EMISPHERE TECHNOLOGIES INC Form 10-K March 16, 2009

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

#### Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES þ **EXCHANGE ACT OF 1934** For the fiscal year ended December 31, 2008

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 0 **EXCHANGE ACT OF 1934** For the transition period from to

**Commission file number 0-17758** 

### **EMISPHERE TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

incorporation or organization)

240 Cedar Knolls Road, Suite 200 Cedar Knolls, NJ (Address of principal executive offices)

(973) 532-8000

(Registrant s telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock \$.01 par value **Preferred Stock Purchase Rights** 

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

(I.R.S. Employer Identification Number)

13-3306985

07927 (Zip Code)

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that Registrant was required to file such reports) and (2) has been subject to such filing requirements for at least the past 90 days. Yes p No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant sknowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

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

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

As of June 30, 2008 (the last business day of the registrant s most recently completed second quarter), the aggregate market value of the common stock held by non-affiliates of the Registrant (i.e. excluding shares held by executive officers, directors, and control persons) was \$68,662,707 computed at the closing price on that date.

The number of shares of the Registrant s common stock, \$.01 par value, outstanding as of March 11, 2009 was 30,341,078.

### DOCUMENTS INCORPORATED BY REFERENCE

Part III of this 10-K incorporates information by reference from the registrant s definitive proxy statement which will be filed no later than 120 days after December 31, 2008.

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# PART I

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements made under the captions Business (Item 1) and Management s Discussion and Analysis of Financial Condition and Results of Operations (Item 7), the notes to our audited financial statements (Item 8) and elsewhere in this Annual Report on Form 10-K, as well as statements made from time to time by our representatives may constitute

forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding planned or expected studies and trials of oral formulations that utilize our Eligen<sup>®</sup> Technology; the timing of the development and commercialization of our product candidates or potential products that may be developed using our Eligen<sup>®</sup> Technology; the potential market size, advantages or therapeutic uses of our potential products; variation in actual savings and operating improvements resulting from restructurings; and the sufficiency of our available capital resources to meet our funding needs. We do not undertake any obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results or achievements to be materially different from any future results or achievements expressed or implied by such forward-looking statements. Such factors include the factors described under Item 1A. Risk Factors and the other factors discussed in connection with any forward-looking statements.

# ITEM 1. BUSINESS

### **Overview of Emisphere**

### Introduction and History

Emisphere Technologies, Inc. ( Emisphere , our , us or we ) is a biopharmaceutical company that focuses on a unique and improved delivery of therapeutic molecules or nutritional supplements using its Eligen<sup>®</sup> Technology. These molecules could be currently available or are under development. Such molecules are usually delivered by injection; in many cases, their benefits are limited due to poor bioavailability, slow on-set of action or variable absorption. In those cases, our technology may increase the benefit of the therapy by improving bioavailability or absorption or by accelerating the onset of action. The Eligen<sup>®</sup> Technology can be applied to the oral route of administration as well other delivery pathways, such as buccal, rectal, inhalation, intra-vaginal or transdermal. Our website is www.emisphere.com. The contents of that website are not incorporated herein by reference thereto. Investor related questions should be directed to info@emisphere.com.

Emisphere was originally founded as Clinical Technologies Associates, Inc. in 1986. We conducted an initial public offering in 1989 and were listed on NASDAQ under the ticker symbol CTAI. In 1990 we decided to focus on our oral drug delivery technology, now known as the Eligen<sup>®</sup> Technology. In 1991, we changed our name to Emisphere Technologies, Inc., and we continued to be listed on NASDAQ under the new ticker symbol EMIS.

Since our inception in 1986, substantial efforts and resources have been devoted to understanding the Eligen<sup>®</sup> Technology and establishing a product development pipeline that incorporated this technology with selected molecules. Although no products have been commercialized to date, research and investment is now being placed behind both the pipeline and the advancement of this technology. Further development and exploration of the technology entail risk and operational expenses. However, we have made significant progress on refocusing our efforts on strategic development initiatives and cost control and continue to aggressively seek to reduce non-strategic

spending.

Emisphere underwent many positive changes in 2007 and 2008. A new senior management team, led by Michael V. Novinski, was hired; the Eligen<sup>®</sup> Technology was reevaluated; and our corporate strategy was refocused on commercializing the Eligen<sup>®</sup> Technology as quickly as possible, building high-value partnerships and reprioritizing the product pipeline. Spending was redirected and aggressive cost control initiatives were implemented. These changes resulted in redeployment of resources to programs that may yield commercial

products in a shorter period of time. In addition to product candidates we are developing in-house, we planned to demonstrate and enhance the value of our Eligen<sup>®</sup> Technology by attracting new partners and rejuvenating existing partnerships. Results of these changes are evidenced by our June 2008 exclusive Development and License Agreement with Novo Nordisk A/S ( Novo Nordisk ), progress on the development of EligenB12, and cost savings which continued to be evident in financial results for 2008.

# The Eligen<sup>®</sup> Technology

The Eligen<sup>®</sup> Technology is a broadly applicable proprietary oral drug delivery technology based on the use of proprietary synthetic chemical compounds known as EMISPHERE<sup>®</sup> delivery agents, or carriers. These delivery agents facilitate and enable the transport of therapeutic macromolecules (such as proteins, peptides, and polysaccharides) and poorly absorbed small molecules across biological membranes targeted in the stomach. We believe no other carrier system or drug delivery company can do this. The result is rapid absorption. The stomach as an absorptive organ also contradicts normal absorption mechanisms and makes the proposition easy to understand, but at the same time difficult to believe. The second characteristic that distinguishes Eligen<sup>®</sup> from the competition is that this permeability in the stomach takes place through a transcellular pathway and not paracellular. This underscores the safety of Eligen<sup>®</sup> as the passage of the Eligen<sup>®</sup> carrier and the molecule preserve the integrity of the tight junctions within the cell and reduces any likelihood of inflammatory processes and autoimmune gastrointestinal diseases. Furthermore, because the Eligen<sup>®</sup> Technology is rapidly absorbed, metabolized and eliminated from the body; it does not accumulate in the organs and tissues and is considered safe at anticipated dose and dosing regimens.

The Eligen<sup>®</sup> Technology was extensively evaluated in 2007 by our scientists, senior management and expert consultants. Based on this analysis, we believe that our technology can enhance overall healthcare, including patient accessibility and compliance, while benefiting the commercial pharmaceutical marketplace and driving company valuation. The application of the Eligen<sup>®</sup> Technology is potentially broad and may provide for a number of opportunities across a spectrum of therapeutic modalities. During 2008, we continued to develop our product pipeline utilizing the Eligen<sup>®</sup> Technology with prescription and nonprescription product candidates. We prioritized our development efforts based on overall potential returns on investment, likelihood of success, and market and medical need.

Implementing the Eligen<sup>®</sup> Technology is quite simple. It only requires co-mixing of a drug or nutritional supplement and an Eligen<sup>®</sup> carrier powder to produce an active formulation. The carrier does not alter the chemical properties of the drug nor its biological activities. Some therapeutic molecules are better suited for use with the Eligen<sup>®</sup> Technology than others. Drugs or nutritional supplements with molecules whose bioavailability is limited by poor membrane permeability or chemical or biological degradation, and which have a moderate-to-wide therapeutic index, appear to be the best candidates. Drugs or nutritional supplements with a narrow therapeutic window or high molecular weight may not be favorable to the technology.

We believe that our Eligen<sup>®</sup> Technology makes it possible to safely deliver a therapeutic macromolecule orally or increase the absorption of a poorly absorbed small molecule without altering its chemical composition or compromising the integrity of biological membranes.

Our goal is to implement our Eligen<sup>®</sup> Technology to enhance overall healthcare, including patient accessibility and compliance, while benefiting the commercial pharmaceutical or healthcare marketplace and driving company valuation. We believe that the key benefit of our Eligen<sup>®</sup> Technology is that it improves the ability of the body to absorb small and large molecule drugs.

### Emisphere Today

During 2008, the management team continued to focus on efforts to apply the technology and realize its value by developing profitable commercial applications. We continued to develop our product pipeline utilizing the Eligen<sup>®</sup> Technology with prescription and nonprescription product candidates. We prioritized our development efforts based on overall potential returns on investment, likelihood of success, and market and medical need. Additionally, we continued to improve operational effectiveness and efficiency.

To accelerate commercialization of the technology, Emisphere has embarked on a two pronged strategy. Concentration will be on unique prescription molecules and nutritional supplements obtained through partnerships and collaborations with other pharmaceutical companies for molecules where oral absorption is difficult yet substantially beneficial if proven. With prescription molecules, we will attempt to generate new interest in the Eligen<sup>®</sup> Technology with new potential partners and also attempt to expand our current collaborative relationships to take advantage of the critical knowledge that others have gained by working with our technology. In addition, we will also continue to pursue commercialization of product candidates developed internally. We believe that these internal candidates must be capable of development with reasonable investments in an acceptable time period and with a reasonable risk-benefit profile.

During 2008 Emisphere successfully engaged a new drug development partner. On June 21, 2008, we entered into an exclusive Development and License Agreement with Novo Nordisk pursuant to which Novo Nordisk will develop and commercialize oral formulations of Novo Nordisk proprietary products in combination with Emisphere carriers. Under such Agreement Emisphere could receive more than \$87 million in contingent product development and sales milestone payments including a \$10 million non-refundable license fee which was received during June 2008. Emisphere would also be entitled to receive royalties in the event Novo Nordisk commercializes products developed under such Agreement. Under the terms of the Agreement, Novo Nordisk is responsible for the development and commercialization of the products. Initially Novo Nordisk is focusing on the development of oral formulations of its proprietary GLP-1 receptor agonists.

To support our internal development programs, Emisphere initiated a new commercialization strategy. Because extensive safety data is available for certain carriers and these carriers are pharmacologically inactive, the company will seek a status of GRAS ( Generally Recognized as Safe ) for at least one of these carriers, and then seek to apply the technology with other GRAS substances where bioavailability and absorption is difficult and improving such absorption would yield substantial benefit and value. Examples of such other GRAS substances would include vitamins such as B12, Iron, Vitamin D, and other supplements such as the polyphenols and catechins, among others. Gaining GRAS status and successfully applying the technology to a vitamin such as B12 could shorten the time to commercialize the technology and could lead to an Eligen<sup>®</sup> based product introduction during early 2010 in the US.

Funding required to continue developing the pipeline may be partially paid by income-generating license arrangements whose value tends to increase as product candidates move from pre-clinical into clinical development. It is our intention that any additional funding that may be required to continue our research and development efforts will be approached incrementally in order to minimize disruption or dilution.

During 2008, Emisphere also continued to focus on improving operational efficiency. On December 8, 2008 we announced plans to strengthen our financial foundation while maintaining our focus on advancing and commercializing the Eligen® Technology. By closing our research and development facility in Tarrytown, New York and utilizing independent contractors to conduct essential research and development, we estimate that we will reduce our annual operating costs by approximately 60% from 2008 levels. Emisphere estimates it will reduce cash expenditures by approximately \$11 million annually, with a targeted cash burn rate of between \$7 and \$8 million per year. Additionally, we expect to accelerate the commercialization of the Eligen® Technology in a cost effective way and to gain operational efficiencies by tapping into more advanced scientific processes independent contractors can provide. The amount of savings realized in 2009 depends on how quickly these actions can be fully implemented. Implementation began immediately in December 2008 and is expected to be completed during the second quarter 2009.

### **Overall Product Pipeline**

Emisphere has a deep and varied pipeline that includes product candidates in varying stages of development. We have two products in Phase III studies, two that have reached Phase II, several in Phase I and a number of pre-clinical (research stage) projects. Some of the pre-clinical projects are partnered; others are Emisphere-initiated. Our product pipeline includes prescription and nutritional supplements candidates.

Both of our products in Phase III are with our partner Novartis Pharma AG ( Novartis ), which is using our drug delivery technology in combination with salmon calcitonin, parathyroid hormone, and human growth

hormone. Their most advanced programs are testing oral formulations of salmon calcitonin to treat osteoarthritis and osteoporosis. Novartis is conducting two Phase III clinical studies for osteoarthritis and one Phase III clinical study for osteoporosis.

During the third quarter 2008 Novartis completed enrollment for the first trial for osteoarthritis, a multi-center Phase III study exploring the safety and efficacy of an oral formulation of salmon calcitonin using Emisphere s proprietary Eligen<sup>®</sup> Technology to treat patients with osteoarthritis of the knee. This study, which will be used to support the filing with health authorities worldwide, includes more than 1,100 patients between the ages of 51 and 80 years old with a medical history and symptoms of knee osteoarthritis. This study will be conducted mainly in Europe and is estimated to be completed during the second half of 2010. In October, Emisphere also announced that Novartis and Nordic Bioscience initiated a second multi-center Phase III study exploring the safety and efficacy of an oral formulation of salmon calcitonin to treat patients with osteoarthritis of the knee. This second study, designed to meet the Food and Drug Administration (FDA) requirements for U.S. registration, will examine patients between 51 and 80 years of age suffering from painful symptoms of knee osteoarthritis. The study will be conducted in multiple sites, including the U.S., with an estimated completion during the second half of 2011.

Approximately 21 million patients are managed for osteoarthritis in the U.S. alone, and that number is expected to increase as the Baby Boomer generation continues to age. Assuming a successful outcome of the Phase III program, this product candidate will also fulfill a substantial unmet need. Pre-clinical and Phase II data indicate that oral calcitonin could become the first disease modifying osteoarthritis drug.

Novartis is also conducting a Phase III trial for a second product, an oral formulation of salmon calcitonin using Emisphere s proprietary Eligen Technology to treat patients with osteoporosis. This Phase III trial, which started in 2007, is a multi-center study exploring the safety and efficacy of oral Eligen® salmon calcitonin to treat vertebral fractures in postmenopausal women aged 60-80 with osteoporosis. The last of over 4,500 patients was recruited for the osteoporosis study in the final week of June 2008, and the three-year study is being conducted in North and South America, Europe and Asia. Over 5,500 clinical study patients will be using the Eligen® Technology during 2009.

The results of a study conducted by Novartis and its partner Nordic Bioscience were published in the October 2008 issue of BMC Clinical Pharmacology. The study demonstrated that oral salmon calcitonin using Emisphere s proprietary Eligen® Technology taken 30 to 60 minutes before meals with 50 ml of water results in improved absorption and improved efficacy measured by the biomarker of reduced bone resorption (sCTX-I) compared to the commonly prescribed nasal formulation. The study was a randomized, partially-blind, placebo-controlled, single dose exploratory crossover clinical trial using 56 healthy postmenopausal women.

During February 2009, the Company announced the results of another study indicating that orally administered salmon calcitonin using Emisphere s carrier (5-CNAC) and Eligen oral delivery Technology is effective in reducing bone breakdown. The results of this study were published in the December 2008 issue of BMC Clinical Pharmacology. The study was conducted on behalf of Emisphere s partner Novartis Pharma AG by Nordic Bioscience. The results of this study add to evidence of the effectiveness of oral calcitonin using Eligen® Technology in suppression of bone resorption.

This most recent study, a randomized, double-blind, double-dummy, placebo-controlled study among 81 subjects in Copenhagen, was conducted by M.A. Karsdal, I. Byrjalsen, B.J. Riis and C. Christiansen. The study suggests that orally administered 0.8 mg of salmon calcitonin was effective in suppression of Serum CTX irrespective of time of dosing. Serum CTX-1 (Serum C-terminal telo-peptide of collagen type I) is the biochemical marker used to measure bone resorption. There were no safety concerns with the salmon calcitonin oral formulation using Emisphere s carrier 5-CNAC, which had been previously demonstrated in earlier studies.

According to the National Osteoporosis Foundation, ten million people in the U.S. are estimated to have the disease with an estimated 34 million more to have low bone mass and are at risk. This product candidate for the treatment of osteoporosis, if successful, will meet an unmet market need, with oral salmon calcitonin expected to offer a safe, effective, and convenient alternative to existing therapies.

Two of our product candidates have entered or completed Phase II studies: oral insulin and oral heparin. Emisphere has devoted, for many years, substantial resources to the oral delivery of insulin and heparin. Neither program has resulted in an approved product. Both product candidates continue to be evaluated and numerous experts have been consulted. Both candidates could represent potential opportunities for Emisphere and, in theory, could meet unmet market needs. However, both products also present varying and significant challenges. Our efforts to partner these programs have not achieved satisfactory endpoints. Emisphere will continue to explore all strategic options for both candidates.

Emisphere also has several products in Phase I and a number of pre-clinical (research stage) projects. Some of the pre-clinical projects are partnered others are Emisphere-initiated.

Novartis is conducting a Phase I study in postmenopausal women to determine the safety and tolerability of oral PTH-1-34, a combination of human PTH-1-34 and Emisphere s delivery agent 5-CNAC, for the treatment of postmenopausal osteoporosis. The study is designed to assess the bioavailability profile of increasing doses of PTH-1-34 combined with different amounts of 5-CNAC administered orally. The trial was conducted in Switzerland and its first interpretable results were released during November 2008.

The results of the study demonstrated the achievement of a suitable PK profile of a new oral formulation of Parathyroid Hormone (PTH) using Emisphere s Elfget chnology. This initial study of 20 healthy postmenopausal female patients aged 40 to 70 years resulted in peak concentrations (Cmax) in the range of those obtained with the commercially available subcutaneous formulation Forteo (teriparatide). This initial trial reported no significant adverse affects, no hypocalcaemia, and no drug-exposure related discontinuation. The plan is to continue the development program. Recombinant PTH, currently approved for the treatment of osteoporosis, is available only by injection. PTH exists naturally in the body; it increases bone density and bone strength to help prevent fractures. It may also be used to treat osteoporosis in patients at high risk of bone fracture.

Genta released final results from the Company s Phase I clinical trial of G4544, a new tablet formulation of a proprietary small molecule intended as a treatment for diseases associated with accelerated bone loss using Emisphere s Eligen Technology. Results showed that the drug was very well-tolerated, and that blood levels were achieved in a range that is known to be clinically bioactive. The data were featured in a poster session at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago on Saturday, May 31, 2008.

Our preclinical programs focus on the development of oral formulations of potentially new treatments for diabetes and on the development and potential expansion of nutritional supplements products.

Our research indicates that the development of oral formulations of Novo Nordisk s proprietary GLP-1 receptor agonists may represent an opportunity for Emisphere. In addition to continuing to pursue oral insulin for Type 1 diabetes, we believe that a potentially more productive pathway is to move forward with GLP-1 and its analogs, an oral form of which might be used to treat Type 2 diabetes and other metabolic conditions.

Research using Eligen<sup>®</sup> Technology and GLP-1, a potential treatment for Type 2 diabetes is being conducted by Novo Nordisk and by Dr. Christoph Beglinger, M.D., an independent medical researcher at University Hospital in Basel, Switzerland. We had previously conducted extensive tests on oral insulin for Type 1 diabetes and concluded that a more productive pathway is to move forward with GLP-1 and its analogs, an oral form of which might be used to treat Type 2 diabetes and related conditions. Consequently, on June 21, 2008 we entered an exclusive Development and License Agreement with Novo Nordisk focused on the development of oral formulations of Novo Nordisk s proprietary GLP-1 receptor agonists. Novo Nordisk s development efforts are in the early preclinical stage.

Separately, an early stage human study of an oral formulation that combines PYY and native GLP-1 with Emisphere s proprietary delivery agent known as SNAC was conducted at University Hospital by Professor Beglinger. The study demonstrated the oral delivery of the GLP-1 peptide was safe and effective and that the oral formulation of GLP-1 stimulated an early increase in fasting insulin and a decrease in fasting glucose as compared to placebo.

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In October 2008, Professor Beglinger published the results of another study assessing the oral delivery of GLP-1 and PYY3-36 using Emisphere s proprietary delivery technology. The study showed, for the first time, that satiety peptides such as GLP-1 and PYY3-36 can be delivered orally in humans with safety and efficiency. The study, conducted in 12 healthy subjects, was designed to establish the pharmacokinetics and pharmacodynamics of increasing oral doses of GLP-1 and PYY3-36. Emisphere s delivery agent, known as SNAC, was formulated as a tablet with GLP-1 or PYY3-36. Both oral GLP-1 and PYY3-36 induce rapid and dose-dependent increases in plasma drug concentrations; GLP-1 induces a relevant insulin release; and, both peptides suppressed ghrelin secretion in healthy male volunteers. This clinical study of the compound confirms Professor Beglinger s earlier results that SNAC allows for rapid oral absorption of GLP-1 or PYY3-36. The study results were published in the October 2008 issue of Clinical Pharmacology & Therapeutics.

Intravenous or subcutaneous applications of GLP-1 are cumbersome and impractical for chronic treatment regimens. Current oral application of peptides is ineffective because peptides have a low oral bioavailability due to their molecular size and physico-chemical characteristics. Professor Beglinger s studies show that Emisphere s Eligen Technology can overcome some of these oral delivery issues safely and efficiently.

Our other product candidates in development are in earlier or preclinical research phases, and we continue to assess them for their compatibility with our technology and market need. Our intent is to seek partnerships with pharmaceutical and biotechnology companies for certain of these products. We plan to expand our pipeline with product candidates that demonstrate significant opportunities for growth. Our focus is on molecules that meet the criteria for success based on our increased understanding of our Eligen<sup>®</sup> Technology.

### Vitamin B12

B12 is an important nutrient that is poorly absorbed in the oral form. In most healthy people, vitamin B12 is absorbed in a receptor-mediated pathway in the presence of an intrinsic factor. A large number of people take B12 supplements by the oral route, many in megadoses, and by injection.

Emisphere is independently developing Eligen<sup>®</sup> B12 as a nutritional supplement product candidate. Following our proof of concept animal studies of the absorption of vitamin B12 using our Eligen<sup>®</sup> Technology, additional preclinical studies using dogs further demonstrated that the Eligen<sup>®</sup> Technology enhances the absorption of oral B12 and confirmed earlier proof of concept studies conducted in rats. We have completed our first clinical study testing our new vitamin B12 formulation in twenty normal healthy males.

The data from our first pharmacokinetic study showed mean vitamin B12 peak blood levels were more than 10 times higher for the Eligen<sup>®</sup> B12 5mg formulation than for the 5mg commercial formulation. The mean time to reach peak concentration (Tmax) was reduced by over 90% to 0.5 hours for the Eligen<sup>®</sup> B12 5mg from 6.8 hours for the commercial 5mg product. Improvement in bioavailability was approximately 240%, with absorption time at 30 minutes and a mean bioavailability of 5%. The study was conducted with a single administration of Eligen<sup>®</sup> B12; there were no adverse reactions, and Eligen<sup>®</sup> B12 was well-tolerated.

The data from our first Eligen<sup>®</sup> B12 clinical study demonstrates that our Eligen<sup>®</sup> B12 may be a new, more bioavailable oral form vitamin B12 and a potential new avenue for addressing the problems with B12 supplementation. Eligen<sup>®</sup> B12 avoids the normal specialized absorption process that limits absorption of vitamin B12 from current formulations. By circumventing the current absorption process, Eligen<sup>®</sup> B12 may present an opportunity to reduce the potential uncertainty associated with oral megadoses of vitamin B12 and may reduce the substantial number of injections being taken by millions of individuals.

The Company is planning one or more additional clinical studies, including pharmacokinetic and safety and efficacy studies in vitamin B12 deficient people to further elucidate the advantages of the Eligen<sup>®</sup> Technology. Currently, it is estimated that at least five million people in the U.S. are taking 40 million injections of vitamin B12 per year to treat a variety of debilitating medical conditions (as noted above). Another estimated five million are consuming more than 600 million tablets of vitamin B12 orally. The international market may be as large as the U.S. market. Many B12 deficient patients suffer from pernicious anemia and neurological disorders. Many of these patients are infirm or elderly. Vitamin B12 deficiency can

cause severe and irreversible damage, especially to the brain and nervous system. At levels only slightly lower than normal, a range of symptoms such as fatigue, depression, and poor memory may be experienced.

The safety of the carrier we plan to use to deliver Eligen<sup>®</sup> B12 has been demonstrated in earlier preclinical and clinical studies. Since vitamins are regulated by the FDA under different provisions than those used for drugs and biologicals, we anticipate that our development of vitamins may be shorter and less expensive than for a prescription drug.

We have obtained patents for the carrier we are using in the oral B12 formulation and have filed applications covering the combination of the carrier and many other compounds, including vitamin B12.

### **Business Financing**

Since our inception in 1986, we have generated significant losses from operations and we anticipate that we will continue to generate significant losses from operations for the foreseeable future. As of December 31, 2008, our accumulated deficit was approximately \$434 million. Our loss from operations was \$26.3 million, \$20.7 million and \$27.1 million for the years ended December 31, 2008, 2007 and 2006, respectively. Our net loss was \$24.4 million, \$16.9 million and \$41.8 million for the years ended December 31, 2008, 2007 and 2006, respectively. Our cash outlays from operations and capital expenditures were \$6.8 million, \$14.7 million and \$22.8 million for the years ended December 31, 2008, 2007 and \$37.0 million, \$13.7 million and \$6.1 million as of December 31, 2008, 2007 and 2006, respectively.

We have limited capital resources and operations to date have been funded with the proceeds from collaborative research agreements, public and private equity and debt financings and income earned on investments. We anticipate that our existing capital resources will enable us to continue operations through approximately August 2009 or earlier if unforeseen events or circumstances arise that negatively affect our liquidity. While our plan is to raise capital when needed and/or to pursue partnering opportunities, we cannot be sure that our plans will be successful. These conditions raise substantial doubt about our ability to continue as a going concern. The audit report prepared by our independent registered public accounting firm relating to our financial statements for the years ended December 31, 2008, 2007 and 2006 includes an explanatory paragraph expressing the substantial doubt about our ability to continue as a going concern.

If we are successful in raising additional capital to continue operations, our business will still require substantial additional investment that we have not yet secured. Further, we will not have sufficient resources to fully develop new products or technologies unless we are able to raise substantial additional financing on acceptable terms or secure funds from new or existing partners. We cannot assure you that financing will be available on favorable terms or at all. See Item 1A-Risk Factors.

### **Overview of Drug Delivery Industry**

The drug delivery industry develops technologies for the improved administration of therapeutic molecules with the goal of expanding markets for existing products and extending drug franchises. Drug delivery companies also seek to develop products on their own that would be patent-protected by applying proprietary technologies to off-patent pharmaceutical products. Primarily, drug delivery technologies are focused on improving safety, efficacy, ease of patient use and/or patient compliance. Pharmaceutical and biotechnology companies consider improved drug delivery as a means of gaining competitive advantage over their peers.

Therapeutic macromolecules, of which proteins are the largest sub-class, are prime targets for the drug delivery industry for a number of reasons. Most therapeutic macromolecules must currently be administered by injection (most common) or other device such as an inhaler or nasal spray system. Many of these compounds address large markets

for which there is an established medical need. These drugs are widely used, as physicians are familiar with them and accustomed to prescribing them. Therapeutic macromolecules could be significantly enhanced through alternative delivery. These medicines are comprised of proteins and other large or highly charged molecules (carbohydrates, peptides, ribonucleic acids) that, if orally administered using

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traditional oral delivery methods, would degrade in the stomach or intestine before they are absorbed into the bloodstream. Also, these molecules are typically not absorbed following oral administration due to their poor permeability. Therefore, the vast majority are administered parenterally. Parenteral administration is undesirable, however, for many reasons, including patient discomfort, inconvenience and risk of infection. Poor patient acceptance of parenteral therapies can lead to medical complications. In addition, parenteral therapies can often require incremental costs associated with administration in hospitals or doctors offices.

Previously published research indicates that patient acceptance of and adherence to a dosing regimen is higher for orally delivered medications than it is for non-orally delivered medications. Our business strategy is partly based upon our belief that the development of an efficient and safe oral delivery system for therapeutic macromolecules represents a significant commercial opportunity. We believe that more patients will take orally delivered drugs more often, spurring market expansion.

### Leading Current Approaches to Drug Delivery

#### Transdermal (via the skin) and Needleless Injection

The size of most macromolecules makes penetration into or through the skin inefficient or ineffective. Some peptides and proteins can be transported across the skin barrier into the bloodstream using high-pressure needleless injection devices. Needleless devices, which inject proteins through the skin into the body, have been in development for many years. We believe these devices have not been well accepted due to patient discomfort, relatively high cost, and the inconvenience of placing the drugs into the device.

#### Nasal (via the nose)

The nasal route (through the membranes of the nasal passage) of drug administration has been limited by low and variable bioavailability for proteins and peptides. As a result, penetration enhancers often are used with nasal delivery to increase bioavailability. These enhancers may cause local irritation to the nasal tissue and may result in safety concerns with long-term use. A limited number of peptides delivered nasally have been approved for marketing in the U.S. including MIACALCIN<sup>®</sup>, developed by Novartis as an osteoporosis therapy, a therapeutic area we have targeted.

#### Pulmonary (via the lung)

Pulmonary delivery (through the membranes of the lungs) of drugs is emerging as a delivery route for large molecules. Although local delivery of respiratory drugs to the lungs is common, the systemic delivery (i.e., delivery of the drugs to the peripheral vasculature) of macromolecular drugs is less common because it requires new formulations and delivery technologies to achieve efficient, safe and reproducible dosing. Only one protein using pulmonary delivery has been approved for marketing in the U.S., which is EXUBERA<sup>®</sup>, an insulin product developed by Pfizer and Nektar, as a diabetes therapy, a therapeutic area we have targeted. However after market acceptance of EXUBERA<sup>®</sup> was demonstrated to be limited, Pfizer withdrew from further commercialization of, and terminated its license with Nektar for EXUBERA<sup>®</sup>.

### Intraoral (via the membranes in the mouth)

Intraoral delivery is also emerging as a delivery route for large molecules. Buccal delivery (through the membrane of the cheek) and sublingual delivery (through the membrane under the tongue) are forms of intraoral delivery. Some vitamin B12 manufactures sell and distribute sublingual versions of their product.

### Oral (via the mouth)

We believe that the oral method of administration is the most patient-friendly option, in that it offers convenience, is a familiar method of administration that enables increased compliance and, for some therapies, may be considered the most physiologically appropriate. We, and other drug delivery and pharmaceutical companies, have developed or are developing technologies for oral delivery of drugs. We believe that our Eligen<sup>®</sup> Technology provides an important competitive advantage in the oral route of administration because it

does not alter the chemical composition of the therapeutic macromolecules. We have conducted over 140,000 human dosings and have witnessed no serious adverse events that can be attributed to the EMISPHERE® delivery agents dosed or the mechanism of action of the Eligen® Technology.

In general, we believe that oral administration will be preferred to other methods of administration. However, such preference may be offset by possible negative attributes of orally administered drugs such as the quantity or frequency of the dosage, the physical size of the capsule or tablet being swallowed or the taste. For example, in our previous Phase III Trial with heparin as an oral liquid formulation, patient compliance was hindered by patients distaste for the liquid being administered. In addition, patients and the marketplace will more likely respond favorably to improvements in absorption, efficacy, safety, or other attributes of therapeutic molecules. It is possible that greater convenience alone may not lead to success.

### The Eligen<sup>®</sup> Technology

The Eligen<sup>®</sup> Technology is a broadly applicable proprietary oral drug delivery technology based on the use of proprietary synthetic chemical compounds known as EMISPHERE<sup>®</sup> delivery agents, or carriers. These delivery agents facilitate and enable the transport of therapeutic macromolecules (such as proteins, peptides, and polysaccharides) and poorly absorbed small molecules across biological membranes targeted in the stomach; enabling the therapeutic molecules to exert their desired pharmacological effect. The delivery agents have no known pharmacological activity themselves at the intended clinical dose levels. Emisphere s Eligen Technology makes it possible to deliver therapeutic molecules orally without altering their chemical form or biological integrity.

### **Proposed Delivery Agent Mechanism**

The Eligen<sup>®</sup> Technology facilitates absorption in the stomach and takes place through a transcellular, not paracellular, pathway. This underscores the safety of Eligen<sup>®</sup> as the passage of the Eligen<sup>®</sup> carrier and the molecule preserve the integrity of the tight junctions within the cell and reduces any likelihood of inflammatory processes and autoimmune gastrointestinal diseases. Furthermore, because the Eligen<sup>®</sup> Technology is rapidly absorbed, metabolized and eliminated from the body; it does not accumulate in the organs and tissues and is considered safe at anticipated dose and dosing regimens.

Drug molecules exist in many different shapes, or conformations. Some conformations can be transported across the cell membranes while others are too large or too charged to do so. The Eligen<sup>®</sup> Technology uses the body s natural passive transcellular transport process to enable large or highly charged molecules to cross cell membranes. Once the drug molecule crosses the membrane, the EMISPHERE<sup>®</sup> delivery agent dissociates from the drug molecule, which then reestablishes its natural conformation and returns to its therapeutically active state. Studies have shown that this process does not involve chemical modification of the drug molecule and the integrity of cell membrane and cytoskeletal structure are maintained.

We have designed and synthesized a library of approximately 4,000 delivery agents and continue to evaluate our delivery agents for their ability to facilitate the delivery of therapeutic macromolecules across biological membranes.

### **Ongoing Collaborative Agreements**

We are a party to certain collaborative agreements with corporate partners to provide development and commercialization services relating to the products under collaboration. These agreements are in the form of research and development collaborations and licensing agreements. Under these agreements, we have granted licenses or the rights to obtain licenses to our oral drug delivery technology. In return, we are entitled to receive certain payments upon the achievement of milestones and royalties on the sales of the products should a product ultimately be

commercialized. We also are entitled to be reimbursed for certain research and development costs that we incur.

All of our collaborative agreements are subject to termination by our corporate partners, without significant financial penalty to them. Under the terms of these agreements, upon a termination we are entitled to reacquire all rights in our technology at no cost and are free to re-license the technology to other collaborative partners.

Novartis Pharma AG Oral Salmon Calcitonin ( sCT ) Program for Osteoporosis and Osteoarthritis

#### **Osteoporosis**

In December 1997, we entered into a collaboration agreement with Novartis to develop an oral form of sCT, currently used to treat osteoporosis. sCT is a hormone that inhibits the bone-tissue resorbing activity of specialized bone cells called osteoclasts, enabling the bone to retain more of its mass and functionality. sCT has demonstrated efficacy in increasing lumbar spine bone mineral density and in reducing vertebral fractures. sCT is estimated to be about 30 times more potent than the human version. Synthetic sCT, which is identical to the naturally occurring one, currently is available only as a nasal spray or injectable therapy. Novartis markets synthetic sCT in the U.S. as MIACALCIN<sup>®</sup> nasal spray, which is indicated for the treatment of post-menopausal osteoporosis in women greater than five years post menopause with low bone mass.

Treatment with sCT has been shown to increase bone mineral density in the spine and reduce the risk of new vertebral fractures in post-menopausal women with osteoporosis. It is also used to treat Paget s disease, a disease that results in, among other things, bone pain and breakdown. In its nasal spray forms, it is believed that sCT s major advantages are its efficacy resulting from a lack of serious side effects, excellent long-term safety profile and ease of administration. Some studies even suggest that sCT produces an analgesic effect. Worldwide market sales for products to treat osteoporosis are forecasted to reach \$10.4 billion by 2011, from approximately \$5.0 billion in 2003.

In February 2003, we announced favorable results of a Phase IIa study conducted by Novartis evaluating the performance in post-menopausal women of an oral tablet form of sCT. The purpose of the study was to assess the efficacy and safety of various doses of an oral tablet of sCT in post-menopausal women and to confirm the activity of sCT when given orally, as reflected by changes in markers of bone formation or resorption. Oral sCT was dosed for 90 days in the study, the longest time period that the Eligen<sup>®</sup> Technology has been dosed in human testing. The study demonstrated activity on bone markers over a three month dosing period when the peptide was delivered in combination with the EMISPHERE<sup>®</sup> delivery agent. Only two serious adverse events were reported, neither of which were related to the EMISPHERE<sup>®</sup> delivery agent or to sCT. The side effects (mainly gastrointestinal in nature) seen with the highest doses of sCT were consistent with those normally seen with high plasma levels of sCT when administered by injection. These results were presented by Novartis at the American Society of Bone and Mineral Research in September of 2003.

In December 2005, we announced positive clinical data generated by Drs. Daniel Manicourt and Jean-Pierre Devogelaer from the Department of Rheumatology at the University Hospital St-Luc, Universite Catholique de Louvain, Brussels, Belgium. The results of this study, which evaluated oral salmon calcitonin supplied by Novartis using our Eligen<sup>®</sup> Technology in treating osteoarthritis (OA) were presented at the 10th World Congress of the Osteoarthritis Research Society International in Boston, MA. Results of this study suggest that oral sCT (enabled by our proprietary Eligen<sup>®</sup> Technology licensed to Novartis for use with sCT) exhibits not only clinical efficacy but also reduces the levels of several biochemical markers of joint metabolism, which all have been shown to have a pejorative prognostic value of the OA disease process in longitudinal studies including large cohorts of patients.

The randomized, double-blind, placebo-controlled, parallel study was conducted for three months in OA patients to assess the efficacy of this novel form of sCT in patients suffering from knee OA. Patients received daily either a placebo (n=16), 0.5 mg of oral sCT (n=17) or 1 mg of oral sCT (n=18).

In February 2007, Novartis and its development partner Nordic Bioscience notified us of the initiation of a Phase III clinical trial for the treatment of osteoporosis with an oral form of salmon calcitonin (referred to as SMC021), a new drug candidate, using the Company s Eligen Technology. The Phase III program that started in 2007 is a three year trial with enrollment of over 4,500 patients completed in June 2008. The study is

exploring the safety and efficacy of salmon calcitonin and Emisphere s proprietary Eligen Technology in the treatment of vertebral fractures in postmenopausal women aged 60-80 with osteoporosis. It will be conducted in North and South America, Europe and Asia. This product candidate, if successful, will meet an unmet market need, with oral calcitonin expected to offer a safe, effective, and convenient alternative to existing therapies.

The results of a study conducted by Novartis and its partner Nordic Bioscience was published in the October 2008 issue of BMC Clinical Pharmacology demonstrated that oral salmon calcitonin using Emisphere s proprietary Eligent Technology taken 30 to 60 minutes before meals with 50 ml of water results in improved absorption and improved efficacy measured by the biomarker of reduced bone resorption (sCTX-I) compared to the commonly prescribed nasal formulation. The study was a randomized, partially-blind, placebo-controlled, single dose exploratory crossover clinical trial using 56 healthy postmenopausal women.

Under the sCT agreements, Novartis has an option to an exclusive worldwide license to develop in conjunction with us, make, have made, use and sell products developed under this program. Novartis also had the right to exercise an option to commence a research collaboration with us on a second compound under this agreement. Novartis rights to certain specified financial terms concerning a license of a second compound have since expired. We have no payment obligations with respect to this program; we are, however, obligated to collaborate with Novartis by providing access to our technology that is relevant to this program. We are also obligated to help to manage this program through a joint steering committee with Novartis.

### Osteoarthritis

On a parallel track, Novartis is also pursuing an osteoarthritis indication for salmon calcitonin. Approximately 21 million patients are managed for osteoarthritis in the U.S. alone, and that number is expected to increase as the Baby Boomer generation continues to age. Osteoarthritis (OA) is a clinical syndrome in which low-grade inflammation results in joint pain, caused by a wearing-away of cartilage that cushions the joints and the destruction or decrease of synovial fluid that lubricates those joints. As OA progresses, pain can result when the patient bears weight upon the joints, including walking and standing. OA is the most common form of arthritis, and affects nearly 21 million people in the U.S., accounting for 25% of visits to primary care physicians, and half of all non-steroidal anti-inflammatory drug prescriptions. It is estimated that 80% of the population will have radiographic evidence of OA by age 65.

Novartis is engaged in two, simultaneous Phase III trials for salmon calcitonin in the treatment of osteoarthritis. During September 2008, Novartis and Nordic Bioscience completed recruitment for a multi-center Phase III study exploring the safety and efficacy of an oral formulation of salmon calcitonin using Emisphere s proprietary Eligent Technology to treat patients with osteoarthritis of the knee. This study, which will be used to support the filing with health authorities worldwide, includes more than 1,100 patients between 51 and 80 years old with a medical history and symptoms of knee osteoarthritis. The study will be conducted mainly in Europe and is estimated to be completed during second half 2010.

During October 2008, Novartis and Nordic Bioscience initiated a second multi-center Phase III study exploring the safety and efficacy of an oral formulation of salmon calcitonin using Emisphere s proprietary Eligen Technology to treat patients with osteoarthritis of the knee. This second study, designed to meet FDA requirements for U.S. registration, will examine patients between 51 and 80 years old suffering from painful symptoms of knee osteoarthritis. The study will be conducted in multiple sites, including the U.S. Enrollment is scheduled to be completed during 2009 with an estimated completion during the second half of 2011.

Assuming a successful outcome of the Phase III program, this product candidate will also fulfill a substantial unmet medical need. Pre-clinical and Phase II data indicate that oral salmon calcitonin could become the first disease

modifying osteoarthritis drug.

Within the various Phase III trials with Novartis, over 5,500 patients are expected to be using the Eligen® Technology during 2009.

To date, we have received \$12.4 million in payments from Novartis under the sCT programs. Under the terms of the sCT agreement, we may receive up to \$5 million in additional milestone payments, as well as royalties based on sales.

### Novartis Pharma AG Oral PTH-1-34 Program

On December 1, 2004, we entered into a Research Collaboration Option and License Agreement with Novartis whereby Novartis obtained an option to license our existing technology to develop oral forms of PTH-1-34. At the time we entered this new agreement, Novartis also purchased from us a \$10 million convertible note maturing December 1, 2009 that we may repay, at our option, in either stock or cash. On March 7, 2006, Novartis exercised its option to the license. Based on the terms of the agreement, we may receive milestone payments totaling up to a maximum of \$30 million, plus royalties on sales of product developed using our Eligen<sup>®</sup> Technology. Novartis will fund all necessary pre-clinical, clinical and manufacturing costs for all products.

Parathyroid hormone continues on a progressive clinical development path in collaboration with Novartis. During June 2008, Novartis launched a Phase I study in postmenopausal women to determine the safety and tolerability of oral PTH-1-34, a combination of human PTH-1-34 and the absorption enhancer 5-CNAC using Emisphere s proprietary Eligen<sup>®</sup> Technology, for the treatment of postmenopausal osteoporosis. The study is designed to assess the bioavailability profile of increasing doses of PTH-1-34 combined with different amounts of 5-CNAC administered orally. The trial was conducted in Switzerland and its first interpretable results were released during November 2008.

The results of the study demonstrated the achievement of a suitable PK profile of a new oral formulation of Parathyroid Hormone (PTH) using Emisphere s Ellegenchnology. This initial study of 20 healthy postmenopausal female patients aged 40 to 70 years resulted in peak concentrations (Cmax) in the range of those obtained with the commercially available subcutaneous formulation Forteo (teriparatide). This initial trial reported no significant adverse affects, no hypocalcaemia, and no drug-exposure related discontinuation. The plan is to continue the development program. Recombinant PTH, currently approved for the treatment of osteoporosis, is available only by injection. PTH exists naturally in the body; it increases bone density and bone strength to help prevent fractures. It may also be used to treat osteoporosis in patients at high risk of bone fracture.

### Novartis Pharma AG Oral Recombinant Human Growth Hormone Program

From 1998 through August 2003, we developed oral rhGH in collaboration with Eli Lilly and Company (Lilly). As of August 2003, Lilly returned to us all rights to the oral rhGH program pursuant to the terms of our license agreement. On September 23, 2004 we announced a new partnership with Novartis to develop our oral rhGH program. Under this collaboration, we are working with Novartis to initiate clinical trials of a convenient oral human growth hormone product using the Eligen<sup>®</sup> Technology. On May 1, 2006, we announced that Novartis will initiate the development of an oral rhGH product using Emisphere s Eligen<sup>®</sup> Technology.

Under this agreement, Novartis has an exclusive worldwide license to develop, make, have made, use and sell products developed under this program. We have no payment obligations with respect to this program; we are, however, obligated to collaborate with Novartis by providing access to our technology that is relevant to this program. We are also obligated to help to manage this program through a joint steering committee with Novartis.

To date, we have received \$6 million in non-refundable payments from Novartis under this program, including the \$5 million milestone payment received in 2006. We may receive up to \$28 million in additional milestone payments during the course of product development and royalties based on sales.

### Novo Nordisk AS Agreement

On June 21, 2008, we entered into an exclusive Development and License Agreement with Novo Nordisk pursuant to which Novo Nordisk will develop and commercialize oral formulations of Novo Nordisk proprietary products in combination with Emisphere carriers. Under such agreement Emisphere could receive more than \$87 million in contingent product development and sales milestone payments, including a \$10 million non-refundable license fee which was received in June 2008. Emisphere would also be entitled to

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receive royalties in the event Novo Nordisk commercializes products developed under such Agreement. Under the Agreement, Novo Nordisk is responsible for the development and commercialization of the products.

#### Genta, Incorporated Oral Gallium Program

In March 2006, we announced that we have entered into an exclusive worldwide licensing agreement with Genta, Incorporated (Genta) to develop an oral formulation of a gallium-containing compound. Under the agreement, we will utilize our Eligen<sup>®</sup> Technology to supply a finished oral dosage form to Genta. Genta will be responsible for toxicology, clinical development, regulatory submissions, and worldwide commercialization. In addition to royalties on net sales of the product, Genta has agreed to fund Emisphere s development activities and to pay performance milestones related to the filing and approval of regulatory applications. An Investigational New Drug application was filed by Genta on gallium on July 31, 2007. Genta released final results from the Company s Phase I clinical trial of G4544, a new tablet formulation of a proprietary small molecule intended as a treatment for diseases associated with accelerated bone loss using delivery technology developed by Emisphere Technologies, Inc. Results showed that the drug was very well-tolerated, and that blood levels were achieved in a range that is known to be clinically bioactive. The data were featured in a poster session at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago on Saturday, May 31, 2008.

### Revenue Recognized From Significant Collaborators 2006 through 2008 (in thousands)

Collaborator	2008	2007	2006
Novartis Pharma AG Roche	\$	\$ 2,666 73	\$ 5,254 1,600
Novo Nordisk AS	46		
Genta	118	1,159	207

#### **Research and Development Costs**

We have devoted substantially all of our efforts and resources to research and development conducted on our own behalf (self-funded) and in collaborations with corporate partners (partnered). Generally, research and development expenditures are allocated to specific research projects. Due to various uncertainties and risks, including those described in Item 1A. Risk Factors below, relating to the progress of our product candidates through development stages, clinical trials, regulatory approval, commercialization and market acceptance, it is not possible to accurately predict future spending or time to completion by project or project category.

The following table summarizes research and development spending to date by project category:

	<u>'</u>	Year Ended December 31,           2008         2007         2006			Cumulative Spending 2008(1)				
		(In thousands)							
Research(2) Feasibility projects	\$	1,143	\$	1,954	\$	2,247	\$	51,849	
Self-funded Partnered		1,688 425		457 178		275 343		9,757 4,186	

392	3,834	2,175		99,289
53	1,184	1,982		21,283
59	611	302		12,156
9,025	12,858	11,568		101,457
\$ 12,785	\$ 21,076	\$ 18,892	\$	299,977
	53 59	531,184596119,02512,858	531,1841,982596113029,02512,85811,568	531,1841,982596113029,02512,85811,568

(1) Cumulative spending from August 1, 1995 through December 31, 2008.

- (2) Research is classified as resources expended to expand the ability to create new carriers, to ascertain the mechanisms of action of carriers, and to establish computer based modeling capabilities, prototype formulations, animal models, and *in vitro* testing capabilities.
- (3) Other includes indirect costs such as rent, utilities, training, standard supplies and management salaries and benefits.

### Patents and Other Forms of Intellectual Property

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing the proprietary rights of others (see Risk Factors- Our business will suffer if we cannot adequately protect our patent and proprietary rights ). We seek patent protection on various aspects of our proprietary chemical and pharmaceutical delivery technologies, including the delivery agent compounds and the structures which encompass Emisphere s delivery agents, their method of preparation, the combination of our compounds with a pharmaceutical, and use of our compounds with therapeutic molecules to treat various disease states. We have patents and patent applications in the U.S. and certain foreign countries. As of February 17, 2009, we had 121 granted U.S. Patents as well as 109 patent families with pending patent applications.

We intend to file additional patent applications when appropriate, and to aggressively prosecute, enforce, and defend our patents and other proprietary technology.

We have five trademarks granted by the U.S. Patent and Trademark office. They include EMISPHERE<sup>®</sup>, Elaprin<sup>®</sup> (oral heparin), the Emisphere logo, Emigent<sup>®</sup> and Eligen<sup>®</sup>.

We also rely on trade secrets, know-how, and continuing innovation in an effort to develop and maintain our competitive position. Patent law relating to the patentability and scope of claims in the biotechnology and pharmaceutical fields is evolving and our patent rights are subject to this additional uncertainty. Others may independently develop similar product candidates or technologies or, if patents are issued to us, design around any products or processes covered by our patents. We expect to continue, when appropriate, to file product and other patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that the patents issued to or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

### Manufacturing

The primary raw materials used in making the delivery agents for our product candidates are readily available in large quantities from multiple sources. In the past we manufactured delivery agents internally using our own facilities on a small scale for research purposes and for early stage clinical supplies. We believed that our manufacturing capabilities complied with the FDA s current Good Manufacturing Practice (GMP). Beginning in 2004, we manufactured early stage clinical supplies under GMP conditions for our oral insulin program and heparin multiple arm studies. The FDA inspected our in-house facilities in 2003 and again in 2005. The 2003 inspection resulted in only minor observations on Form 483 which were quickly resolved to FDA s satisfaction, while the 2005 inspection yielded no Form 483 observations.

Currently, EMISPHERE<sup>®</sup> delivery agents are manufactured by third parties in accordance with GMP regulations. We have identified other commercial manufacturers meeting the FDA s GMP regulations that have the capability of producing EMISPHERE<sup>®</sup> delivery agents and we do not rely on any particular manufacturer to supply us with needed quantities.

#### Competition

Our success depends in part upon maintaining a competitive position in the development of product candidates and technologies in an evolving field in which developments are expected to continue at a rapid pace. We compete with other drug delivery, biotechnology and pharmaceutical companies, research organizations, individual scientists and non-profit organizations engaged in the development of alternative drug delivery technologies or new drug research and testing, and with entities developing new drugs that may be orally active. Our product candidates compete against alternative therapies or alternative delivery systems for each of the medical conditions our product candidates address, independent of the means of delivery. Many of our competitors have substantially greater research and development capabilities, experience, marketing, financial and managerial resources than we have. In many cases we rely on our development partners to develop and market our product candidates.

### **Oral Osteoporosis Competition**

An injectable form of PTH-1-34 is manufactured and sold by Eli Lilly, as FORTEO<sup>®</sup>. Unigene Laboratories, Inc. (Unigene) has reported that, in collaboration with GlaxoSmithKline plce (GSK), it is developing an oral form of PTH-1-34. Unigene also reported that it is developing an oral form of sCT. Both candidates are in early stage clinical testing.

Novartis currently offers a nasal dosage form of sCT, MIACALCIN<sup>®</sup>. Other companies are currently developing pulmonary forms of PTH-1-34. Other osteoporosis therapies include estrogen replacement therapy, selective estrogen receptor modulators, bisphosphonates and several new biologics that are under development.

#### Oral Osteoarthritis Competition

There has been no cure for Osteoarthritis, as cartilage has not been induced to regenerate. Current treatment is with NSAIDs, local injections of glucocorticoid or hyaluronan, and in severe cases, with joint replacement surgery. Future potential treatments might include Autologous Chondrocyte Implantation and cartilage regeneration.

If Novartis succeeds in developing its oral treatment for osteoarthritis, we believe it could face competition from existing and potentially future products and treatment regimens under development.

### Oral Diabetes Competition Type 2 Diabetes

In diabetes, there are a number of unmet needs which amplify the need for further product development in the area. There are three main areas of drug therapy, oral anti-diabetes, Insulin, and Injectable in which companies are attempting to develop innovative products for the treatment of patients.

The need for new medicines due to unmet treatment needs recently resulted in two new products; Amylin s Byetta and Symlin. These products initially performed exceedingly well in the market place however due to pancreatitis associated with Byetta, the trajectory for the Amylin s franchise has leveled off as of the third quarter 2008.

There are four leading classes for new product development in the area of diabetes. All four seek to take advantage of the potential to improve upon currently available products:

### **GLP-1** Agonists

**Pulmonary Insulin** 

**DPP-IV** Inhibitors

PPAR modulators.

The objective of our collaboration with Novo Nordisk is to develop an orally available GLP-1 agonist for the treatment of Type 2 diabetes and potentially obesity. A product with the benefits of glucose control,

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promotion of weight loss, low risk of hypoglycemia, and other benefits is expected to significantly improve therapeutic options and can be expected to perform as well as or better than the existing competition.

### Oral Vitamin B12 Competition

We believe that the potential current addressable market for oral vitamin B12 includes the approximately five million patients in the U.S. who receive approximately 40 million doses of vitamin B12 injections annually, and a minimum of five million patients consuming over 600 million tablets per year. Moving into the international market, these numbers could double.

Emisphere s potential competition in the vitamin B12 market will depend on the direction the company takes in the development and commercialization of the product. In the event that Emisphere pursues the nutritional supplements market, competition would include a number of companies selling generic vitamin B12 in a variety of dosage strengths and methods of delivery (e.g., oral, transdermal, nasal, sublingual) many of which have substantial distribution and marketing capabilities that exceed and will likely continue to exceed our own. In addition, our competition is likely to include many sellers, distributors, and others who are in the business of marketing, selling, and promoting multiple vitamins, vitamin-mineral, and specialized vitamin combinations. Many of these competitors are engaged in low cost, high volume operations that could provide substantial market barriers or other obstacles for a higher cost, potentially superior product that has no prior market history.

If Emisphere pursues the 40 million dose injection market, the Company would need to successfully demonstrate to physicians, nurse-practitioners and payors that an oral dose would be safe, efficacious, readily accessible and improve compliance. Vitamin B12 injections are relatively low cost and have a substantial history of safety and effectiveness. These factors will likely require the Company to engage in a substantial educational and promotional product launch and a marketing outreach initiative, the time, cost, and outcome of which are uncertain.

### **Oral Heparin Competition**

LOVENOX<sup>®</sup> (enoxaparin sodium injection), which is manufactured by Sanofi-Aventis U.S LLC, is a chemical entity in a class of antithrombotic agents known as low-molecular-weight heparins (LMWH). LOVENOX<sup>®</sup> was approved in the U.S. and Canada in 1993, and it has been available in Europe since 1987. LOVENOX<sup>®</sup> is the only low-molecular-weight heparin in the U.S. approved by the FDA in seven approved indications for the prophylaxis and treatment of thromboembolic disease.

COUMADIN<sup>®</sup> (warfarin sodium tablets, USP) is manufactured by Bristol-Myers Squibb and is the only oral anticoagulant on the market today.

ARIXTRA<sup>®</sup>, an injectable form of a synthetic anti-clotting agent, is currently marketed by GlaxoSmithKline. A number of other companies reportedly are currently testing direct thrombin or Xa inhibitors, some of which may eventually be indicated for the prevention of DVT in patients undergoing surgery for hip fracture, hip replacement or knee replacement.

Other technologies use micro-encapsulation to orally deliver heparin. We believe our oral heparin delivery technology is distinguished from other announced technologies because we believe that it preserves the chemical integrity of the drug and the integrity of the intestinal membrane.

### **Oral Insulin Competition**

Other private and public companies, as well as academic institutions, are developing oral insulin analogs. One such company is BIOCON Ltd, which in March 2006 acquired the intellectual property rights to Nobex Corporation s oral insulin product. We believe these analogues differ from our product, in that insulin is chemically modified, creating a new chemical entity. Other alternative insulin delivery systems include pulmonary insulin s. Pfizer/Nektar s EXUBERA<sup>®</sup>, a pulmonary treatment that has been approved for marketing in the U.S. and the European Union, was introduced and then withdrawn from the market. We believe our oral

insulin delivery technology is distinguished from other announced technologies as it demonstrates the preservation of both the biological effects of the drug and the integrity of the intestinal membrane.

#### **Competition Summary**

Although we believe that our oral formulations, if successful, will likely compete with well established injectable versions of the same drugs, we believe that we will enjoy a competitive advantage because physicians and patients prefer orally delivered forms of products over injectable forms. Oral forms of products enable improved compliance, and for many programs, the oral form of products enable improved therapeutic regimens.

#### **Government Regulation**

Our operations and product candidates under development are subject to extensive regulation by the FDA, other governmental authorities in the U.S. and governmental authorities in other countries.

The duration of the governmental approval process for marketing new pharmaceutical substances, from the commencement of pre-clinical testing to receipt of governmental approval for marketing a new product, varies with the nature of the product and with the country in which such approval is sought. The approval process for new chemical entities could take eight to ten years or more. The process for reformulations of existing drugs is typically shorter, although a combination of an existing drug with a currently unapproved carrier could require extensive testing. In either case, the procedures required to obtain governmental approval to market new drug products will be costly and time-consuming to us, requiring rigorous testing of the new drug product. Even after such time and effort, regulatory approval may not be obtained for our products.

The steps required before we can market or ship a new human pharmaceutical product commercially in the U.S. include pre-clinical testing, the filing of an Investigational New Drug Application ( IND ), the conduct of clinical trials and the filing with the FDA of either a New Drug Application ( NDA ) for drugs or a Biologic License Application ( BLA ) for biologics.

In order to conduct the clinical investigations necessary to obtain regulatory approval of marketing of new drugs in the U.S., we must file an IND with the FDA to permit the shipment and use of the drug for investigational purposes. The IND sets forth, in part, the results of pre-clinical (laboratory and animal) toxicology testing and the applicant s initial Phase I plans for clinical (human) testing. Unless notified that testing may not begin, the clinical testing may commence 30 days after filing an IND.

Under FDA regulations, the clinical testing program required for marketing approval of a new drug typically involves three clinical phases. In Phase I, safety studies are generally conducted on normal, healthy human volunteers to determine the maximum dosages and side effects associated with increasing doses of the substance being tested. Phase II studies are conducted on small groups of patients afflicted with a specific disease to gain preliminary evidence of efficacy, including the range of effective doses, and to determine common short-term side effects and risks associated with the substance being tested. Phase III involves large-scale trials conducted on disease-afflicted patients to provide statistically significant evidence of efficacy and safety and to provide an adequate basis for product labeling. Frequent reports are required in each phase and if unwarranted hazards to patients are found, the FDA may request modification or discontinuance of clinical testing until further studies have been conducted. Phase IV testing is sometimes conducted, either to meet FDA requirements for additional information as a condition of approval. Our drug product candidates are and will be subjected to each step of this lengthy process from conception to market and many of those candidates are still in the early phases of testing.

Once clinical testing has been completed pursuant to an IND, the applicant files an NDA or BLA with the FDA seeking approval for marketing the drug product. The FDA reviews the NDA or BLA to determine whether the drug is safe and effective, and adequately labeled, and whether the applicant can demonstrate proper and consistent manufacture of the drug. The time required for initial FDA action on an NDA or BLA is set on the basis of user fee goals; for most NDA or BLAs the action date is 10 months from receipt of the NDA or BLA at the FDA. The initial FDA action at the end of the review period may be approval or a request

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for additional information that will be needed for approval depending on the characteristics of the drug and whether the FDA has concerns with the evidence submitted. Once our product candidates reach this stage, we will be subjected to these additional costs of time and money.

The FDA has different regulations and processes governing and regulating food products, including vitamin supplements and nutraceuticals. These products are variously referred to as dietary supplements , food additives , dietary ingredients , medical foods , and, most broadly, food . These foods products do not require the IND, NDA or BLA process outlined above.

The facilities of each company involved in the commercial manufacturing, processing, testing, control and labeling of pharmaceutical products must be registered with and approved by the FDA. Continued registration requires compliance with GMP regulations and the FDA conducts periodic establishment inspections to confirm continued compliance with its regulations. We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development work.

While we do not currently manufacture any commercial products ourselves, if we did, we would bear additional cost of FDA compliance.

#### Employees

As of December 31, 2008, we had 20 employees, 7 of whom are engaged in scientific research and technical functions and 13 of whom are performing accounting, information technology, engineering, facilities maintenance, legal and regulatory and administrative functions. Of the 7 scientific employees, 5 hold Ph.D. and/or D.V.M. degrees. We believe our relations with our employees are good.

#### **Available Information**

Emisphere files annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, (the SEC) under the Securities Exchange Act of 1934 (the Exchange Act). The public may read and copy any materials that we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including Emisphere, that file electronically with the SEC. The public can obtain any documents that Emisphere files with the SEC at www.sec.gov.

We also make available free of charge on or through our Internet website (www.emisphere.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Section 16 filings, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or Section 16 of the Exchange Act as soon as reasonably practicable after we or the reporting person electronically files such material with, or furnishes it to, the SEC. Our Internet website and the information contained therein or connected thereto are not intended to be incorporated into the Annual Report or this Form 10-K.

Our Board of Directors has adopted a Code of Business Conduct and Ethics which is posted on our website at http://ir.emisphere.com/documentdisplay.cfm?DocumentID=4947.

#### ITEM 1A. RISK FACTORS

From time to time, information provided by us, statements made by our employees or information included in our filings with the Securities and Exchange Commission (including this Report) may contain statements that are not historical facts, so-called forward-looking statements, which involve risks and uncertainties. Such forward-looking statements are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. In some cases you can identify forward-looking statements by terminology such as may, should, could, wi expect, intend, plans, predict,

anticipate, estimate, continue, believe or the negative of these terms or other similar words. These statements discu future expectations, contain projections of results of operations or of financial condition or state other forward-looking information. When considering forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Report.

Our actual future results may differ significantly from those stated in any forward-looking statements. Factors that may cause such differences include, but are not limited to, the factors discussed below. Each of these factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission.

Our operating results may fluctuate because of a number of factors, many of which are beyond our control. If our operating results are below the expectations of public market analysts or investors, then the market price of our common stock could decline. Some of the factors that affect our quarterly and annual results, but which are difficult to control or predict, are:

# We have a history of operating losses and we may never achieve profitability. If we continue to incur losses or we fail to raise additional capital or receive substantial cash inflows from our partners by August 2009, we may be forced to cease operations.

As of December 31, 2008, we had approximately \$7.5 million in cash and restricted cash, approximately \$8.0 million in working capital deficiency, a stockholders deficit of approximately \$37.0 million and an accumulated deficit of approximately \$433.7 million. Our operating and net loss for the year ended December 31, 2008 (after receipt of approximately \$0.3 million of collaboration and feasibility payments which do not recur with regularity or at all) was approximately \$26.3 million and \$24.4 million, respectively. We anticipate that we will continue to generate significant losses from operations for the foreseeable future, and that our business will require substantial additional investment that we have not yet secured. These conditions raise substantial doubt about our ability to continue as a going concern. The audit report prepared by our independent registered public accounting firm relating to our financial statements for the year ended December 31, 2008 included an explanatory paragraph expressing the substantial doubt about our ability to continue as a going concern.

We anticipate that our existing capital resources will enable us to continue operations through approximately August 2009, or earlier if unforeseen events or circumstances arise that negatively affect our liquidity. If we fail to raise additional capital or obtain substantial cash inflows from existing partners prior to August 2009, we will be forced to cease operations. On September 20, 2007, we filed a shelf registration on Form S-3 to sell up to 7,000,000 shares of Common Stock which was declared effective by the Securities and Exchange Commission on October 1, 2007.

While our plan is to raise capital when needed and/or to pursue product partnering opportunities, we cannot be sure how much we will need to spend in order to develop, market, and manufacture new products and technologies in the future. We expect to continue to spend substantial amounts on research and development, including amounts spent on conducting clinical trials for our product candidates. Further, we will not have sufficient resources to develop fully any new products or technologies unless we are able to raise substantial additional financing or to secure funds from new or existing partners. We cannot assure you that financing will be available when needed, or on favorable terms or at all. The current economic environment combined with a number of other factors pose additional challenges to the Company in securing adequate financing under acceptable terms. If additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders. Additionally, these conditions may increase the costs to raise capital. Our failure to raise capital when needed would adversely affect our business, financial condition, and results of operations, and could force us to reduce or discontinue operations.

# We may not be able to meet the covenants detailed in the Convertible Notes with MHR Institutional Partners IIA LP, which could result in an increase in the interest rate on the Convertible Notes and/or accelerated maturity of the Convertible Notes, which we would not be able to satisfy.

On September 26, 2005, we executed a Senior Secured Loan Agreement (the Loan Agreement ) with MHR Institutional Partners IIA LP (together with its affiliates, MHR). The Loan Agreement, as amended, provides for a seven year, \$15 million secured loan from MHR to us at an interest rate of 11% (the Loan). Under the Loan Agreement, MHR requested, and on May 16, 2006 we effected, the exchange of the Loan for 11% senior secured convertible notes (the Convertible Notes) with substantially the same terms as the Loan agreement, except that the Convertible Notes are convertible, at the sole discretion of MHR or any assignee thereof, into shares of our common stock at a price per share of \$3.78. Interest will be payable in the form of additional Convertible Notes rather than in cash and we have the right to call the Convertible Notes after September 26, 2010 if certain conditions are satisfied. The Convertible Notes are secured by a first priority lien in favor of MHR on substantially all of our assets.

The Convertible Notes provide for certain events of default including failure to perfect liens in favor of MHR created by the transaction, failure to observe any covenant or agreement, failure to maintain the listing and trading of our common stock, sale of a substantial portion of our assets, or merger with another entity without the prior consent of MHR, or any governmental action renders us unable to honor or perform our obligations under the Convertible Notes or results in a material adverse effect on our operations among other things. If an event of default occurs, the Convertible Notes provide for the immediate repayment of the Notes and certain additional amounts described above and as set forth in the Convertible Notes. At such time, we may not be able to make the required payment, and if we are unable to pay the amount due under the Notes, the resulting default would enable MHR to foreclose on all of our assets. Any of the foregoing events would have a material adverse effect on our business and on the value of our stockholders investments in our common stock. We currently have a waiver from MHR for failure to perfect liens on certain intellectual property rights, through March 18, 2010.

#### We may not be able to make the payments we owe to Novartis.

On December 1, 2004 we issued a \$10 million convertible note (the Novartis Note ) to Novartis in connection with a research collaboration option relating to the development of PTH-1-34. The Novartis Note, as amended, bears interest at a rate of 3% prior to December 1, 2006, 5% from December 1, 2006 through December 1, 2008, and 7% from that point until maturity on December 1, 2009. We have the option to pay interest in cash on a current basis or accrue the periodic interest as an addition to the principal amount of the Novartis Note. In the event that interest accrues on the Novartis Note, the accretion to principal will cause future interest payments to rise. We may convert the Novartis Note at any time prior to maturity into a number of shares of our common stock equal to the principal and accrued and unpaid interest to be converted divided by the then market price of our common stock, provided certain conditions are met, including that the number of shares issued to Novartis, when issued, does not exceed 19.9% of the total shares of the Company s common stock outstanding, that at the time of such conversion no event of default under the Note has occurred and is continuing, and that there is either an effective shelf registration statement in effect covering the resale of the shares issued in connection with such conversion or the shares may be resold by Novartis pursuant to SEC Rule 144. These conditions may not be met and we may be unable to convert the Novartis Note, in which case we would be required to continue to make interest payments (and the rates of such interest payments will increase over time) and repay the notes when due in 2009.

Under the Novartis Note, an event of default would include failure to timely cure a default in the payment of any other indebtedness in excess of a certain material threshold, or there occurs an acceleration of indebtedness in excess of that threshold, becoming entitled to terminate the registration of our securities or the filing of reports under the Securities Exchange Act of 1934, our common stock is no longer listed on a national exchange, a change of control (including by, among other things, a change in the composition of a majority of our board other than as approved by the board) in

any one-year period, a merger which results in our stockholders holding shares that represent less than a majority of the voting power of the merged entity, and any other acquisition by a third party of shares that represent a majority of the voting power of the

company), sale of substantially all of our assets, or our inability to honor or perform our obligations under the new research collaboration option relating to the development of PTH-1-34, among other things. Upon the occurrence of any such event of default prior to conversion, any unpaid principal and accrued interest on the Novartis Note would become immediately due and payable. At such time, we may not be able to make the required payment, and if we are unable to pay the amount due under the Novartis Note, the resulting default would have a material adverse effect on our business and on the value of our stockholders investments in our common stock. Further, if the Novartis Note has been converted into our common stock, Novartis would have the right to require us to repurchase the shares of common stock within six months after an event of default under the Novartis Note, for an aggregate purchase price equal to the principal and interest that was converted, plus interest from the date of conversion, as if no conversion had occurred. If we are unable to make the repurchase, the resulting default would have a material adverse effect on our business and on the value of our stockholders investments in our common stock.

#### Our stock may be de-listed from Nasdaq.

On October 21, 2008, we received a letter from The NASDAQ Stock Market advising that, for the 10 consecutive trading days prior to October 21, 2008, the market value of our listed securities had been below the minimum \$35.0 million requirement for continued inclusion on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 4310(c)(3)(B) (the Rule ). In accordance with NASDAQ Marketplace Rule 4310(c)(8)(C), we were provided thirty calendar days, or until November 20, 2008, to regain compliance with the Rule. This required, at a minimum, that the market value of listed securities of the Company s common stock remained above \$35.0 million for a minimum of 10 consecutive business days at anytime prior to November 20, 2008.

We were not compliant with the Rule by November 20, 2008 and received notice (the NASDAQ Notice ) from the NASDAQ Listing Qualifications Department on November 21, 2008 stating that we were in violation of the requirement for continued listing on The NASDAQ Capital Market and that, therefore, our common stock was subject to delisting from The NASDAQ Capital Market. We are currently in the process of appealing this decision with the NASDAQ Listing Qualifications Department. Our common stock will remain listed on The NASDAQ Capital Market throughout the appeal process. At the current time, the decision to delist our common stock is at the sole discretion of the NASDAQ and such delisting could occur on short notice.

We cannot be sure that the market value of our securities will comply with the requirements for continued listing of our common stock on The NASDAQ Capital Market, or that our appeal of the decision to de-list our common stock will be successful. If our common stock loses its status on The NASDAQ Capital Market, then we may pursue listing and trading of our common stock on another securities exchange or association with different listing standards than NASDAQ or the shares of our common stock would likely trade on the over-the-counter market bulletin board, commonly referred to as the pink sheets.

If our stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts coverage of us may be reduced. In addition, in the event our common stock is de-listed, broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in our common stock, further limiting the liquidity thereof. These factors could result in lower prices and larger spreads in the bid and ask prices for shares of our common stock and/or limit an investors ability to execute a transaction.

Such delisting from The NASDAQ Capital Market or future declines in our stock price could also greatly impair our ability to raise additional necessary capital through equity or debt financing, and could significantly increase the ownership dilution to stockholders caused by our issuing equity in financing or other transactions.

### We are highly dependent upon collaborative partners to develop and commercialize compounds using our delivery agents.

A key part of our strategy is to form collaborations with pharmaceutical companies that will assist us in developing, testing, obtaining government approval for and commercializing oral forms of therapeutic macromolecules using the Eligen<sup>®</sup> Technology. We have a collaborative agreement for candidates in clinical development with Novartis, Novo Nordisk and Genta.

We negotiate specific ownership rights with respect to the intellectual property developed as a result of the collaboration with each partner. While ownership rights vary from program to program, in general we retain ownership rights to developments relating to our carrier and the collaborator retains rights related to the drug product developed.

Despite our existing agreements, we cannot make any assurances that:

we will be able to enter into additional collaborative arrangements to develop products utilizing our drug delivery technology;

any existing or future collaborative arrangements will be sustainable or successful;

the product candidates in collaborative arrangements will be further developed by partners in a timely fashion;

any collaborative partner will not infringe upon our intellectual property position in violation of the terms of the collaboration contract; or

milestones in collaborative agreements will be met and milestone payments will be received.

If we are unable to obtain development assistance and funds from other pharmaceutical companies to fund a portion of our product development costs and to commercialize our product candidates, we may be unable to issue equity to allow us to raise sufficient capital to fund clinical development of our product candidates. Lack of funding would cause us to delay, curtail, or stop clinical development of one or more of our projects. The determination of the specific project to curtail would depend upon the relative future economic value to us of each program.

### Our collaborative partners control the clinical development of the drug candidates and may terminate their efforts at will.

Novartis controls the clinical development of oral salmon calcitonin, PTH, and rhGH. Novo Nordisk controls the clinical development of oral GLP-1 analogs. Genta controls the clinical development of oral gallium. Novartis, Novo Nordisk and Genta control the decision-making for the design and timing of their clinical studies.

Moreover, the agreements with Novartis, Novo Nordisk and Genta provide that they may terminate their programs at will for any reason and without any financial penalty or requirement to fund any further clinical studies. We cannot make any assurance that Novartis, Novo Nordisk or Genta will continue to advance the clinical development of the drug candidates subject to collaboration.

#### Our collaborative partners are free to develop competing products.

Aside from provisions preventing the unauthorized use of our intellectual property by our collaborative partners, there is nothing in our collaborative agreements that prevent our partners from developing competing products. If one of our

partners were to develop a competing product, our collaboration could be substantially jeopardized.

## Our product candidates are in various stages of development, and we cannot be certain that any will be suitable for commercial purposes.

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market, and distribute our products under development, or secure a partner to provide financial and other assistance with these steps. The time necessary to achieve these goals for any individual pharmaceutical product is long and can be uncertain. Before we or a potential partner can sell any of the pharmaceutical products currently under development, pre-clinical (animal) studies and clinical (human) trials must demonstrate that the product is safe and effective for human use for each targeted indication. We have never successfully commercialized a drug or a nonprescription candidate and we cannot be certain that we or our current or future partners will be able to begin, or continue, planned clinical trials for our product candidates, or if we are able, that the product candidates will prove to be safe and will produce their intended effects.

Even if safe and effective, the size of the solid dosage form, taste, and frequency of dosage may impede their acceptance by patients.

A number of companies in the drug delivery, biotechnology, and pharmaceutical industries have suffered significant setbacks in clinical trials, even after showing promising results in earlier studies or trials. Only a small number of research and development programs ultimately result in commercially successful drugs. Favorable results in any pre-clinical study or early clinical trial do not imply that favorable results will ultimately be obtained in future clinical trials. We cannot make any assurance that results of limited animal and human studies are indicative of results that would be achieved in future animal studies or human clinical studies, all or some of which will be required in order to have our product candidates obtain regulatory approval. Similarly, we cannot assure you that any of our product candidates for a specific disease or condition and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners ability to successfully manufacture and commercialize our product candidates.

## Our future business success depends heavily upon regulatory approvals, which can be difficult and expensive to obtain.

Our pre-clinical studies and clinical trials of our prescription drug and biologic product candidates, as well as the manufacturing and marketing of our product candidates, are subject to extensive, costly and rigorous regulation by governmental authorities in the U.S. and other countries. The process of obtaining required approvals from the FDA and other regulatory authorities often takes many years, is expensive, and can vary significantly based on the type, complexity, and novelty of the product candidates. We cannot assure you that we, either independently or in collaboration with others, will meet the applicable regulatory criteria in order to receive the required approvals for manufacturing and marketing. Delays in obtaining U.S. or foreign approvals for our self-developed projects could result in substantial additional costs to us, and, therefore, could adversely affect our ability to compete with other companies. Additionally, delays in obtaining regulatory approvals encountered by others with whom we collaborate also could adversely affect our business and prospects. Even if regulatory approval of a product is obtained, the approval may place limitations on the intended uses of the product, and may restrict the way in which we or our partner may market the product.

The regulatory approval process for our prescription drug product candidates presents several risks to us:

In general, pre-clinical tests and clinical trials can take many years, and require the expenditure of substantial resources. The data obtained from these tests and trials can be susceptible to varying interpretation that could

delay, limit or prevent regulatory approval

Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, a regulatory agency s requirements for safety, efficacy, and quality or, in the case of a product seeking an orphan drug indication, because another designee received approval first

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Requirements for approval may become more stringent due to changes in regulatory agency policy or the adoption of new regulations or guidelines

New guidelines can have an effect on the regulatory decisions made in previous years

The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and may impose significant limitations in the nature of warnings, precautions, and contraindications that could materially affect the profitability of the drug

Approved drugs, as well as their manufacturers, are subject to continuing and on-going review, and discovery of problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their manufacture, sale or use or in their withdrawal from the market

Regulatory authorities and agencies may promulgate additional regulations restricting the sale of our existing and proposed products

Once a product receives marketing approval, the FDA may not permit us to market that product for broader or different applications, or may not grant us clearance with respect to separate product applications that represent extensions of our basic technology. In addition, the FDA may withdraw or modify existing clearances in a significant manner or promulgate additional regulations restricting the sale of our present or proposed products

Additionally, we face the risk that our competitors may gain FDA approval for a product before us. Having a competitor reach the market before us would impede the future commercial success for our competing product because we believe that the FDA uses heightened standards of approval for products once approval has been granted to a competing product in a particular product area. We believe that this standard generally limits new approvals to only those products that meet or exceed the standards set by the previously approved product.

The regulatory approval process for nonprescription product candidates will likely vary by the nature of therapeutic molecule being delivered,

## Our business will suffer if we fail or are delayed in developing and commercializing an improved oral form of vitamin B12.

We are focusing substantial resources on the development of an oral dosage form of vitamin B12 that will demonstrate improved bioavailability compared with current B12 tablets. In addition, we anticipate that our oral B12 will be a commercially reasonable replacement for at least certain B12 injections now given to B12 deficient patients and for certain generic over-the-counter B12. Our inability or delay in developing or commercializing the B12 product candidate could have a significant material adverse effect on our business.

To commercialize this product candidate, we will be required to timely and effectively complete additional pre-clinical development, obtain Generally Recognized As Safe (GRAS) status, and conduct certain clinical studies, among other things. We cannot assure you that we will succeed in these efforts as these involve activities (or portions of activities) that we have not previously completed. In addition, if we succeed in these activities, vitamin B12 is available at reasonably low prices both in injections and tablet forms (as well as other forms) through a variety of distributors, sellers, and other sources. We have no current commercial capabilities. Therefore, we would be entering a highly competitive market with an untested, newly-established commercial capability. This outline of risks involved in the development and commercialization of B12 is not exhaustive, but illustrative. For example, it does not include additional competitive, intellectual property, commercial, product liability, and commercial risks involved in a launch

of the B12 product candidate outside the U.S. or certain of such risks in the U.S.

#### Our business will suffer if we cannot adequately protect our patent and proprietary rights.

Although we have patents for some of our product candidates and have applied for additional patents, there can be no assurance that patents applied for will be granted, that patents granted to or acquired by us

now or in the future will be valid and enforceable and provide us with meaningful protection from competition, or that we will possess the financial resources necessary to enforce any of our patents. Also, we cannot be certain that any products that we (or a licensee) develop will not infringe upon any patent or other intellectual property right of a third party.

We also rely upon trade secrets, know-how, and continuing technological advances to develop and maintain our competitive position. We maintain a policy of requiring employees, scientific advisors, consultants, and collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship with us. We cannot assure you that these agreements will provide meaningful protection for our trade secrets in the event of unauthorized use or disclosure of such information.

Part of our strategy involves collaborative arrangements with other pharmaceutical companies for the development of new formulations of drugs developed by others and, ultimately, the receipt of royalties on sales of the new formulations of those drugs. These drugs are generally the property of the pharmaceutical companies and may be the subject of patents or patent applications and other rights of protection owned by the pharmaceutical companies. To the extent those patents or other forms of rights expire, become invalid or otherwise ineffective, or to the extent those drugs are covered by patents or other forms of protection owned by third parties, sales of those drugs by the collaborating pharmaceutical company may be restricted, limited, enjoined, or may cease. Accordingly, the potential for royalty revenues to us may be adversely affected.

## We may be at risk of having to obtain a license from third parties making proprietary improvements to our technology.

There is a possibility that third parties may make improvements or innovations to our technology in a more expeditious manner than we do. Although we are not aware of any such circumstance related to our product portfolio, should such circumstances arise, we may need to obtain a license from such third party to obtain the benefit of the improvement or innovation. Royalty s payable under such a license would reduce our share of total revenue. Such a license may not be available to us at all or on commercially reasonable terms. Although we currently do not know of any circumstances related to our product portfolio which would lead us to believe that a third party has developed any improvements or innovation with respect to our technology, we cannot assure you that such circumstances will not arise in the future. We cannot reasonably determine the cost to us of the effect of being unable to obtain any such license.

#### We are dependent on third parties to manufacture and test our products.

Currently, we have no manufacturing facilities for production of our carriers or any therapeutic compounds under consideration as products. We have no facilities for clinical testing. The success of our self-developed programs is dependent upon securing manufacturing capabilities and contracting with clinical service and other service providers.

The availability of manufacturers is limited by both the capacity of such manufacturers and their regulatory compliance. Among the conditions for NDA approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures continually conform with the FDA s current GMP (GMP are regulations established by the FDA that govern the manufacture, processing, packing, storage and testing of drugs intended for human use). In complying with GMP, manufacturers must devote extensive time, money, and effort in the area of production and quality control and quality assurance to maintain full technical compliance. Manufacturing facilities and company records are subject to periodic inspections by the FDA to ensure compliance. If a manufacturing facility is not in substantial compliance with these requirements, regulatory enforcement action may be taken by the FDA, which may include seeking an injunction against shipment of products from the facility and recall of products previously shipped from the facility. Such actions could severely delay our ability to obtain product from that

particular source.

The success of our clinical trials and our partnerships is dependent on the proposed or current partner s capacity and ability to adequately manufacture drug products to meet the proposed demand of each respective market. Any significant delay in obtaining a supply source (which could result from, for example, an FDA determination that such manufacturer does not comply with current GMP) could harm our potential for

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success. Additionally, if a current manufacturer were to lose its ability to meet our supply demands during a clinical trial, the trial may be delayed or may even need to be abandoned.

#### We may face product liability claims related to participation in clinical trials or future products.

We have product liability insurance with a policy limit of \$3.0 million per occurrence and in the aggregate. The testing, manufacture, and marketing of products for humans utilizing our drug delivery technology may expose us to potential product liability and other claims. These may be claims directly by consumers or by pharmaceutical companies or others selling our future products. We seek to structure development programs with pharmaceutical companies that would complete the development, manufacturing and marketing of the finished product in a manner that would protect us from such liability, but the indemnity undertakings for product liability claims that we secure from the pharmaceutical companies may prove to be insufficient.

#### We are subject to environmental, health, and safety laws and regulations for which we incur costs to comply.

We use some hazardous materials in our research and development activities and are subject to environmental, health, and safety laws and regulations governing the use of such materials. For example, our operations involve the controlled use of chemicals, biologicals and radioactive materials and we bear the costs of complying with the various regulations governing the use of such materials. Costs of compliance have not been material to date. While we believe we are currently in compliance with the federal, state, and local laws governing the use of such materials, we cannot be certain that accidental injury or contamination will not occur. Should we be held liable or face regulatory actions regarding an accident involving personal injury or an environmental release, we potentially could incur costs in excess of our resources or insurance coverage, although, to date, we have not had to deal with any such actions. During each of 2008, 2007, and 2006, we incurred costs of approximately \$0.2 million in our compliance with environmental, health, and safety laws and regulations.

#### We face rapid technological change and intense competition.

Our success depends, in part, upon maintaining a competitive position in the development of products and technologies in an evolving field in which developments are expected to continue at a rapid pace. We compete with other drug delivery, biotechnology and pharmaceutical companies, research organizations, individual scientists, and non-profit organizations engaged in the development of alternative drug delivery technologies or new drug research and testing, as well as with entities developing new drugs that may be orally active. Many of these competitors have greater research and development capabilities, experience, and marketing, financial, and managerial resources than we have, and, therefore, represent significant competition.

Our products, when developed and marketed, may compete with existing parenteral or other versions of the same drug, some of which are well established in the marketplace and manufactured by formidable competitors, as well as other existing drugs. For example, our salmon calcitonin product candidate, if developed and marketed, would compete with a wide array of existing osteoporosis therapies, including a nasal dosage form of salmon calcitonin, estrogen replacement therapy, selective estrogen receptor modulators, bisphosphonates, and other compounds in development.

Our competitors may succeed in developing competing technologies or obtaining government approval for products before we do. Developments by others may render our product candidates, or the therapeutic macromolecules used in combination with our product candidates, noncompetitive or obsolete. At least one competitor has notified the FDA that it is developing a competing formulation of salmon calcitonin. If our products are marketed, we cannot assure you that they will be preferred to existing drugs or that they will be preferred to or available before other products in development.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or an approval by a regulatory agency of the marketing of a competitive product, such announcement may have a material adverse effect on our operations or future prospects resulting from reduced sales of future products that we may wish to bring to market or from an adverse impact on the price of our common stock or our ability to obtain regulatory approval for our product candidates.

### We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are dependent on our executive officers. Our President and Chief Executive Officer, Michael V. Novinski, joined the Company in May of 2007. We could be significantly disadvantaged if Mr. Novinski were to leave Emisphere. The loss of other officers could have an adverse effect as well, given their specific knowledge related to our proprietary technology and personal relationships with our pharmaceutical company partners. If we are not able to retain our executive officers, our business may suffer. None of our key officers have announced any intention to leave Emisphere. We do not maintain key-man life insurance policies for any of our executive officers.

There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Additionally, because of the knowledge and experience of our scientific personnel and their specific knowledge with respect to our drug carriers the continued development of our product candidates could be adversely affected by the loss of any significant number of such personnel.

# Provisions of our corporate charter documents, Delaware law, and our stockholder rights plan may dissuade potential acquirers, prevent the replacement or removal of our current management and may thereby affect the price of our common stock.

Our Board of Directors has the authority to issue up to 1,000,000 shares of preferred stock and to determine the rights, preferences and privileges of those shares without any further vote or action by our stockholders. Of these 1,000,000 shares, 200,000 are currently designated Series A Junior Participating Cumulative Preferred Stock ( A Preferred Stock ) in connection with our stockholder rights plan, and the remaining 800,000 shares remain available for future issuance. Rights of holders of common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future.

We also have a stockholder rights plan, commonly referred to as a poison pill, in which Preferred Stock Purchase Rights (the Rights ) have been granted at the rate of one one-hundredth of a share of A Preferred Stock at an exercise price of \$80 for each share of our common stock. The Rights are not exercisable or transferable apart from the common stock, until the earlier of (i) ten days following a public announcement that a person or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of our outstanding common stock or (ii) ten business days (or such later date, as defined) following the commencement of, or announcement of an intention to make a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person, or group, of 20% or more of our outstanding common stock. If we enter into consolidation, merger, or other business combinations, as defined, each Right would entitle the holder upon exercise to receive, in lieu of shares of A Preferred Stock, a number of shares of common stock of the acquiring company having a value of two times the exercise price of the Right, as defined. By potentially diluting the ownership of the acquiring company, our rights plan may dissuade prospective acquirors of our company. MHR is specifically excluded from the provisions of the plan.

The A Preferred Stockholders will be entitled to a preferential cumulative quarterly dividend of the greater of \$1.00 per share or 100 times the per-share dividend declared on our stock and are also entitled to a liquidation preference, thereby hindering an acquirer s ability to freely pay dividends or to liquidate the company following an acquisition. Each A Preferred Stock share will have 100 votes and will vote together with the common shares, effectively preventing an acquirer from removing existing management. The Rights contain anti-dilutive provisions and are redeemable at our option, subject to certain defined restrictions for \$.01 per Right. The Rights expire on April 7, 2016.

# Provisions of our corporate charter documents, Delaware law and financing agreements may prevent the replacement or removal of our current management and members of our Board of Directors and may thereby affect the price of our common stock.

In connection with the MHR financing transaction, and after approval by our Board of Directors, Dr. Mark H. Rachesky was appointed to the Board of Directors by MHR (the MHR Nominee ) and Dr. Michael Weiser was appointed to the Board of Directors by both the majority of our Board of Directors and MHR (the Mutual Director ), as contemplated by our bylaws. Our certificate of incorporation provides that the MHR Nominee and the Mutual Director may be removed only by the affirmative vote of at least 85% of the shares of common stock outstanding and entitled to vote at an election of directors. Our certificate of incorporation also provides that the MHR Nominee may be replaced only by an individual designated by MHR unless the MHR Nominee has been removed for cause, in which case the MHR Nominee may be replaced only by an individual approved by both a majority of our Board of Directors and MHR. Furthermore, the amendments to the by-laws and the certificate of incorporation provide that the rights granted to MHR by these amendments may not be amended or repealed without the unanimous vote or unanimous written consent of the Board of Directors or the affirmative vote of the holders of at least 85% of the shares of Common Stock outstanding and entitled to vote at the election of directors. The amendments to the by-laws and the certificate of incorporation will remain in effect as long as MHR holds at least 2% of the shares of fully diluted Common Stock. The amendments to the by-laws and the certificate of incorporation will have the effect of making it more difficult for a third party to gain control of our Board of Directors.

Additional provisions of our certificate of incorporation and by-laws could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting common stock. These include provisions that classify our Board of Directors, limit the ability of stockholders to take action by written consent, call special meetings, remove a director for cause, amend the by-laws or approve a merger with another company.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a business combination includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is a person who, either alone or together with affiliates and associates, owns (or within the past

interested stockholder is a person who, either alone or together with affiliates and associates, owns (or within the past three years, did own) 15% or more of the corporation s voting stock.

#### Our stock price has been and may continue to be volatile.

The trading price for our common stock has been and is likely to continue to be highly volatile. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies have historically been highly volatile.

Factors that could adversely affect our stock price include:

fluctuations in our operating results; announcements of partnerships or technological collaborations;

innovations or new products by us or our competitors;

governmental regulation;

developments in patent or other proprietary rights;

public concern as to the safety of drugs developed by us or others;

the results of pre-clinical testing and clinical studies or trials by us, our partners or our competitors;

litigation;

general stock market and economic conditions;

number of shares available for trading (float); and

inclusion in or dropping from stock indexes.

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As of December 31, 2008, our 52-week high and low closing market price for our common stock was \$4.21 and \$.57, respectively.

#### Future sales of common stock or warrants, or the prospect of future sales, may depress our stock price.

Sales of a substantial number of shares of common stock or warrants, or the perception that sales could occur, could adversely affect the market price of our common stock. As of December 31, 2008, we have 7,000,000 shares of common stock registered on a shelf registration for future sale. Additionally, as of December 31, 2008, there were outstanding options to purchase up to 1,281,786 shares of our common stock that are currently exercisable, and additional outstanding options to purchase up to 927,068 shares of common stock that are exercisable over the next several years. As of December 31, 2008, the Novartis Note is convertible into 7,537,921 shares of common stock and the MHR Convertible Notes are convertible into 5,362,596 shares of our stock. The holders of these options have an opportunity to profit from a rise in the market price of our common stock with a resulting dilution in the interests of the other. The existence of these options may adversely affect the terms on which we may be able to obtain additional financing. The weighted average exercise price of issued and outstanding options is \$8.30 and the weighted average exercise price of warrants is \$3.88 which compares to the \$0.79 market price at closing on December 31, 2008.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 2. PROPERTIES

We lease approximately 80,000 square feet of office space at 765 Old Saw Mill River Road, Tarrytown, New York for use as administrative offices and laboratories. The lease for our administrative and laboratory facilities is set to expire on August 31, 2012. Of the approximately 80,000 square feet at Tarrytown, approximately 2,275 square feet of space is subleased to PsychoGenics, Inc. and approximately 16,000 square feet of space is subleased to Regeneron Pharmaceuticals, Inc. The sublease with Psychogenics is set to expire on August 31, 2012 and the sublease with Regeneron is set to expire at March 31, 2010. Regeneron has the option to extend their sublease through September 30, 2010. We also lease approximately 15,000 square feet of office space at 240 Cedar Knolls Road, Suite 200, Cedar Knolls, New Jersey for use as executive offices. The lease for our executive offices is set to expire on January 31, 2013. On December 8, we announced plans to maintain one corporate location in Cedar Knolls, New Jersey. Emisphere s current facility in Tarrytown, New York was closed and key employees were relocated to Cedar Knolls, New Jersey.

#### ITEM 3. LEGAL PROCEEDINGS

In April 2005, the Company entered into an employment contract with its then Chief Executive Officer, Dr. Michael M. Goldberg, for services through July 31, 2007. On January 16, 2007, the Board of Directors terminated Dr. Goldberg s services. On April 26, 2007, the Board of Directors held a special hearing at which it determined that Dr. Goldberg s termination was for cause. On March 22, 2007, Dr. Goldberg, through his counsel, filed a demand for arbitration asserting that his termination was without cause and seeking \$1,048,000 plus attorney s fees, interest, arbitration costs and other relief alleged to be owed to him in connection with his employment agreement with the Company. Dr. Goldberg s employment agreement provides, among other things, that in the event he is terminated without cause, Dr. Goldberg would be paid his base salary plus bonus, if any, monthly for a severance period of eighteen months or, in the event of a change of control, twenty-four months, and he would also be entitled to continued health and life insurance coverage during the severance period and all unvested stock options and restricted

stock awards would immediately vest in full upon such termination. Dr. Goldberg s employment agreement provided that in the event he is terminated with cause, he will receive no additional compensation. During the year ended December 31, 2007, the Company accrued the estimated costs to settle this matter. No settlement has been reached and the dispute continues. In February 2008, the Company received \$0.5 million as a result of a cancellation of a split dollar life insurance policy on Dr. Goldberg. Dr. Goldberg claimed approximately \$0.2 million was due him as a return of policy premium. In June 2008, Dr. Goldberg commenced a separate lawsuit in the New York State Supreme Court (New York County) claiming

that the Company breached his employment agreement by not remitting to Dr. Goldberg that portion of the cash value of the life insurance policy. During the year ended December 31, 2008, the Company adjusted its accrual to reflect estimated costs to settle this matter accordingly. On January 29, 2009, after transfer from the New York State Supreme Court (New York County) to an independent arbitrator, the Company received a finding from such arbitrator awarding a partial summary judgment to Dr. Goldberg for compensatory damages in an amount equal to \$240,101. The company paid Dr. Goldberg such amount on February 5, 2009. All remaining claims were deferred by the Arbitrator pending further proceedings between the parties. The Company believes the remaining claims are without merit and will vigorously defend itself against Dr. Goldberg s claims. The ultimate cost to resolve this matter could be in excess of the amount provided for and such amount could be material to the Company.

On August 18, 2008, Emisphere filed a complaint in the United States District Court for the District of New Jersey against Laura A. Kragie and Kragie BioMedWorks, Inc. seeking a declaratory judgment affirming Emisphere s sole rights to its proprietary technology for the oral administration of Vitamin B12, as set forth in several Emisphere United States provisional patent applications. The complaint also includes a claim under the Lanham Act arising from statements made by defendants on their web site. Laura A. Kragie, M.D., is a former consultant for Emisphere who later was employed by Emisphere. On February 13, 2009, the defendants filed an answer, affirmative defenses and counterclaims, adding as counterclaim defendants current or former Emisphere executives or employees, including Michael V. Novinski. The countersuit against Emisphere alleges breach of contract, fraudulent inducement, trademark infringement, false advertising, and other claims. Emisphere believes that the counterclaims are without merit, and will litigate all claims vigorously. At the current time, we are unable to estimate a loss, if any, that may result from the resolution of this matter.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

#### PART II

#### ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### **Nasdaq Listing**

Emisphere common stock is traded on The NASDAQ Stock Market under the symbol EMIS .

On October 21, 2008, the Company received a letter from The NASDAQ Stock Market advising that, for the 10 consecutive trading days prior to October 21, 2008, the Company s market value of listed securities had been below the minimum \$35.0 million requirement for continued inclusion on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 4310(c)(3)(B) (the Rule ). In accordance with NASDAQ Marketplace Rule 4310(c)(8)(C), the Company was provided thirty calendar days, or until November 20, 2008, to regain compliance with the Rule. This required, at a minimum, that the market value of listed securities of the Company s common stock remained above \$35.0 million, for a minimum of 10 consecutive business days at anytime prior to November 20, 2008.

The Company was not compliant with the Rule by November 20, 2008 and received notice (the NASDAQ Notice) from the NASDAQ Listing Qualifications Department on November 21, 2008 stating that the Company was in violation of the requirement for continued listing on The NASDAQ Capital Market and that, therefore, the Company s securities were subject to delisting from The NASDAQ Capital Market. The Company is in the process of appealing this decision with the NASDAQ Listing Qualifications Department. The Company s securities will remain listed on

The NASDAQ Capital Market throughout the appeal process. At the current time, the decision to delist our common stock is at the sole discretion of the NASDAQ and such delisting could occur on short notice.

The Company is currently considering actions that may allow it to regain compliance with the NASDAQ continued listing standards and maintain its NASDAQ listing. If the Company is unsuccessful in maintaining its NASDAQ listing, then the Company may pursue listing and trading of the Company s common stock on another securities exchange or association with different listing standards than NASDAQ.

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The following table sets forth the range of high and low intra-day sale prices as reported by The NASDAQ Stock Market for each period indicated:

	High	Low
2007		
First quarter	\$ 5.82	\$ 2.94
Second quarter	4.98	2.80
Third quarter	5.13	3.65
Fourth quarter	5.17	2.60
2008		
First quarter	2.78	1.43
Second quarter	2.69	1.33
Third quarter	4.21	1.98
Fourth quarter	2.05	0.57
2009		
First quarter (through March 10, 2009)	0.90	0.44

As of March 10, 2009 there were 226 stockholders of record, including record owners holding shares on behalf of an indeterminate number of beneficial owners, and 30,341,078 shares of common stock outstanding. The closing price of our common stock on March 10, 2009 was \$0.58.

We have never paid cash dividends and do not intend to pay cash dividends in the foreseeable future. We intend to retain earnings, if any, to finance the growth of our business.

#### **Equity Compensation Plan Information**

The following table provides information as of December 31, 2008 about the common stock that may be issued upon the exercise of options granted to employees, consultants or members of our board of directors under all of our existing equity compensation plans, including the 1991 Stock Option Plan, 1995 Stock Option Plan, 2000 Stock Option Plan, the 2002 Broad Based Plan, the 2007 Stock Award and Incentive Plan, (collectively the Plans ), the Stock Incentive Plan for Outside Directors, and the Directors Deferred Compensation Plan:

	<b>(a)</b>		(c)
	Number of	<b>(b</b> )	Number of Securities
	Securities to be	Weighted	Remaining Available for
	Issued Upon	Average	Future Issuance Under Equity Compensation
	Exercise of	Exercise Price of	Plans
	Outstanding	Outstanding	(Excluding Securities
Plan Category	Options	Options	<b>Reflected in Column (a))</b>

**Equity Compensation Plans Approved by Security Holders** 

The Plans	2,032,854	\$ 8.30	2,757,859
Stock Incentive Plan for Outside Directors	156,000	13.38	
Directors Deferred Compensation Plan			3,122
Equity Compensation Plans not approved			
by Security Holders(1)	20,000	14.84	
Total	2,208,854	\$ 8.72	2,760,981

 Our Board of Directors has granted options which are currently outstanding for a former consultant. The Board of Directors determines the number and terms of each grant (option exercise price, vesting and expiration date). These grants were made on July 12, 2001, July 12, 2002 and July 14, 2003.

#### **Comparative Stock Performance Graph**

The graph below compares the cumulative total stockholder return on Emisphere s Common Stock with the cumulative total stockholder return of (i) the NASDAQ Composite Index and (ii) the NASDAQ Pharmaceutical Index, assuming an investment of \$100 on December 31, 2003 in each of the Company s Common Stock, the stocks comprising the NASDAQ Composite Index and the stocks comprising the NASDAQ Pharmaceutical Index.

#### COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\* Among Emisphere Technologies, Inc., The NASDAQ Composite Index And The NASDAQ Pharmaceutical Index

\* \$100 invested on 12/31/03 in stock & index-including reinvestment of dividends.

Fiscal year ending December 31.

Emisphere Technologies, Inc.	<b>12/03</b> 100.00	<b>12/04</b> 74.17	<b>12/05</b> 80.07	<b>12/06</b> 97.60	<b>12/07</b> 50.37	<b>12/08</b> 14.58
NASDAQ Composite	100.00	110.08	112.88	126.51	138.13	80.47
NASDAQ Pharmaceutical	100.00	110.22	111.87	114.89	106.37	97.32

#### ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data for the years ended December 31, 2008, 2007, 2006, 2005, and 2004 have been derived from the financial statements of Emisphere and notes thereto, which have been audited by our independent registered public accounting firm. In January 2006, the start of the first quarter of fiscal 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS No. 123(R)), which requires that the costs resulting from all stock based payment transactions be recognized in the financial statements at their fair values. Results from prior periods have not been restated.

	Year Ended December 31,								
	2008		2007		2006		2005		2004
		(In	thousand	ds, e	except per	sha	are data)		
Statement of Operations Data:									
Revenue	\$ 251	\$	4,077	\$	7,259	\$	3,540	\$	1,953
Costs, expenses and income from settlement of lawsuit:									
Research and development expenses	12,785		21,076		18,892		18,915		17,462
General and administrative expenses	9,176		14,459		11,693		13,165		11,765
Other costs and expenses	779		1,083		3,802		3,915		4,942
Restructuring charge	3,831								
Income from settlement of lawsuit, net			(11,890)						
Total costs, expenses and income from									
settlement of lawsuit	26,571		24,728		34,387		35,995		34,169
Operating loss Beneficial conversion of convertible security	(26,320	)	(20,651)		(27,128) (12,215)		(32,455)		(32,216)
Gain on extinguishment of note payable							14,663		
Change in fair value of derivative instruments	2,220		5,057		(1,390)		(624)		(136)
Sale of patent	1,500								
Net loss	(24,388	)	(16,928)		(41,766)		(18,051)		(37,522)
Net loss per share Basic	(0.80	)	(0.58)		(1.58)		(0.81)		(2.04)
Net loss per share Diluted	(0.80	)	(0.76)		(1.58)		(0.81)		(2.04)

	2008		2007	December 31, 2006 (In thousands)		2005	2004
Balance Sheet Data: Cash, cash equivalents, restricted cash and investments Working capital (deficit) Total assets Derivative instruments	\$ 7,469 (7,954) 10,176 267	\$	14,100 9,868 19,481 2,487	\$	21,533 13,377 28,092 6,498	\$ 9,218 (522) 18,988 6,528	\$ 17,550 12,858 36,292 762

31,531	27,648	24,744	23,121	40,238
(433,688)	(409,300)	(392,372)	(350,606)	(332,555)
(37,028)	(13,674)	(6,106)	(14,895)	(11,274)
	(433,688)	(433,688) (409,300)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

#### ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management s Discussion and Analysis of Financial Conditions and Results of Operations (MD&A) is provided to supplement the accompanying financial statements and notes in Item 8 to help provide an understanding of our financial condition, changes in our financial condition and results of operations. To supplement its audited financial statements presented in accordance with US GAAP, the company is providing a comparison of operating results describing net income and operating expenses which removed certain non-cash and one-time or nonrecurring charges and receipts. The Company believes that this presentation of net income and operating expense provides useful information to both management and investors concerning the approximate impact of the items above. The Company also believes that considering the effect of these items allows management and investors to better compare the Company s financial performance from period to period and to better compare the Company s financial performance of this additional information is not meant to be considered in isolation of, or as a substitute for, results prepared in accordance with US GAAP.

#### CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

The following discussion and analysis contain forward-looking statements that involve risks and uncertainties. When used in this report, the words, intend, anticipate, believe, estimate, plan, expect and similar expressions as the to us are included to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of factors, including those set forth under Item 1A. Risk Factors (above) and elsewhere in this report. This discussion and analysis should be read in conjunction with the Selected Financial Data and the Financial Statements and notes thereto included in this report.

#### Overview

Emisphere Technologies, Inc. is a biopharmaceutical company that focuses on a unique and improved delivery of therapeutic molecules or nutritional supplements using its Eligen<sup>®</sup> Technology. These molecules could be currently available or are under development. Such molecules are usually delivered by injection; in many cases, their benefits are limited due to poor bioavailability, slow on-set of action or variable absorption. In those cases, our technology may increase the benefit of the therapy by improving bioavailability or absorption or by increasing the onset of action. The Eligen<sup>®</sup> Technology can be applied to the oral route of administration as well other delivery pathways, such as buccal, rectal, inhalation, intra-vaginal or transdermal.

Since our inception in 1986, substantial efforts and resources have been devoted to understanding the Eligen<sup>®</sup> Technology and establishing a product development pipeline that incorporated this technology with selected molecules. Although no products have been commercialized to date, research and investment is now being placed behind both the pipeline and the advancement of this technology. Further development and exploration of the technology entail risk and operational expenses. However, we have made significant progress on refocusing our efforts on strategic development initiatives and cost control and continue to aggressively seek to reduce non-strategic spending.

In 2007 and 2008, Emisphere reevaluated the Eligen<sup>®</sup> Technology and refocused our corporate strategy on commercializing the Eligen<sup>®</sup> Technology as quickly as possible, building high-value partnerships and reprioritizing the product pipeline. Spending was redirected and aggressive cost control initiatives were implemented. These changes resulted in redeployment of resources to programs that may yield commercial products in a shorter period of time. In addition to continuing to develop product candidates in-house, we demonstrated and enhanced the value of our Eligen<sup>®</sup> Technology by attracting new partners like Novo Nordisk and rejuvenating existing partnerships like Novartis.

The application of the Eligen<sup>®</sup> Technology is potentially broad and may provide for a number of opportunities across a spectrum of therapeutic modalities. During 2008, we continued to develop our product pipeline utilizing the Eligen<sup>®</sup> Technology with prescription and nonprescription product candidates. We

prioritized our development efforts based on overall potential returns on investment, likelihood of success, and market and medical need. Our goal is to implement our Eligen<sup>®</sup> Technology to enhance overall healthcare, including patient accessibility and compliance, while benefiting the commercial pharmaceutical marketplace and driving company valuation.

Investments required to continue developing our product pipeline may be partially paid by income-generating license arrangements whose value tends to increase as product candidates move from pre-clinical into clinical development. It is our intention that incremental investments that may be required to fund our research and development will be approached incrementally in order to minimize disruption or dilution.

We plan to attempt to expand our current collaborative relationships to take advantage of the critical knowledge that others have gained by working with our technology. We will also continue to pursue product candidates for internal development and commercialization. We believe that these internal candidates must be capable of development with reasonable investments in an acceptable time period and with a reasonable risk-benefit profile.

Our product pipeline includes prescription and nutritional supplements candidates. On the prescription side, our licensees include Novartis Pharma AG, which is using our drug delivery technology in combination with salmon calcitonin, parathyroid hormone, and human growth hormone. Their most advanced program is testing an oral formulation of calcitonin to treat osteoarthritis and osteoporosis. Novartis is conducting two Phase III clinical studies for osteoarthritis and one Phase III clinical study for osteoporosis. During the third quarter 2008 Novartis completed enrollment for the first trial for osteoarthritis; a multi-center Phase III study exploring the safety and efficacy of an oral formulation of salmon calcitonin using Emisphere s proprietary Eligen Technology to treat patients with osteoarthritis of the knee. This study, which will be used to support the filing with health authorities worldwide, includes more than 1,100 patients between the ages of 51 and 80 years old with a medical history and symptoms of knee osteoarthritis. This study will be conducted mainly in Europe and is estimated to be completed during the second half 2010. In October, Emisphere also announced that Novartis Pharma AG and Nordic Bioscience initiated a second multi-center Phase III study exploring the safety and efficacy of an oral formulation of salmon calcitonin to treat patients with osteoarthritis of the knee. This second study, designed to meet FDA requirements for U.S. registration, will examine patients between 51 and 80 years of age suffering from painful symptoms of knee osteoarthritis. The study will be conducted in multiple sites, including the U.S., with an estimated completion during the second half of 2011.

Novartis is also conducting a Phase III trial for osteoporosis. This Phase III trial is a multi-center study exploring the safety and efficacy of oral Eligen<sup>®</sup> salmon calcitonin to treat vertebral fractures in postmenopausal women aged 60-80 with osteoporosis. The last of 4,500+ patients was recruited for the osteoporosis study in the final week of June 2008, and the three-year study will be conducted in North and South America, Europe and Asia. Now that these Phase III studies are fully enrolled, over 5,500 clinical study patients will be using the Eligen<sup>®</sup> Technology in 2008.

A study Novartis Pharma AG and its partner Nordic Bioscience published in the October 2008 issue of BMC Clinical Pharmacology demonstrated that oral salmon calcitonin using Emisphere s proprietary Eligent Technology taken 30 to 60 minutes before meals with 50 ml of water results in improved absorption and improved efficacy measured by the biomarker of reduced bone resorption (sCTX-I) compared to the commonly prescribed nasal formulation. The study was a randomized, partially-blind, placebo-controlled, single dose exploratory crossover clinical trial using 56 healthy postmenopausal women.

Novartis is also conducting a Phase I study in postmenopausal women to determine the safety and tolerability of oral PTH134, a combination of human PTH-1-34 and Emisphere s delivery agent 5-CNAC, for the treatment of postmenopausal osteoporosis. The study is designed to assess the bioavailability profile of increasing doses of PTH-1-34 combined with different amounts of 5-CNAC administered orally. The trial is being conducted in

Switzerland and is estimated to yield first interpretable results by the end of the year.

Research using the Eligen<sup>®</sup> Technology and GLP-1, a potential treatment for Type 2 diabetes is being conducted by Novo Nordisk and by Dr. Christoph Beglinger, M.D., an independent medical researcher at University Hospital in Basel, Switzerland. We had previously conducted extensive tests on oral insulin for

Type 1 diabetes and concluded that a more productive pathway is to move forward with GLP-1 and its analogs, an oral form of which might be used to treat Type 2 diabetes and related conditions. Consequently, on June 21, 2008 we entered into an exclusive Development and License Agreement with Novo Nordisk focused on the development of oral formulations of Novo Nordisk s proprietary GLP-1 receptor agonists. Novo Nordisk s development efforts are in the early preclinical stage. Additionally, a second early stage human study of an oral formulation that combines PYY and native GLP-1 with Emisphere s proprietary delivery agent known as SNAC was conducted at University Hospital by Professor Beglinger. The study demonstrated the oral delivery of the GLP-1 peptide was safe and effective and that the oral formulation of GLP-1 stimulated an early increase in fasting insulin and a decrease in fasting glucose as compared to placebo.

Emisphere is independently developing Eligen<sup>®</sup> B12 as a nutritional supplement product candidate. Following our proof of concept animal studies of the absorption of vitamin B12 using our Eligen<sup>®</sup> Technology, additional preclinical studies using dogs further demonstrated that the Eligen<sup>®</sup> Technology enhances the absorption of oral B12 and confirmed earlier proof of concept studies conducted in rats. We have completed our first clinical study testing our new vitamin B12 formulation in 20 normal healthy males.

The data from our first pharmacokinetic study showed mean vitamin B12 peak blood levels were more than 10 times higher for the Eligen<sup>®</sup> B12 5mg formulation than for the 5mg commercial formulation. The mean time to reach peak concentration (Tmax) was reduced by over 90%; to 0.5 hours for the Eligen<sup>®</sup> B12 5mg from 6.8 hours for the commercial 5mg product. Improvement in bioavailability was approximately 240%, with absorption time at 30 minutes and a mean bioavailability of 5%. The study was conducted with a single administration of Eligen<sup>®</sup> B12; there were no adverse reactions, and Eligen<sup>®</sup> B12 was well-tolerated.

The data from our first Eligen<sup>®</sup> B12 clinical study demonstrates a new, more bioavailable oral form vitamin B12 and a potential new avenue for addressing the problems with B12 supplementation. Eligen<sup>®</sup> B12 avoids the normal specialized absorption process that limits absorption of vitamin B12 from current formulations. By circumventing the current absorption process, Eligen<sup>®</sup> B12 may present an opportunity to reduce the potential uncertainty associated with oral megadoses of vitamin B12 and may reduce the substantial number of injections being taken by millions of individuals.

The Company is planning one or more additional clinical studies, including pharmacokinetic and safety and efficacy studies in vitamin B12 deficient people to further elucidate the advantages of the Eligen<sup>®</sup> technology. Currently, it is estimated that at least five million people in the U.S. are taking 40 million injections of vitamin B12 per year to treat a variety of debilitating medical conditions (as noted above). Another estimated five million are consuming more than 600 million tablets of vitamin B12 orally.

The safety of the carrier we plan to use to deliver Eligen<sup>®</sup> B12 has been demonstrated in earlier preclinical and clinical studies. Since vitamins are regulated by the FDA under different provisions than those used for drugs and biologicals, we anticipate that our development of vitamins may be shorter and less expensive than for a prescription drug.

During 2008, Emisphere also continued to focus on improving operational efficiency. On December 8, 2008 we announced plans to strengthen our financial foundation while maintaining our focus on advancing and commercializing the Eligen<sup>®</sup> Technology. By closing our research and development facility in Tarrytown, New York and utilizing independent contractors to conduct essential research and development, we estimate that we will reduce our annual operating costs by approximately 60% from 2008 levels. Emisphere estimates it will reduce cash expenditures by over \$11 million annually, with a targeted cash burn rate of between \$7 and \$8 million per year. Additionally, we expect to accelerate the commercialization of the Eligen<sup>®</sup> Technology in a cost effective way and to gain operational efficiencies by tapping into more advanced scientific processes independent contractors can provide. The amount of savings realized in 2009 depends on how quickly these actions can be fully implemented.

Implementation began immediately in December 2008 and is expected to be completed during the second quarter 2009.

#### Liquidity and Capital Resources

Since our inception in 1986, we have generated significant losses from operations and we anticipate that we will continue to generate significant losses from operations for the foreseeable future. As of December 31, 2008, our working capital deficit was \$8.0 million, our accumulated deficit was approximately \$434 million and our stockholders deficit was \$37.0 million. Our operating loss was \$26.3 million, \$20.7 million and \$27.1 million for the years ended December 31, 2008, 2007, and 2006, respectively, after receipts of collaboration and feasibility payments of \$0.3 million, \$4.1 million, and \$7.3 million, respectively (which do not occur with regularity or at all), as well as income from the settlement of a lawsuit in 2007 of \$11.9 million. Our net loss was \$24.4 million, \$16.9 million, and \$41.8 million for the years ended December 31, 2008, 2007, and 2006, respectively. Our operating and net losses for 2008 include a \$3.8 million one time restructuring charge which represents our best estimate of current and future costs associated with the closure of our research and development facility in Tarrytown, New York. During 2008 we received \$11.2 million from Novo Nordisk in connection with the exclusive Development and License Agreement with Novo Nordisk focused on the development of oral formulations of Novo Nordisk s proprietary GLP-1 receptor agonists. In accordance with GAAP, these payments were deferred and included in deferred revenue on our balance sheet (please see the Critical Accounting Estimates section for more information). We have limited capital resources and operations to date have been funded primarily with the proceeds from collaborative research agreements, public and private equity and debt financings and income earned on investments. As of December 31, 2008, total cash, cash equivalents, restricted cash and investments were \$7.5 million. We anticipate that our existing capital resources, without implementing cost reductions, raising additional capital, or obtaining substantial cash inflows from potential partners for our products, will enable us to continue operations through approximately August 2009. However, this expectation is based on the current operating plan that could change as a result of many factors and additional funding may be required sooner than anticipated. These conditions raise substantial doubt about our ability to continue as a going concern. The audit report prepared by our independent registered public accounting firm relating to our financial statements for the years ended December 31, 2008, 2007 and 2006 includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern.

Our business will require substantial additional investment that has not yet been secured. While our plan is to raise capital when needed and/or to pursue partnering opportunities, we cannot be sure how much we will need to spend in order to develop, market and manufacture new products and technologies in the future. We expect to continue to spend substantial amounts on research and development, including amounts spent on conducting clinical trials for our product candidates. Further, we will not have sufficient resources to develop fully any new products or technologies unless we are able to raise substantial additional financing on acceptable terms or secure funds from new or existing partners. We cannot assure you that financing will be available on favorable terms or at all. Additionally, these conditions may increase the cost to raise capital. If additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders. Additionally, these conditions may increase costs to raise capital and/or result in further dilution. Our failure to raise capital when needed would adversely affect our business, financial condition and results of operations, and could force us to reduce or cease our operations.

During the year ended December 31, 2008, our cash liquidity (consisting of \$7.2 million cash at December 31, 2008) decreased as follows:

#### Cash and Investments:

	(In th	ousands)
At December 31, 2007	\$	13,900
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At December 31, 2008	7,200
Decrease in cash and investments	\$ 6,700

The (decrease) increase in cash and investments is comprised of the following components for the years ended December 31:

		2008 (In thou	san	2007 ands)	
Proceeds, net, from issuance of equity securities Proceeds from collaboration, sale of patent, real estate sublease and other projects Net proceeds from settlement of lawsuit	\$	14,500	\$	7,300 4,100 11,900	
Sources of cash and investments		14,500		23,300	
Cash used in operations (grossed up for collaborations and settlement of lawsuit in 2007) Repayment of debts and capital expenditures Restriction of cash		20,900 100 200		30,400 300 200	
Uses of cash and investments		21,200		30,900	
(Decrease) increase in cash and investments	\$	(6,700)	\$	(7,600)	

During the year ended December 31, 2008, our working capital liquidity decreased by \$17.6 million as follows:

	December 31,							
	2008 (In 1					2008 2007 (In thousands)		Change
Current assets Current liabilities	\$	7,700 15,700	\$	15,100 5,500	\$ (7,400) 10,200			
Working capital (deficiency)	\$	(8,000)	\$	9,600	\$ (17,600)			

The decrease in current assets is driven primarily by the decrease in cash and investments. The increase in current liabilities is driven largely by the reclassification of the note payable to Novartis which matures December 1, 2009 from long term to current liability and the current portion of the restructuring charge of \$0.9 million in connection with closing our laboratory facilities in Tarrytown; offset by decreases in the derivative instrument liability as a result of the decline in our stock price.

#### Primary Sources of Cash

During 2008 we received a \$10.0 million upfront payment and reimbursement of \$1.3 million in costs from Novo Nordisk in connection with the development and license agreement to develop an oral formulation of GLP-1 receptor agonists for diabetes. Also during 2008 we received an initial \$1.5 million payment for sale of certain Emisphere patents and a patent application relating to diketopiparazine technology to MannKind Corporation. Also during 2008 we received \$800 thousand in sublease and related payments in connection with sublease agreements for space at our laboratory and office facilities located at 765 Old Saw Mill River Road, Tarrytown, NY.

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During 2007, we received a \$2 million milestone payment and reimbursement of \$0.7 in costs from Novartis on the oral salmon calcitonin program. Also during 2007, we received \$6.9 million through the issuance of common stock and derivative instruments from the August 2007 offering of 2 million shares of our common stock and warrants. MHR was a purchaser in this offering.

During 2006, we received a \$5 million milestone payment from Novartis on the oral recombinant human growth Hormone (rhGH) program. Also during 2006, we received \$35.2 million through the issuance of common stock and derivative instruments, including \$31.1 million from the May 2006 offering of four million shares of our common stock and warrants, \$3.6 million from the exercise of warrants and stock options and \$0.6 million from the purchase of warrants. MHR was a purchaser in this offering.

During 2005, we received net proceeds of approximately \$12.9 million under a \$15 million secured loan agreement (the Loan Agreement ) executed with MHR. Under the Loan Agreement, MHR requested, and on May 16, 2006, we effected, the exchange of the loan from MHR for senior secured convertible notes (the Convertible Notes ) with substantially the same terms as the Loan Agreement, except that the Convertible Notes are convertible, at the sole discretion of MHR, into shares of our common stock at a price per share of \$3.78. The Convertible Notes are due on September 26, 2012, bear interest at 11% and are secured by a first priority lien in favor of MHR on substantially all of our assets. Interest is payable in the form of additional Convertible Notes rather than in cash and we have the right to call the Convertible Notes after September 26, 2010 if certain conditions are satisfied. Further, the Convertible Notes provide MHR with the right to require redemption in the event of a change in control, as defined, prior to September 26, 2009. The Convertible Notes provide for various events of default. If an event of default occurs, the Convertible Notes provide for the immediate repayment and certain additional amounts as set forth in the Convertible Notes. We have received a waiver from MHR, through March 18, 2010 for certain defaults under the agreement. Additionally, MHR was granted certain registration rights.

In connection with the MHR financing, the Company agreed to appoint a representative of MHR (MHR Nominee) and another person (the Mutual Director) to its Board of Directors. MHR nominees constitute 33% of our Directors. Further, the Company amended its certificate of incorporation to provide for continuity of the MHR Nominee and the Mutual Nominee on the Board, as described therein, so long as MHR holds at least 2% of the outstanding common stock of the Company.

On December 1, 2004 we received \$10.0 million in exchange for issuance of a convertible note to Novartis (the Novartis Note ) in connection with a new research collaboration option relating to the development of PTH-1-34. The Novartis Note is convertible, at our option, at any time prior to maturity on December 1, 2009 into a number of shares of our common stock equal to the principal and accrued and unpaid interest divided by the then market price of our common stock, provided certain conditions are met. The Novartis Note bears interest at a rate of 3% until December 1, 2006, 5% from then until December 1, 2008, and 7% from that point until maturity on December 1, 2009. We have the option to pay interest in cash on a current basis or accrue the periodic interest as an addition to the principal amount of the Novartis Note. We are accruing interest which is being recorded using the effective interest rate method, which results in a level interest rate of 4.6%.

## **Results of Operations**

## Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

	Year Ended December 31,					
		2008	(In f	2007	(	Change
			(111)	housands)		
Revenue	\$	251	\$	4,077	\$	(3,826)
Operating expenses (excluding income from settlement of lawsuit in						
2007, net; including the \$3.8 million restructuring charge in 2008)	\$	26,571	\$	36,618	\$	(10,047)
Income from settlement of lawsuit, net	\$		\$	11,890	\$	(11,890)
Operating loss	\$	(26,320)	\$	(20,651)	\$	(5,669)
Change in fair value of derivative instruments	\$	2,220	\$	5,057	\$	(2,837)
Net loss	\$	(24,388)	\$	(16,928)	\$	(7,460)

Revenue decreased \$3.8 million for the year ended December 31, 2008 compared to year ended December 31, 2007 due to the receipt of milestone payments during 2007. In connection with the development and license agreement with Novo Nordisk to develop an oral formulation of GLP-1 receptor agonists for diabetes we received a \$10.0 million non-refundable license fee payment and \$1.2 million in reimbursement of costs in 2008; all of which was deferred in accordance with the Company s revenue recognition policy. Under such agreement Emisphere could receive more than \$87.0 million in contingent product development and sales

milestone payments. Emisphere would also be entitled to receive royalties in the event Novo Nordisk commercializes products developed under such agreement.

Our principal operating costs include the following items as a percentage of total expenses:

	Year Ended			
	December 31, 2008	December 31, 2007		
Human resource costs, including benefits Professional fees for legal, intellectual property, accounting and	42%	50%		
consulting	22%	17%		
Occupancy for our laboratory and operating space	19%	12%		
Clinical costs	5%	8%		
Depreciation and amortization	4%	3%		
Other	8%	10%		

Operating expenses, excluding income from settlement of lawsuit, net, and excluding the restructuring charge, decreased by \$13.9 million (38%) as a result of the following items:

	(In thousand			
Decrease in human resource costs	\$	(8,800)		
Decrease in clinical costs and lab fees		(2,800)		
Decrease in professional and consulting fees		(1,400)		
Decrease in occupancy costs		(100)		
Reduction in depreciation and amortization		(100)		
All other		(700)		
Net decrease	\$	(13,900)		

Human resource costs decreased by approximately \$8.8 million primarily due to a 77% reduction in headcount from 87 as of December 31, 2007 to 20 as of December 31, 2008; in addition to a reduction in severance payments and approximately \$2.0 reduction in non-cash compensation expense due to the cancellation or expiration of employee stock options.

Clinical costs and lab fees decreased approximately \$2.8 million primarily as a result of the completion of clinical and toxicology studies in connection with the anticipated heparin trial.

The decrease of approximately \$1.4 million in professional and consulting fees is primarily due to an approximately \$0.8 million reduction in legal fees in connection with the settlement of our law suit with Eli Lilly, and streamlining corporate legal support; a \$0.3 million reduction in professional and consulting fees in connection with the completion of toxicology and clinical studies and an \$0.1 million reduction in recruiting costs.

All other operating costs decreased by \$0.9 million primarily due to decreases in insurance, travel related, software licensing and maintenance, depreciation and amortization, utilities and a gain on the sale of fixed assets and a

reduction in other operating expenses.

As a result of the factors above Emisphere s operating expenses were \$26.6 million for the year ended December 31, 2008, including the \$3.8 million one time restructuring charge in connection with the closure of the research and development facility in Tarrytown, New York; an increase of \$1.8 million or 7% compared to operating expenses for the year ended December 31, 2007. Total operating expenses for the year ended December 31, 2008, excluding the one time restructuring charge of \$3.8 million would have been \$22.7 million, compared to \$36.6 million operating costs, excluding \$11.9 million net proceeds from the settlement of the lawsuit with Eli Lilly for the year ended December 31, 2007, a decrease of \$13.9 million or 38%.

Other non-operating income decreased by approximately \$1.8 million for the year ended December 31, 2008 in comparison to the same period last year primarily due to a reduction of approximately \$2.8 million in

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the change in the value of derivative instruments, a \$0.7 decrease in investment income, and an approximately \$0.3 million increase in interest expense; offset by the \$1.5 million gain from sale of patent to MannKind Corporation and an increase of approximately \$0.6 million in sublease income during 2008, Income from the change in the fair value of derivatives instruments for 2008 and 2007 is the result of the decrease in stock price from \$2.73 on December 31, 2007 to \$0.79 on December 31, 2008 and from \$5.29 on December 31, 2006 to \$2.73 on December 31, 2007, partially offset by the addition of 400,000 warrants in connection with the August 2007 offering. The change in value of derivative instruments: increases in value of the underlying shares of the Company s common stock increase the liability with a corresponding loss recognized in the Company s operating gain recognized in the Company s operating results from changes in value of the derivative instrument. Future gains and losses recognized in the Company s operating results from changes in value of the derivative instrument liability are based in part on the fair value of the Company s common stock which is outside the control of the Company. Gains and losses could be material.

As a result of the above factors, we reported a net loss of \$24.4 million, including the \$3.8 million one-time restructuring charge in connection with the closure of its research and development facility in Tarrytown, New York; compared to a net loss of \$16.9 million, including \$11.9 million net proceeds from the settlement of the lawsuit with Eli Lilly and Company. The net loss for year ended December 31, 2008 excluding the one time restructuring charge of \$3.8 million would have been \$20.6 million, compared to \$28.8 million, or \$8.3 million (29%) lower than the net loss for the year ended December 31, 2007, excluding \$11.9 million net proceeds from the settlement of the lawsuit with Eli Lilly in 2007.

The \$3.8 million one-time restructuring charge related to the closure of the Tarrytown facility is comprised of \$2.6 million present value in rent, net of sub-lease income through the expiration of the lease; termination benefits of \$0.2 million; and a \$1.0 million charge to write down the net book value of leasehold improvements in space no longer used by the Company as of December 8, 2008.

## Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

	Year Ended December 31,					
		2007		2006		Change
	(In thousands)					
Revenue	\$	4,077	\$	7,259	\$	(3,182)
Operating expenses (excluding income from settlement of lawsuit, net)	\$	36,618	\$	34,387	\$	2,231
Income from settlement of lawsuit, net	\$	11,890	\$		\$	11,890
Operating loss	\$	(20,651)	\$	(27,128)	\$	(6,477)
Beneficial conversion of convertible security	\$		\$	(12,215)	\$	(12,215)
Change in fair value of derivative instruments	\$	5,057	\$	(1,390)	\$	6,447
Net loss	\$	(16,928)	\$	(41,766)	\$	24,838

Revenue decreased significantly as compared to 2006 as a result of the \$5 million milestone payment received from Novartis for rhGH in 2006. In 2007 we received a milestone payment from Novartis on the oral salmon calcitonin program of \$2 million plus \$0.7 million for reimbursement of costs.

Our principal operating costs include the following items as a percentage of total expenses:

	Year Ended			
	December 31, 2007	December 31, 2006		
Human resource costs, including benefits Professional fees for legal, intellectual property, accounting and	50%	45%		
consulting	17%	16%		
Occupancy for our laboratory and operating space	12%	12%		
Clinical costs	8%	5%		
Depreciation and amortization	3%	11%		
Other	10%	11%		

Operating expenses, excluding income from settlement of lawsuit, net, increased by \$2.2 million (6%) as a result of the following items:

	(In thousands)			
Increase in human resource costs	\$	3,000		
Increase in clinical costs and lab fees		1,300		
Increase in professional and consulting fees		600		
Increase in occupancy costs		300		
Reduction in depreciation and amortization		(2,800)		
All other		(200)		
Net increase	\$	2,200		

Human resource costs increased by \$3.0 million primarily due to the recording of \$1.9 million in severance expense for terminated employees as well as an increase in FAS 123(R) expense of \$1.5 million and the accrual of the annual bonus for the Chief Executive Officer of \$0.4 million. The severance expense includes the accrual of costs estimated to settle the dispute with the Company s former Chief Executive Officer and severance expense related to the termination of approximately 30 employees during 2007. The termination of these employees was primarily done in an effort to fully utilize the staff of the Company as well as to reduce future operating costs. The increase in FAS 123(R) expense is primarily related to the \$1.3 million charge for the granting of options to the new Chief Executive Officer as well as the charges for terminated executives whose options were extended. These increases were partially offset by decreases in salaries related to the reduction in employees.

Clinical costs and lab fees increased primarily as a result of the toxicology studies being performed in anticipation of a Heparin trial.

The increase of \$0.6 million in professional and consulting fees is primarily related to the formulation of the Scientific Advisory Board for Insulin as well as an increase in the outsourcing for data analysis and network maintenance. We do not anticipate that the Scientific Advisory Board will continue beyond early 2008, although we do plan to consult with certain members of the Board.

The increase in occupancy costs of \$0.3 million is related to the extension of the lease in the Tarrytown, New York location, which resulted in an increase in rental expense. During the last quarter of 2007, the Company started to surrender space in the Tarrytown location back to the landlord. In addition, in November 2007, the Company moved its executive offices from Tarrytown, New York to Cedar Knolls, New Jersey in an effort to save on occupancy costs. The decrease from the surrender of space in Tarrytown will be partially offset by an increase in occupancy costs for Cedar Knolls in 2008. The cumulative effect of the real estate initiatives planned by the Company could cumulatively result in long-term savings of over \$1 million annually.

The reduction in depreciation and amortization expense is primarily related to the change in the estimated useful life of leasehold improvements as a result of the five year extension of the lease for our Tarrytown facility on March 1, 2007.

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The income from the settlement of the lawsuit, net is due to the settlement of the litigation with Eli Lilly. On September 25, 2007, Emisphere agreed to accept \$18 million from Lilly to settle the pending litigation between the two companies. Emisphere received \$11.9 million of the settlement, net of attorneys fees and expenses.

The charge for beneficial conversion in 2006 is due to the conversion feature in the MHR notes, which did not exist until 2006. There was no such charge for 2007.

The income from the change in the fair value of the derivatives instruments for 2007 is primarily the result of the decrease in stock price from \$5.29 at December 31, 2006 to \$2.73 at December 31, 2007, partially offset by the addition of 400,000 warrants from the August 2007 offering.

As a result of the above factors, we sustained a net loss of \$16.9 million for the year ended December 31, 2007, compared to a net loss of \$41.8 million for the year ended December 31, 2006. These results include a number of non-recurring transactions the charge for the beneficial conversion in 2006, and the charges for severance payments to former employees, and are therefore not necessarily indicative of future results.

#### **Critical Accounting Estimates and New Accounting Pronouncements**

#### **Critical Accounting Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

It requires assumptions to be made that were uncertain at the time the estimate was made, and

Changes in the estimate or different estimates that could have been selected could have a material impact on our results of operations or financial condition

*Share-Based Payments* On January 1, 2006, we adopted SFAS 123(R), Share-Based Payment , which establishes standards for share-based transactions in which an entity receives employee s services for (a) equity instruments of the entity, such as stock options, or (b) liabilities that are based on the fair value of the entity s equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123(R) supersedes the option of accounting for share-based compensation transactions using APB Opinion No. 25, Accounting for Stock Issued to Employees , and requires that companies expense the fair value of stock options and similar awards, as measured on the awards grant date. SFAS 123(R) applies to all awards granted after the date of adoption, and to awards modified, repurchased or cancelled after that date. We have elected to apply SFAS 123(R) using a modified version of prospective application, under which compensation cost is recognized only for the portion of awards outstanding for which the requisite service has not been rendered as of the adoption date, based on the grant date fair value of those awards calculated under SFAS 123 for pro forma disclosures.

We estimate the value of stock option awards on the date of grant using the Black-Scholes-Merton option-pricing model (the Black-Scholes model). The determination of the fair value of share-based payment awards on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, expected term, risk-free interest rate, expected dividends and expected forfeiture rates.

If factors change and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the

current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS 123(R). Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Employee stock options may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that are significantly in

excess of the fair values originally estimated on the grant date and reported in our financial statements. During the year ended December 31, 2008, we do not believe that reasonable changes in the projections would have had a material effect on share-based compensation expense.

*Revenue Recognition* Revenue includes amounts earned from collaborative agreements and feasibility studies. Revenue from feasibility studies, which are typically short term in nature, is recognized upon delivery of the study, provided that all other revenue recognition criteria are met. Revenue from collaboration agreements are recognized using the proportional performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best effort basis and based on expected payments. Under the proportional performance method, periodic revenue related to nonrefundable cash payments is recognized as the percentage of actual effort expended to date as of that period to the total effort expected for all of our performance obligations under the arrangement. Actual effort is generally determined based upon actual hours incurred and include research and development ( R&D ) activities performed by us and time spent for joint steering committee (JSC) activities. Total expected effort is generally based upon the total R&D and JSC hours incorporated into the project plan that is agreed to by both parties to the collaboration. Significant management judgments and estimates are required in determining the level of effort required under an arrangement and the period over which we expect to complete the related performance obligations. Estimates of the total expected effort included in each project plan are based on historical experience of similar efforts and expectations based on the knowledge of scientists for both the Company and its collaboration partners. The Company periodically reviews and updates the project plan for each collaborative agreement; the most recent reviews took place in January 2009. In the event that a change in estimate occurs, the change will be accounted for using the cumulative catch-up method which provides for an adjustment to revenue in the current period. Estimates of our level of effort may change in the future, resulting in a material change in the amount of revenue recognized in future periods.

Generally under collaboration arrangements, nonrefundable payments received during the period of performance may include time- or performance-based milestones. The proportion of actual performance to total expected performance is applied to the expected payments in determining periodic revenue. However, revenue is limited to the sum of (1) the amount of nonrefundable cash payments received and (2) the payments that are contractually due but have not yet been paid.

With regard to revenue recognition from collaboration agreements: the Company previously interpreted expected payments to equate to total payments subject to each collaboration agreement. On a prospective basis, the Company has revised its application of expected payments to equate to a best estimate of payments. Under this application, expected payments typically include (i) payments already received and (ii) those milestone payments not yet received but that the Company believes are more likely than not of receiving. Our support for the assertion that the next milestone is likely to be met is based on the (a) project status updates discussed at JSC meetings; (b) clinical trial/development results of prior phases; (c) progress of current clinical trial/development phases; (c) directional input of collaboration partners and (d) knowledge and experience of the Company scientific staff. After considering the above factors, the Company believes those payments included in expected payments are more likely than not of being received. While this interpretation differs from that used previously by the Company, it does not result in any change to previously recognized revenues in either timing or amount for periods through December 31, 2008.

With regard to revenue recognition in connection with the agreement with Novo Nordisk: such agreement includes multiple deliverables including the license grant, several versions of the Company s Eligen Technology (or carriers), support services and manufacturing. Emisphere s management reviewed the relevant terms of the Novo Nordisk agreement and determined such deliverables should be accounted for as a single unit of accounting in accordance with the Emerging Issues Taskforce No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21) since the delivered license and Eligen<sup>®</sup> Technology do not have stand-alone value and Emisphere does not have objective evidence of fair value of the undelivered Eligen<sup>®</sup> Technology or the manufacturing value of all the undelivered items.

Such conclusion will be reevaluated as each item in the arrangement is delivered. Consequently any payments received from Novo Nordisk pursuant to such agreement, including the initial \$10 million upfront payment and any payments received for support services, will be deferred and included in Deferred Revenue within our balance sheet. Management cannot

currently estimate when all of such deliverables will be delivered nor can they estimate when, if ever, Emisphere will have objective evidence of the fair value for all of the undelivered items, therefore all payments from Novo Nordisk are expected to be deferred for the foreseeable future.

As of December 31, 2008 total deferred revenue from the agreement was \$11.2 million, comprised of the \$10.0 million non-refundable license fee and \$1.2 million in support services.

*Purchased Technology* Purchased technology represents the value assigned to patents and the rights to use, sell or license certain technology in conjunction with our proprietary carrier technology. These assets underlie our research and development projects related to various research and development projects.

*Warrants* Warrants issued in connection with the equity financing completed in March 2005 and August 2007 and to MHR have been classified as liabilities due to certain provisions that may require cash settlement in certain circumstances. At each balance sheet date, we adjust the warrants to reflect their current fair value. We estimate the fair value of these instruments using the Black-Scholes option pricing model which takes into account a variety of factors, including historical stock price volatility, risk-free interest rates, remaining term and the closing price of our common stock. Changes in the assumptions used to estimate the fair value of these derivative instruments could result in a material change in the fair value of the instruments. We believe the assumptions used to estimate the fair values of the warrants are reasonable. See Item 7A. Quantitative and Qualitative Disclosures about Market Risk for additional information on the volatility in market value of derivative instruments.

*Equipment and Leasehold Improvements* Equipment and leasehold improvements are stated at cost. Depreciation and amortization are provided for on a straight-line basis over the estimated useful life of the asset. Leasehold improvements are amortized over the life of the lease or of the improvements, whichever is shorter. Expenditures for maintenance and repairs that do not materially extend the useful lives of the respective assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts and any gain or loss is recognized in operations.

*Impairment of Long-Lived Assets* In accordance with Statement of Financial Accounting Standards (SFAS) 144 and SFAS 146, we review our long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. An impairment loss, measured as the amount by which the carrying value exceeds the fair value, is triggered if the carrying amount exceeds estimated undiscounted future cash flows. Actual results could differ significantly from these estimates, which would result in additional impairment losses or losses on disposal of the assets. During the years ended December 31, 2007 and 2006, we did not recognize any significant impairment losses. During the year ended December 31, 2008 we recognized an approximately \$1.0 million charge to write down the value of leasehold improvements in connection with the restructuring charge to estimate current and future costs to close the laboratory and office facility located in Tarrytown, NY. In addition, with regards to the restructuring, we accelerated the useful life of approximately \$0.2 million in leasehold improvements for a portion of the laboratory facility in Tarrytown that we continued to use through January 29, 2009. Approximately \$0.1 million in additional depreciation expense was recognized during December 2008 and approximately \$0.1 million during January 2009.

*Clinical Trial Accrual Methodology* Clinical trial expenses represent obligations resulting from our contracts with various research organizations in connection with conducting clinical trials for our product candidates. We account for those expenses on an accrual basis according to the progress of the trial as measured by patient enrollment and the timing of the various aspects of the trial. Accruals are recorded in accordance with the following methodology: (i) the costs for period expenses, such as investigator meetings and initial start-up costs, are expensed as incurred based on management s estimates, which are impacted by any change in the number of sites, number of patients and patient start dates; (ii) direct service costs, which are primarily on-going monitoring costs, are recognized on a straight-line basis

over the life of the contract; and (iii) principal investigator expenses that are directly associated with recruitment are recognized based on actual patient recruitment. All changes to the contract amounts due to change orders are analyzed and recognized in accordance with the above methodology. Change orders are triggered by changes in the scope, time to completion and the number of sites. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates.

#### **New Accounting Pronouncements**

In June 2008, the Financial Accounting Standards Board (FASB) affirmed the conclusions of the Emerging Issues Taskforce (EITF) with respect to EITF Issue No. 07-03 Accounting for Advance Payments for Goods and Services to Be Used in Future Research and Development Activities. EITF 07-03 concluded that non-refundable advance payments for future research and development activities pursuant to an executory contractual arrangement should be capitalized until the goods have been delivered or the related services have been performed. This EITF became effective January 1, 2008, and requires entities to recognize the effects of applying the guidance in this Issue prospectively for new contracts entered into after January 1, 2008. The adoption of EITF Issue No. 07-03 did not have a material impact on our financial position, results of operations or cash flows.

In December 2007, the FASB ratified the consensus reached by the EITF with respect to EITF Issue No. 07-01 Accounting for Collaborative Arrangements. The EITF defined collaborative arrangements and established reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This issue is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently evaluating the effects of this EITF on the Company s financial statements.

In March 2008, the FASB issued Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities . The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company has not determined the impact, if any, on future financial statements.

Effective January, 2008, the Company adopted SFAS No. 157, Fair Value Measurements (SFAS 157). In February 2008, the FASB issued Staff Position (FSP) FAS 157-1 to exclude SFAS no. 13, Accounting for Leases and its related interpretive accounting pronouncements that address leasing transactions, from the scope of SFAS No. 157. In February 2008, the FASB also issued FASB Staff Position No. 157-2, Effective Date of FASB Statement 157, which provides a one year deferral of the effective date of AFAS 157 for non-financial assets and non-financial; liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, the Company has adopted the provision of SFAS 157 with respect to its financial assets and liabilities only. For the portion of SFAS 157 that has been deferred, the Company is currently evaluating the effects of SFAS 157 will have on its financial statements. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for an asset or liability in an orderly transaction between participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities

The adoption of this statement did not have a material impact on the Company s results of operations and financial condition.

Effective for periods beginning on or after December 15, 2008, the FASB issued SFAS 141R, Business Combinations . S FAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. This standard requires an acquirer to recognize the assets acquired and liabilities assumed at the acquisition date fair values with limited exceptions. Additionally, FAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, that acquired in-process research and development be capitalized and recorded as intangible assets at the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. The impact of this standard will not have an impact on the Company s financial statements.

Effective January 1, 2008, the Company could have adopted SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by contract basis. The Company did not elect to adopt the fair value option under this SFAS.

#### **Off-Balance Sheet Arrangements**

As of December 31, 2008, we had no material off-balance sheet arrangements.

In the ordinary course of business, we enter into agreements with third parties that include indemnification provisions which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or incurred by the indemnified parties with respect to our product candidates, use of such product candidates, or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, we have no liabilities recorded for these provisions as of December 31, 2008.

In the normal course of business, we may be confronted with issues or events that may result in a contingent liability. These generally relate to lawsuits, claims, environmental actions or the actions of various regulatory agencies. We consult with counsel and other appropriate experts to assess the claim. If, in our opinion, we have incurred a probable loss as set forth by accounting principles generally accepted in the U.S., an estimate is made of the loss and the appropriate accounting entries are reflected in our financial statements. After consultation with legal counsel, we do not anticipate that liabilities arising out of currently pending or threatened lawsuits and claims, including the pending litigation described in Part I, Item 3 **Legal Proceedings**, will have a material adverse effect on our financial position, results of operations or cash flows.

## **Contractual Arrangements**

Significant contractual obligations as of December 31, 2008 are as follows:

		Amount Due in				
Type of Obligation	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
Notes Payable(1)(2)	\$ 43,032	\$ 12,515	In thousand: \$	\$ 30,517	\$	

Derivative liabilities(3)	267	267			
Operating lease obligations	9,248	2,471	6,746	31	
Total	\$ 52,547	\$ 15,253	\$ 6,746	\$ 30,548	\$

(1) Amounts include both principal and related interest payments.

(2) In December 2004, we issued a \$10.0 million convertible note payable to Novartis (the Novartis Note ) due December 2009. Interest may be paid annually or accreted as additional principal. We may convert the Novartis Note at any time prior to maturity into a number of shares of our common stock equal to the principal and accrued and unpaid interest to be converted divided by the then market price of our common

stock, provided certain conditions are met. Upon the occurrence of an event of default prior to conversion, or within six months of conversion, any unpaid principal and accrued interest on the Novartis Note would become immediately due and payable. At December 31, 2008, the balance on the Novartis Note was \$12 million.

We have outstanding \$18.2 million in Convertible Notes payable to MHR and its affiliates (MHR) due September 2012 and convertible at the sole discretion of MHR into shares of our common stock at a price of \$3.78. Interest at 11% is payable in additional Convertible Notes rather than in cash and we have the right to call the Convertible Notes after September 10, 2010 if certain conditions are satisfied. The Convertible Notes are subject to acceleration upon the occurrence of certain events of default.

(3) We have issued warrants to purchase shares of our common stock which contain provisions requiring us to make a cash payment to the holders of the warrant for any gain that could have been realized if the holders exercise the warrants and we subsequently fail to deliver a certificate representing the shares to be issued upon such exercise by the third trading day after such warrants have been exercised. As a result, these warrants have been recorded at their fair value and are classified as current liabilities. The value and timing of the actual cash payments, if any, related to these derivative instruments could differ materially from the amounts and periods shown.

On April 6, 2007, the Board of Directors appointed Michael V. Novinski to the position of President and Chief Executive Officer. Pursuant to his appointment, the Company has entered into a three year employment agreement with Mr. Novinski. If Mr. Novinski s contract is terminated without cause or at any time by the executive for good reason as defined in his contract, we are obligated to make severance payments to Mr. Novinski.

In April 2005, the Company entered into an employment contract with its then Chief Executive Officer, Dr. Michael M. Goldberg, for services through July 31, 2007. On January 16, 2007, the Board of Directors terminated Dr. Goldberg s services. On April 26, 2007, the Board of Directors held a special hearing at which it determined that Dr. Goldberg s termination was for cause. On March 22, 2007, Dr. Goldberg, through his counsel, filed a demand for arbitration asserting that his termination was without cause and seeking \$1,048,000 plus attorney s fees, interest, arbitration costs and other relief alleged to be owed to him in connection with his employment agreement with the Company. Dr. Goldberg s employment agreement provides, among other things, that in the event he is terminated without cause, Dr. Goldberg would be paid his base salary plus bonus, if any, monthly for a severance period of eighteen months or, in the event of a change of control, twenty-four months, and he would also be entitled to continued health and life insurance coverage during the severance period and all unvested stock options and restricted stock awards would immediately vest in full upon such termination. Dr. Goldberg s employment agreement provided that in the event he is terminated with cause, he will receive no additional compensation. During the year ended December 31, 2007, the Company accrued the estimated costs to settle this matter. No settlement has been reached and the dispute continues. In February 2008, the Company received \$0.5 million as a result of a cancellation of a split dollar life insurance policy on Dr. Goldberg. Dr. Goldberg claimed approximately \$0.2 million was due him as a return of policy premium. In June 2008, Dr. Goldberg commenced a separate lawsuit in the New York State Supreme Court (New York County) claiming that the Company breached his employment agreement by not remitting to Dr. Goldberg that portion of the cash value of the life insurance policy. During the year ended December 31, 2008, the Company adjusted its accrual to reflect estimated costs to settle this matter accordingly. On January 29, 2009, after transfer from the New York State Supreme Court (New York County) to an independent arbitrator, the Company received a finding from such arbitrator awarding a partial summary judgment to Dr. Goldberg for compensatory damages in an amount equal to \$240,101. The company paid Dr. Goldberg such amount on February 5, 2009. All remaining claims were deferred by the Arbitrator pending further proceedings between the parties. The Company believes the remaining claims are without merit and will vigorously defend itself against Dr. Goldberg s claims. The ultimate cost to resolve this matter could be in excess of the amount provided for and such amount could be material to the Company.

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## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

*Fair Value of Warrants and Derivative Liabilities.* At December 31, 2008, the value of derivative instruments was \$267 thousand. We estimate the fair values of these instruments using the Black-Scholes option pricing model which takes into account a variety of factors, including historical stock price volatility, risk-free interest rates, remaining term and the closing price of our common stock. We are required to revalue this liability each quarter. We believe that the assumption that has the greatest impact on the determination of fair value is the closing price of our common stock. The following table illustrates the potential effect on the fair value of derivative instruments from changes in the assumptions made:

	(Decrease) ousands)
<ul> <li>25% increase in stock price</li> <li>50% increase in stock price</li> <li>5% increase in assumed volatility</li> <li>25% decrease in stock price</li> <li>50% decrease in stock price</li> <li>5% decrease in assumed volatility</li> </ul>	\$ 132 288 39 (109) (192) (36)

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

## EMISPHERE TECHNOLOGIES, INC.

#### FINANCIAL STATEMENTS

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# Emisphere Technologies, Inc.52Report of Independent Registered Public Accounting Firm52Balance Sheets as of December 31, 2008 and 200753Statements of Operations for the years ended December 31, 2008, 2007 and 200654Statements of Cash Flows for the years ended December 31, 2008, 2007 and 200655Statements of Stockholders (Deficit) Equity for the years ended December 31, 2008, 2007 and 200656Notes to the Financial Statements57

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Emisphere Technologies, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, of cash flows and of stockholders (deficit) equity present fairly, in all material respects, the financial position of Emisphere Technologies, Inc. (the Company ) at December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, appearing under Management s Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our integrated 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 financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has experienced recurring operating losses, has limited capital resources and has significant future commitments that raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

New York, New York March 16, 2009

# EMISPHERE TECHNOLOGIES, INC.

## **BALANCE SHEETS**

		Decem	ber 31,
		2008	2007
		(In tho	usands,
		except sh	are data)
	ASSETS		
Current assets:			

Cash and cash equivalents	\$ 7,214	\$ 3,938
Short-term investments		9,916
Accounts receivable, net of allowance of \$9 in 2008 and \$0 in 2007)	232	292
Prepaid expenses and other current assets	273	983
	7710	15 120
Total current assets	7,719	15,129
Equipment and leasehold improvements, net	465	2,074
Restricted cash	255	246
Purchased technology, net	1,316	1,555
Other assets	421	477
Total assets	\$ 10,176	\$ 19,481

## LIABILITIES AND STOCKHOLDERS DEFICIT

Current liabilities:	_		
Notes payable, including accrued interest and net of related discount	\$	12,011	\$
Accounts payable and accrued expenses		2,361	2,874
Derivative instruments:			
Related party		153	1,238
Others		114	1,249
Deferred revenue, current		87	73
Restructuring charge, current		927	
Other current liabilities		20	73
Total current liabilities		15,673	5,507
Notes payable, including accrued interest and net of related discount			
Related party		18,209	15,836
Others			11,484
Restructuring charge, non-current		1,953	
Deferred revenue, non-current		11,240	
Deferred lease liability, non current, and other liabilities		129	328
Total liabilities		47,204	33,155

Commitments and contingencies (Note 15) Stockholders deficit: Preferred stock, \$.01 par value; authorized 1,000,000 shares; issued and outstanding-none			
Common stock, \$.01 par value; authorized 100,000,000 shares; issued			
30,630,810 shares (30,341,078 outstanding) in 2008 and 30,626,660 shares			
(30,336,928 outstanding) in 2007		306	306
Additional paid-in capital	4	-00,306	399,282
Accumulated deficit	(4	33,688)	(409,300)
Accumulated other comprehensive loss			(10)
Common stock held in treasury, at cost; 289,732 shares		(3,952)	(3,952)
Total stockholders deficit	(	(37,028)	(13,674)
Total liabilities and stockholders deficit	\$	10,176	\$ 19,481

The accompanying notes are an integral part of the financial statements

# EMISPHERE TECHNOLOGIES, INC.

## STATEMENTS OF OPERATIONS

	Year Ended December 31,2008200720					2006
	(In thousands, except share and per sha					are data)
Revenue	\$	251	\$	4,077	\$	7,259
Costs, expenses and income from settlement of lawsuit:						
Research and development		12,785		21,076		18,892
General and administrative		9,176		14,459		11,693
Loss (gain) on disposal of fixed assets		(135)		35		2
Restructuring charge		3,831				• • • • •
Depreciation and amortization		914		1,048		3,800
Income from settlement of lawsuit:						
Proceeds from settlement of lawsuit				(18,000)		
Expenses from settlement of lawsuit				6,110		
Income from settlement of lawsuit, net				(11,890)		
Total costs, expenses and income from settlement of lawsuit		26,571		24,728		34,387
Operating loss		(26,320)		(20,651)		(27,128)
Other non-operating income (expense):						
Beneficial conversion of convertible security						(12,215)
Sale of patent		1,500				
Sublease income		797		215		167
Investment and other income		371		1,066		1,135
Change in fair value of derivative instruments						
Related party		1,085		2,561		(593)
Others		1,135		2,496		(797)
Interest expense						
Related party		(2,428)		(2,111)		(1,846)
Others		(528)		(504)		(489)
Total other income (expense)		1,932		3,723		(14,638)
Net loss	\$	(24,388)	\$	(16,928)	\$	(41,766)
Net loss per share, basic	\$	(0.80)	\$	(0.58)	\$	(1.58)
Net loss per share, diluted	\$	(0.80)	\$	(0.76)	\$	(1.58)
Weighted average shares outstanding, basic		30,337,442	,	29,039,101		26,474,072

Weighted average shares outstanding, diluted 29,128,013 30,337,442 26,474,072

The accompanying notes are an integral part of the financial statements

# EMISPHERE TECHNOLOGIES, INC.

## STATEMENTS OF CASH FLOWS

	Year	Year Ended December 31,		
	2008	2007	2006	
		(In thousands)		
Cash flows from operating activities:				
Net loss	\$ (24,388)	\$ (16,928)	\$ (41,766)	
	¢ ( <u>1,000</u> )	¢ (10,7 <b>-</b> 0)	¢ (.1,, 00)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	914	1,048	3,800	
Non-cash beneficial conversion feature			12,215	
Non-cash interest expense:				
Related party	2,428	2,111	1,420	
Others	528	504	489	
Changes in the fair value of derivative instruments:				
Related party	(1,085)	(2,561)	593	
Others	(1,135)	(2,496)	797	
Non-cash restructuring charge	1,040			
Non-cash compensation	1,011	3,068	1,653	
Net unrealized loss (gain) on sale of investments			6	
Loss (gain) on disposal of fixed assets	(135)	35	2	
Impairment of intangible and fixed assets and other		86	(42)	
Changes in assets and liabilities excluding non-cash charges:				
(Increase) decrease in accounts receivable	60	(76)	(145)	
Decrease (increase) in prepaid expenses and other current assets	710	400	(156)	
Increase (decrease) in accounts payable, accrued expenses and other	(513)	225	(667)	
Increase (decrease) in deferred revenue	11,254	43	(260)	
Increase (decrease) in deferred lease and other liabilities	(253)	137	(397)	
Restructuring charge	2,880			
Total adjustments	17,704	2,524	19,308	
Net cash used in operating activities	(6,684)	(14,404)	(22,458)	
1 6				
Cash flows from investing activities:				
Proceeds from sale and maturity of investments	9,927	15,650	14,994	
Purchases investments and short term instruments		(12,084)	(25,450)	
Equipment purchases	(109)	(293)	(322)	
(Increase) decrease in restricted cash	(9)	(246)	4,294	
Proceeds from sale of fixed assets	138	28	6	
Net cash provided by (used in) investing activities	9,947	3,055	(6,478)	
Cash flows from financing activities:				
Proceeds from exercise of stock options and warrants	13	346	3,637	

Net proceeds from issuance of common stock Proceeds from issuance of warrants Repayment of notes payable and capital lease obligation		5,954 952	31,059 551 (226)
Net cash provided by financing activities	13	7,252	35,021
Net (decrease) increase in cash and cash equivalents Cash and cash equivalents, beginning of year	3,276 3,938	(4,097) 8,035	6,085 1,950
Cash and cash equivalents, end of year	\$ 7,214	\$ 3,938	\$ 8,035
Supplemental disclosure of cash flow information:			
Interest paid	\$	\$	\$ 426
Non-cash investing and financing activities:			
Settlement of derivative instrument liability	\$	\$	\$ 958
Issuance of stock options to consultants	\$	\$ (6)	\$ 32

The accompanying notes are an integral part of the financial statements

## EMISPHERE TECHNOLOGIES, INC.

## STATEMENTS OF STOCKHOLDERS (DEFICIT) EQUITY For the years ended December 31, 2008, 2007 and 2006

	Common S Shares	Stock Amount	Additional Paid-in Capital (In tl	Accumulated Other Comprehensive Common Stock Accumulated (Loss) Held in Treasury Deficit Income Shares Amount Total housands, except share data)	
Balance, December 31, 2005 Net loss Unrealized gain on investments	23,673,299	\$ 237	\$ 339,452	\$ (350,606) \$ (26) 289,732 \$ (3,952) \$ (14,8 (41,766) 24	
Comprehensive loss				(41,7	42)
Exercise of warrants Beneficial conversion of	400,000	4	3,520	3,5	24
conversion of security Equity proceeds from issuance of common stock, net			12,215	12,2	15
of share issuance expenses Sale of common stock under employee stock	4,000,000	40	31,018	31,0	58
purchase plans and exercise of options Stock based compensation	450,918	4	2,077	2,0	81
expense for employees Stock based			1,581	1,5	81
compensation expense for directors Issuance of stock options for	4,460		40		40
consulting services			32		32

Balance, December 31, 2006 Net loss Unrealized gain on investments	28,528,677	285	389,935	(392,372) (16,928)	(2) (8)	289,732	(3,952)	(6,106) (16,928) (8)
Comprehensive loss								(16,936)
Equity proceeds from issuance of common stock, net of share issuance expenses Sale of common stock under employee stock	2,000,000	20	5,934					5,954
purchase plans and exercise of options Stock based compensation	82,023	1	345					346
expense for employees Stock based			3,014					3,014
compensation expense for directors Issuance of stock	15,960		60					60
options for consulting services			(6)					(6)
Balance, December 31, 2007 Net loss Unrealized loss on investments	30,626,660	306	399,282	(409,300) (24,388)	(10) 10	289,732	(3,952)	(13,674) (24,388) 10
Comprehensive loss								(24,378)
Sale of common stock under exercise of options Stock based compensation expense for employees	4,150		13 1,011					13 1,011
Balance, December 31, 2008	30,630,810	\$ 306	\$ 400,306	\$ (433,688)		289,732	\$ (3,952)	\$ (37,028)

The accompanying notes are an integral part of the financial statements

## EMISPHERE TECHNOLOGIES, INC.

## NOTES TO THE FINANCIAL STATEMENTS

#### 1. Nature of Operations, Risks and Uncertainties and Liquidity

*Nature of Operations*. Emisphere Technologies, Inc. (Emisphere, our, us, the company or we) is a biopharmace company that focuses on our improved delivery of therapeutic molecules and pharmaceutical compounds using its Eligen<sup>®</sup> Technology. These molecules and compounds could be currently available or are in pre-clinical or clinical development.

Our core business strategy is to develop oral forms of drugs that are not currently available or have poor bioavailability in oral form, either alone or with corporate partners, by applying the Eligen<sup>®</sup> Technology to those drugs. Typically, the drugs that we target have received regulatory approval, have demonstrated safety and efficacy, and are currently available on the market. Since inception, we have no product sales from these product candidates.

*Risks and Uncertainties.* We have no products approved for sale by the U.S. FDA. There can be no assurance that our research and development will be successfully completed, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. In addition, we operate in an environment of rapid change in technology and are dependent upon the continued services of our current employees, consultants and subcontractors.

*Liquidity.* As of December 31, 2008, we had approximately \$7.5 million in cash, restricted cash and investments, approximately \$8.0 million in working capital deficiency, a stockholders deficit of approximately \$37.0 million and an accumulated deficit of approximately \$434.0 million. Our net loss and operating loss for the year ended December 31, 2008 was approximately \$24.4 million and \$26.3 million, respectively. We anticipate that we will continue to generate significant losses from operations for the foreseeable future, and that our business will require substantial additional investment that we have not yet secured. As such, we anticipate that our existing cash resources will enable us to continue operations only through approximately August 2009 or earlier if unforeseen events arise that negatively affect our liquidity. Further, we have significant future commitments and obligations. These conditions raise substantial doubt about our ability to continue as a going concern.

Our plan is to raise capital when needed and/or to pursue product partnering opportunities. We expect to continue to spend substantial amounts on research and development, including amounts spent on conducting clinical trials for our product candidates. Expenses will be partially offset with income-generating license agreements, if possible. Further, we will not have sufficient resources to develop fully any new products or technologies unless we are able to raise substantial additional financing on acceptable terms or secure funds from new or existing partners. We cannot assure that financing will be available when needed, or on favorable terms or at all. If additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in dilution to our existing stockholders. Our failure to raise capital before August 2009 will adversely affect our business, financial condition and results of operations, and could force us to reduce or cease our operations. No adjustment has been made in the accompanying financial statements to the carrying amount and classification of recorded assets and liabilities should we be unable to continue operations.

#### 2. Basis of Presentation

Certain reclassifications have been made to prior year amounts to conform to current period presentation.

## 3. Summary of Significant Accounting Policies

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*Use of Estimates.* The preparation of financial statements in accordance with accounting principles generally accepted in the U.S. involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses and performance period for revenue recognition. Actual results may differ substantially from these

## **EMISPHERE TECHNOLOGIES, INC.**

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

estimates. Significant estimates include the fair value and recoverability of the carrying value of purchased technology, recognition of on-going clinical trial costs, estimated costs to complete research collaboration projects, accrued expenses, the variables and method used to calculate stock-based compensation, derivative instruments and deferred taxes.

*Concentration of Credit Risk.* Financial instruments, which potentially subject us to concentrations of credit risk, consist of cash, cash equivalents, restricted cash and investments. We invest excess funds in accordance with a policy objective seeking to preserve both liquidity and safety of principal. We generally invest our excess funds in obligations of the U.S. government and its agencies, bank deposits, money market funds, and investment grade debt securities issued by corporations and financial institutions. We hold no collateral for these financial instruments.

*Cash, Cash Equivalents, and Investments.* We consider all highly liquid, interest-bearing instruments with original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents may include demand deposits held in banks and interest bearing money market funds. Our investment policy requires that commercial paper be rated A-1, P-1 or better by either Standard and Poor s Corporation or Moody s Investor Services or another nationally recognized agency and that securities of issuers with a long-term credit rating must be rated at least A (or equivalent).

As of December 31, 2008 we held no investments.

*Equipment and Leasehold Improvements.* Equipment and leasehold improvements are stated at cost. Depreciation and amortization are provided on a straight-line basis over the estimated useful life of the asset. Leasehold improvements are amortized over the term of the lease or useful life of the improvements, whichever is shorter. Expenditures for maintenance and repairs that do not materially extend the useful lives of the respective assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts and any gain or loss is recognized in operations.

*Purchased Technology*. Purchased technology represents the value assigned to patents and the right to use, sell or license certain technology in conjunction with our proprietary carrier technology that were acquired from Ebbisham Ltd. These assets are utilized in various research and development projects. Such purchased technology is being amortized over 15 years, until 2014, which represents the average life of the patents acquired.

*Impairment of Long-Lived Assets.* In accordance with SFAS 144, we review our long-lived assets including purchased technology, for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. An impairment loss, measured as the amount by which the carrying value exceeds the fair value, is recognized if the carrying amount exceeds estimated undiscounted future cash flows.

*Deferred Lease Liability.* Our leases provide for rental holidays and escalations of the minimum rent during the lease term, as well as additional rent based upon increases in real estate taxes and common maintenance charges. We record rent expense from leases with rental holidays and escalations using the straight-line method, thereby prorating the total rental commitment over the term of the lease. Under this method, the deferred lease liability represents the difference between the minimum cash rental payments and the rent expense computed on a straight-line basis.

*Revenue Recognition.* We recognize revenue in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104), Financial Accounting Standards Board (FASB) and Emerging Issues Task Force No. 00-21 Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). Revenue includes amounts earned from collaborative agreements and feasibility studies and is comprised of reimbursed research and development costs,

as well as upfront and research and development milestone

## EMISPHERE TECHNOLOGIES, INC.

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

payments. Deferred revenue represents payments received which are related to future performance. Revenue from feasibility studies, which are typically short term in nature, is recognized upon delivery of the study, provided that all other revenue recognition criteria are met.

Revenue from collaboration agreements are recognized using the proportional performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best effort basis and based on expected payments. Under the proportional performance method, periodic revenue related to nonrefundable cash payments is recognized as the percentage of actual effort expended to date as of that period to the total effort expected for all of our performance obligations under the arrangement. Actual effort is generally determined based upon actual hours incurred and include research and development ( R&D ) activities performed by us and time spent for joint steering committee ( JSC ) activities. Total expected effort is generally based upon the total R&D and JSC hours incorporated into the project plan that is agreed to by both parties to the collaboration. Significant management judgments and estimates are required in determining the level of effort required under an arrangement and the period over which we expect to complete the related performance obligations. Estimates of the total expected effort included in each project plan are based on historical experience of similar efforts and expectations based on the knowledge of scientists for both the Company and its collaboration partners. The Company periodically reviews and updates the project plan for each collaborative agreement; the most recent reviews took place in January 2009. In the event that a change in estimate occurs, the change will be accounted for using the cumulative catch-up method which provides for an adjustment to revenue in the current period. Estimates of our level of effort may change in the future, resulting in a material change in the amount of revenue recognized in future periods.

Generally under collaboration arrangements, nonrefundable payments received during the period of performance may include time- or performance-based milestones. The proportion of actual performance to total expected performance is applied to the expected payments in determining periodic revenue. However, revenue is limited to the sum of (i.) the amount of nonrefundable cash payments received and (ii.) the payments that are contractually due but have not yet been paid.

*Research and Development and Clinical Trial Expenses.* Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, pre-clinical development, and clinical trials. All costs associated with research and development are expensed as incurred.

Clinical research expenses represent obligations resulting from our contracts with various research organizations in connection with conducting clinical trials for our product candidates. We account for those expenses on an accrual basis according to the progress of the trial as measured by patient enrollment and the timing of the various aspects of the trial. Accruals are recorded in accordance with the following methodology: (i) the costs for period expenses, such as investigator meetings and initial start-up costs, are expensed as incurred based on management s estimates, which are impacted by any change in the number of sites, number of patients and patient start dates; (ii) direct service costs, which are primarily ongoing monitoring costs, are recognized on a straight-line basis over the life of the contract; and (iii) principal investigator expenses that are directly associated with recruitment are recognized based on actual patient recruitment. All changes to the contract amounts due to change orders are analyzed and recognized in accordance with

the above methodology. Change orders are triggered by changes in the scope, time to completion and the number of sites. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates.

*Income Taxes.* Deferred tax liabilities and assets are recognized for the expected future tax consequences of events that have been included in the financial statements or tax returns. These liabilities and assets are determined based on differences between the financial reporting and tax basis of assets and liabilities measured

#### EMISPHERE TECHNOLOGIES, INC.

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recognized to reduce deferred tax assets to the amount that is more likely than not to be realized. In assessing the likelihood of realization, management considered estimates of future taxable income.

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109. The implementation of FIN 48 had no impact on the Company s financial statements as the Company has not recognized any uncertain income tax positions.

*Stock-Based Employee Compensation.* Beginning January 1, 2006, we account for Stock-Based Compensation in accordance with SFAS 123(R) Share-Based Payment and SAB 107. We adopted SFAS 123(R) using a modified version of prospective application, under which compensation cost is recognized for new awards or awards modified, repurchased or cancelled and only for the portion of outstanding awards for which the requisite service has not been rendered as of the adoption date. The expense related to such portion of outstanding awards upon adoption is based on the grant date fair value of those awards calculated under SFAS 123 for pro forma disclosures. SFAS 123(R) supersedes the option of accounting for share-based compensation transactions using APB Opinion No. 25,

Accounting for Stock Issued to Employees. Since we have adopted SFAS 123(R) under the modified version of prospective application, there is no restatement of prior periods. Therefore the 2008, 2007 and 2006 operations reflect a stock based compensation charge and employee stock options.

We estimate the value of stock option awards on the date of grant using the Black-Scholes-Merton option-pricing model (the Black-Scholes model ). The determination of the fair value of share-based payment awards on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, expected term, risk-free interest rate, expected dividends and expected forfeiture rates. The forfeiture rate is estimated using historical option cancellation information, adjusted for anticipated changes in expected exercise and employment termination behavior. Our outstanding awards do not contain market or performance conditions therefore we have elected to recognize share-based employee compensation expense on a straight-line basis over the requisite service period.

*Fair Value of Financial Instruments.* The carrying amounts for cash, cash equivalents, accounts payable, and accrued expenses approximate fair value because of their short-term nature. We have determined that it is not practical to estimate the fair value of our notes payable because of their unique nature and the costs that would be incurred to obtain an independent valuation. We do not have comparable outstanding debt on which to base an estimated current borrowing rate or other discount rate for purposes of estimating the fair value of the notes payable and we have not yet obtained or developed a valuation model. Additionally, we are engaged in research and development activities and have not yet developed products for sale. Accordingly, at this stage of our development, a credit risk assessment is highly judgmental. These factors all contribute to the impracticability of estimating the fair value of the notes payable. At December 31, 2008, the carrying value of the notes payable and accrued interest was \$30.2 million. See Note 7 for further discussion of the notes payable.

*Derivative Instruments.* Derivative instruments consist of common stock warrants, and certain instruments embedded in the certain Notes payable and related agreements. These financial instruments are recorded in the balance sheets at fair value as liabilities. Changes in fair value are recognized in earnings in the period of change.

*Comprehensive Loss.* Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The disclosures required by Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income for the years ended December 31, 2008, 2007 and 2006 have been included in the statements of stockholders equity (deficit).

#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

*Exit activities.* We have adopted SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as defined in Issue 94-3 was recognized at the date of an entity s commitment to an exit plan. A fundamental conclusion reached by the Board in this Statement is that an entity s commitment to a plan, by itself, does not create a present obligation to others that meets the definition of a liability. Therefore, this Statement eliminates the definition and requirements for recognition of exit costs in Issue 94-3. This Statement also establishes that fair value is the objective for initial measurement of the liability. This Statement specifies that a liability for a cost associated with an exit or disposal activity is incurred when the definition of a liability is statement also establishes that fair value is the objective for initial measurement of the liability.

Fair Value Measurements. Effective January, 2008, the Company adopted SFAS No. 157, Fair Value Measurements (SFAS 157). In February 2008, the FASB issued Staff Position (FSP) FAS 157-1 to exclude SFAS no. 13, Accounting for Leases and its related interpretive accounting pronouncements that address leasing transactions, from the scope of SFAS No. 157. In February 2008, the FASB also issued FASB Staff Position No. 157-2, Effective Date of FASB Statement 157, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, the Company has adopted the provision of SFAS 157 with respect to its financial assets and liabilities only. For the portion of SFAS 157 that has been deferred, the Company is currently evaluating the effects of SFAS 157 will have on its financial statements. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for an asset or liability in an orderly transaction between participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities

Effective January 1, 2008, the Company could have adopted SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by contract basis. The Company did not elect to adopt the fair value option under this SFAS.

#### Future Impact of Recently Issued Accounting Standards.

In June 2007, the Financial Accounting Standards Board (FASB) affirmed the conclusions of the Emerging Issues Taskforce (EITF) with respect to EITF Issue No. 07-03 Accounting for Advance Payments for Goods and Services to Be Used in Future Research and Development Activities. EITF 07-03 concluded

## **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

that non-refundable advance payments for future research and development activities pursuant to an executory contractual arrangement should be capitalized until the goods have been delivered or the related services have been performed. This EITF became effective January 1, 2008, and requires entities to recognize the effects of applying the guidance in this Issue prospectively for new contracts entered into after January 1, 2008. The adoption of EITF Issue No. 07-03 did not have a material impact on our financial position, results of operations or cash flows.

In December 2007, the FASB ratified the consensus reached by the EITF with respect to EITF Issue No. 07-01 Accounting for Collaborative Arrangements. The EITF defined collaborative arrangements and established reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This issue is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently evaluating the effects of this EITF on the Company s financial statements.

In March 2008, the FASB issued Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities . The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We have not determined the impact, if any, on future financial statements.

Effective for periods beginning on or after December 15, 2008, the FASB issued SFAS 141R, Business Combinations . SFAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. This standard requires an acquirer to recognize the assets acquired and liabilities assumed at the acquisition date fair values with limited exceptions. Additionally, FAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, that acquired in-process research and development be capitalized and recorded as intangible assets at the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. The impact of this standard will not have an impact on the Company s financial statements.

#### 4. Investments

Realized gains and losses are included as a component of investment income. In computing realized gains and losses, we determine the cost of our investments on a specific identification basis. Such cost includes the direct costs to acquire the investments, adjusted for the amortization of any discount or premium. The following is a summary of sales of investments, which resulted in a realized gain or loss:

	Amortized Cost		Realized			
	Basis	Proceeds (In th	Gains ousands)	Losses	Net	
Year ended December 31, 2008	\$	\$	\$	\$	\$	

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2007 2006		1,000	994	(6)	(6)
	62				

#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

The following is a summary of the fair value of available for sale investments:

	Amortized Cost Basis	Decemb	ber 31, 2007 Unrealized Holding					
		Fair Value (In th	Gains ousands)	Lo	DSSES	]	Net	
Maturities less than one year: Auction rate securities Corporate debt securities U.S. government securities	\$ 3,500 3,521 2,905	\$ 3,500 3,515 2,901		\$	(6) (4)	\$	(6) (4)	
	\$ 9,926	\$ 9,916		\$	(10)	\$	(10)	

The following table shows the unrealized losses and fair value of the Company s marketable securities with unrealized losses that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual security has been in a continuous loss position at December 31, 2008 and 2007. The securities listed at December 31, 2007 matured at various dates through November 2008.

	Less Than 12 Months				Aonths or Greater	Т	otal	
	Fair Value	Unrea Los		Fair Value	Unrealized Loss	Fair Value		ealized Aoss
At December 31, 2007: Corporate debt securities U.S. Government securities	\$ 3,515 2,901	\$	(6) (4)			\$ 3,515 2,901	\$	(6) (4)
	\$ 6,416	\$	(10)			\$ 6,416	\$	(10)

During 2007, the unrealized losses on our investments were primarily caused by interest rate increases, which generally resulted in a decrease in the market value of our portfolio. Changes in fair value due to interest rate changes typically diminish as the securities approach maturity. We held these securities for their full term. As a result, we did not consider these marketable securities at December 31, 2007 to be other-than-temporarily impaired.

Interest income, as well as realized gains and losses were included in investment income and are recognized as earned.

#### 5. Fixed Assets

*Tarrytown Facility.* On December 8, 2008, we decided to close our research and development facilities in Tarrytown, NY to reduce costs and improve operating efficiency. As of December 8, 2008 we had ceased using approximately 85% of the facilities which resulted in a restructuring charge of approximately \$3.8 million in the fourth quarter, 2008. As a result, the Company wrote down the value of approximately \$1.0 million (net) in leasehold improvements related to the Tarrytown facility no longer in use as of December 31, 2008. In addition, the useful lives of approximately \$0.2 million in leasehold improvements were shortened because we ceased using the facilities on January 29, 2009 resulting in an accelerated charge to amortization expense for 2008 of approximately \$0.1 million. Please refer to Footnote 16 Commitments and Contingencies for more information on this subject.

### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

Fixed Assets. Equipment and leasehold improvements, net, consists of the following:

	December 31	,		
	Useful Lives In Years		2008 (In tho	2007 ds)
Equipment	3-7	\$	9,080	\$ 9,190
Leasehold improvements	Life of lease		3,013	18,412
			12,093	27,602
Less, accumulated depreciation and amortization			11,628	25,528
		\$	465	\$ 2,074

Depreciation expense for the years ended December 31, 2008, 2007 and 2006, was \$0.7 million, \$0.8 million and \$3.6 million, respectively.

On March 1, 2007, we exercised the first extension option under the lease for our Tarrytown facility resulting in an extension of the term from August 31, 2007 to August 31, 2012. This resulted in a change in the estimated useful life of the related leasehold improvements under which the remaining net book value at January 1, 2007 will be amortized over the period through August 31, 2012. The effect of this change in useful life was to lower depreciation and amortization expense by approximately \$2.4 million in the year ended December 31, 2007 compared to the prior year.

#### 6. Purchased Technology

The carrying value of the purchased technology is comprised as follows:

	Decemb 2008 (In thou			
Gross carrying amount Less, accumulated amortization	\$ 4,533 3,217	\$ 4,533 2,978		
Net book value	\$ 1,316	\$ 1,555		

Annual amortization of purchased technology was \$239 thousand for 2008, 2007 and 2006 and is estimated to be \$239 thousand for each of the next five years.

#### 7. Accounts Payable and Accrued Expenses

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Accounts payable and accrued expenses consist of the following:

	2008	ber 31, 2007 usands)
Accounts payable and accrued expenses Severance accrual	\$ 1,539	\$ 824 1,278
Accrued legal, professional fees and other	636	454
Accrued vacation	132	301
Clinical trial expenses and contract research	54	17
	\$ 2,361	\$ 2,874

## **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

#### 8. Notes Payable and Restructuring of Debt

Notes payable consist of the following:

	Decem	December 31,		
	2008	2007		
	(In tho	usands)		
MHR Note	\$ 18,209	\$ 15,836		
Novartis Note	12,011	11,484		
	\$ 30,220	\$ 27,320		

*MHR Note.* On September 26, 2005, we received net proceeds of approximately \$12.9 million under a \$15 million secured loan agreement (the Loan Agreement ) executed with MHR Institutional Partners IIA LP (together with its affiliates, MHR). Under the Loan Agreement, MHR requested, and on May 16, 2006, we effected, the exchange of the loan from MHR for senior secured convertible notes (the Convertible Notes) with substantially the same terms as the Loan Agreement, except that the Convertible Notes are convertible, at the sole discretion of MHR, into shares of our common stock at a price per share of \$3.78. At December 31, 2008, the Convertible Notes were convertible into 5,362,596 shares of our common stock. The Convertible Notes are due on September 26, 2012, bear interest at 11% and are collateralized by a first priority lien in favor of MHR on substantially all of our assets. Interest is payable in the form of additional Convertible Notes rather than in cash and we have the right to call the Convertible Notes after September 26, 2010 if certain conditions are satisfied. Further, the Convertible Notes provide MHR with the right to require redemption in the event of a change in control, as defined, prior to September 26, 2009. Such required redemption would be at 102% of the then outstanding principal through September 26, 2008 and decreasing to 101% through September 26, 2009. Additionally, MHR was granted certain registration rights.

In connection with the Loan Agreement, we amended MHR s previously existing warrants to purchase 387,374 shares of common stock (MHR 2005 Warrants) to provide additional anti-dilution protection. We also granted MHR the option (MHR Option) to purchase warrants for up to 617,211 shares of our common stock. The MHR Option was exercised during April 2006 whereby MHR acquired 617,211 warrants (MHR 2006 Warrants) to acquire an equal number of shares of common stock. The exercise price for the MHR 2006 warrants is \$0.01 per warrant for the first 67,084 warrants and \$1.00 per warrant for each additional warrant. See Note 9 for a further discussion of the liability related to these warrants.

Total issuance costs associated with the Loan Agreement were \$2.1 million, of which \$1.9 million were allocated to the MHR Note and \$0.2 million were allocated to the related derivative instruments. Of the \$1.9 million allocated to the MHR Note, \$1.4 million represents reimbursement of MHR s legal fees and \$0.5 million represents our legal and other transaction costs. The \$1.4 million paid on behalf of the lender has been recorded as a reduction of the face value of the note, while the \$0.5 million of our costs has been recorded as deferred financing costs, which is included in other assets on the balance sheet.

The Company has calculated the fair value of the beneficial conversion feature of the Convertible Notes based on the effective conversion price after allocating a portion of the proceeds of the loan to the warrant purchase option and adjusting for financing costs paid by us on behalf of the lender. Since the calculated value for the beneficial conversion feature exceeded the net proceeds allocated to the Convertible Notes, the beneficial conversion feature was recorded at an amount equal to the net proceeds allocated to the Convertible Notes, or \$12.2 million, with a corresponding amount being recorded as additional paid-in-capital. Since MHR can convert the Convertible Notes to realize a return at any time, the beneficial conversion feature was charged to expense in January 2006, the date the Company received shareholder approval to exchange the MHR Note for the Convertible Notes.

## **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

The Convertible Notes provide MHR with the right to require us to redeem the Loan in the event of a change in control. Based on the provisions of SFAS 133, the change in control redemption feature has been determined to be an embedded derivative instrument which must be separated from the host contract. For the year ended December 31, 2006, the fair value of the change in control redemption feature was estimated using a combination of a put option model for the penalties and the Black-Scholes option pricing model for the conversion option that would exist under the Convertible Note. The estimate resulted in a value that was de minimis and therefore, no separate liability was recorded. Changes in the assumptions used to estimate the fair value of this derivative instrument, in particular the probability that a change in control will occur, could result in a material change to the fair value of the instrument. For the years ended December 31, 2008 and 2007, management determined the probability of exercise of the right due to change in control to be remote. The fair value of the change in control redemption feature is de minimis.

The book value of the MHR Note is comprised of the following:

	Dec	cember 31,
	2008	2007
	(In	thousands)
Face value of the note	\$ 20,27	0 \$ 18,168
Discount (related to the warrant purchase option)	(96	6) (1,093)
Lender s financing costs	(1,09	5) (1,239)
	\$ 18,20	9 \$ 15,836

The debt discount, lenders financing costs, deferred financing costs and amounts attributed to derivative instruments are being amortized to interest expense over the life of the Convertible Notes using an effective interest method to yield an effective interest rate of 14.3%.

In connection with the MHR financing, the Company agreed to appoint a representative of MHR (MHR Nominee) and another person (the Mutual Director) to its Board of Directors. Further, the Company agreed to amend, and in January 2006 did amend, its certificate of incorporation to provide for continuity of the MHR Nominee and the Mutual Nominee on the Board, as described therein, so long as MHR holds at least 2% of the outstanding common stock of the Company.

The Convertible Notes provide for various events of default including for failure to perfect any of the liens in favor of MHR, failure to observe any covenant or agreement, failure to maintain the listing and trading of our common stock, sale of a substantial portion of our assets, merger with another entity without the prior consent of MHR, or any governmental action renders us unable to honor or perform our obligations under the Loan Agreement or results in a material adverse effect on our operations. If an event of default occurs, the Convertible Notes provide for the immediate repayment and certain additional amounts as set forth in the Convertible Notes. We have received a waiver from MHR, through March 18, 2010 for certain defaults under the agreement.

*Novartis Note*. On December 1, 2004 we received \$10.0 million in exchange for issuance of a convertible note to Novartis (the Novartis Note ) in connection with a new research collaboration option relating to the development of PTH-1-34. The Novartis Note is convertible, at our option, at any time prior to maturity on December 1, 2009 into a number of shares of our common stock equal to the principal and accrued and unpaid interest divided by the then market price of our common stock, provided certain conditions are met. Those conditions include that the number of shares issued to Novartis does not exceed 19.9% of the total shares of our common stock outstanding, that at the time of such conversion no event of default under the Note has occurred and is continuing and that there is either an effective shelf registration statement in effect covering the resale of the shares issued in connection with such conversion or the shares may be resold by Novartis pursuant to SEC Rule 144. At December 31, 2008, the Novartis Note was convertible into 7,537,921 shares of our common stock.

#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

Until December 1, 2008, the Novartis Note initially accrued interest at a rate of 3% -5%. From that date through maturity on December 1, 2009; it bears interest at a rate of 7%. We have the option to pay interest in cash on a current basis or accrue the periodic interest as an addition to the principal amount of the Novartis Note. We are accruing interest which is being recorded using the effective interest rate method, which results in an effective interest rate of 4.6%.

The Novartis Note contains customary events of default including our failure to timely cure a default in the payment of certain other indebtedness, acceleration of certain indebtedness, we become entitled to terminate the registration of our securities or the filing of reports under the Securities Exchange Act of 1934, our common stock is no longer listed on a national exchange, we experience a change of control (including by, among other things, a change in the composition of a majority of our board (other than as approved by the board) in any one-year period, a merger which results in our stockholders holding shares that represent less than a majority of the voting power of the merged entity, and any other acquisition by a third party of shares that represent a majority of the voting power of the company), we sell substantially all of our assets, or we are effectively unable to honor or perform our obligations under the new research collaboration option relating to the development of PTH-1-34. Upon the occurrence of an event of default prior to conversion, any unpaid principal and accrued interest on the Novartis Note would become immediately due and payable. If the Novartis Note is converted into our common stock, Novartis would have the right to require us to repurchase the shares of common stock within six months after an event of default under the Novartis Note, for an aggregate purchase price equal to the principal and interest that was converted, plus interest from the date of conversion, as if no conversion had occurred.

For as long as any portion of the principal amount of this Note or any accrued and unpaid Interest thereon remains outstanding, the Issuer shall not (i) pay any dividend or otherwise make any distribution, directly or indirectly, in respect of any shares of its capital stock, other than such dividends or distributions payable solely in shares of its capital stock or (ii) except to any employee or former employee of the Issuer upon the death, disability or termination of such employee pursuant any employee stock incentive plan of the issuer or employment agreement with such employee of the Issuer, in each case as in effect on the date hereof and in an aggregate amount not to exceed \$2.0 million , make any payment, directly or indirectly, on account of the purchase, redemption, retirement or acquisition of any shares of its capital stock, or any option, warrant or other convertible or exchangeable security or other right to acquire shares of its capital stock.

The scheduled repayments of all debt outstanding as of December 31, 2008 are as follows:

	(In	Debt thousands)
2009 2010	\$	12,011
2011 2012		20,270
	\$	32,281

*Restructuring of Debt.* Ebbisham was an Irish corporation which had been formed by Elan Corporation, plc (Elan) and us to develop and market heparin products using technologies contributed by both parties. In July 1999, we acquired from Elan its ownership interest in Ebbisham in exchange for a seven year, \$20 million zero coupon note due July 2006 carrying a 15% interest rate, compounding semi-annually (the Original Elan Note), plus royalties on oral heparin product sales, subject to an annual maximum and certain milestone payments. On February 28, 2002 Ebbisham was voluntarily liquidated.

On December 27, 2004, we entered into a Security Purchase Agreement with Elan, providing for our purchase of our indebtedness to Elan under the Original Elan Note. The value of the Original Elan Note plus

## **EMISPHERE TECHNOLOGIES, INC.**

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

accrued interest on December 27, 2004 was \$44.2 million. Pursuant to the Security Purchase Agreement, we paid Elan \$13 million and issued to Elan 600,000 shares of our common stock with a market value of \$2 million. Also, we issued to Elan a new zero coupon note with an issue price of \$29.2 million (the Modified Elan Note ), representing the accrued value of the Original Elan Note minus the sum of the cash payment and the value of the 600,000 shares.

As of March 31, 2005, we issued to Elan a warrant to purchase up to 600,000 shares of our common stock at an exercise price of \$3.88. The warrants provide for certain anti-dilution protection. On April 1, 2005, we made a \$13 million payment to Elan, which completed the repurchase of our indebtedness to Elan. This transaction was accounted for as a troubled debt restructuring. The carrying amount of the debt was reduced to an amount equal to the total cash payments, or \$13 million. The fair value of the warrant issued, estimated using the Black-Scholes option pricing model, was \$1.6 million at the date of issuance. As such, a gain of \$14.7 million, calculated as the difference between the carrying value of approximately \$29 million and the fair value of cash paid and warrants issued, was recognized in our consolidated statement of operations for 2005. Under the accounting for a restructuring of debt, no interest expense was recorded during 2005. As of December 31, 2008 the 600,000 warrants remain outstanding and expire on September 30, 2010.

### 9. Derivative Instruments

Derivative instruments consist of the following:

	2008	nber 31, 2007 pusands)
March 2005 equity financing warrants MHR warrants August 2007 equity financing warrants	\$ 31 115 121	\$ 1,163 764 560
	\$ 267	\$ 2,487

*March 2005 Equity Financing Warrants*. In connection with the March 2005 offering, Emisphere sold warrants to purchase 1.5 million shares of common stock to MHR and other unrelated investors. The warrants were originally issued with an exercise price of \$4.00 and expire on March 31, 2010. The warrants provide for certain anti-dilution protection as provided therein. Warrants to purchase up to 967,464 shares of common stock provide that under no circumstances will the adjusted exercise price be less than \$3.81. The remaining warrants do not limit adjustments to the exercise price. The anti-dilution feature of the warrants was triggered in connection with the August 2007 financing, resulting in an increase to the warrant shares of 4,838, as well as an adjustment to the exercise price. At December 31, 2008, we have outstanding warrants to purchase up to 1,354,838 shares of common stock. The adjusted exercise price for 967,464 of the warrants, we have an obligation to make a cash payment to the holders of the warrants for any gain that could have been realized if the holders exercise the warrants and we subsequently fail to deliver a certificate representing the shares to be issued upon such exercise by the third trading day after such warrants have

been exercised. Accordingly, the warrants have been accounted for as a liability. The fair value of the warrants is estimated, at the end of each quarterly reporting period, using the Black-Scholes option pricing model. The assumptions used in computing the fair value as of December 31, 2008 are a closing stock price of \$0.79, expected volatility of 80.78% over the remaining term of one year and three months and a risk-free rate of 0.76%. The fair value of the warrants decreased by \$1.1 million and \$3.0 million and increased \$0.2 million for the years ended December 31, 2008, 2007 and 2006, respectively, and the fluctuation has been recorded in the statement of operations. In October 2006, 150,000 of these warrants were exercised. The Company realized proceeds of \$0.6 million related to the exercise of the warrants, and as a result, the related liability was reclassified as equity. The fair value of the warrants that were exercised increased by \$0.6 million from the period between

### EMISPHERE TECHNOLOGIES, INC.

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

January 1, 2006 and the exercise. The warrants will be adjusted to estimated fair value for each future period they remain outstanding.

MHR Warrants (MHR 2006 Warrants). In connection with the exercise in April 2006 of the MHR Option discussed in Note 8 above, the Company issued warrants for 617,211 shares to MHR for proceeds of \$0.6 million. The MHR 2006 Warrants have an original exercise price of \$4.00 and are exercisable through September 26, 2011. The MHR 2006 Warrants have the same terms as the August 2007 equity financing warrants (see below), with no limit upon adjustments to the exercise price. The anti-dilution feature of the MHR 2006 Warrants was triggered in connection with the August 2007 equity financing, resulting in an adjusted exercise price of \$3.76. Based on the provisions of SFAS 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133), the MHR 2006 Warrants have been determined to be an embedded derivative instrument which must be separated from the host contract. The MHR 2006 Warrants contain the same potential cash settlement provisions as the August 2007 equity financing warrants and therefore they have been accounted for as a separate liability. The fair value of the warrants is estimated, at the end of each quarterly period, using the Black-Scholes option pricing model. The assumptions used in computing the fair value as of December 31, 2008 are a closing stock price of \$0.79, expected volatility of 93.91% over the remaining term of two years and nine months and a risk-free rate of .97%. The fair value of the MHR 2006 Warrants decreased by \$0.7 million and \$1.6 million for the years ended December 31, 2008 and 2007, respectively, and increased by \$0.4 million for the year ended December 31, 2006 and the fluctuation has been recorded in the statement of operations. The MHR 2006 Warrants will be adjusted to estimated fair value for each future period they remain outstanding. See Note 8 for a further discussion of the MHR Note.

*August 2007 Equity Financing Warrants.* In connection with the August 2007 offering, Emisphere sold warrants to purchase up to 400,000 shares of common stock. Of these 400,000 warrants, 91,073 were sold to MHR. Each of the warrants were issued with an exercise price of \$3.948 and expire on August 21, 2012. The warrants provide for certain anti-dilution protection as provided therein. Under the terms of the warrants, we have an obligation to make a cash payment to the holders of the warrants for any gain that could have been realized if the holders exercise the warrants and we subsequently fail to deliver a certificate representing the shares to be issued upon such exercise by the third trading day after such warrants have been exercised. Accordingly, the warrants have been accounted for as a liability. The fair value of the warrants were accounted for with an initial value of \$1.0 million on August 22, 2007. The assumptions used in computing the fair value as of December 31, 2008 are a closing stock price of \$0.79, expected volatility of 100.87% over the remaining term of three years and eight months and a risk-free rate of 1.55%. The fair value of the warrants decreased by \$0.4 million for the year ended December 31, 2008 and \$0.5 million for the period between August 22, 2007 and December 31, 2007 and the fluctuations have been recorded in the statements of operations. The warrants will be adjusted to estimated fair value for each future period they remain outstanding.

*Kingsbridge Warrant.* On December 27, 2004, we entered into a Common Stock Purchase Agreement (the Common Stock Purchase Agreement ) with Kingsbridge, providing for the commitment of Kingsbridge to purchase up to \$20.0 million of our common stock until December 27, 2006. In return for the commitment, we issued to Kingsbridge a warrant to purchase 250,000 shares of our common stock at an exercise price of \$3.811 (representing a premium to the market price of shares of our common stock on the date of issuance of the warrant) together with certain registration rights. On September 21, 2005, the Common Stock Purchase Agreement was terminated as a condition of closing the Loan Agreement with MHR. In January 2006, Kingsbridge exercised all of the warrants for proceeds of approximately \$1.0 million, and as a result, the related liability was reclassified as equity. The fair value of the

warrants increased by \$0.2 million from the period between January 1, 2006 and the exercise and sale of all shares, and this increase is included in the statement of operations.

## **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

#### 10. Income Taxes

Since the Company has recurring losses and a full valuation allowance against deferred tax assets, there is no tax expense (benefit) for all periods presented.

As of December 31, 2008, we have available unused federal net operating loss (NOL) carry-forwards of \$331.5 million and New York NOL carry-forwards of \$320.8 million, of which \$7.6 million, \$5.7 million and \$4.4 million will expire in 2009, 2010 and 2011, respectively, with the remainder expiring in various years from 2012 to 2028. We have New Jersey NOL carry-forwards of \$29.4 million, which will expire in 2014 and 2015. We have research and development tax credit carry-forwards which will expire in various years from 2009 through 2028.

The effective rate differs from the statutory rate of 34% for 2008 and 2007 primarily due to the following:

	2008	2007
Statutory rate on pre-tax book loss	(34.00)%	(34.00)%
Stock option issuance	0.32%	5.71%
Disallowed interest	0.93%	1.17%
Derivatives	(3.09)%	(10.16)%
Research and experimentation tax credit	(0.71)%	(1.44)%
Expired net operating losses and credits	12.12%	14.03%
Other	0.04%	1.38%
Change in federal valuation allowance	24.39%	23.31%
	0.00%	0.00%

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2008 and 2007 is as follows:

	December 2008 (In thousands)		er 31, 2007	
Deferred tax assets and valuation allowance: Current deferred tax asset: Accrued liabilities Valuation Allowance	\$	240 (240)	\$ 271 (271)	
Net current deferred tax asset	\$		\$	

Noncurrent deferred tax assets:		
Fixed and intangible assets	\$ 5,709	\$ 5,544
Net operating loss carry-forwards	114,516	130,163
Capital loss and charitable carry-forwards	2,795	2,783
Research and experimental tax credits	12,559	12,940
Stock compensation	462	149
Deferred Revenue	4,551	
Interest	1,737	1,026
Valuation allowance	(142,329)	(152,605)
Net noncurrent deferred tax asset	\$	\$

## **EMISPHERE TECHNOLOGIES, INC.**

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

Future ownership changes may limit the future utilization of these net operating loss and research and development tax credit carry-forwards as defined by the Internal Revenue Code. The amount of any potential limitation is unknown. The net deferred tax asset has been fully offset by a valuation allowance due to our history of taxable losses and uncertainty regarding our ability to generate sufficient taxable income in the future to utilize these deferred tax assets.

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109. The implementation of FIN 48 had no impact on the Company s financial statements as the Company has not recognized any uncertain income tax positions.

#### 11. Stockholders Deficit

On April 20, 2007, the stockholders of the Company approved an increase in the Company s authorized common stock from 50 million to 100 million shares.

On August 22, 2007, we completed the sale of two million registered shares of common stock at \$3.785 per share. Proceeds from this offering were \$6.9 million, net of total issuance costs of \$0.7 million, which will be used for general corporate purposes. As the shares of stock were sold in connection with warrants, \$5.9 million was allocated to the issuance of the stock and \$1.0 million was allocated to the warrants.

Our certificate of incorporation provides for the issuance of 1,000,000 shares of preferred stock with the rights, preferences, qualifications, and terms to be determined by our Board of Directors. As of December 31, 2008 and 2007, there were no shares of preferred stock outstanding.

We have a stockholder rights plan in which Preferred Stock Purchase Rights (the Rights ) have been granted at the rate of one one-hundredth of a share of Series A Junior Participating Cumulative Preferred Stock ( A Preferred Stock ) at an exercise price of \$80 for each share of our common stock. The Rights expire on April 7, 2016.

The Rights are not exercisable, or transferable apart from the common stock, until the earlier of (i) ten days following a public announcement that a person or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of our outstanding common stock or (ii) ten business days (or such later date, as defined) following the commencement of, or announcement of an intention to make a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person, or group, of 20% or more of our outstanding common stock. MHR is specifically excluded from the provisions of the plan.

Furthermore, if we enter into consolidation, merger, or other business combinations, as defined, each Right would entitle the holder upon exercise to receive, in lieu of shares of A Preferred Stock, a number of shares of common stock of the acquiring company having a value of two times the exercise price of the Right, as defined. The Rights contain anti-dilutive provisions and are redeemable at our option, subject to certain defined restrictions for \$.01 per Right.

As a result of the Rights dividend, the Board of Directors designated 200,000 shares of preferred stock as A Preferred Stock. A Preferred Stockholders will be entitled to a preferential cumulative quarterly dividend of the greater of \$1.00 per share or 100 times the per share dividend declared on our common stock. Shares of A Preferred Stock have a liquidation preference, as defined, and each share will have 100 votes and will vote together with the common shares.

## 12. Stock-Based Compensation Plans

Total compensation expense recorded during the years ended December 31, 2008, 2007 and 2006 for share-based payment awards was \$1.0 million, \$3.1 million and \$1.6 million, respectively, of which \$0.4 million, \$1.4 million and \$0.9 million is recorded in research and development and \$0.6 million,

## **EMISPHERE TECHNOLOGIES, INC.**

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

\$1.7 million and \$0.7 million is recorded in general and administrative expenses in the statement of operations. Included in compensation expense during the year ended December 31, 2007 are incremental costs of \$0.8 million resulting from the modification of previously granted stock option awards for 4 former executives. Under the terms of the separation agreements with these executives, certain option grants received accelerated vesting, extended exercise period or both.

At December 31, 2008, total unrecognized estimated compensation expense related to non-vested stock options granted prior to that date was approximately \$1.6 million, which is expected to be recognized over a weighted-average period of 2.1 years. No tax benefit was realized due to a continued pattern of operating losses. We have a policy of issuing new shares to satisfy share option exercises. Cash received from options exercised totaled \$0.01 million, \$0.4 million and \$2.1 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Using the Black-Scholes model, we have estimated our stock price volatility using the historical volatility in the market price of our common stock for the expected term of the option. The risk-free interest rate is based on the yield curve of U.S. Treasury STRIP securities for the expected term of the option. We have never paid cash dividends and do not intend to pay cash dividends in the foreseeable future. Accordingly, we assumed a 0% dividend yield. The forfeiture rate is estimated using historical option cancellation information, adjusted for anticipated changes in expected exercise and employment termination behavior. Forfeiture rates and the expected term of options are estimated separately for groups of employees that have similar historical exercise behavior. The ranges presented below are the result of certain groups of employees displaying different behavior.

The following weighted-average assumptions were used for grants made under the stock option plans for the years ended December 31, 2008, 2007 and 2006:

	2008			
	Directors	Executives	Employees	
Expected volatility	84.9%	85.0%	85.0%	
Expected term	10 years	10 years	10 years	
Risk-free interest rate	3.89%	3.89%	3.89%	
Dividend yield	0%	0%	0%	
Annual forfeiture rate	5%	5%	5%	

	2007			
	Directors		Employees	
Expected volatility	84.9%	82.9%	83.0%	
Expected term	5 years	10 years	5.5 years	
Risk-free interest rate	4.28%	4.82%	4.62%	
Dividend yield	0%	0%	0%	
Annual forfeiture rate	0%	0%	5%	

	200	2006		
	Directors	Employees		
Expected volatility	73.7%	82.9%		
Expected term	0.5 years	5.5 years		
Risk-free interest rate	4.8%	4.54%		
Dividend yield	0%	0%		
Annual forfeiture rate	0%	5%		
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## EMISPHERE TECHNOLOGIES, INC.

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

*Stock Option Plans.* On April 20, 2007, the stockholders approved the 2007 Stock Award and Incentive Plan (the 2007 Plan ). The 2007 Plan provides for grants of options, stock appreciation rights, restricted stock, deferred stock, bonus stock and awards in lieu of obligations, dividend equivalents, other stock based awards and performance awards to executive officers and other employees of the Company, and non-employee directors, consultants and others who provide substantial service to us. The 2007 Plan provides for the issuance of 3,275,334 shares as follows: 2,500,000 new shares, 374,264 shares remaining and transferred from the Company s 2000 Stock Option Plan (the 2000 Plan ) (which was then replaced by the 2007 Plan) and 401,070 shares remaining and transferred from the Company s 2000 Stock Option Plan (the 2000 Plan ) in cash, settled by delivery of fewer shares than the number underlying the award, or otherwise terminated under the 2000 Plan will become available for issuance under the 2007 Plan, once registered. As of December 31, 2008 2,757,859 shares remain available for issuance under the 2007 Plan. Generally, the options vest at the rate of 20% per year and expire within a five-to-ten-year period, as determined by the compensation committee of the Board of Directors and as defined by the Plans.

The Company s other active Stock Option Plan is the 2002 Broad Based Plan (the 2002 Plan ). Under the 2002 Plan, a maximum of 160,000 shares are authorized for issuance to employees in the form of either incentive stock options (ISOs), as defined by the Internal Revenue Code, or non-qualified stock options, which do not qualify as ISOs. As of December 31, 2008, 109,644 shares remain available for issuance under the 2002 Plan.

The Company also has grants outstanding under various expired and terminated Stock Option Plans, including the 1991 Stock Option Plan (the 1991 Plan ), the 1995 Non-Qualified Stock Option Plan (the 1995 Plan ) and the 2000 Stock Option Plan (the 2000 Plan ). Under our 1991, 1995 and 2000 Plans a maximum of 2,500,000, 2,550,000 and 1,945,236 shares of our common stock, respectively, were available for issuance. The 1991 Plan was available to employees and consultants; the 2000 Plan was available to employees, directors and consultants. The 1991 Plan and 2000 Plan provide for the grant of either incentive stock options (ISOs ), as defined by the Internal Revenue Code, or non-qualified stock options, which do not qualify as ISOs. The 1995 Plan provides for grants of non-qualified stock options to officers and key employees. Generally, the options vest at the rate of 20% per year and expire within a five-to ten-year period, as determined by the compensation committee of the Board of Directors and as defined by the Plans.

#### EMISPHERE TECHNOLOGIES, INC.

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

Transactions involving stock options awarded under the Stock Option Plans described above during the years ended December 31, 2007 and 2006 are summarized as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	In	gregate trinsic /alue (In usands)
Outstanding at December 31, 2005	3,799,513	\$ 16.65			
Granted	241,305	\$ 5.99			
Expired	(30,342)	\$ 12.69			
Forfeited	(119,397)	\$ 5.70			
Exercised	(84,067)	\$ 4.24		\$	396
Outstanding at December 31, 2006	3,807,012	\$ 16.63	4.3		
Granted	1,514,735	\$ 4.55			
Expired	(2,041,125)	\$ 21.29			
Forfeited	(381,696)	\$ 4.30			
Exercised	(31,050)	\$ 1.56		\$	89
Outstanding at December 31, 2007	2,867,876	\$ 8.73	6.4		
Granted	133,600	\$ 2.84			
Expired	(300,087)	\$ 12.72			
Forfeited	(664,385)	\$ 8.75			
Exercised	(4,150)	\$ 3.04		\$	3
Outstanding at December 31, 2008	2,032,854	\$ 8.30	6.7		
Vested and exercisable at December 31,					
2008	1,281,786	\$ 10.29	5.9	\$	
Vested and expected to vest at December 31, 2008	1,985,534	\$ 8.26	6.8	\$	
,	, , -	-		•	

The weighted-average grant date fair value of options granted during the years ended December 31, 2008, 2007 and 2006 was \$2.16, \$3.15 and \$4.25, respectively.

*Outside Directors Plan.* We previously issued options to outside directors who are neither officers nor employees of Emisphere nor holders of more than 5% of our common stock under the Stock Option Plan for Outside Directors (the Outside Directors Plan). As amended, a maximum of 725,000 shares of our common stock were available for issuance

under the Outside Directors Plan in the form of options and restricted stock. The outside Directors Plan expired on January 29, 2007. Options and restricted stock are now granted to directors under the 2007 Plan discussed above.

#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

Transactions involving stock options awarded under the Outside Directors Plan during the years ended December 31, 2008, 2007 and 2006 are summarized as follows:

	Number of Shares	Weighted Average Exercise Price		Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2005 Granted Exercised	240,000 25,460 (88,460)	\$ \$ \$	11.21 7.40 5.69		\$86
Outstanding at December 31, 2006 Expired	177,000 (21,000)	\$ \$	13.42 13.75		
Outstanding at December 31, 2007	156,000	\$	13.38	5.0	
Outstanding at December 31, 2008	156,000	\$	13.38	4.0	
Vested and Exercisable at December 31, 2008	156,000	\$	13.38	4.0	\$

The weighted-average grant date fair value of options granted during the year ended December 31, 2006 was \$1.94.

*Directors Deferred Compensation Stock Plan.* The Directors Deferred Compensation Stock Plan (the Directors Deferred Plan ) ceased as of May 2004. Under the Director s Deferred Plan, directors who were neither officers nor employees of Emisphere had the option to elect to receive one half of the annual Board of Directors retainer compensation, paid for services as a Director, in deferred common stock. An aggregate of 25,000 shares of our common stock has been reserved for issuance under the Directors Deferred Plan. During the years ended December 31, 2004 and 2003, the outside directors earned the rights to receive an aggregate of 1,775 shares and 2,144 shares, respectively. Under the terms of the Directors Deferred Plan, shares are to be issued to a director within six months after he or she ceases to serve on the Board of Directors. We recorded as an expense the fair market value of the common stock issuable under the plan. As of December 31, 2008, there are 3,122 shares issuable under this plan. No grants were awarded in 2008, 2007 and 2006, and none were outstanding as of December 31, 2008.

*Non-Plan Options*. Our Board of Directors has granted options (Non-Plan Options) which are currently outstanding for the accounts of two consultants. The Board of Directors determines the number and terms of each grant (option exercise price, vesting, and expiration date).

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#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

Transactions involving awards of Non-Plan Options during the year ended December 31, 2008, 2007 and 2006 are summarized as follows:

	Number of Shares	Weighted Average Exercise Price		Weighted Average Remaining Contractual Term in Years	]	aggregate Intrinsic Value (In nousands)
Outstanding at December 31, 2005 Exercised	50,000 30,000	\$ \$	8.86 4.88		\$	117
Outstanding at December 31, 2006	20,000	\$	14.84	5.3		
Outstanding at December 31, 2007	20,000	\$	14.84	4.3		
Outstanding at December 31, 2008 Vested and Exercisable at December 31, 2008	20,000 20,000	\$ \$	14.84 14.84	3.3 3.3	\$	

*Employee Stock Purchase Plans.* We also previously granted options under two employee stock purchase plans (the Purchase Plans ) the 1994 Employee Stock Purchase Plan (the Qualified Plan ) and the 1994 Non-Qualified Employee Stock Purchase Plan (the Non-Qualified Plan ). These plans were terminated effective October 31, 2006. The Purchase Plans provided for the grant to qualified employees of options to purchase our common stock. These options were granted for dollar amounts of up to 15% of an employee s quarterly compensation. The exercise price per share was equal to the lesser of the fair market value of our common stock on the date of grant or 85% of the fair market value on the date of exercise. Options were granted automatically on February 1, May 1, August 1, and November 1 and expired six months after the date of grant. The Qualified Plan was not available for employees owning more than 5% of our common stock and imposes certain other quarterly limitations on the option grants. Options under the Non-Qualified Plan were granted to the extent that the option grants are restricted under the Qualified Plan. The Purchase Plans provided for the issuance of up to 1,500,000 shares of our common stock under the Qualified Plan and 200,000 shares under the Non-Qualified Plan.

The financial statement impact of Purchase Plans for all periods presented is not material.

## 13. Collaborative Research Agreements

We are a party to collaborative agreements with corporate partners to provide development and commercialization services relating to the collaborative products. These agreements are in the form of research and development collaboration and licensing agreements. In connection with these agreements, we have granted licenses or the rights to obtain licenses to our oral drug delivery technology. In return, we are entitled to receive certain payments upon the

achievement of milestones and will receive royalties on sales of products should they be commercialized. Under these agreements, we are entitled to also be reimbursed for research and development costs. We also have the right to manufacture and supply delivery agents developed under these agreements to our corporate partners.

We also perform research and development for others pursuant to feasibility agreements, which are of short duration and are designed to evaluate the applicability of our drug delivery agents to specific drugs. Under the feasibility agreements, we are generally reimbursed for the cost of work performed.

All of our collaborative agreements are subject to termination by our corporate partners without significant financial penalty to them. Milestone and upfront payments received in connection with these agreements was \$11.4 million, \$2 million and \$6.5 million in the years ended December 31, 2008, 2007 and 2006, respectively. Expense reimbursements received in connection with these agreements was \$1.3 million,

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## **EMISPHERE TECHNOLOGIES, INC.**

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

\$1.9 million and \$0.5 million for the years ended December 31, 2008, 2007 and 2006, respectively. Expenses incurred in connection with these agreements and included in research and development were \$0.1 million, \$0.6 million and \$0.3 million in the years ended December 31, 2008, 2007 and 2006, respectively. Significant agreements are described below.

*Novartis Pharma AG.* In September 2004, we entered into a licensing agreement with Novartis to develop our oral recombinant human growth hormone ( rhGH ) program. Under this collaboration, we are working with Novartis to initiate clinical trials of a convenient oral human growth hormone product using the Eligen<sup>®</sup> Technology. In November 2004, we received a non-refundable upfront payment of \$1 million. On May 3, 2006, we received a \$5 million payment from Novartis for development commencement. We may receive up to \$28 million in additional milestone payments during the course of product development, and royalties based on sales.

In December 2004, we entered into an agreement with Novartis whereby Novartis obtained an option to license our existing technology to develop oral forms of parathyroid hormone (PTH-1-34). On March 7, 2006, Novartis exercised its option to the license. Based on the terms of the agreement, we are eligible for milestone payments totaling up to a maximum of \$30 million, plus royalties on sales of product developed using our Eligen<sup>®</sup> Technology.

In December 1997, we entered into a collaboration agreement with Novartis to develop an oral salmon calcitonin (sCT), currently used to treat osteoporosis. In February 2000, Novartis agreed to execute its option to acquire an exclusive license to develop and commercialize oral sCT and as a result, Novartis made a \$2 million milestone payment to us. In March 2000, Novartis paid us \$2.5 million to obtain the license to our technology for sCT, and to obtain an option to use the Eligen® Technology for a second compound. Novartis rights to certain financial terms concerning the second compound have since expired. In February 2003, we announced favorable results of a Phase IIa study conducted by Novartis evaluating the performance in post-menopausal women of an oral tablet form of salmon calcitonin for the treatment of osteoarthritis. In February 2007, Novartis and its development partner Nordic Bioscience notified us of the initiation of a Phase III clinical trial for the treatment of osteoporosis with an oral form of salmon calcitonin (referred to as SMC021), a new drug candidate, using the Company s Eligefi Technology. As a result of the initiation of the trial, Emisphere received a milestone payment from Novartis of \$2 million as well as reimbursement for approximately \$0.7 million in costs. The \$2.7 million was able to be recognized when received as we have met the requirements under our revenue recognition policy. Under the terms of the agreement, we may receive up to \$5 million in additional milestone payments.

## Novo Nordisk A/S Agreement

On June 21, 2008, we entered into an exclusive Development and License Agreement with Novo Nordisk pursuant to which Novo Nordisk will develop and commercialize oral formulations of Novo Nordisk proprietary products in combination with Emisphere carriers. Under such agreement Emisphere could receive more than \$87.0 million in contingent product development and sales milestone payments including a \$10.0 million non-refundable license fee which was received during June 2008. Emisphere would also be entitled to receive royalties in the event Novo Nordisk commercializes products developed under such agreement. Under the terms of the agreement, Novo Nordisk is responsible for the development and commercialization of the products. Initially Novo Nordisk is focusing on the development of oral formulations of its proprietary GLP-1 receptor agonists.

The agreement with Novo Nordisk includes multiple deliverables including the license grant, several versions of the Company s Eligen Technology (or carriers), support services and manufacturing. Emisphere management reviewed the relevant terms of the Novo Nordisk agreement and determined that such deliverables should be accounted for as a single unit of accounting in accordance with the Emerging Issues Taskforce

## **EMISPHERE TECHNOLOGIES, INC.**

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21) since the delivered license and Pligen Technology do not have stand-alone value and Emisphere does not have objective evidence of fair value of the undelivered Eligen® Technology or the manufacturing value of all the undelivered items. Such conclusion will be reevaluated as each item in the arrangement is delivered. Consequently any payments received from Novo Nordisk pursuant to such agreement, including the initial \$10 million upfront payment and any payments received for support services, will be deferred and included in Deferred Revenue within our balance sheet. Management cannot currently estimate when all of such deliverables will be delivered nor can they estimate when, if ever, Emisphere will have objective evidence of the fair value for all of the undelivered items, therefore all payments from Novo Nordisk are expected to be deferred for the foreseeable future.

As of December 31, 2008 total deferred revenue from the agreement was \$11.2 million, comprised of the \$10.0 million non-refundable license fee and \$1.2 million in support services.

*Genta.* In March 2006, we entered into a collaborative agreement with Genta, Incorporated (Genta) to develop an oral formulation of a gallium-containing compound. We currently receive reimbursements from Genta for the work performed during the formulation phase. We have recognized \$0.1 million and \$1.2 million in revenue related to these reimbursements for the years ended December 31, 2008 and 2007, respectively. We are eligible for future milestone payments totaling up to a maximum of \$24.3 million under this agreement.

## 14. Defined Contribution Retirement Plan

We have a defined contribution retirement plan (the Retirement Plan ), the terms of which, as amended, allow eligible employees who have met certain age and service requirements to participate by electing to contribute a percentage of their compensation to be set aside to pay their future retirement benefits, as defined by the Retirement Plan. We have agreed to make discretionary contributions to the Retirement Plan. For the years ended December 31, 2008, 2007 and 2006, we made contributions to the Retirement Plan totaling approximately \$162 thousand, \$327 thousand and \$368 thousand, respectively.

## **15.** Net Loss Per Share

The following table sets forth the information needed to compute basic and diluted earnings per share for the years ended December 31, 2008, 2007 and 2006:

	Year Ended December 31,								
	2008		2007			2006			
	(In thousands, except per share amounts)								
Basic net loss Dilutive securities:	\$	(24,388)	\$	(16,928)	\$	(41,766)			
Warrants				(5,061)					
Diluted net loss	\$	(24,388)	\$	(21,989)	\$	(41,766)			

Weighted average common shares outstanding Dilutive securities: Warrants	3	0,337,442	29	,039,101 88,911	26	26,474,072		
Diluted average common stock equivalents outstanding	3	0,337,442	20	,128,012	26,474,072			
Difuted average common stock equivalents outstanding	common stock equivalents outstanding 50,53		29	,120,012	20,474,072			
Basic net loss per share	\$	(0.80)	\$	(0.58)	\$	(1.58)		
Diluted net loss per share	\$	(0.80)	\$	(0.76)	\$	(1.58)		
	78							

### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

The following table sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share because their effect was anti-dilutive:

	Year Ended December 31,						
	2008	2007	2006				
Options to purchase common shares	2,208,854	3,043,876	4,079,155				
Outstanding warrants and options to purchase warrants	2,972,049	604,838	2,567,211				
Novartis convertible note payable	7,537,921	3,743,700	2,050,785				
MHR note payable	5,362,596	4,806,404	4,307,899				
	18,081,420	12,198,818	13,005,050				

#### 16. Commitments and Contingencies

*Commitments.* We currently lease office and laboratory space located at 765 Old Saw Mill River Road, Tarrytown, NY 10591, under a non-cancelable operating lease expiring in 2012 as well as office space in Cedar Knolls, NJ under a non-cancelable operating lease expiring in 2013. The present value of this rent obligation was a contributing factor in estimating the restructuring charge in connection with closing our laboratory facilities in Tarrytown. Although the Company intends to sublease its laboratory and related space in Tarrytown, it is still obligated to make these future rental payments under the terms of its lease agreement with the landlord. As of December 31, 2008, future minimum rental payments are as follows:

Years Ending December 31,	(In thousands)
2009	2,471
2010	2,478
2011	2,486
2012	1,782
2013	31
Total	9,248

Rent expense for the years ended December 31, 2008, 2007 and 2006 was \$2.3 million, \$2.0 million and \$1.4 million, respectively. Additional charges under this lease for real estate taxes and common maintenance charges for the years ended December 31, 2008, 2007 and 2006, were \$0.8 million, \$0.8 million and \$1.1 million, respectively. The lease for our principal executive, administrative and laboratory facilities was set to expire on August 31, 2007. On March 1, 2007, we exercised the first extension option under the existing lease for our premises for a term of five years.

Of the approximately 80,000 square feet at Tarrytown, approximately 2,275 square feet of space is subleased to PsychoGenics, Inc. and approximately 16,000 square feet of space is subleased to Regeneron Pharmaceuticals, Inc.. The sublease with Psychogenics is set to expire on August 31, 2012 and the sublease with Regeneron is set to expire at March 31, 2010. Regeneron has the option to extend their sublease through September 30, 2010. During the year ended December 31, 2008, we received approximately \$0.1 million from PsychoGenics, Inc. and \$0.2 million from Regeneron Pharmaceuticals, Inc. in rent payments.

#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

Future rent payments for the space under sublease in Tarrytown:

Years Ending December 31,	(In thousands)
2009	441
2010	142
2011	60
2012	40
Total	683

In accordance with the lease agreement in Cedar Knolls, NJ, the Company has entered into a standby letter of credit in the amount of \$246 thousand as a security deposit. The standby letter of credit is fully collateralized with a time certificate of deposit account in the same amount. The certificate of deposit has been recorded as a restricted cash balance in the accompanying financials. As of December 31, 2008, there are no amounts outstanding under the standby letter of credit.

On April 6, 2007, the Board of Directors appointed Michael V. Novinski to the position of President and Chief Executive Officer. Pursuant to his appointment, the Company has entered into a three year employment agreement with Mr. Novinski. If Mr. Novinski s contract is terminated without cause by the Board of Directors or at any time by the executive for good reason as defined in his contract, we are obligated to make severance payments to Mr. Novinski.

In April 2005, the Company entered into an employment contract with its then Chief Executive Officer, Dr. Michael M. Goldberg, for services through July 31, 2007. On January 16, 2007, the Board of Directors terminated Dr. Goldberg s services. On April 26, 2007, the Board of Directors held a special hearing at which it determined that Dr. Goldberg s termination was for cause. On March 22, 2007, Dr. Goldberg, through his counsel, filed a demand for arbitration asserting that his termination was without cause and seeking \$1,048,000 plus attorney s fees, interest, arbitration costs and other relief alleged to be owed to him in connection with his employment agreement with the Company. Dr. Goldberg s employment agreement provides, among other things, that in the event he is terminated without cause, Dr. Goldberg would be paid his base salary plus bonus, if any, monthly for a severance period of eighteen months or, in the event of a change of control, twenty-four months, and he would also be entitled to continued health and life insurance coverage during the severance period and all unvested stock options and restricted stock awards would immediately vest in full upon such termination. Dr. Goldberg s employment agreement provided that in the event he is terminated with cause, he will receive no additional compensation. During the year ended December 31, 2007, the Company accrued the estimated costs to settle this matter. No settlement has been reached and the dispute continues. In February 2008, the Company received \$0.5 million as a result of a cancellation of a split dollar life insurance policy on Dr. Goldberg. Dr. Goldberg claimed approximately \$0.2 million was due him as a return of policy premium. In June 2008, Dr. Goldberg commenced a separate lawsuit in the New York State Supreme Court (New York County) claiming that the Company breached his employment agreement by not remitting to Dr. Goldberg that portion of the cash value of the life insurance policy. During the year ended December 31, 2008, the Company adjusted its accrual to reflect estimated costs to settle this matter accordingly. On January 29, 2009, after

transfer from the New York State Supreme Court (New York County) to an independent arbitrator, the Company received a finding from such arbitrator awarding a partial summary judgment to Dr. Goldberg for compensatory damages in an amount equal to \$240,101. The company paid Dr. Goldberg such amount on February 5, 2009. All remaining claims were deferred by the Arbitrator pending further proceedings between the parties. The Company believes the remaining claims are without merit and will vigorously defend itself against Dr. Goldberg s claims. The ultimate cost to resolve this matter could be in excess of the amount provided for and such amount could be material to the Company.

## EMISPHERE TECHNOLOGIES, INC.

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

The Company has made an accrual of costs estimated to settle this matter. However, it is impossible to predict with certainty the ultimate impact the resolution of this matter will have on our financial statements. It is possible that additional costs could be incurred to resolve the matter and such costs could be material. The ultimate resolution could have a material adverse impact on our financial statements.

On August 18, 2008, Emisphere filed a complaint in the United States District Court for the District of New Jersey against Laura A. Kragie and Kragie BioMedWorks, Inc. seeking a declaratory judgment affirming Emisphere s sole rights to its proprietary technology for the oral administration of Vitamin B12, as set forth in several Emisphere United States provisional patent applications. The complaint also includes a claim under the Lanham Act arising from statements made by defendants on their web site. Laura A. Kragie, M.D., is a former consultant for Emisphere who later was employed by Emisphere. On February 13, 2009, the defendants filed an answer, affirmative defenses and counterclaims, adding as counterclaim defendants current or former Emisphere executives or employees, including Michael V. Novinski. The countersuit against Emisphere alleges breach of contract, fraudulent inducement, trademark infringement, false advertising, and other claims. Emisphere believes that the counterclaims are without merit, and will litigate all claims vigorously. At the current time, we are unable to estimate a loss, if any, that may result from the resolution of this matter.

The Company evaluates the financial consequences of legal actions periodically or as facts present themselves and books accruals to account for its best estimate of future costs accordingly.

*Contingencies.* In the ordinary course of business, we enter into agreements with third parties that include indemnification provisions which, in our judgment, are normal and customary for companies in our industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally agree to indemnify, hold harmless, and reimburse indemnified parties for losses suffered or incurred by the indemnified parties with respect to our product candidates, use of such product candidates, or other actions taken or omitted by us. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, we have no liabilities recorded for these provisions as of December 31, 2008.

In the normal course of business, we may be confronted with issues or events that may result in a contingent liability. These generally relate to lawsuits, claims, environmental actions or the action of various regulatory agencies. If necessary, management consults with counsel and other appropriate experts to assess any matters that arise. If, in our opinion, we have incurred a probable loss as set forth by accounting principles generally accepted in the U.S., an estimate is made of the loss and the appropriate accounting entries are reflected in our financial statements. After consultation with legal counsel, we do not anticipate that liabilities arising out of currently pending or threatened lawsuits and claims will have a material adverse effect on our financial position, results of operations or cash flows.

#### **Restructuring Expense**

On December 8, 2008, as part of our efforts to improve operational efficiency we decided to close our research and development facilities in Tarrytown to reduce costs and improve operating efficiency. As of December 8, 2008 we terminated all research and development staff and ceased using approximately 85% of the facilities which resulted in a restructuring charge of approximately \$3.8 million in the fourth quarter, 2008. As part of the restructuring charge, we

wrote down the value of our leasehold improvements in Tarrytown by approximately \$1.0 million (net); additionally, the useful life of leasehold improvements in portions of the facility that were still in use as of December 31, 2008 was recalculated, resulting in an accelerated charge to amortization expense of approximately \$0.1 million.

## **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

In accordance with SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities , we estimated our liability for net costs associated with terminating our lease obligation for the laboratory and office facilities in Tarrytown and recorded a charge net of estimated sublease income. To develop our estimate, we considered our liability under the Tarrytown lease, and estimated costs to be incurred to satisfy rental commitments under the lease, the lead time necessary to sublease the space, projected sublease rental rates, and the anticipated duration of subleases. We validated our estimate and assumptions through consultations with independent third parties having relevant expertise. We used a credit adjusted risk free rate of 1.55% to discount estimated cash flows. We intend to review our estimate and assumptions on a quarterly basis or more frequently as appropriate; and will make modifications to the estimated liability as deemed appropriate, based on our judgment to reflect changing circumstances. Any change in our estimate may result in additional restructuring charges, and those charges may be material.

The restructuring liability at December 31, 2008 of \$2.9 million relates primarily to the portion of the Tarrytown facility we ceased using as of December 8, 2008, is recorded at net present value, and includes several obligations related to the restructuring. We classified \$0.9 million as short term as of December 31, 2008 and \$2.0 million as long term. The short term portion represents what we expect to pay in 2009 and the long term portion subsequently thereafter, through August 2012.

We recorded \$3.8 million in restructuring expenses comprised of \$2.6 million lease restructuring expense (net of subleases), \$0.2 million in termination benefits (employee severance and related costs) and \$1.0 million in leasehold improvement abandonment. In December 2008, we made \$47 thousand in net rental payments (calculated at net present value) on the Tarrytown property and made termination payments of \$91 thousand which represent employee severance and benefits charges. The restructuring liability was reduced by these amounts.

The restructuring activity and related liability are as follows (\$ thousands):

	Charge	Amounts Previously Charge Accrued		Cash Payments		Non-Cash Expense		Liability at December 31, 2008	
Lease restructuring expense Employee severance and related costs Leasehold improvements abandonment	\$ 2,592 199 1,040	)	227	\$	(47) (91)	\$	(1,040)	\$	2,772 108
	\$ 3,831	L \$	227	\$	(138)	\$	(1,040)	\$	2,880

#### **17.** Summarized Quarterly Financial Data (Unaudited)

Following are summarized quarterly financial data (unaudited) for the years ended December 31, 2008 and 2007:

	March 31 June 30 (In			Sept thous	tember 30 ands)	December 31		
Total revenue	\$	154	\$	14	\$	77	\$	6
Operating (loss) income		(6,462)		(5,895)		(5,740)		(8,223)
Net (loss) income		(3,942)		(7,643)		(5,100)		(7,703)
Net (loss) income per share, basic	\$	(0.13)	\$	(0.25)	\$	(0.17)	\$	(0.25)
Net (loss) income per share, diluted	\$	(0.13)	\$	(0.25)	\$	(0.17)	\$	(0.25)
		82						
		02						

#### **EMISPHERE TECHNOLOGIES, INC.**

#### NOTES TO THE FINANCIAL STATEMENTS (Continued)

	2007 March 31 June 30 Sept (In thousa				tember 30 December 31 ands)			
Total revenue	\$	2,809	\$	398	\$	571	\$	299
Operating loss		(7,102)		(9,542)		3,453		(7,460)
Net income (loss)		(3,888)		(12,104)		2,956		(3,892)
Net income (loss) per share, basic	\$	(0.14)	\$	(0.43)	\$	0.10	\$	(0.13)
Net income (loss) per share, diluted	\$	(0.26)	\$	(0.43)	\$	0.09	\$	(0.18)

#### 18. Fair Value

In accordance with SFAS 157, the following table represents the Company s fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2008 and 2007:

	Level 2 2008 (In thousands)				
Corporate debt U.S. government agency obligations	\$				
Derivative instruments	(267)	)			
Total	\$ (267)	)			

The derivative instruments were valued using the market approach, which is considered Level 2 because it uses inputs other than quoted prices in active markets that are either directly or indirectly observable. Accordingly, the derivatives were valued using the Black-Scholes model.

Some of the Company s financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate fair value due to their liquid or short-term nature, such as cash and cash equivalents, receivables and payables.

The estimated fair value of the Company s loans payable (including current portion) at December 31, 2008 was \$30.2 million as compared to \$27.3 million at December 31, 2007, which are the carrying values of these instruments

#### **19.** Settlement of Litigation

On September 25, 2007, Emisphere agreed to accept \$18 million from Eli Lilly to settle the pending litigation between the two companies. Additional terms and conditions of the settlement were confidential. Emisphere received \$11.9 million of the settlement, net of attorneys fees and expenses.

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#### 20. Other

On February 8, 2008, Emisphere reported that it had entered into an agreement with MannKind Corporation to sell certain Emisphere patents and a patent application relating to diketopiperazine technology for a total purchase price of \$2.5 million. An initial payment of \$1.5 million was received in February 2008. An additional \$0.5 million will be paid no later than July 5, 2009 with the remaining payment to be made no later than October 5, 2010.

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

The Company s senior management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act ) designed to ensure that the information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer s management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

The Company has evaluated the effectiveness of the design and operation of its disclosure controls and procedures under the supervision of and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

#### Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2008.

PricewaterhouseCoopers LLP, our independent registered public accounting firm, has issued a report on the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included herein at page 52.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate

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because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## ITEM 9B. OTHER INFORMATION

None.

## PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item is incorporated by reference to the Proxy Statement to be distributed in connection with our next annual meeting of stockholders. We have adopted a Code of Ethics applicable to our directors, chief executive officer, chief financial officer, controller and senior financial management. Our Code of Ethics is available on our website at www.emisphere.com/ovr \_ cgcoe.asp.

#### ITEM 11. EXECUTIVE COMPENSATION

Information required by this item is incorporated by reference to the Proxy Statement to be distributed in connection with our next annual meeting of stockholders.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this item is incorporated by reference to the Proxy Statement to be distributed in connection with our next annual meeting of stockholders.

#### ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information required by this item is incorporated by reference to the Proxy Statement to be distributed in connection with our next annual meeting of stockholders.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this item is incorporated by reference to the Proxy Statement to be distributed in connection with our next annual meeting of stockholders.

#### PART IV

#### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

A list of the financial statements filed as a part of this report appears on page 51.

#### (2) Financial Statement Schedules

Schedules have been omitted because the information required is not applicable or is shown in the Financial Statements or the corresponding Notes to the Financial Statements.

#### (3) Exhibits

A list of the exhibits filed as a part of this report appears on pages 86 thru 89.

(b) See Exhibits listed under the heading Exhibit Index set forth on page 86.

(c) Schedules have been omitted because the information required is not applicable or is shown in the Financial Statements or the corresponding Notes to the Financial Statements.

## **EXHIBIT INDEX**

Exhibit		by Re	porated ference (1)
3.1	Amended and restated Certificate of Incorporation of Emisphere Technologies, Inc., as amended by the Certificate of Amendment of Amended and Restated Certificate of Incorporation of Emisphere Technologies, Inc., dated April 20, 2007	R	
3.2(a)	By-Laws of Emisphere Technologies, Inc., as amended December 7, 1998 and September 26, 2005	A, L	
3.2(b)	Amendment to the By-Laws, as amended, of Emisphere Technologies, Inc.	V	
4.1	Restated Rights Agreement dated as of April 7, 2006 between Emisphere Technologies, Inc. and Mellon Investor Services, LLC	Р	
10.1(a)	1991 Stock Option Plan, as amended	F	(2)
10.1(b)	Amendment to the 1991 Stock Option Plan	Q	(2)
10.2(a)	Stock Incentive Plan for Outside Directors, as amended	С	(2)
10.2(b)	Amendment to the Amended and Restated Stock Incentive Plan for Outside Directors	Q	(2)
10.3(a)	Directors Deferred Compensation Stock Plan	E	(2)
10.3(b)	Amendment to the Directors Deferred Compensation Stock Plan	Q	(2)
10.4(a)	Employee Stock Purchase Plan, as amended	В	(2)
10.4(b)	Amendment to Emisphere Technologies, Inc. Employee Stock Purchase Plan	Н	(2)
10.5	Non-Qualified Employee Stock Purchase Plan	В	(2)
10.6(a)	1995 Non-Qualified Stock Option Plan, as amended	В	(2)
10.6(b)	Amendment to the 1995 Non-Qualified Stock Option Plan	Q	(2)
10.7(a)	Emisphere Technologies, Inc. 2000 Stock Option Plan	G	(2)
10.7(b)	Amendment to Emisphere Technologies, Inc. 2000 Stock Option Plan	Q	(2)
10.8(a)	Emisphere Technologies, Inc. 2002 Broadbased Stock Option Plan	Н	(2)
10.8(b)	Amendment to Emisphere Technologies, Inc. 2002 Broadbased Stock Option Plan	Q	(2)
10.9	Emisphere Technologies, Inc. 2007 Stock Award and Incentive Plan	R	(2)
10.10	Amended and Restated Employment Agreement, dated April 28, 2005, between Michael M. Goldberg and Emisphere Technologies, Inc.	Ν	(2)
10.11	Stock Option Agreements, dated January 1, 1991, February 15, 1991, December 1, 1991, August 1, 1992 and October 6, 1995 between Michael M. Goldberg and Emisphere Technologies, Inc.	В	(2)(3)
10.12	Stock Option Agreement, dated July 31, 2000, between Michael M. Goldberg and Emisphere Technologies, Inc.	G	(2)
10.13	Employment Agreement dated April 6, 2007 between Michael V. Novinski and Emisphere Technologies, Inc.	S	(2)
10.14	Nonqualified Stock Option Agreement dated April 6, 2007 between Michael V. Novinski and Emisphere Technologies, Inc.	R	(2)
10.15	Incentive Stock Option Agreement dated February 12, 2007 between Lewis H. Bender and Emisphere Technologies, Inc.	R	(2)
10.16	Form of Nonqualified Stock Option Agreement	R	(2)
10.17	Form of Incentive Stock Option Agreement	R	(2)
10.18	Form of Restricted Stock Option Agreement	R	(2)

10.19	Agreement and Release by and between Shepard Goldberg and Emisphere	U	(2)
	Technologies, Inc., dated June 25, 2007		
10.20	Agreement and Release by and between Steve Dinh and Emisphere Technologies, Inc.	Х	(2)

Exhibit		by Re	oorated ference 1)
10.21	Agreement and Release by and between Lewis Henry Bender and Emisphere Technologies, Inc.	Х	(2)
10.22(a)	Amendment to Lease Agreement, dated as of March 31, 2000, between Emisphere Technologies, Inc. and Eastview Holdings, LLC	G	
10.22(b)	Amendment to Lease Agreement, dated as of March 31, 2000, between Emisphere Technologies, Inc. and Eastview Holdings, LLC	G	
10.22(c)	Amendment to Lease Agreement, dated as of September 23, 2003, between Emisphere Technologies, Inc. and Eastview Holdings, LLC	Ι	
10.22(d)	Thirteenth Amendment to Lease	Т	
10.22(e)	Fourteenth Amendment to Lease	Х	
10.23	Lease Agreement, dated as of November 1, 2007 between The Realty Associates Fund VI, L.P. and Emisphere Technologies, Inc.	W	
10.24	Research Collaboration and Option Agreement dated as of December 3, 1997 between Emisphere Technologies, Inc. and Novartis Pharma AG	D	(3)
10.25	Agreement, dated September 23, 2003, between Emisphere Technologies, Inc. and Progenics Pharmaceuticals, Inc	Ι	
10.26	License Agreement dated as of September 23, 2004 between Emisphere Technologies, Inc. and Novartis Pharma AG, as amended on November 4, 2005	J	(3)
10.27(a)	Research Collaboration Option and License Agreement dated December 1, 2004 by and between Emisphere Technologies, Inc. and Novartis Pharma AG	J	(3)
10.27(b)	Convertible Promissory Note due December 1, 2009 issued to Novartis Pharma AG	J	(3)
10.27(c)	Registration Rights Agreement dated as of December 1, 2004 between Emisphere Technologies, Inc. and Novartis Pharma AG	J	
10.28	Development and License Agreement between Genta Incorporated and Emisphere Technologies, Inc., dated March 22, 2006	0	
10.29(a)	Senior Secured Loan Agreement between Emisphere Technologies, Inc. and MHR, dated September 26, 2005, as amended on November 11, 2005	L	
10.29(b)	Investment and Exchange Agreement between Emisphere Technologies, Inc. and MHR, dated September 26, 2005	L	
10.29(c)	Pledge and Security Agreement between Emisphere Technologies, Inc. and MHR, dated September 26, 2005	L	
10.29(d)	Registration Rights Agreement between Emisphere Technologies, Inc. and MHR, dated September 26, 2005	L	
10.29(e)	Amendment No. 1 to the Senior Secured Term Loan Agreement, dated November 11, 2005	М	
10.29(f)	Form of 11% Senior Secured Convertible Note	L	
10.29(g)	Form of Amendment to 11% Senior Secured Convertible Note	R	
10.30(a)	Warrant dated as of March 31, 2005 between Emisphere Technologies, Inc. and NR Securities LTD	K	
10.30(b)	Warrant adjustment notice between Emisphere Technologies, Inc. and NR Securities LTD	W	
10.31(a)	Warrant dated as of March 31, 2005 between Emisphere Technologies, Inc. and Atticus European Fund LTD	K	
10.31(b)		W	

Warrant adjustment notice between Emisphere Technologies, Inc. and Atticus European Fund, LTD

10.32(a) Warrant dated as of March 31, 2005 between Emisphere Technologies, Inc. and Elan K International Services, Ltd.

Exhibit		Incorporated by Reference (1)
10.32(b)	Warrant adjustment notice between Emisphere Technologies, Inc. and Elan International Services, Ltd.	W
10.33	Warrant dated as of September 23, 2005 between Emisphere Technologies, Inc. and MHR Capital Partners (100) LP	Q
10.34	Warrant dated as of September 23, 2005 between Emisphere Technologies, Inc. and MHR Capital Partners (500) LP	Q
10.35(a)	Warrant dated as of September 23, 2005 between Emisphere Technologies, Inc. and Michael Targoff	Q
10.35(b)	Warrant adjustment notice between Emisphere Technologies, Inc. and Michael B. Targoff	W
10.36	Warrant dated as of September 21, 2006 between Emisphere Technologies, Inc. and MHR Institutional Partners IIA LP	Q
10.37	Warrant dated as of September 21, 2006 between Emisphere Technologies, Inc. and MHR Institutional Partners II LP	Q
10.38	Warrant dated as of September 21, 2006 between Emisphere Technologies, Inc. and MHR Capital Partners (100) LP	Q
10.39	Warrant dated as of September 21, 2006 between Emisphere Technologies, Inc. and MHR Capital Partners Masters Account LP	Q
10.40	Warrant adjustment notice between Emisphere Technologies, Inc. and MHR Capital Partners (100) LP, MHR Capital Partners Master Account, LP (formerly MHR Capital Partners (500) LP), MHR Institutional Partners IIA LP, MHR Institutional Partners II LP, MHR Capital Partners (100) LP and MHR Capital Partners Master Account LP	W
10.41	Warrant dated as of August 22, 2007 between Emisphere Technologies, Inc. and SF Capital Partners, Ltd.	W
10.42	Warrant dated as of August 22, 2007 between Emisphere Technologies, Inc. and Fort Mason Master, L.P.	W
10.43	Warrant dated as of August 22, 2007 between Emisphere Technologies, Inc. and Fort Mason Partners, L.P.	W
10.44	Warrant dated as of August 22, 2007 between Emisphere Technologies, Inc. and Montaur Capital/ Platinum Life Montaur Life Sciences Fund I LLC	W
10.45	Warrant dated as of August 22, 2007 between Emisphere Technologies, Inc. and MHR Institutional Partners II LP	W
10.46	Warrant dated as of August 22, 2007 between Emisphere Technologies, Inc. and MHR Institutional Partners IIA LP	W
10.47	Emisphere Technologies, Inc Mankind Corporation Patent Purchase Agreement, dated February 8, 2008	X
10.48	Development and License Agreement, dated as of June 21, 2008, between Emisphere Technologies, Inc. and Novo Nordisk AS.	Y(3)
14.1	Emisphere Technologies, Inc. Code of Business Conduct and Ethics	Ι
23.1	Consent of Independent Registered Public Accounting Firm	*
31.1	Certification Pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002	*
31.2	Certification Pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002	*

32.1 Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of \* the Sarbanes-Oxley Act of 2002

- \* Filed herewith
- (1) If not filed herewith, filed as an exhibit to the document referred to by letter as follows:
- A. Quarterly Report on Form 10-Q for the quarterly period ended January 31, 1999
- B. Annual Report on Form 10-K for the fiscal year ended July 31, 1995
- C. Annual Report on Form 10-K for the fiscal year ended July 31, 1997
- D. Quarterly Report on Form 10-Q for the quarterly period ended October 31, 1997
- E. Annual Report on Form 10-K for the fiscal year ended July 31, 1998
- F. Annual Report on Form 10-K for the fiscal year ended July 31, 1999
- G. Annual Report on Form 10-K for the fiscal year ended July 31, 2000
- H. Registration statement on Form S-8 dated and filed on November 27, 2002
- I. Annual Report on Form 10-K for the year ended December 31, 2003
- J. Registration on Form S-3/A dated and filed February 1, 2005
- K. Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005
- L. Current Report on Form 8-K, filed September 30, 2005
- M. Current Report on Form 8-K, filed November 14, 2005
- N. Current Report on Form 8-K filed May 4, 2005
- O. Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006
- P. Current Report on Form 8-K, filed April 10, 2006
- Q. Annual Report on Form 10-K for the fiscal year ended December 31, 2006
- R. Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2007
- S. Current Report on Form 8-K, filed April 11, 2007
- T. Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2007
- U. Current Report on Form 8-K, filed June 29, 2007
- V. Current Report on Form 8-K, filed September 14, 2007

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- W. Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2007
- X. Annual Report on Form 10-K for the fiscal year ended December 31, 2007
- Y. Current Report on Form 8-K, filed August 11, 2008
- (2) Management contract or compensatory plan or arrangement
- (3) Portions of this exhibit have been omitted based on a request for confidential treatment filed separately with the Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Emisphere Technologies, Inc.

By: /s/ Michael V. Novinski

Michael V. Novinski President and Chief Executive Officer

Date: March 16, 2009

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.

Name and Signature	Title	Date	
/s/ Michael V. Novinski	President and Chief Executive Officer (principal executive officer)	March 16, 2009	
Michael V. Novinski			
/s/ Stephen K. Carter, M.D.	Director	March 16, 2009	
Stephen K. Carter, M.D.			
/s/ John D. Harkey, Jr.	Director	March 16, 2009	
John D. Harkey, Jr.			
/s/ Kenneth I. Moch	Director	March 16, 2009	
Kenneth I. Moch			
/s/ Mark H. Rachesky, M.D.	Director	March 16, 2009	
Mark H. Rachesky, M.D.			
/s/ Michael Weiser, M.D.	Director	March 16, 2009	
Michael Weiser, M.D.			
/s/ Michael R. Garone	Chief Financial Officer (principal financial and accounting officer)	March 16, 2009	
Michael R. Garone	(r · · · · · · · · · · · · · · · · · · ·		