices equal to or greater than the fair value of the underlying stock at the time the stock option was granted.

In adopting SFAS 123R, companies must choose among alternative valuation models and amortization assumptions. After assessing alternative valuation models and amortization assumptions, we chose to use the Black-Scholes option valuation model and use the single-option award approach. The compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally four years. For the year ended December 31, 2006, our expenses under SFAS 123R aggregated \$508,000, which included \$275,000 upon the modification of previously outstanding awards concurrent with the merger transaction.

*Research and development costs.* All costs incurred for research and development are expensed as incurred. Research and development expenses include expenses for clinical trials, which are incurred from planning through patient enrollment to follow-up visits and reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient screening, enrollment and physician visits as reported by each of the various sites involved in the trial. Costs that are associated with patient screening and enrollment are recognized as each patient in the clinical trial completes the procedures. Estimated clinical trial costs related to screening, enrollment and physician visits can vary based on numerous factors, including the total expected number of patients in the trial and at each site, the number of patients that do not qualify for enrollment into the trial, the number of patients that miss scheduled physician visits and do not complete the trial, and the timing of when a patient drops out of a trial. Some of this information only becomes available after we report our expenses for clinical trials, in which case we would evaluate our estimates to determine whether they should be modified. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received.

### **Recent Accounting Pronouncements**

In May 2005, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 154, "*Accounting Changes and Error Corrections*" ("SFAS 154"), which replaces Accounting Principles Board Opinion No. 20, "*Accounting Changes*," and Statement of Financial Accounting Standards No. 3, "*Reporting Accounting Changes in Interim Financial Statements*." SFAS 154 requires retrospective application, unless impracticable, for changes in accounting principles in the absence of transition requirements specific to newly adopted accounting principles. The provisions of SFAS No. 154 were effective for Osteologix beginning on September 1, 2006, and there was no impact upon the Company's adoption of SFAS 154.

In June 2006, the FASB issued FIN 48, "*Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*" ("FIN 48"), which seeks to reduce the diversity in practice associated with the accounting and reporting for uncertainty in income tax positions. FIN 48 prescribes a model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in an income tax return and is effective for fiscal years beginning after December 15, 2006. The Company believes that, due to its operating losses, the implementation of FIN 48 will not have a material impact on its results of operations, financial position or cash flows. The Company is evaluating the impact of the adoption of FIN 48 on the footnote disclosures of its deferred tax valuation allowance.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "*Fair Value Measurements*" ("SFAS 157"), which clarifies and prioritizes methods for measuring fair value under generally accepted accounting principles. SFAS 157 generally increases the level of disclosure required for fair value measurements, although it does not impact the valuations or disclosures required under SFAS 123R. For Osteologix, implementation of SFAS 157 will be required on January 1, 2008. The Company is evaluating the impact of SFAS 157 on its financial statements and disclosures.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB No. 108"). SAB No. 108 was issued in order to eliminate the diversity in practice surrounding how public companies quantify financial statement misstatements. SAB No. 108 requires evaluation of errors using both a balance sheet (iron curtain) approach and an income statement (rollover) approach, and a determination of whether either approach results in a misstated amount that is material. The provisions of SAB No. 108 were effective for Osteologix beginning with the financial statements for the year ended December 31, 2006, and there was no impact upon the Company's adoption of SFAS 154.

### Important Developments

In 2006, two key events impacted the business of Osteologix. The first of these was a merger transaction and financing completed on May 24, 2006, which provided us with:

- financing to initiate and complete a phase II clinical trial for our osteoporosis drug, and
- a public stock listing (under ticker symbol "OLGX") for the first time.

The second key event was the initiation of our human phase II clinical trial in November 2006. In this trial we are evaluating the effect of various doses of NB S101 on markers of bone turnover before conducting our planned, more advanced studies of the investigational drug.

In addition to our financial results, we believe an important indicator of our potential success is the successful completion of human clinical trials and other studies which are necessary for us to continue pursuit of the investigational drugs we have under development (only one of which is currently being studied in humans).

### Revenues

Our products are currently in various stages of research and development. Since we were established, there has only been one source of revenue, which was \$750,000 in 2005 for the license of intellectual property rights to a related party. We recognized the full amount in the statement of operations because we have no on-going obligations under the agreement. Because we are still developing our products, we do not expect significant revenues for several years, if at all.

### Research and Development Expenses

Expenditures relating to research and development are expensed as incurred. Research and development expenses include clinical trial costs, development and manufacturing costs for medicinal products under investigation, payments to contract research organizations, compensation expenses for research and development personnel, preclinical studies, supplies and consulting costs.

Research and development expenses, and the changes compared to the previous year, were as follows (amounts in thousands):

For the Years Ended December 31,			Increase Compared to Previous Year	
2006	2005	2004	2006	2005
\$2,159	\$1,966	\$828	\$193	\$1,138

Research and development expenses increased \$193,000 in 2006 compared to 2005 primarily due to our start-up of a human phase II clinical trial in late 2006. The phase II clinical trial costs include expenditures incurred by the physicians treating the patients being evaluated for and enrolled into the trial, expenditures by a contract research organization that is assisting us with the oversight of the trial, and costs to acquire, manufacture and package the drug products that are being used in the study. Partially offsetting the increase in research and development expenses related to the phase II clinical trial was a decrease in costs in 2006 as a result of a phase I clinical trial that was both started and completed in 2005. Because later-stage clinical trials enroll more patients and treat them for a longer period of time, our incremental costs for the portion of the phase II trial that occurred in 2006 were greater than the costs for the full phase I trial incurred in 2005. In addition to costs related to the clinical trials,

in both 2006 and 2005 we have conducted animal studies of our investigational drug. Research and development costs increased in 2005 compared to 2004 largely due to the phase I human clinical trial conducted in 2005, additional animal studies and work on formulation and manufacturing of the drug substance.

We expect research and development expenses to increase further in 2007 because we plan to continue the current phase II clinical trial throughout most of the year, completing it near the end of 2007.

### General and Administrative Expenses

General and administrative expenses include compensation expense for personnel not directly involved in research and development activities, management and board of directors costs, insurance and accounting, legal and patent expenses.

General and administrative expenses, and the changes compared the previous year, were as follows (amounts in thousands):

For the Years Ended December 31,			Increase Compared to Previous Year	
2006	2005	2004	2006	2005
\$2,929	\$1,996	\$655	\$933	\$1,341

General and administrative expenses increased by \$933,000 in 2006 compared to 2005 as a result of several factors. The largest component of the increase was the costs recorded for the value of stock options granted to our employees and directors following our implementation of SFAS 1213R on January 1, 2006. In addition, we incurred increased expenses, including legal and accounting costs, of operating as a public company since our merger transaction was completed in May 2006. Osteologix also hired a chief financial officer in September 2006, increasing costs for 2006 compared to 2005 when the position was vacant. General and administrative expenses increased in 2005 compared to 2004 because in late 2004 we established a U.S. subsidiary, hired a chief executive officer and opened a U.S. office. We expect general and administrative expenses to increase in 2007 because our incremental costs for operating as a public company were incurred for only a portion of 2006. In addition, in 2007, as required by Section 404 of Sarbanes-Oxley, we will be required to provide a management attestation regarding our internal controls, further increasing general and administrative costs.

### Interest Income

Interest income was \$230,000 in 2006, an increase of \$214,000 compared to 2005. The higher interest income in 2006 was a result of higher average cash and short-term investments balances following our private placement and merger transaction in May 2006.

### LIQUIDITY AND CAPITAL RESOURCES

Osteologix measures its liquidity primarily by the cash, cash equivalents and short-term investments, as well as the working capital, available to fund its operations. Since we were founded in 2003, we have applied the majority of our resources to research and development programs and the administrative expenses to support the operations of the Company. We have operated at a loss since inception and expect to continue to incur losses in the future as a result of our ongoing research and development efforts.

The following table summarizes our cash, cash equivalents and short-term investments, and our working capital available to fund our operations (in thousands):

	December 31, 2006	December 31, 2005
Cash, cash equivalents and short-term investments . . . . .	\$6,200	\$571
Working capital . . . . .	5,788	936

The increase in our cash, cash equivalents and short-term investments of \$5,629,000 during 2006 occurred primarily as a result of the \$9,256,000 net capital from the private placement financing that occurred simultaneously with our merger transaction in May 2006. This increase in cash, cash equivalents and short-term investments was

partially offset by \$3,568,000 used in operations, which funded our continuing development of NB S101 for osteoporosis, including the start-up of the phase II human clinical trial, and the administrative expenses of operating a public company. We have experienced net losses from our inception through December 31, 2006, and we expect losses to continue as we further our research and development programs. We have prepared our financial statements assuming that we will continue as a going concern, which we believe is appropriate because we plan to raise additional funds through one or more of the various alternatives we are considering. However, we may not be able to raise additional funds on acceptable terms or at all. We believe that our current cash, cash equivalents and short-term investments as of December 31, 2006 will provide liquidity to fund our operations into the fourth quarter of 2007.

## **PLAN OF OPERATION**

Our business strategy is to develop drug candidates that target major medical needs and can be rapidly commercialized. We are currently focusing on the treatment and prevention of diseases of bone and joint tissues. NB S101, which is in phase II clinical development for the treatment of osteoporosis, fits this strategy because the osteoporosis market is large, with over \$10 billion in annual product sales, and preclinical studies and phase I human clinical studies have been completed. In addition, a different drug which also contains a strontium compound as its active ingredient (as does NB S101) has been proven safe and effective and is approved for treatment of osteoporosis in Europe, which we believe reduces the development risk for NB S101 as compared to other investigational drugs in completely unproven chemical classes. In executing our business strategy, our management oversees the human clinical trials necessary to establish preliminary evidence of efficacy, and we are seeking to establish collaborative agreements with pharmaceutical and biotechnology companies for their late-stage development and marketing of our product candidates and/or our obtaining rights to develop and market certain of their product candidates. We plan to continue to acquire and develop products, and plan to either develop the resources to market these products in selected world regions or out-license marketing rights to larger pharmaceutical companies.

We believe that our currently available existing resources will provide liquidity to fund our planned operations into the fourth quarter of 2007. Because we are in the business of developing pharmaceutical products, which is time-consuming and expensive, and NB S101, our most advanced investigational drug, has only recently entered phase II clinical trials, we will require additional financial resources to carry out our business strategy. We plan to follow the current phase II clinical trial with a larger phase II clinical trial that we estimate will take approximately two years to complete. After the second phase II clinical trial, either one or two still larger phase III trials will be required. We may license the rights to NB S101 to a larger company before any of the clinical trials are complete, or we may choose to retain all rights ourselves without entering into a license or collaborative agreement. If the results of the clinical trials are positive, we plan to seek approval for NB S101 throughout the world, either on our own or in collaboration with a larger pharmaceutical company that has more financial resources than we do.

Because we are developing NB S101 and are also seeking to expand our line of investigational drugs by acquiring rights to additional drugs in development, we will require additional financial resources to carry out our plans. While we currently plan to seek to secure additional funds prior to obtaining the results from our current phase II clinical trial, we may also choose to wait for results from our the clinical trial before we obtain additional funding, in which case we will need to reduce certain expenditures in order to preserve our cash and short-term investments through the time the trial results are available. We are exploring various options to obtain additional capital, including the licensing of certain rights to NB S101, the sale of equity or debt securities and additional other alternatives. Our ability to successfully raise additional funds for our operations will be based, in part, on overall market conditions, conditions in the biotechnology and pharmaceutical industries, the status and results of our clinical trials, and other parties' opinions about NB S101 and the osteoporosis market, among other factors. Additional funding may not be available on acceptable terms, if at all. The actual amounts we needed for our future capital requirements will vary depending on a number of other factors, including but not limited to:

- the progress we make in our clinical development programs;
- our ability to establish collaborative relationships and the terms of these relationships;
- the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;
- our acquisition or licensing of new drug candidates;

- competing technological and market developments;
- the requirements of regulatory agencies;
- the time and cost involved in obtaining regulatory approvals; and
- the development of commercialization activities and arrangements.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

We do not have any off-balance sheet arrangements as defined by rules recently enacted by the Financial Accounting Standards Board, and accordingly, no such arrangements are likely to have an effect on our consolidated financial position or results of operations.

#### **COMMITMENTS**

Under the terms of the Registration Rights Agreements we entered into in connection with the May 2006 private placement, if our registration statement does not remain effective as specified in the agreements, we will be required to pay liquidated damages of up to 2% of the original purchase price of the shares and may also be required in certain circumstances to continue to pay this amount on each monthly anniversary that the registration statement fails to continue to be effective.

## RISK FACTORS

### Risks Related to Our Business

*We currently have no product revenues.*

To date, we have devoted significant financial resources to the research and development of our products, primarily NB S101. Unless and until we receive approval from the FDA and foreign regulatory authorities for our product candidates, we cannot sell our products and will not have product revenues. As a result, we have generated significant operating losses. As of December 31, 2006, our consolidated balance sheet has an accumulated deficit of approximately \$10 million. We have used substantial amounts of cash to date and expect operating expenditures to increase over the next several years as we increase our research and development activities and further build our infrastructure. For the foreseeable future we will have to fund all of our operations and capital expenditures from our cash and short-term investments, the net proceeds of offerings of our securities (which would be dilutive to holders of our stock), granting the rights to our products to others, and/or government grants and contracts.

*We expect to need additional financing, which may not be available on satisfactory terms or at all.*

We believe that our existing cash will be sufficient to support our current operating plan until the fourth quarter of 2007. As of December 31, 2006, we had \$6.2 million in cash and short-term investments. However, we will need to raise additional funds to support our future development programs, including completion of the clinical trials required to market our products. Our funding requirements may change as a result of many factors, including delays in development activities, underestimates of budget items, unanticipated cash requirements, limitation of development of new potential products, future product opportunities with collaborators, future licensing opportunities and future business combinations. Consequently, we are likely to need to seek additional sources of financing, which may not be available on favorable terms, if at all, and which may be dilutive to our stockholders.

We may seek to raise additional financing through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. To the extent we raise additional capital by issuing equity securities, our stockholders will experience dilution. To the extent that we raise additional capital by issuing debt securities, we will incur interest obligations, may be required to pledge assets as security for the debt and may be constrained by restrictive financial and/or operational covenants. Debt securities would also be superior to our stockholders' interests in bankruptcy or liquidation. To the extent we raise additional funds through collaboration and licensing arrangements, it is likely we will need to relinquish some rights to our technologies or product candidates. We may need to grant licenses that contain unfavorable terms.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and/or other regulatory authorities. In addition, we could be forced to discontinue product development, curtail operations, reduce or forego sales and marketing efforts and lose attractive business opportunities.

*We are not currently profitable and may not become profitable.*

We have a history of losses and expect to incur substantial losses and negative operating cash flows for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2006 and 2005, we had operating losses of \$4.9 million and \$3.2 million, respectively. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating expenditures for the next several years, and anticipate that our expenses will increase substantially in the foreseeable future as we continue clinical development, seek to advance our product candidates closer to market, seek to expand our pipeline of research and development projects, implement additional internal systems and infrastructure and build our infrastructure.

We expect to experience negative cash flow for the foreseeable future as we fund our operating losses and any necessary capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability, which we may not be able to do. This could adversely affect the value of our common stock.

*We have a limited operating history upon which to base an investment decision.*

We are a development-stage company and have not yet demonstrated our ability to successfully commercialize any product candidates. Successful commercialization will require us to, among other things, undertake preclinical development and clinical trials; apply for and receive regulatory approvals for conduct of clinical trials and for marketing of our products when development has been completed; formulate and manufacture products; and conduct sales and marketing activities.

Our operations have been limited to organizing and staffing, acquiring, developing and securing our proprietary technology and undertaking pre-clinical trials and clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

Obtaining and maintaining the necessary U.S. and/or worldwide regulatory approvals for our product candidates will be time consuming, difficult and costly. If we fail to do so, we will be unable to commercialize our product candidates.

Government regulations in the U.S. and other countries have a significant impact on our business and affect research and development, manufacture and marketing of our products. We will require FDA approval to commercialize our product candidates in the U.S., and approvals from similar foreign regulatory authorities to commercialize our product candidates outside the U.S. In order to obtain FDA approval of a product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. These studies will be time consuming, difficult and costly, and we cannot predict whether our efforts will result in any drugs that the FDA or other regulatory authorities consider safe and effective for humans. The FDA has substantial discretion in the drug approval process, and may refuse to accept our application or may deny approval. If the FDA does not accept or approve our application, it may require us to conduct additional pre-clinical testing or manufacturing studies and submit that data before it will reconsider our application, or require us to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals will increase our operating expenses and delay the commercialization of our product candidates and our ability to derive product revenues from them.

Even if we comply with all FDA requests, the FDA may ultimately determine, under its statutory authority, to deny our requests for approval of our drug candidates. We cannot be certain that we will ever obtain regulatory clearance for any product candidate. Failure to obtain FDA approval of NB S101 or any other product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory, pricing and reimbursement authorities before we can commercialize and market our drugs. These processes generally include all of the risks associated with FDA procedures. Pursuing foreign approvals will be time-consuming and expensive. Regulations vary among countries, and foreign authorities may require different or additional clinical trials than we conduct in our attempts to obtain FDA approval. We may never receive any of the approvals necessary to commercialize our product candidates.

We currently plan to commercialize NB S101 and other potential products internationally through collaborative relationships with pharmaceutical companies that have foreign sales capabilities. Future collaborative relationships are important to the success of our products internationally because we do not have regulatory, clinical and commercial resources necessary to obtain approval for and sell our product throughout the world. We may not be able to enter into collaboration agreements with appropriate other companies for important foreign markets on acceptable terms, or at all. Such collaborations may not be effective or profitable for us.

In addition, even if we do get to the point where our product candidates are marketed, the products and our manufacturers are still subject to continual review by applicable regulatory authorities, including FDA adverse event reporting requirements and FDA requirements governing product distribution, advertising, and promotion. At

any stage of development or commercialization, the discovery of previously unknown problems with our product candidates, our own manufacturing or the manufacture by third parties may result in restrictions on our products or in their manufacture, including withdrawal of the product from the market.

***We have only one product that is currently being evaluated for commercial development.***

Our current product candidate NB S101 is the only pharmaceutical product we are testing in humans and it may never be successfully marketed or manufactured. This product candidate is in the early stages of clinical testing on a limited number of subjects. To date we have conducted no studies to determine efficacy. The clinical trials required by the FDA and other regulatory authorities are long and complex and will take a number of years to complete. It is possible that our preferred single-tablet dosage, which we expect to be an advantage over certain existing therapies, will not be accepted by the FDA or supported by the clinical trial data. It also is possible that the FDA and other regulatory authorities will disagree with our current clinical and pre-clinical research plans and require us to conduct more extensive studies than we currently anticipate before considering our products for marketing approval.

Our current phase II study and most of our future studies involve drug exposures for durations that are significantly longer than we have tested thus far. The longer-term studies could reveal safety or other issues that could adversely affect marketing approval. We need to commit substantial time and additional resources in order to conduct further clinical trials before we can submit a NDA with respect to any of these product candidates. We cannot predict with any certainty if or when we might submit any NDA for regulatory approval for any of our product candidates.

***Clinical trials are time-consuming, difficult and costly to design and implement.***

Human clinical trials are expensive and difficult to design and implement. The studies involve human volunteers taking an investigational product that has not been proven safe and effective and the science behind the trials is complex and subject to rigorous regulatory requirements. Further, the medical, regulatory and commercial environment for pharmaceutical products can change quickly, and often in ways we may not be able to predict. In addition to its complexity, the clinical trial process is also time-consuming. We estimate that clinical trials of NB S101 will take at least several more years to complete. Furthermore, as failure can occur at any stage, we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by, among other things, changes in regulatory requirements, unforeseen safety issues, determination of dosing issues, lack of effectiveness in clinical trials, slower than expected patient recruitment, inability to monitor patients adequately during or after treatment, inability or unwillingness of medical investigators to follow our clinical protocols, inability to maintain a sufficient supply of the investigational drug to support the trials, suspension or termination of clinical trials for noncompliance with regulatory requirements and changes in clinical care protocols and standards of care within the institutions in which our trials take place.

In addition, we or the FDA may suspend our clinical trials at any time if it appears we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in any of our submissions or in the conduct of the trials. A number of companies in the biotechnology and drug development industry have suffered significant setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop marketable products.

***Delays in patient enrollment for clinical trials could increase costs and delay regulatory approvals.***

The rate of completion of our clinical trials will depend on the rate of patient enrollment. We may face substantial competition in seeking to enroll qualified patients into our clinical trials. Competition for patients has delayed clinical trials of other biotechnology and drug development companies. In addition, recent improvements in existing drug therapy, particularly for medical products for prophylaxis and treatment of osteoporosis, may make it more difficult for us to enroll patients in our clinical trials as the patient population may choose to enroll in clinical trials sponsored by other companies or choose alternative therapies. Delays in patient enrollment can result in increased development costs and delays in regulatory approvals.

The FDA or other regulatory authorities may also change the requirements for testing new drugs for osteoporosis. For example, the current guidelines require placebo-controlled clinical trials conducted in osteoporotic patients. There are ethical concerns regarding treating osteoporotic patients with placebo, and the FDA or other regulatory authorities may at some time require osteoporosis drugs in the future to include active controls (such as existing osteoporosis treatments) instead of placebo. If the FDA makes these changes, we may need to enroll more patients, conduct longer clinical trials, or otherwise change our planned clinical trial designs, potentially and substantially increasing the costs and/or decreasing our chances of demonstrating the efficacy needed to obtain approval.

***The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.***

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses, which could cause us to abandon a product candidate and may delay or cancel development of others. Any delay of our clinical trials will delay the filing of our NDAs and, ultimately, our ability to commercialize our product candidates and generate revenues. Any cancellation of our clinical trials will eliminate our ability to file an NDA for that product and eliminate our ability to generate any revenue from that product, unless we are later able to conduct a different trial that would satisfy the regulatory authorities.

It is possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of our product candidate's profile. In addition, our clinical trials involve a comparatively small patient population. Because of the small sample size, their results may not be indicative of future results.

In any drug development program, it is typically during the final large phase III studies when large numbers of patients are tested, that most reliable information on side effects are collected. We have not reached this development stage yet, and we cannot accurately predict if phase III studies with our lead product, strontium malonate, in the form of the tablet NB S101, will reveal unexpected side effects. It is our belief, based on previous clinical experience with strontium ranelate, that such side effects will be mild and few serious adverse events will occur, but we have no actual data or information that support this for NB S101. Occurrence of any side effect could delay or terminate further development and hamper or prevent regulatory approval or marketing of our product.

***Physicians and patients may not accept and use our drugs.***

Even if the FDA approves one or more of our drug candidates, physicians and patients may not accept and use them. Acceptance and use of our drugs will depend upon a number of factors, including perceptions by the health care community, including physicians, about their safety and effectiveness, their cost-effectiveness relative to competing products, the availability of reimbursement for our products from government or other healthcare payors, such as major insurance companies, and the effectiveness of marketing and distribution efforts by us, our licensees and distributors.

Because we expect sales of NB S101 to generate substantially all of our product revenues in the future, if it is approved, the failure of NB S101 to find market acceptance would cause us considerable harm because this is our largest anticipated future source of revenue. Likewise, the failure of other product candidates to achieve market acceptance would also reduce our revenue.

***Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate reimbursement.***

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations, health insurers, and other payors.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, routinely challenge prices charged. Government and other healthcare payors limit both coverage and reimbursement. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement may be inadequate. If payors do not provide adequate coverage and reimbursement levels, the post-approval market acceptance of our products could be diminished.

***Our drug-development programs depend upon third-party researchers who are outside our control.***

We depend upon independent investigators and collaborators, such as universities, medical institutions, and clinical research organizations, to conduct our pre-clinical and clinical trials and, in certain cases, to develop a product for its target indication. We contract with these collaborators, but they are not our employees, and we cannot control the amount or timing of resources they devote to our programs. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking them ourselves. If outside collaborators fail to devote sufficient time and resources to our programs, or if their performance is substandard, the approval of our FDA applications, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators were to assist our competitors at our expense, our competitive position would be harmed.

***We rely exclusively on third parties to manufacture our product candidates.***

We rely exclusively on a limited number of vendors to supply raw materials and finished goods for our product candidates, and the loss of one of these parties could harm our business. The FDA and regulatory agencies in other countries also periodically inspect manufacturing facilities, including third parties who manufacture our products or our active ingredients for us. The FDA may not believe that our chosen manufacturers have enough experience making the dosage forms we have contracted them to produce, and may subject those manufacturers to increased scrutiny. Pharmaceutical manufacturing facilities must comply with applicable GMP standards, and manufacturers usually must invest substantial funds, time and effort to ensure full compliance with these standards and make quality products. We do not have control over our manufacturers' compliance with these requirements. Failure to comply with regulatory requirements can result in sanctions, fines, delays, suspensions of approvals, seizures or recalls of products, operating restrictions, manufacturing interruptions, costly corrective actions, injunctions, adverse publicity against us and our products and criminal prosecutions.

If we are unable to obtain sufficient supplies of raw materials or if there is a significant increase in the price of raw materials, our business would be seriously harmed. If any of our product candidates receive FDA approval, we expect to rely on one or more third-party contractors to supply our drugs. The qualification of suppliers is a lengthy and expensive process. If our current or future third-party suppliers cease to supply drugs in the quantity and quality we need, or if they are unable to comply with GMP standards and other government regulations, there may not be adequate alternatives to meet our needs. As a result, we may not be able to supply our products to the market on a timely basis, if at all. This would negatively affect our business.

We currently rely on a sole source for our supply of the active pharmaceutical ingredient in NB S101 for the investigational drug we are using in clinical trials. We also currently rely on a different sole source for our supply of finished tablets of NB S101. If either of these suppliers fails to provide us with sufficient quantities of the active pharmaceutical ingredient or the finished tablets, we may not be able to complete our clinical trials as planned. Although we are currently having discussions with alternative suppliers, we may not be able to find other suppliers on acceptable terms, or at all.

***If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed. We must hire and retain skilled employees in a tight labor market.***

Attracting and retaining qualified personnel is critical to our success. As our business grows, we need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation, manufacturing and sales and marketing, among others. We will require scientific personnel in various fields, some of which have relatively qualified candidates due to the specialization needed. As a result, we may continue to experience difficulty in hiring and retaining highly skilled employees, particularly scientists.

We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions, most of which are more established than we are and have the ability to pay more cash compensation than we can. Competition for such individuals, particularly in the San Francisco Bay area and the Copenhagen, Denmark area, is intense, and we may not be successful in our search for qualified personnel. If we are unable to hire and retain skilled scientists, our business, financial condition, operating results and future prospects could be materially adversely affected.

***If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues, and our business will suffer.***

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues, and our business will suffer.

***Developments by competitors may render our products or technologies obsolete or noncompetitive.***

Companies that currently sell osteoporosis products include Merck, Procter & Gamble, GlaxoSmithKline, Eli Lilly, Wyeth Ayerst, Novartis, Hoffmann-LaRoche and Sanofi-Aventis. Alternative products and technologies are being developed to improve upon or replace current products for the treatment of osteoporosis, several of which are awaiting FDA approval or are in late-stage clinical trials. In addition, companies pursuing similar therapeutic areas also represent substantial competition. All of these competitors have substantially greater financial resources than we do and operate larger research and development organizations. They also have significantly greater experience in drug development and in obtaining FDA and other regulatory approvals, as well as experience in launching, marketing and selling drugs. The greater size and experience of our competitors allows them to develop and market competing products more rapidly and more effectively than we can.

***If we fail to protect adequately or enforce our intellectual property rights, or to secure rights to patents of others, the value of our intellectual property rights could diminish.***

Our success, competitive position and future revenues will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

To date, we have filed over 25 individual patent applications in the U.S. and in other countries. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict the degree and range of protection patents will afford us against competitors, including if and when patents will issue, whether third parties will find ways to invalidate or otherwise circumvent our patents, whether or not others will obtain patents claiming aspects similar to our patent applications, or if we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.

Our success also depends on the skills, knowledge and experience of our scientific and technical personnel, consultants, advisors, licensors and contractors. To help protect our proprietary know-how and inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality and grant-back agreements. However, these agreements may not provide adequate protection. If any of our intellectual property is disclosed, its value may be significantly impaired, and our business and competitive position could suffer.

***If we infringe the rights of third parties, we could be prevented from selling products, forced to pay damages, and compelled to defend against litigation.***

If our products, methods, processes and other technologies infringe proprietary rights of other parties, we could incur substantial costs, and we may have to obtain licenses, which may not be available on commercially reasonable

terms, if at all. We may be required to redesign our products or processes, stop using the subject matter claimed in the asserted patents, pay damages, or defend litigation or administrative proceedings, which may be costly whether we win or lose. All these could result in a substantial diversion of valuable management and scientific resources. Resolving intellectual property issues could result in lengthy and costly legal proceedings, the outcome of which cannot be predicted.

***We may be exposed to liability claims associated with using hazardous materials and chemicals.***

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe our safety procedures for using, storing, handling and disposing of these materials comply with applicable laws and regulations, we cannot eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for resulting damages, which could materially adversely affect our business, financial condition and results of operations. In addition, laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

***We may incur substantial liabilities and be required to limit commercialization of our products in response to product liability lawsuits.***

Testing and marketing medical products entails an inherent risk of product liability. We may be held liable if serious adverse reactions occur either in clinical trials or subsequently after approval. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even if we successfully defend ourselves against such claims, we will be required to divert significant resources to the defense of the claims. Our inability to obtain sufficient product liability insurance at acceptable cost against claims could prevent or inhibit the commercialization of pharmaceutical products we develop, either alone or with collaborators. We currently carry clinical trial insurance but we do not carry product liability insurance. We, or any collaborators, may not be able to obtain insurance at reasonable cost, if at all. Agreements with future collaborators entitling us to indemnification against losses may not be adequate if claims arise.

**Risk Related to Management**

***We may not successfully manage our growth.***

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and administrative, operational, and financial resources. To manage this growth, we must augment our operational, financial and management systems, expand our facilities, and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We rely on key executive officers and scientific and medical advisors. Their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on Charles J. Casamento, our CEO and President, as well as Dr. Stephan Christgau, our Chief Operating Officer and Matthew M. Loar, our Chief Financial Officer. We do not have "key person" life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, inability to obtain financing for our business, and diversion of management resources, which could adversely affect our operating results, our ability to obtain approval for our product candidates, or even our ability to continue operations as planned.

In addition, we rely on members of our scientific advisory board and clinical advisors to assist us in formulating research and development strategy. Our scientific advisory board members and clinical advisors generally have other full-time employment and other commitments, and may be subject to non-disclosure obligations that may limit their availability to work with us.

*The concentrated ownership of our common stock may have the effect of delaying or preventing a change in control of our Company.*

Nordic Biotech K/S, a venture capital firm and limited partnership in Denmark, was the sole investor in and the sole stockholder of Osteologix from our formation until May 24, 2006. Nordic Biotech currently owns 60.1% of the common stock of Osteologix. As a result of their concentrated ownership of our stock, they are able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of mergers, acquisitions and other significant corporate transactions. In addition, if they elect to sell any of their securities in Osteologix, it will likely cause our stock price to decrease.

*Our compliance with the Sarbanes-Oxley Act and SEC rules concerning internal controls may be time consuming, difficult and costly.*

Under current requirements, our management will be required to attest to the adequacy of our internal controls for the first time when we file our 2007 Annual Report on Form 10-KSB, and our auditors will be required to audit these internal controls for the first time when we file our 2008 Annual Report on Form 10-KSB. It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley, and due to our small size the proportion of costs we need to devote to comply with these requirements may be substantially greater than it is for other companies. We may need to hire additional financial reporting, internal controls and other finance staff in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with Sarbanes-Oxley's internal controls requirements when the requirements become effective for us, we may not be able to obtain the independent accountant certifications that Sarbanes-Oxley Act requires publicly-traded companies to obtain.

*We cannot assure you that the common stock will become liquid or that it will be listed on a securities exchange.*

We plan to list our common stock on the American Stock Exchange or the Nasdaq Global Market as soon as we meet the listing requirements. However, we may never be able to meet the initial listing standards of either of those markets or of any other stock exchange, and if we do meet the initial listing standards, we may not be able to maintain any such listing. Until the common stock is listed on an exchange, we expect that it would continue to be eligible to be quoted on the OTC Bulletin Board, another over-the-counter quotation system, or in the "pink sheets." In these venues, however, an investor may find it difficult to obtain accurate quotations as to the market value of the common stock. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling the common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

*There may be issuances of shares of preferred stock in the future.*

Although we currently do not have preferred shares outstanding, the board of directors could authorize the issuance of a series of preferred stock that would grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

*We have never paid dividends.*

We have never paid cash dividends on our common stock and do not anticipate paying any for the foreseeable future.

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of  
Osteologix, Inc.:

We have audited the accompanying consolidated balance sheets of Osteologix, Inc. and subsidiary (the "Company"), (a development stage company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from June 16, 2003 (inception) through December 31, 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Osteologix, Inc. and subsidiary at December 31, 2006 and 2005, and the consolidated results of operations and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from June 16, 2003 (inception) through December 31, 2006, in conformity with the accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006 the Company adopted Statement of Financial Accounting Standard No. 123R "Share-Based Payment" which requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has limited revenues and has experienced net losses and negative cash flows from operations since its inception through December 31, 2006 and expects such losses to increase as research and development programs continue. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Weinberg & Company, P.A.

Boca Raton, Florida  
March 16, 2007

***The concentrated ownership of our common stock may have the effect of delaying or preventing a change in control of our Company.***

Nordic Biotech K/S, a venture capital firm and limited partnership in Denmark, was the sole investor in and the sole stockholder of Osteologix from our formation until May 24, 2006. Nordic Biotech currently owns 60.1% of the common stock of Osteologix. As a result of their concentrated ownership of our stock, they are able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of mergers, acquisitions and other significant corporate transactions. In addition, if they elect to sell any of their securities in Osteologix, it will likely cause our stock price to decrease.

***Our compliance with the Sarbanes-Oxley Act and SEC rules concerning internal controls may be time consuming, difficult and costly.***

Under current requirements, our management will be required to attest to the adequacy of our internal controls for the first time when we file our 2007 Annual Report on Form 10-KSB, and our auditors will be required to audit these internal controls for the first time when we file our 2008 Annual Report on Form 10-KSB. It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley, and due to our small size the proportion of costs we need to devote to comply with these requirements may be substantially greater than it is for other companies. We may need to hire additional financial reporting, internal controls and other finance staff in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with Sarbanes-Oxley's internal controls requirements when the requirements become effective for us, we may not be able to obtain the independent accountant certifications that Sarbanes-Oxley Act requires publicly-traded companies to obtain.

***We cannot assure you that the common stock will become liquid or that it will be listed on a securities exchange.***

We plan to list our common stock on the American Stock Exchange or the Nasdaq Global Market as soon as we meet the listing requirements. However, we may never be able to meet the initial listing standards of either of those markets or of any other stock exchange, and if we do meet the initial listing standards, we may not be able to maintain any such listing. Until the common stock is listed on an exchange, we expect that it would continue to be eligible to be quoted on the OTC Bulletin Board, another over-the-counter quotation system, or in the "pink sheets." In these venues, however, an investor may find it difficult to obtain accurate quotations as to the market value of the common stock. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling the common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

***There may be issuances of shares of preferred stock in the future.***

Although we currently do not have preferred shares outstanding, the board of directors could authorize the issuance of a series of preferred stock that would grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

***We have never paid dividends.***

We have never paid cash dividends on our common stock and do not anticipate paying any for the foreseeable future.

***Our common stock is considered a "penny stock."***

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock is less than \$5.00 per share and therefore is a "penny stock." Broker and dealers effecting transactions in "penny stock" must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect your ability to sell shares.

**Item 7. *Financial Statements***

Our Consolidated Financial Statements are set forth in the "Osteologix, Inc. Index to Consolidated Financial Statements" on page F-1 of this Annual Report on Form 10-KSB.

**Item 8. *Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.***

None.

**Item 8A. *Controls and Procedures.***

Under the supervision and with the participation of the Company's management, including our principal executive officer and principal accounting officer, the Company conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of the end of the period covered by this report (the "Evaluation Date"). Based on this evaluation, the Company's principal executive officer and principal accounting officer concluded as of the Evaluation Date that the Company's disclosure controls and procedures were effective such that the material information required to be included in our Securities and Exchange Commission ("SEC") reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms relating to the Company, including our consolidating subsidiaries, and was made known to them by others within those entities, particularly during the period when this report was being prepared.

Additionally, there were no changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the Evaluation Date. We have not identified any significant deficiencies or material weaknesses in our internal controls, and therefore there were no corrective actions taken.

**Item 8B. *Other Information.***

Not applicable.

**PART III**

**Item 9. *Directors, Executive Officers, Promoters, Control Persons, and Corporate Governance; Compliance With Section 16(a) of the Exchange Act.***

The information required by Item 9 is incorporated herein by reference to the sections of the Proxy Statement entitled "Directors and Executive Officers of the Company," "Certain Relationships and Related Transactions," and "Compliance With Section 16(a) of the Exchange Act."

**Item 10. *Executive Compensation.***

The information required by Item 10 is incorporated herein by reference to the section of the Proxy Statement entitled "Executive Compensation."

**Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by Item 11 is incorporated herein by reference to the sections of the Proxy Statement entitled "Proposal 2 — Ratification of the Company's Equity Incentive Plan," and "Security Ownership of Management and Certain Beneficial Owners."

**Item 12. Certain Relationships and Related Transactions, and Director Independence.**

The information required by Item 10 is incorporated herein by reference to the section of the Proxy Statement entitled "Certain Relationships and Related Transactions" and "Proposal 1 — Election of Directors."

**Item 13. Exhibits.**

The following exhibits are filed as part of this report:

<u>Exhibit Number</u>	<u>Description</u>
2.1	Share and Warrant Exchange Agreement, dated as of May 24, 2006, by and among Castle & Morgan Holdings, Inc., various Warrantholders, Nordic Biotech K/S, Charles J. Casamento as attorney-in-fact for various investors, and Osteologix A/S (incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on May 31, 2006 (the "May 31, 2006 Form 8-K")).
3.1	Articles of Incorporation, as amended.*
3.2	Amended and Restated Bylaws of Osteologix, Inc. (incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-QSB filed for the quarter ended September 30, 2006).
10.1	Subscription Agreement, dated as of May 24, 2006 (incorporated herein by reference to Exhibit 10.2 to the May 31, 2006 Form 8-K).
10.2	Registration Rights Agreement, dated as of May 24, 2006 (incorporated herein by reference to Exhibit 10.3 to the May 31, 2006 Form 8-K).
10.3	Patent License Agreement between Osteologix A/S and Aditech Pharma AB dated November 30, 2005.*
10.4	Service Agreement between Nordic Bone A/S and Charles J. Casamento.*
10.5	Osteologix, Inc. Equity Incentive Plan.*
21.1	Subsidiary List.*
23.1	Consent of Independent Registered Public Accounting Firm.*
31.1	Certification of Chief Executive Officer pursuant to Rules 13A-14(A) and 15D-14(A) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Rules 13A-14(A) and 15D-14(A) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).*

\* filed herewith

**Item 14. Principal Accountant Fees and Services.**

The information required by Item 14 is incorporated herein by reference to the section of the Proxy Statement entitled "Proposal 3 — Ratification of the Appointment of the Independent Registered Public Accounting Firm."

**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**OSTEOLOGIX, INC.**  
Principal Executive Officer:

By: /s/ Charles J. Casamento  
Name: Charles J. Casamento  
Title: Chief Executive Officer and President

Date: March 27, 2007

Principal Financial and Accounting Officer:

By: /s/ Matthew M. Loar  
Name: Matthew M. Loar  
Title: Chief Financial Officer

Date: March 27, 2007

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Charles J. Casamento and Matthew M. Loar as his true and lawful attorney-in-fact, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this Annual Report on Form 10-KSB, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Klaus Eldrup-Jørgensen</u> Klaus Eldrup-Jørgensen	Chairman of the Board	March 27, 2007
<u>/s/ Charles J. Casamento</u> Charles J. Casamento	Chief Executive Officer, President and Director	March 27, 2007
<u>/s/ Matthew M. Loar</u> Matthew M. Loar	Chief Financial Officer	March 27, 2007
<u>/s/ Jeremy Curnock Cook</u> Jeremy Curnock Cook	Director	March 27, 2007

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Christian Hansen</u> Christian Hansen	Director	March 27, 2007
<u>/s/ Bobby W. Sandage,</u> Bobby W. Sandage, Jr.	Director	March 27, 2007
<u>/s/ Florian Schönharting</u> Florian Schönharting	Director	March 27, 2007
<u>/s/ Christopher B. Wood</u> Christopher B. Wood	Director	March 27, 2007

(This page intentionally left blank)

**Osteologix, Inc.**

**Index to Consolidated Financial Statements**

Report of Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets as of December 31, 2006 and 2005 . . . . .	F-3
Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004 and for the period from June 16, 2003 (Inception) through December 31, 2006 . . . . .	F-4
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the period from June 16, 2003 (Inception) through December 31, 2006 . . . . .	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004 and for the period from June 16, 2003 (Inception) through December 31, 2006 . . . . .	F-6
Notes to the Consolidated Financial Statements . . . . .	F-7

•

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of  
Osteologix, Inc.:

We have audited the accompanying consolidated balance sheets of Osteologix, Inc. and subsidiary (the "Company") (a development stage company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from June 16, 2003 (inception) through December 31, 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Osteologix, Inc. and subsidiary at December 31, 2006 and 2005, and the consolidated results of operations and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from June 16, 2003 (inception) through December 31, 2006, in conformity with the accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006 the Company adopted Statement of Financial Accounting Standard No. 123R "Share-Based Payment" which requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has limited revenues and has experienced net losses and negative cash flows from operations since its inception through December 31, 2006 and expects such losses to increase as research and development programs continue. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Weinberg & Company, P.A.

Boca Raton, Florida  
March 16, 2007

**Osteologix, Inc.**  
**(a development stage company)**

**Consolidated Balance Sheets**

	<u>December 31,</u> <u>2006</u>	<u>December 31,</u> <u>2005</u>
	(In thousands, except per share amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 481	\$ 571
Short-term investments .....	5,719	—
Receivable from related party .....	—	750
Prepaid expenses and other assets .....	<u>333</u>	<u>296</u>
Total current assets .....	6,533	1,617
Equipment, net .....	<u>9</u>	<u>7</u>
Total assets .....	<u>\$ 6,542</u>	<u>\$ 1,624</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 600	\$ 481
Accrued liabilities .....	<u>145</u>	<u>200</u>
Total current liabilities .....	<u>745</u>	<u>681</u>
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, \$0.0001 par value, 1,000 shares authorized, none issued or outstanding at December 31, 2006; none authorized, issued or outstanding at December 31, 2005 .....	—	—
Common stock, \$0.0001 par value, 100,000 shares authorized, 21,021 shares issued and outstanding at December 31, 2006, 10,505 shares authorized, issued and outstanding at December 31, 2005 .....	2	1
Additional paid-in capital .....	15,622	5,859
Accumulated other comprehensive loss .....	(56)	(4)
Deficit accumulated during development stage .....	<u>(9,771)</u>	<u>(4,913)</u>
Total stockholders' equity .....	<u>5,797</u>	<u>943</u>
Total liabilities and stockholders' equity .....	<u>\$ 6,542</u>	<u>\$ 1,624</u>

See accompanying notes to consolidated financial statements.

**Osteologix, Inc.**  
**(a development stage company)**  
**Consolidated Statements of Operations**

	For the Years Ended December 31,			For the Period from June 16, 2003 (Inception) through December 31, 2006
	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2006</u>
	(In thousands, except per share amounts)			
Revenues . . . . .	\$ —	\$ 750	\$ —	\$ 750
Operating expenses:				
Research and development . . . . .	2,159	1,966	828	5,084
General and administrative . . . . .	2,929	1,996	655	5,697
Total operating expenses . . . . .	<u>5,088</u>	<u>3,962</u>	<u>1,483</u>	<u>10,781</u>
Loss from operations . . . . .	(5,088)	(3,212)	(1,483)	(10,031)
Interest income, net . . . . .	230	16	12	260
Net loss . . . . .	<u>\$ (4,858)</u>	<u>\$ (3,196)</u>	<u>\$ (1,471)</u>	<u>\$ (9,771)</u>
Net loss per common share, basic and diluted . . . . .	<u>\$ (0.29)</u>	<u>\$ (0.34)</u>	<u>\$ (0.23)</u>	
Weighted average number of common shares outstanding — basic and diluted . . . . .	<u>16,872</u>	<u>9,415</u>	<u>6,502</u>	

See accompanying notes to consolidated financial statements.

**Osteologix, Inc.**  
(a development stage company)

**Consolidated Statement of Stockholders' Equity and Comprehensive Loss**  
**For the Period From June 16, 2003 (Inception) through December 31, 2006**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount				
(In thousands, except per share amounts)						
Issuance of common stock to founders for cash of \$0.02 per share in June 2003	4,897	\$ 1	\$ 84	\$ —	\$ —	\$ 85
Issuance of common stock for cash of \$0.95 per share in October 2003	979	—	930	—	—	930
Comprehensive loss:						
Net loss for the period	—	—	—	—	(246)	(246)
Foreign currency translations	—	—	—	(21)	—	(21)
Total comprehensive loss	—	—	—	—	—	(267)
<b>Balance at December 31, 2003</b>	<b>5,876</b>	<b>1</b>	<b>1,014</b>	<b>(21)</b>	<b>(246)</b>	<b>748</b>
Issuance of common stock for cash of \$1.01 per share in May 2004	979	—	988	—	—	988
Comprehensive loss:						
Net loss for the period	—	—	—	—	(1,471)	(1,471)
Foreign currency translations	—	—	—	(148)	—	(148)
Total comprehensive loss	—	—	—	—	—	(1,619)
<b>Balance at December 31, 2004</b>	<b>6,855</b>	<b>1</b>	<b>2,002</b>	<b>(169)</b>	<b>(1,717)</b>	<b>117</b>
Issuance of common stock for cash of \$0.83 per share in January 2005, net of issuance costs	1,430	—	1,158	—	—	1,158
Issuance of common stock for cash of \$1.24 per share in June 2005, net of issuance costs	2,220	—	2,699	—	—	2,699
Comprehensive loss:						
Net loss for the period	—	—	—	—	(3,196)	(3,196)
Foreign currency translations	—	—	—	165	—	165
Total comprehensive loss	—	—	—	—	—	(3,031)
<b>Balance at December 31, 2005</b>	<b>10,505</b>	<b>1</b>	<b>5,859</b>	<b>(4)</b>	<b>(4,913)</b>	<b>943</b>
Common shares transferred in merger with Castle & Morgan Holdings, Inc.	2,860	—	—	—	—	—
Common shares issued for \$1.31 per share in private placement, net of issuance costs	7,656	1	9,255	—	—	9,256
Stock based compensation expense	—	—	508	—	—	508
Comprehensive loss:						
Net loss for the period	—	—	—	—	(4,858)	(4,858)
Unrealized gain on short-term investments	—	—	—	2	—	2
Foreign currency translations	—	—	—	(54)	—	(54)
Total comprehensive loss	—	—	—	—	—	(4,910)
<b>Balance at December 31, 2006</b>	<b>21,021</b>	<b>\$ 2</b>	<b>\$15,622</b>	<b>\$ (56)</b>	<b>\$ (9,771)</b>	<b>\$ 5,797</b>

See accompanying notes to consolidated financial statements.

**Osteologix, Inc.**  
**(a development stage company)**  
**Consolidated Statements of Cash Flows**

	For the Years Ended December 31,			For the Period from June 16, 2003 (Inception) through December 31, 2006
	<u>2006</u>	<u>2005</u>	<u>2004</u>	
	(In thousands)			
<b>Operating activities</b>				
Net loss .....	\$(4,858)	\$(3,196)	\$(1,471)	\$(9,771)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation .....	5	3	3	11
Stock based compensation .....	508	—	—	508
Changes in operating assets and liabilities:				
Receivable from related party .....	750	(750)	—	—
Prepaid expenses and other current assets .....	(37)	(216)	(67)	(333)
Accounts payable .....	119	337	125	600
Accrued liabilities .....	(55)	122	27	145
Net cash used in operating activities .....	<u>(3,568)</u>	<u>(3,700)</u>	<u>(1,383)</u>	<u>(8,840)</u>
<b>Investing activities</b>				
Purchases of short-term investments .....	(6,547)	—	—	(6,547)
Sales and maturities of short-term investments .....	830	—	—	830
Purchases of equipment .....	(7)	—	(5)	(20)
Net cash used in investing activities .....	<u>(5,724)</u>	<u>—</u>	<u>(5)</u>	<u>(5,737)</u>
<b>Financing activities</b>				
Net proceeds from issuance of common stock .....	9,256	3,857	988	15,116
Effect of exchange rates on cash and cash equivalents ...	(54)	165	(148)	(58)
Net (decrease)/increase in cash and cash equivalents .....	(90)	322	(548)	481
Cash and cash equivalents at beginning of period .....	571	249	797	—
Cash and cash equivalents at end of period .....	<u>\$ 481</u>	<u>\$ 571</u>	<u>\$ 249</u>	<u>\$ 481</u>

See accompanying notes to consolidated financial statements.

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements**

**December 31, 2006**

**(Tabular amounts in thousands, except per share amounts)**

**1. Basis of Presentation and Summary of Significant Accounting Policies**

***Business Description***

Osteologix, Inc. and subsidiary ("Osteologix" or the "Company") is in the business of developing pharmaceuticals for the treatment and prevention of diseases of bone and joint tissues. The Company's lead product candidate, NB S101, is in clinical development for the treatment of osteoporosis. Osteologix has not yet generated substantial revenues from its operations and, accordingly, the Company is in the development stage.

***Basis of Presentation***

The consolidated financial statements include the accounts of the Company and its wholly owned Danish subsidiary, Osteologix Aps (which was previously incorporated as Osteologix A/S). All intercompany accounts and transactions have been eliminated. Osteologix operates in one business segment, the development of pharmaceutical products.

The consolidated financial statements have been prepared assuming the Company will continue as a going concern. Osteologix has experienced net losses and negative cash flows from operations since its inception and expects its losses to continue as the Company furthers its research and development programs. The Company's management believes that its current cash and short-term investments will enable it to continue planned operations only into the fourth quarter of 2007. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management plans to raise additional capital in order to fund its operations, and therefore believes it is appropriate for the consolidated financial statements to be prepared on a going concern basis. The consolidated financial statements do not contain any adjustments that may be required if Osteologix is unable to continue as a going concern.

***Background of Company Organization and Description of Merger Transaction***

Osteologix A/S was formed in Denmark on June 16, 2003 under the name Nordic Bone A/S, and on November 18, 2004 changed its name to Osteologix A/S. All of the issued and outstanding shares of Osteologix A/S were owned by Nordic Biotech K/S, a Danish venture capital fund, prior to a merger transaction that occurred on May 24, 2006. On May 24, 2006, Osteologix A/S completed a "reverse merger" transaction with Castle & Morgan Holdings, Inc., a U.S. public company incorporated in Delaware and traded on the Over-the-Counter Bulletin Board. In the merger, Castle and Morgan Holdings, Inc. issued new shares of common stock in exchange for all of the issued and outstanding common stock of Osteologix A/S. Also on May 24, 2006, a subsidiary of Osteologix A/S completed a private placement transaction, raising \$10 million in gross proceeds, also by issuing new shares of common stock. Immediately following these transactions, Castle & Morgan Holdings, Inc. changed its name to Osteologix, Inc. and the newly issued shares in the subsidiary of Osteologix A/S converted into Osteologix, Inc. shares. As a result of these transactions, Nordic Biotech K/S's previous ownership of 100% of the outstanding stock of Osteologix A/S exchanged into a 50.0% ownership position in Osteologix, Inc. The stock in the subsidiary of Osteologix A/S that was sold in the private placement exchanged into a 36.4% ownership position in Osteologix, Inc. The previously outstanding stock in Castle & Morgan Holdings represented 13.6% of the total outstanding stock in Osteologix, Inc. Because Nordic Biotech K/S participated in the private placement financing, following the transactions of May 24, 2006 they owned 60.1% of Osteologix, Inc.

Although Osteologix A/S became a wholly owned subsidiary of Castle & Morgan Holdings Inc. (subsequently renamed Osteologix, Inc.) in the merger, for financial reporting purposes Osteologix A/S is treated as the acquirer because its' previous shareholder continued to own a majority of the surviving company. Accordingly, the historical consolidated financial statements prior to the date of the merger that are included in these consolidated financial

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

statements for comparative purposes are the consolidated financial statements of Osteologix A/S and its subsidiary. The number of shares of common stock, the par value and additional paid-in capital reported prior to May 24, 2006 in the consolidated financial statements have been amended to reflect the impact of the merger with Castle & Morgan Holdings, Inc. Following the merger, the functional currency of the Company became the United States Dollar whereas it was previously the Danish Krone.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts may differ from those estimates.

***Concentration of Credit and Other Risks and Uncertainties***

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company's cash and cash equivalents are generally invested in deposit accounts or money market accounts with U.S and Danish banks, and deposits may exceed the amount covered by insurance for loss. As of December 31, 2006 and 2005, the Company's uninsured cash totaled \$324,000 and \$505,000, respectively. Short-term investments are invested in high quality government or corporate debt securities, and, other than U.S. Government securities, the Company limits its exposure to any single corporation to no more than 5% of its debt security portfolio.

The Company's lead product candidate, NB S101, is in clinical development for the treatment of osteoporosis and is currently the Company's only pharmaceutical product being tested in humans. Development of new pharmaceutical products involves a high degree of risk, and failure can occur at any point in a product's development. Accordingly, NB S101 may never be successfully marketed. The business risk as a result of the Company concentrating its efforts in a single product under development is significant.

***Fair Value of Financial Instruments***

For financial instruments consisting of cash and cash equivalents, short-term investments, receivable from related party, prepaid expenses and other assets, accounts payable and accrued liabilities included in the consolidated financial statements, the carrying amounts are reasonable estimates of the fair value due to their short maturities. The fair value of other short-term and long-term obligations is estimated based on current interest rates available for debt instruments with similar terms, degrees of risk and remaining maturities. The carrying values of these obligations approximate their fair values.

***Foreign Currency Translation***

These financial statements are presented in U.S. dollars for all periods presented. Translation of balance sheet accounts denominated in foreign currencies is made at the exchange rate in effect on the balance sheet date. Translation of amounts reported in the statement of operations and statement of cash flows is made at the average exchange rate for the periods reported. Translation gains and losses are recognized within "Other Comprehensive Loss."

***Revenue Recognition***

Revenue recognized under corporate license agreements and collaborations is recognized as earned based on the performance requirements of the contracts. Revenue from non-refundable license fees where the Company continues involvement is recognized on a straight-line basis over the period of the Company's continued involvement. Revenue from non-refundable license fees for which no further performance obligations exist and

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

for which the Company has no continuing involvement is recognized either when the payments are received or collection is assured.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with a maturity period of three months or less at the time of acquisition to be cash equivalents.

***Equipment***

Equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which is generally three years. Upon sale or retirement of the assets, the costs and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in the statement of operations. Repair and maintenance expenses are charged to the statement of operations as they are incurred.

***Impairment of Long-Lived Assets***

The Company reviews long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when future estimated undiscounted cash flows expected to result from use of the asset, and its eventual disposition, are less than the carrying amount of the asset. The impairment loss would be based on the excess of the carrying value over its respective fair value. Through December 31, 2006, the Company has not recorded any impairment losses.

***Research and Development Expenses***

The Company's research and development costs are expensed as incurred. Research and development costs include clinical trial costs, preclinical studies, payments to contract research organizations, compensation expenses for research and development personnel, development and manufacturing costs for investigational drugs, supplies, and related consulting and advisor costs.

***General and Administrative Expenses***

The Company's general and administrative expenses include compensation expense for personnel not directly involved in research and development activities, management and board of directors costs, insurance and accounting, legal and patent expenses.

***Stock-based Compensation***

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which changed the required accounting treatment of compensation to employees that is based on the price of the Company's common stock. SFAS 123R now requires stock-based compensation awards issued to employees to be accounted for using an estimate of the fair value of the stock award. Prior to adoption of SFAS 123R, Osteologix accounted for stock-based awards to employees using the intrinsic value method. To date, all employee stock-based compensation at Osteologix (prior to and since the date of adoption of SFAS 123R) has been in the form of warrants or options to purchase stock. Under SFAS 123R, stock-based compensation expense is measured on the date stock options are granted, based on the estimated fair value of the stock options, and is recognized in the statement of operations on a straight-line basis over the vesting period of the stock options.

The Company adopted the requirements of SFAS 123R effective January 1, 2006, utilizing the prospective transition method. Under the prospective application, prior periods were not restated to reflect the impact of

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

SFAS 123R for comparative purposes. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the effective date and subsequently modified. Estimated compensation expense for existing awards that were outstanding on the effective date is recognized in the statement of operations over the remaining vesting periods using the expense as calculated for pro forma disclosure purposes under the previous stock-based compensation requirements.

***Income Taxes***

The Company uses the liability method of accounting for income taxes, and determines deferred tax assets and liabilities based on differences between the financial reporting and tax reporting basis of assets and liabilities. The Company measures these assets and liabilities using enacted tax rates and laws that are scheduled to be in effect when the differences are expected to reverse. Because the realization of deferred tax assets is dependent on future earnings, if any, and the Company's future earnings are uncertain, all of the Company's net deferred tax assets have been fully offset by a valuation allowance.

***Net Loss per Share and Anti-dilutive Securities***

Net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. During the years ended December 31, 2006, 2005 and 2004, potentially dilutive options and warrants to purchase common stock aggregating 2,129,000, 979,000 and 392,000 shares, respectively, were outstanding and not considered because their effect would have been antidilutive.

***Recent Accounting Pronouncements***

In May 2005, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 154, "*Accounting Changes and Error Corrections*" ("SFAS 154"), which replaces Accounting Principles Board Opinion No. 20, "*Accounting Changes*," and Statement of Financial Accounting Standards No. 3, "*Reporting Accounting Changes in Interim Financial Statements*." SFAS 154 requires retrospective application, unless impracticable, for changes in accounting principles in the absence of transition requirements specific to newly adopted accounting principles. The provisions of SFAS No. 154 were effective for Osteologix beginning on September 1, 2006, and there was no impact upon the Company's adoption of SFAS 154.

In June 2006, the FASB issued FIN 48, "*Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*" ("FIN 48"), which seeks to reduce the diversity in practice associated with the accounting and reporting for uncertainty in income tax positions. FIN 48 prescribes a model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in an income tax return and is effective for fiscal years beginning after December 15, 2006. The Company believes that, due to its operating losses, the implementation of FIN 48 will not have a material impact on its results of operations, financial position or cash flows. The Company is evaluating the impact of the adoption of FIN 48 on the footnote disclosures of its deferred tax valuation allowance.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "*Fair Value Measurements*" ("SFAS 157"), which clarifies and prioritizes methods for measuring fair value under generally accepted accounting principles. SFAS 157 generally increases the level of disclosure required for fair value measurements, although it does not impact the valuations or disclosures required under SFAS 123R. For Osteologix, implementation of SFAS 157 will be required on January 1, 2008. The Company is evaluating the impact of SFAS 157 on its consolidated financial statements and disclosures.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, "*Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*" ("SAB No. 108"). SAB No. 108 was issued in order to eliminate the diversity in practice surrounding

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

how public companies quantify financial statement misstatements. SAB No. 108 requires evaluation of errors using both a balance sheet (iron curtain) approach and an income statement (rollover) approach, and a determination of whether either approach results in a misstated amount that is material. The provisions of SAB No. 108 were effective for Osteologix beginning with the consolidated financial statements for the year ended December 31, 2006, and there was no impact upon the Company's adoption of SFAS 154.

***Reclassifications***

Certain prior period amounts have been reclassified to conform to the current presentation, increasing general and administrative expenses and correspondingly decreasing research and development expenses by \$285,000 and \$147,000 for 2005 and 2004, respectively. In order to conform to the 2006 presentation, dollar amounts have been rounded to the nearest thousand for 2005 and 2004.

**2. Short-Term Investments**

The Company invests funds that are not required for immediate operating needs primarily in a diversified portfolio of debt securities which are classified as short-term investments on the balance sheet. Management determines the appropriate classification of these marketable debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. As of December 31, 2006, all marketable securities are classified as available-for-sale. These securities are stated at their estimated fair value based upon market quotes. Unrealized gains and losses are included in accumulated other comprehensive loss. Amortization of premiums and discounts and realized gains and losses are included in interest income. The cost of securities sold is based on the specific identification method. The Company has not experienced any significant losses on its investments.

As of December 31, 2006, all of the Company's short-term investments had maturity dates of less than one year. The components of short-term investments were as follows:

	December 31, 2006
Corporate securities .....	\$3,982
Asset-backed and other securities .....	1,112
U.S. government securities .....	474
Municipal obligations .....	151
	\$5,719

The fair value of corporate securities included unrealized gains of \$2,000 at December 31, 2006. There were no unrealized losses in the Company's short-term investments. Realized gains and losses on sales of the Company's short-term investments have not been material.

**3. Receivable from Related Party**

At December 31, 2005, the Receivable from Related Party represented an amount owed to the Company from Aditech AB ("Aditech") as a result of a patent license agreement with Aditech. At the time of the agreement both Osteologix and Aditech were 100% owned by Nordic Biotech K/S. The agreement provided Aditech with rights to develop pharmaceutical products for certain non-osteoporosis indications included in Osteologix's patent portfolio. Aditech has an exclusive worldwide license to the Company's patents containing certain compounds other than strontium compounds, which are outside the core focus of the Company's business. In return, Aditech agreed to pay the Company \$750,000, which was received in February 2006. Aditech also agreed to pay the Company a 2.5% royalty on future net sales of products Aditech develops under the agreement. Also in the agreement, Aditech granted to the Company an exclusive worldwide license to Aditech's patents for strontium compounds. Aditech is

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

entitled to a 1.5% royalty on future net sales of products containing strontium compounds developed by the Company.

**4. Prepaid Expenses and Other Assets**

The components of prepaid expenses and other assets are as follows:

	<u>December 31, 2006</u>	<u>December 31, 2005</u>
Danish value-added tax (VAT) receivable . . . . .	\$232	\$263
Prepaid expenses and deposits . . . . .	<u>101</u>	<u>33</u>
	<u>\$333</u>	<u>\$296</u>

**5. Equipment**

Equipment primarily consists of computer equipment. As of December 31, 2006 and 2005, accumulated depreciation on equipment aggregated \$11,000 and \$6,000, respectively.

**6. Commitments and Contingencies**

The Company has one noncancelable lease with an initial term in excess of 12 months, which is an operating lease for the Company's corporate headquarters. The agreement was signed in June 2006 and expires in October 2007. At December 31, 2006, future minimum payments required under the agreement aggregate \$65,000, all due in 2007. Total rental expense was \$81,000, \$55,000 and \$15,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

The Company has an employment agreement in place with its Chief Executive Officer and President which requires the Company to pay for a \$1,400,000 life insurance policy, all family medical expenses, \$1,275 per month for an auto lease, all auto maintenance and operating expenses, and disability insurance coverage aggregating \$20,000 per month.

The Company, as permitted under Delaware law and in accordance with its Bylaws, has agreed to pay certain expenses and indemnify its officers and directors, subject to certain limits, if the officer or director becomes involved in a lawsuit or other proceeding arising from his service to the Company. The maximum amount of potential future indemnification is unlimited. The Company has a director and officer insurance policy that may enable the Company to recover a portion of any future amounts paid under the Company's indemnity obligations. The Company believes that the fair value of its obligations under its indemnification commitments is minimal and at present no claims are being asserted against the Company for indemnification under these obligations. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2006.

**7. Stockholders' Equity**

***Preferred Stock***

The Company is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock and to fix the rights, preferences and privileges of the preferred stock. As of December 31, 2006, no shares of preferred stock have been issued.

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

***Rights of Common Stockholders***

The Company has only common stock issued and outstanding. Accordingly, all outstanding shares are of the same class and have equal liquidation, preference and adjustment rights. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

***Issuances of Common Stock***

In May 2006, Osteologix completed the sale of 7,656,000 shares of its common stock to a group of investors, including Nordic Biotech K/S, at a price of \$1.31 per share, for gross proceeds of \$10,000,000. Net proceeds were \$9,256,000 after issuance costs.

In June 2005, Osteologix completed the sale of 2,220,000 shares of its common stock to Nordic Biotech K/S at a price of \$1.24 per share, for gross proceeds of \$2,747,000. Net proceeds were \$2,699,000 after issuance costs.

In January 2005, Osteologix completed the sale of 1,430,000 shares of its common stock to Nordic Biotech K/S at a price of \$0.83 per share, for gross proceeds of \$1,180,000. Net proceeds were \$1,158,000 after issuance costs.

In May 2004, Osteologix completed the sale of 979,000 shares of its common stock to Nordic Biotech K/S at a price of \$1.01 per share, for gross and net proceeds of \$988,000.

In October 2003, Osteologix completed the sale of 979,000 shares of its common stock to Nordic Biotech K/S at a price of \$0.95 per share for gross and net proceeds of \$930,000.

In June 2003, at the Company's formation, Osteologix completed the sale of 4,897,000 shares of its common stock to its founder, Nordic Biotech K/S, at a price of \$0.02 per share, for gross and net proceeds of \$85,000.

**8. Stock-Based Compensation**

***Osteologix's Stock-based Compensation Plans***

In 2003, the Osteologix A/S board of directors adopted the 2003 Equity Incentive Plan (the "2003 Equity Plan") which provided for the issuance of warrants to purchase common stock at fair market value on the date of the grant. A total of 100,000 warrants to purchase shares of Osteologix A/S common stock were issued under the plan prior to the merger transaction. As a part of the merger transaction, the warrants to purchase shares of Osteologix A/S were cancelled and new warrants to purchase Osteologix, Inc. common stock were issued at a conversion ratio of 9.793 per share, resulting in warrants to approximately 979,000 shares of Osteologix, Inc. common stock. The 2003 Equity Plan has been cancelled and there are no additional warrants available to issue.

In 2006, the Castle & Morgan Holdings, Inc. board of directors adopted the 2006 Equity Incentive Plan (the "2006 Stock Option Plan") which provides for the issuance of stock options to employees at or above the fair market value on the date of grant. The 2006 Stock Option Plan is scheduled for ratification by the Company's stockholders at the 2007 annual meeting of stockholders. A total of 1,123,000 shares have been reserved for issuance under the 2006 Stock Option Plan. As of December 31, 2006, options to purchase up to 900,000 shares had been issued under the plan, with 223,000 shares available for future issuance.

***Stock-based Compensation under SFAS 123R***

Under the provisions of SFAS 123R, the Company has elected to use the Black-Scholes option-pricing model (the "Black-Scholes model") as its method of valuation for stock-based compensation. All of the Company's 1,150,000 outstanding stock options were granted during 2006, including 900,000 under the 2006 Stock Option Plan and 250,000 outside of the plan. The options were granted with exercise prices ranging from \$1.00 to \$1.50 per share, have vesting periods of up to four years and expire ten years from the date of grant. The estimated weighted

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

average per share fair value of the options granted was \$0.80 with the following assumptions: expected volatility of 70%; expected terms of 6.1 years; annualized risk-free interest rates of 4.6% to 4.7%; and dividend yield of zero.

In addition to the options granted in 2006, when the merger transaction occurred Osteologix exchanged warrants to purchase stock of Osteologix A/S for warrants to purchase stock of Osteologix, Inc. at the same exercise price and exchange ratio as received by the shareholder of Osteologix A/S. In accordance with SFAS 123R, the Company recorded an expense for the modification to the stock awards based on the excess of the fair value of the replacement warrant over the fair value of the cancelled warrant. The incremental stock-based compensation expense on the date of the merger for the increased fair value of the modified warrants aggregated \$372,000, of which \$275,000 was immediately recognized in the consolidated statement of operations for the warrants that were vested. The remaining \$97,000 is being recognized over the remaining vesting period of the warrants ending in 2008. During 2006, \$40,000 of the remaining \$97,000 was recognized as stock-based compensation expense. The estimated per share fair value of the modified warrants was \$0.73 with the following assumptions: expected volatility of 70%; expected term of 3.0 years; annualized risk-free interest rate of 5.0%; and dividend yield of zero.

The expected volatility was determined by the Company based on the historical volatility of comparable companies, the expected term was determined within the guidelines of the safe harbor calculation established in Staff Accounting Bulletin 107. The risk-free interest rate was based upon the U.S. Treasury yield for expected life of the Company's stock options. The dividend rate was based on the Company's projections that show it will not be able to pay dividends for the foreseeable future.

The 2006 stock-based compensation expense of \$508,000 includes \$480,000 related to stock options and warrants modified or granted during 2006 and stock-based compensation expense of \$28,000 related to stock warrants granted prior to 2006. As of December 31, 2006, the total unrecognized expense for unvested stock warrants and options is \$821,000, which will be expensed over the remaining vesting period of 3.9 years. The Company recorded no income tax benefits for share-based compensation arrangements for the year ended December 31, 2006 because the Company has cumulative operating losses for which a valuation allowance has been established.

Stock option transactions for the years 2004 through 2006 are summarized as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2003 .....	392	\$1.03
Granted .....	<u>—</u>	<u>—</u>
Outstanding at December 31, 2004 .....	392	1.03
Granted .....	<u>587</u>	<u>1.03</u>
Outstanding at December 31, 2005 .....	979	1.03
Granted or modified .....	2,279	1.18
Canceled .....	<u>(1,129)</u>	<u>1.05</u>
Outstanding at December 31, 2006 .....	<u>2,129</u>	<u>\$1.18</u>

**Osteologix, Inc.**  
(a development stage company)

**Notes to Consolidated Financial Statements — (Continued)**

The following table summarizes information about stock options and warrants outstanding and exercisable as of December 31, 2006:

<u>Exercise Price</u>	<u>Number Of Options Outstanding</u>	<u>Weighted Average Remaining Contractual Life (Years)</u>	<u>Number Exercisable</u>	<u>Weighted Average Remaining Contractual Life (Years)</u>
\$1.00 - \$1.03 .....	1,004	7.4	808	7.4
\$1.20 .....	725	9.8	150	9.8
\$1.50 .....	400	9.7	—	—
	<u>2,129</u>	<u>8.6</u>	<u>958</u>	<u>7.7</u>

The weighted average exercise price for options that were exercisable at December 31, 2006 was \$1.06. There were options for 527,000 and 185,000 shares exercisable at December 31, 2005 and 2004, respectively.

The aggregate intrinsic value of the options and warrants outstanding as of December 31, 2006 was \$258,000, and the aggregate intrinsic value of the options and warrants that were exercisable was \$185,000.

***Pro-Forma Information under SFAS 123 (for periods prior to January 1, 2006)***

Prior to adopting the provisions of SFAS 123R, the Company applied APB Opinion No. 25 "Accounting for Stock Issued to Employees" in accounting for its stock-based compensation. Because the Company granted warrants to purchase its common stock with an exercise price that was equal to the fair market value of the stock on the date of grant, Osteologix accordingly recognized no compensation expense for the warrants. The Company followed the disclosure-only provisions of SFAS 123, as amended by SFAS No. 148, and for purposes of pro forma disclosures the estimated fair value of the warrants was amortized to expense over the vesting period of the warrants using the straight-line method. The following table presents information showing the effects to the reported net loss and net loss per share as if Osteologix had accounted for stock-based compensation using the fair-value method:

	<u>For the Years Ended December 31,</u>	
	<u>2005</u>	<u>2004</u>
Net loss applicable to common stockholders, as reported .....	\$(3,196)	\$(1,471)
Less: total stock-based employee compensation determined under fair value based method for all awards .....	<u>(120)</u>	<u>(47)</u>
Net loss applicable to common stockholders, pro forma .....	<u>\$(3,316)</u>	<u>\$(1,518)</u>
Net loss per common share, basic and diluted:		
As reported .....	\$ (0.34)	\$ (0.23)
Pro forma .....	<u>\$ (0.35)</u>	<u>\$ (0.23)</u>

All warrants were granted with an initial vesting period of three years and an exercise price of \$1.03 per share .

The fair value of employee warrants granted prior to the adoption of SFAS 123R was estimated on the date of grant using the Black-Scholes option valuation model under the minimum value method, which assumes a volatility of 0%, expected term of five years for employee grants and ten years for non-employee director grants, expected dividend of zero, and a risk free rate for periods related to the expected life of the warrants based on the U.S. Treasury yield curve in effect at the time of grant.

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

***General Stock Option Accounting Information***

The Company believes it is important for investors to be aware that there is a high degree of subjectivity involved in estimating the value of stock-based compensation, including under the requirements of SFAS 123R, and that changes in input assumptions, particularly the estimated volatility and estimated term, can materially affect the resulting estimates of the fair values of the options and warrants granted. The expenses recorded for stock-based compensation in the Company's consolidated financial statements may differ significantly from the actual value realized by the recipients of the stock awards. The stock awards may expire worthless or otherwise result in zero intrinsic value to the recipient, or value may be realized from these instruments that are significantly in excess of the fair values reported in consolidated financial statements. Under SFAS 123R, the expenses recorded in the consolidated financial statements are not adjusted to the actual amounts realized by the stock option recipients. The expenses recognized under SFAS 123R will not result in any payment of cash by the Company.

Stock-based compensation arrangements to non-employees are accounted for using a fair value approach, and the compensation costs of such arrangements are subject to re-measurement over their vesting terms, as earned.

**9. Income Taxes**

The Company is subject to income taxes in the United States and in Denmark based on its operations in each country. The losses for each country are as follows:

	For the Years Ended December 31,		
	2006	2005	2004
United States . . . . .	\$(1,719)	\$ (474)	\$ (61)
Denmark . . . . .	(3,139)	(2,722)	(1,410)
	(4,858)	(3,196)	(1,471)

There is no provision for income taxes because the Company has incurred operating losses. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. For 2006, 2005 and 2004, the valuation allowance increased by \$1,727,000, \$849,000 and \$293,000, respectively.

The significant components of the Company's deferred tax assets are as follows:

	December 31, 2006	December 31, 2005
Net operating loss carryforwards . . . . .	\$ 1,969	\$ 937
Capitalized start-up costs . . . . .	677	196
Stock-based compensation . . . . .	209	—
Accrued expenses & depreciation . . . . .	14	9
	2,869	1,142
Valuation allowance . . . . .	(2,869)	(1,142)
	\$ —	\$ —

Because the Company has capitalized its start-up costs for U.S. tax purposes, at December 31, 2006, the Company had negligible U.S. and state tax net operating loss carryforwards. At December 31, 2006, the Company's Danish net operating loss carryforwards, which do not expire, were \$7,023,000. The availability of the Company's Danish net operating loss carryforwards may be subject to limitations based on ownership changes as defined in the

**Osteologix, Inc.**  
**(a development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

Danish tax codes, which could prevent the Company from realizing some or all of its net operating loss carryforwards.

A reconciliation of income taxes at the statutory federal income tax rate to income taxes included in the consolidated statements of operations is as follows:

	<b>For the Years Ended December 31</b>		
	<u>2006</u>	<u>2005</u>	<u>2004</u>
United States federal tax rate . . . . .	35%	35%	35%
State taxes, net of federal benefit . . . . .	6	6	6
Difference in tax rate for foreign earnings . . . . .	(5)	(6)	(7)
Non-deductible items . . . . .	1	1	1
Effect of graduated tax rates & other . . . . .	(1)	(9)	(15)
Change in valuation allowance . . . . .	<u>(36)</u>	<u>(27)</u>	<u>(20)</u>
	<u>==</u>	<u>==</u>	<u>==</u>

(This page intentionally left blank)

## BOARD OF DIRECTORS

### **Klaus Eldrup-Jørgensen, M.D.**

Chairman of the Board, Osteologix  
President and Chief Executive Officer, ISG A/S

### **Charles J. Casamento**

Former Chief Executive Officer and President, Osteologix

### **Jeremy Curnock Cook**

Executive Chairman, Bioscience Managers Limited

### **Christian Hansen, Ph.D.**

Co-Founder & Partner, Nordic Biotech K/S

### **Bobby W. Sandage, Jr., Ph.D.**

Executive Vice President, Research and Development  
and Chief Scientific Officer, Indevus Pharmaceuticals, Inc.

### **Florian Schönharting, M.Sc.**

Co-Founder & Partner, Nordic Biotech K/S

### **Christopher B. Wood, M.D.**

Chairman and Chief Executive Officer, Bioenvision, Inc.

## MANAGEMENT

### **Philip J. Young**

President and Chief Executive Officer  
beginning May 1, 2007

### **Stephan Christgau, Ph.D.**

Chief Operating Officer

### **Matthew M. Loar**

Chief Financial Officer

## CORPORATE COUNSEL

### **Loeb & Loeb LLP**

New York, New York

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

### **Weinberg & Company, P.A.**

Boca Raton, Florida

## TRANSFER AGENT

### **Continental Stock Transfer & Trust Company**

New York  
212.509.4000, ext. 206  
[www.continentalstock.com](http://www.continentalstock.com)

## SCIENTIFIC ADVISORS

### **Jens E.T. Andersen, Ph.D.**

Associate Professor, Technical University of Denmark

### **Leslie Z. Benet, Ph.D.**

Professor of Biopharmaceutical Sciences and  
Pharmaceutical Chemistry,  
University of California, San Francisco

### **Susan Greenspan, M.D.**

Professor of Medicine, University of Pittsburg Medical  
Center and Director of the Osteoporosis Prevention  
and Treatment Center and the Bone Health Program

### **Göran Samsioe, M.D., Ph.D.**

Professor of Gynecological Endocrinology,  
University of Lund

## PHASE II CLINICAL TRIAL SITES

### **Principal Investigator**

Richard Eastell, M.D.  
University of Sheffield, Metabolic Bone Centre,  
Northern General Hospital, Sheffield, United Kingdom

### **Sites in Denmark**

Odense University Hospital, Odense, Kim Brixen, M.D.  
PhaseOneTrials, Hvidovre, Kim Krosgaard, M.D.

### **Sites in the United Kingdom**

Medinova Clinic, Northwood, Middlesex, Naren Savani, M.D.  
Synexus Crosby Clinical Research Centre, Waterloo, Irana Pavel, M.D.  
Synexus Reading Clinical Research Centre, Reading, Hilary Shaw, M.D.  
Synexus Scotland Clinical Research Centre, Glasgow, Jacqueline Maroni, M.D.  
Synexus Wales Clinical Research Centre, Cardiff, Hawys Thomas, M.D.  
Synexus Wigan Clinical Research Centre, Wigan, Ravi Pawa, M.D.  
University of Sheffield, Sheffield, Richard Eastell, M.D.

## ANNUAL MEETING

The Annual Meeting of Stockholders will take place on  
June 7, 2007 at 10:00 am at the Grand Hyatt San Francisco,  
345 Stockton Street, San Francisco, CA 94108

## STOCKHOLDER INFORMATION

As of April 20, 2007, there were 21,082,686 shares of  
common stock outstanding. The common stock of  
Osteologix, Inc. is traded on the Over-the-Counter Bulletin  
Board under the symbol OLGX. Some quotation systems  
require the symbol to be entered as OLGX.OB.

### **Osteologix, Inc.**

425 Market Street, Suite 2230  
San Francisco, CA 94105  
(415) 955-2720



**OSTEOLOGIX**

425 MARKET ST., SUITE 2230  
SAN FRANCISCO, CA 94105  
415.955.2720  
[WWW.OSTEOLOGIX.COM](http://WWW.OSTEOLOGIX.COM)

*END*