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

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009.

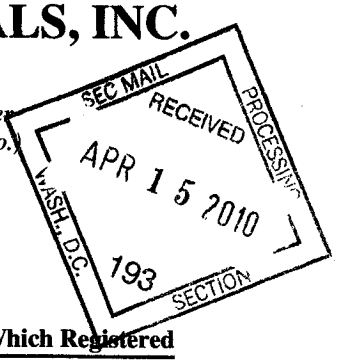
OR

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

Commission File Number 001-33284

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

Massachusetts	**04-0562086**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
160 Second Street, Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	*(Zip Code)*



(617) 492-5554
(Registrant's telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01 per share	**The Nasdaq Stock Market LLC**

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting Company ☐
(Do not check if a smaller reporting company)

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

As of June 30, 2009, the last business day of the registrant's completed second fiscal quarter, the aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, computed by reference to the last sale price of such stock on the Nasdaq Global Market on June 30, 2009, was approximately $82,394,000.

As of March 12, 2010, there were 25,268,327 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive Proxy Statement for the 2010 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this annual report on Form 10-K, are incorporated herein by reference into Part III of this annual report on Form 10-K.

TABLE OF CONTENTS

Forward-Looking Statements

Statements in this annual report on Form 10-K that are not strictly historical in nature are forward-looking statements. Such statements include, but are not limited to, statements about our financial performance, our corporate strategy, our business operations, our negotiations with our Bond holders and the consequences of the failure to reach agreement with the Bond holders in regard to avoiding acceleration of the debt obligations under the Bond Indenture and restructuring such debt on acceptable terms, our ability to meet our obligations under the Bond Indenture, our potential insolvency and other consequences caused by a default under the Bond Indenture, our clinical trials of Azedra™, Onalta™, Trofex™, Solazed™ and Zemiva™ and anticipated regulatory requirements and the timing of launches of such products, our business development strategy regarding the European rights to Onalta™ and anticipated compassionate use and clinical trials in the licensed territories, anticipated revenues from product supply to BioMedica, from regulatory milestone payments and from milestone and tiered royalties on sales, our capital requirements and our needs for additional financing, potential severe dilution of our stock ownership, and potential delisting of our stock. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "goal," and similar expressions intended to identify forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth in "ITEM 1A. RISK FACTORS" and elsewhere in this annual report on Form 10-K. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. *BUSINESS*

In this annual report on Form 10-K, unless the context indicates otherwise, references to "Molecular Insight," "the Company," "our company," "we," "us," and similar references, refer to Molecular Insight Pharmaceuticals, Inc. All references to years in this Form 10-K, unless otherwise noted, refer to our fiscal years, which end on December 31. For example, a reference to "2009" or "fiscal 2009" means the 12-month period that ended December 31, 2009.

Recent Developments

On November 16, 2007, we sold $150,000,000 in Senior Secured Floating Rate Bonds due 2012 ("Bonds") and warrants to purchase 6,021,247 shares of common stock at an exercise price of $5.87 per share ("Bond Warrants") under an indenture ("Bond Indenture"). Based on our current projections of our cash flow, we will breach the minimum liquidity requirements under the Bond Indenture in the second half of 2010, unless we are able to raise sufficient additional capital. Additionally, under the Bond Indenture, we are required to deliver audited annual financial statements to Bond holders which are not subject to a "going concern" or like qualification or exception from our independent auditors. In light of recurring losses from our operations and net stockholders' capital deficiency, the uncertainty of our obtaining additional financing on a timely basis, and the fact we will likely not comply with the minimum liquidity requirements under the Bond Indenture if we do not procure such additional financing, as well as other factors described in Note 1 to the financial statements for the year ended December 31, 2009 attached to this Annual Report on Form 10-K, in the report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2009, our independent auditors have included an emphasis of a matter paragraph relating to substantial doubt whether we can continue as a going concern. Consequently, the inclusion of such a "going concern" paragraph would result in a default under the terms of the Bond Indenture, unless waived by the Bond holders.

We discussed with the holders of our Bond the foregoing circumstances and a restructuring of our outstanding debt. On March 15, 2010 we executed a waiver agreement with the holders of at least a majority of the Bonds and the Bond Indenture trustee. Under the terms of the waiver agreement, the Bond holders and Bond Indenture trustee have agreed to waive the default arising from the inclusion of a "going concern" paragraph in the report of our independent registered public accounting firm on our financial statements and other technical defaults under the Bond Indenture until 12:01 AM Eastern Standard Time on April 16, 2010, subject to earlier termination upon certain circumstances. The waiver is also subject to a number of terms and conditions, relating to our provision of certain information to the Bond holders, among other conditions and matters. In the event that the waiver expires or terminates prior to the successful restructuring of the outstanding debt, then we will be in default of our obligations under the Bond Indenture and the Bond holders may choose to accelerate the debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations.

We are continuing to negotiate with the Bond holders regarding the restructuring of the outstanding debt in a manner designed to avoid the acceleration of our debt obligations. Although our management team remains optimistic regarding the possibility of reaching an agreement with the Bond holders that will allow us to avoid such an acceleration of the debt obligations and position us for future growth through a restructuring of these obligations, there is no assurance that we will reach such an agreement on terms favorable to us, or at all. See Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview," and Note 1, "Nature of Business and Operations" for a further discussion.

Company Overview

We are a clinical-stage biopharmaceutical company and a pioneer in molecular medicine. We are focused on the discovery and development of targeted therapeutic and imaging radiopharmaceuticals for use in oncology.

We have five clinical-stage candidates in development. Our lead oncology product candidates include Azedra™, Onalta™, Trofex™ and Solazed™. Azedra™ and Onalta™ are being developed for the treatment of neuroendocrine cancers; Trofex™ is being developed for the detection of metastatic prostate cancer; and Solazed™ is being developed for the treatment of metastatic melanoma. Our non-oncology product candidate, Zemiva™, is being developed for the diagnosis of cardiac ischemia (insufficient blood flow to the heart muscle).

We are taking advantage of specific disease-related changes at the cellular level that occur in cancers in order to specifically deliver therapeutic radiopharmaceuticals to treat tumor cells that have spread throughout the body. The selective accumulation of radiotherapeutic compounds in cancers allows direct tumor killing while sparing normal tissues of serious toxicity. Targeted radiotherapy for widespread cancers brings a well understood and successful therapy (radiation) to the treatment of late-stage cancers. Since the 'therapy' is localized in the tumors and the mass of nonradioactive compound is very low, side effects may be less severe than conventional chemotherapy.

Also, due to the exquisite sensitivity of radiopharmaceutical molecular imaging (nuclear medicine), it is possible to detect disease at the cellular level, before anatomical changes occur, which are apparent in later stages of disease. Imaging the disease-related changes at the level of the cell enables early disease detection and a more sensitive means of monitoring disease progression and response to therapy compared with current imaging technologies.

We were incorporated in the Commonwealth of Massachusetts in 1997. We have had no significant revenue from product sales since inception and have funded our operations primarily through the public and private placement of equity and debt securities, government grant funding and upfront license payments from collaborations. We have never been profitable and have incurred an accumulated deficit of $292.9 million from inception through December 31, 2009. Research and development expenses relating to our clinical and pre-clinical product candidates fluctuate depending on the stage of development of our product candidates. We expect to incur increased development costs relevant to our ongoing development efforts and clinical trials and expect to incur significant operating losses for the next several years.

Our Product Candidates

Our product candidates and their stages of development as of December 31, 2009 are summarized below:

Program	Primary Indication(s)	Stage of Development
Oncology		
Azedra (Ultratrace iobenguane I 131)	Pheochromocytoma (*and paraganglioma*; together referred to singly as "pheochromocytoma")	In Pivotal Phase 2b
	Neuroblastoma	In Phase 2a
Onalta (Yttrium-90 edotreotide)	Metastatic carcinoid and pancreatic neuroendocrine tumors	Pre-Phase 3 (Europe)
Trofex (MIP-1072)	Metastatic prostate cancer	In Phase 1
Solazed (Ioflubenzamide I 131)	Metastatic melanoma	Initiating Phase 1
Non-Oncology		
Zemiva (Iodofiltic acid I 123)	Acute cardiac ischemia	Completed Phase 2

Our Oncology Product Candidates: Azedra, Onalta, Trofex, and Solazed

Azedra (Ultratrace Iobenguane I 131)

Azedra is our lead radiotherapeutic oncology product candidate. Azedra is being developed as a treatment for pheochromocytoma / paraganglioma in adults and neuroblastoma in children. Pheochromocytomas are rare tumors that are usually found within one or both adrenal glands, but may arise in other areas of the body (paraganglioma). About 50% of these tumors are found to be malignant at initial presentation while others are found to be malignant or recurrent disease after a median interval of 5.6 years. These tumors produce significant unpleasant effects throughout the body, and quality of life is poor. Two groups of patients can be defined based upon metastatic disease location. One group are those with short-term survival rate with liver and/or lung metastases and usually have less than two (2) years of survival. A second group with only bone metastases and have longer survival rates of between 20%-60%; averaging about 35%. For these malignant tumors, radiation therapy offers short-term symptomatic relief of selected lesions but does not cure the patient. Chemotherapy trials have failed to produce cures or significant remissions and are often poorly tolerated.

Neuroblastoma is a neuroendocrine malignancy affecting children. It develops in approximately 1 per 7,000 live births, is the most common extra-cranial solid tumor in children, and is extremely rare beyond childhood. The median age at diagnosis is 22 months and most cases are diagnosed prior to 4 years of age. Neuroblastoma originates in the nervous system. About two-thirds of cases arise in the abdomen (near the adrenal glands). Most patients have metastases at diagnosis, with metastatic sites including lymph nodes, bone, bone marrow, liver, and skin. Treatment of high-risk neuroblastoma includes surgery, chemotherapy, and radiation; however, there are no standard therapies for high-risk patients if they relapse or fail to respond to such treatment.

Azedra Mechanism of Action

Neuroendocrine tumors such as pheochromocytoma and neuroblastoma secrete catecholamines, which causes most of the unpleasant physiological symptoms from these tumors. Azedra circulates throughout the body and selectively localizes in distant metastatic tumors because of its ability to bind to the norepinephrine transporter found on these active tumor cells. Azedra's anti-cancer activity is due to its ability to selectively deliver lethal therapeutic radiation directly to cancer cells. Azedra consists of iobenguane which has been radiolabeled with iodine-131 to a high specific activity using our Ultratrace™ platform technology. Administration to patients is by a well tolerated intravenous injection.

Ultratrace is our proprietary solid-phase chemistry technology that allows for substantially greater radiolabeling efficiency, and it significantly reduces quantities of cold (non-radioactive) iobenguane from being included in the final formulation of the product. The lack of cold-contaminating iobenguane in the therapeutic

provides two significant benefits: greater tumor uptake with more therapeutic radiation delivered in a more precise and targeted manner, and better control over dosing with the potential for reduced pharmacological toxicity and side effects, such as hypertension, nausea or vomiting, during the infusion. In vivo imaging and therapy studies in rodents confirm that tumor uptake of Azedra is at least twice as high and tumor kill is dramatically enhanced compared to efficacy of iobenguane using standard radiolabeling procedures.

Azedra Clinical Development Plan

Azedra is under development for the systemic treatment of the metastatic neuroendocrine cancers pheochromocytoma and neuroblastoma. We are currently pursuing adult clinical trials for pheochromocytoma and pediatric clinical trials for neuroblastoma, which are detailed below.

We entered into an agreement with MDS Nordion to manufacture Azedra using the Ultratrace platform, on August 6, 2009. Under the agreement MDS Nordion will dedicate a section of its existing Ottawa facility to Food and Drug Administration ("FDA") / European Medicines Agency ("EMEA") compliant manufacture of Azedra, for our requirements of the therapeutic during clinical trials and if approved, in the commercial phase following product approval. The FDA has granted Azedra Orphan Drug Designation in the United States and the EMEA has granted Azedra, for the treatment of neuroblastoma, Orphan Drug Designation in the European Union ("EU").

Pheochromocytoma

Azedra is under development for the treatment of pheochromocytoma, and if approved would be the first therapeutic in the United States for this indication.

In March 2009 we received a Special Protocol Assessment ("SPA") letter from the FDA regarding the design of a pivotal Phase 2 trial for registration of Azedra. In the summer of 2009, we began enrolling patients in this trial. Currently, patients are being enrolled. The study (IB-12b) will be a single-arm clinical trial to enroll 58 evaluable patients with pheochromocytoma. Pheochromocytoma tumors cause excess release of the hormones epinephrine and norepinepherine, and produce severe adverse effects on the patients' heart rate and blood pressure. The primary endpoint of the IB-12b study will be Azedra's sustained decrease of anti- hypertensive medications of at least 50%. Secondary endpoints will include demonstration of overall anti-tumor response, and the improvement in patients' daily functioning and performance including improvement in quality of life, in particular pain reduction.

Two trials of Azedra in adult pheochromocytoma patients have already been completed. The first was a Phase 1 study (IB-11) of the pharmacokinetics and safety of Azedra in 11 patients. The aim of this study was to determine the metabolism, excretion, and radiation dosimetry in patients with pheochromocytoma and carcinoid tumors. The data from this study was used to plan the initial therapeutic evaluation of Azedra. The second trial IB-12, was a Phase 1 study to determine the maximal tolerated dose of Azedra in patients with pheochromocytoma. This study provided data on safety and toxicity of Azedra as well as preliminary data on efficacy. The IB-12 study also informed the dose we later adopted in the design of our pivotal Phase 2 study above. At the North American Neuroendocrine Tumor Society ("NANETS") 2009 Neuroendocrine Tumor Symposium, we presented one-year follow-up data from the IB-12 Phase 1 dose-escalation clinical study of Azedra demonstrating a positive safety profile and durable objective tumor responses in patients with neuroendocrine cancers.

Neuroblastoma

A Phase 2a study (IB-13), designed to define the maximum tolerated dose and provide data on safety and toxicity as well as efficacy, is ongoing and has completed three dose cohorts without dose limiting toxicity. This has allowed a dose selection for the planned pivotal Phase 2b efficacy study (IB-N201). Endpoints for this study will include tumor response, biomarker response, and progression-free survival. We are awaiting on an SPA letter from the FDA before commencing the Phase 2b study.

Onalta (Yttrium-90 edotreotide)

Onalta is our lead radiotherapeutic product candidate that was in-licensed from Novartis AG, which is under development for the treatment of metastatic carcinoid and pancreatic neuroendocrine tumors in patients whose symptoms are not controlled by conventional therapy.

Carcinoid tumors are neuroendocrine tumors of the gastrointestinal tract and bronchus. Between 11,000 and 12,000 carcinoid tumor patients are diagnosed each year in the United States and there are about 170,000 people suffering from this condition in the United States. Patients with metastatic disease are at increased risk of severe and debilitating symptoms that greatly diminish their quality of life. Most patients are not diagnosed until the carcinoid syndrome has become life-threatening and/or liver metastases have developed. By then, less than 30% of the patients survive five years. In these cases, surgery is the only treatment that can potentially be a cure. The therapeutic goal for patients who have an endocrine-active tumor that cannot be treated adequately by surgery is decreasing hormone production to control symptoms.

Onalta Mechanism of Action

Onalta is our brand name for yttrium-90 radiolabeled edotreotide, which is a radiolabeled somatostatin analog. Onalta binds selectively to tumor cells that have receptors for the peptide hormone somatostatin on their surface since these cells do not differentiate substantially between edotreotide and somatostatin, so edotreotide serves as a carrier for targeted delivery of yttrium-90. Onalta therefore delivers a therapeutic dose of radiation directly to the cancer cells.

Onalta Clinical Development Plan

We acquired rights to edotreotide from Novartis which had previously conducted three Phase 1 and three Phase 2 clinical trials involving more than 300 patients. While we have worldwide rights to edotreotide, clinical progress is furthest in Europe and immediate efforts are being focused there. At present, an unapproved version of 90-Y edotreotide is currently used in some European countries as a compassionate use therapeutic, and in 2009, the EMEA reviewed and accepted Onalta's Phase 3 clinical trial protocol design and granted Onalta Orphan Drug Designation in the EU.

In September 2009, we sub-licensed Onalta to BioMedica Life Sciences S.A. ("BioMedica"), Athens, Greece, for development in certain countries in Europe, the Middle East, North Africa, Russia and Turkey. We continue to retain all rights to all other markets and territories, including the United States, Japan and Asia. The agreement provides BioMedica an exclusive sub-license to ours and Novartis' intellectual property rights and know-how with respect to Onalta. Under the agreement, BioMedica is expected to perform clinical studies and market, distribute and commercialize Onalta in the specified territories and secure all regulatory approvals. BioMedica is expected to commence European pivotal Phase 3 clinical studies in 2010.

In October 2009, we finalized a supply agreement with BioMedica, where BioMedica will purchase finished product, including compassionate use and clinical trial supplies exclusively from us. We also finalized an agreement with Eckert & Ziegler Nuclitec GmbH ("EZN") to manufacture Onalta for its supply in the Biomedica territories.

Trofex (MIP-1072)

Trofex is our molecular imaging radiopharmaceutical product candidate under development for the diagnosis and detection of metastatic prostate cancer. Prostate cancer is a widespread disease, and metastatic prostate cancer affects more than 2.5 million men, with approximately 200,000 new diagnoses in the United States annually. It is estimated that the disease will affect one in six men between the ages of 60 and 80, leading to nearly 30,000 deaths per year. The cancer-related mortality from the disease is second only to lung cancer. The global costs associated with prostate cancer are estimated at $15 billion-$20 billion.

The management of the prostate cancer patient is challenging as there are numerous clinical factors and treatment options to consider in deciding on the optimal therapy for a given patient. Since men are living much longer with the disease due to early detection, clinical decision making may have long-term consequences. Accurately defining the extent of disease burden and aggressiveness of the disease at diagnosis and during disease progression are important factors in treatment selection. Rising prostate specific membrane-antigen ("PSMA") values in the setting of other non-definitive diagnostic information often occur, causing patient management challenges or uncertainty. Hence, the ability to visualize the disease is increasingly important for informing therapeutic selection and treatment planning. Imaging agents that will more accurately detect and stage the disease, as well as monitor response to therapy, will enable improved disease management allowing better patient outcome and quality of life. Current imaging techniques offer limited opportunity to visualize the disease in various parts of the body but none provide for both highly specific and sensitive detection of metastatic prostate cancer. A sensitive and specific means of imaging tumor burden throughout the body, in both soft tissue and bone, is the goal for our diagnostic product candidate Trofex. Trofex (MIP-1072) is labeled with iodine-123 which has optimal diagnostic gamma ray energy for imaging applications. Importantly, if iodine-123 were replaced with beta emitter iodine-131, this molecule could then deliver therapeutic amount of radiation to the prostate cancer cells. Because of this molecular capability, Trofex is also under development for the treatment of metastatic prostate cancer, which is made possible by radiolabeling Trofex with a therapeutic isotope instead of a diagnostic isotope, as described above.

Trofex Mechanism of Action

Trofex is a small molecule inhibitor of PSMA, a naturally occurring enzyme that is found in the membrane of prostate cells in both healthy prostate tissues and cancerous prostate cells. Trofex binds to PSMA, and for diagnostic purposes Trofex is iodine 123-labeled and delivered to the patient by intravenous injection. Trofex accumulates on the prostate cancer cells and is retained for a prolonged period of time, allowing non-invasive molecular imaging of metastatic prostate cancer. The ability to specifically visualize prostate cancer using sensitive techniques such as nuclear medicine ushers in a new era of prostate cancer care for the patient suffering from this disease.

Our clinical data on Trofex from the Phase 1 (Tx-P101) dosimetry, safety and pharmacokinetics trial in prostate cancer patients, was presented at the Society of Nuclear Medicine Annual Meeting in June 2009, and generated substantial industry as well as national media interest. We reported that Trofex demonstrates the potential to rapidly detect prostate cancer in soft tissues and bone, confirming that targeting the extracellular domain of PSMA is a viable approach for the molecular targeting of this cancer. In May 2009, we presented the paper "Novel Small Molecules for Imaging Soft Tissue and Bone Metastasis in Prostate Cancer" at the 3rd International Symposium on Cancer Metastasis and the Lymphovascular System: Basis for Rational Therapy in San Francisco. We also participated in a conference panel at the session that considered the diagnostic and therapeutic imaging of cancer, where we discussed the applications for Trofex.

Trofex Clinical Development Plan

Based on this initial encouraging clinical data, we believe Trofex could offer unprecedented same-day detection and the type of staging that will have a significant impact on patient care and disease management. We have completed the Phase 1 (TX-P101), proof of concept study for Trofex in men with documented prostate cancer and confirmed metastatic disease. We evaluated the ability of two candidate compounds (MIP-1072 and MIP-1095) to visualize the disease and also define the pharmacokinetic profile of each. Both of our compounds were uniquely able to detect metastases in both bone and soft tissue within a few hours after injection and visualized tumors that would have been considered clinically "normal" by conventional cross sectional imaging techniques such as magnetic resonance imaging ("MRI") or computerized axial tomography ("CAT") scans. These conventional imaging techniques are known to be insensitive for picking up metastatic spread and lack specificity for disease detection. The data from this study allowed us to select MIP-1072 for further clinical development and evaluation. In August 2009, we initiated a second Phase 1 (Tx-P102) imaging study of Trofex

to define the distribution and pharmacokinetics of Trofex in normal men to confirm subject dosimetry and Trofex distribution in non-cancerous prostate glands. In November 2009, an additional exploratory Phase 1 (TX-P103) was initiated for the detection of metastatic prostate cancer that will inform development of further clinical trials and support a fast track designation for approval by the FDA, for Trofex as a diagnostic agent. Finally, we expect an important collaborative study (TX-P104) with the National Cancer Institute/National Institute of Health to begin in 2010 where patients with known prostate cancer scheduled for surgery or biopsy will be evaluated with Trofex.

Solazed (MIP-1145)

Solazed is our targeted radiotherapeutic under development for the treatment of malignant metastatic melanoma, the most serious type of skin cancer. We in-licensed Solazed, along with a family of similar compounds, from Bayer Schering Pharma Aktiengesellschaft. According to the National Cancer Institute, the incidence of malignant melanoma is rising faster than that of any other cancer in the United States with nearly 70,000 estimated new cases in 2009 with nearly 9,000 deaths. Since chemotherapeutic agents have limited activity and no survival benefit in the treatment of metastatic melanoma, patients continue to have a poor prognosis and effective treatment still represents a challenge to oncologists. Treatment paradigms of the 1990s have not been replicated in subsequent Phase 3 follow-up trials and it is widely accepted by medical oncologists that no evidence exists to indicate that treatment of metastatic melanoma has any impact on survival, which ranges from 5 to 11 months (median of 8.5 months). Combination studies also failed to improve survival rates. The Company is leveraging its expertise in nuclear medicine to develop Solazed as a targeted radiotherapeutic for this serious disease, to help improve the poor outcomes of current therapeutic regimens.

Solazed Mechanism of Action

Solazed is an iodine-131 labeled small molecule that binds selectively to melanin, a protein that is found in high concentration in melanoma cells. Solazed delivers a lethal dose of radiation to the cancer cells through the radioactive decay of iodine-131.

Solazed Development Plan

Solazed has completed preliminary preclinical data which has shown selective targeting to melanin in human models of malignant melanoma with rapid washout from normal organs. In a human melanoma mouse tumor model, Solazed administered in single or multiple dose schedules significantly reduced tumor burden for a prolonged period of time and enhanced survival compared to controls and standard chemotherapy treatment. Solazed also exhibited a favorable toxicity profile in preclinical evaluations. Based on these findings Solazed was being advanced, and the Company is designing the Phase 1 clinical study to confirm proof of concept in man and to define the pharmacokinetics, normal organ distribution, radiation dosimetry, and urinary excretion.

In July 2009, we were awarded a two-year grant from the National Cancer Institute that could total as much as $1.5 million to support development of Solazed. The grant provides funding for our Phase 1 dosimetry trial and will be shared with the University of Pennsylvania, where the trial will be initiated.

Our Non-Oncology Product Candidate: Zemiva

Zemiva (iodofiltic acid I 123)

Zemiva is a molecular cardiovascular imaging radiopharmaceutical product candidate under development for the diagnosis of cardiac ischemia, or insufficient blood flow to the heart muscle. Many needs for ischemic myocardial evaluation exist and represent unmet medical needs. One application in the United States is in the emergency department where approximately 6 million people visit each year complaining of chest pain. Some of these patients will have initial testing performed that clearly indicates the patient is having a heart attack; however the majority will not have definitive test results. This lack of certainty means a delay in detecting the

patients who need immediate care and drives a conservative medical approach leading to a large number of hospital admissions for prolonged observation. This results in 3 million hospital admissions for non-cardiac chest pain patients; a low-risk patient population that could be safely discharged if more rapid and reliable diagnostic techniques were available. The healthcare costs associated with these admissions is greater than $6 billion in the United States alone.

One possible target market for Zemiva is for the diagnosis of cardiac ischemia or heart attack in the emergency department setting in chest pain patients who have an uncertain diagnosis after initial evaluation. The ability to more rapidly and accurately detect cardiac ischemia will lead to improved patient outcomes by allowing more timely intervention. The ability to rule out cardiac ischemia allows doctors to send patients home safely thereby reducing unnecessary admissions and the associated costs. Zemiva imaging can be adopted on a widespread basis because all accredited hospitals in the United States have nuclear medicine imaging capabilities. Additional patient populations with unmet diagnostic medical needs who could benefit from Zemiva include, but not limited to: those with end-stage renal disease, acute decompensated heart failure, diabetes, and microvascular atherosclerosis in women.

Zemiva Mechanism of Action

The heavy work load of the heart requires large amounts of energy for cardiac muscle to function properly. The heart obtains the majority of its energy by metabolizing fatty acids as its preferred high energy source. In order to produce energy from fatty acids efficiently, the cardiac muscle cells must have a sufficient supply of oxygen. If the oxygen supply to a cell is limited, it shifts from consuming fatty acids to using carbohydrates as an alternative but lower energy source. In this way the cells of the heart in a reduced oxygen environment can maintain viability by burning a fuel that requires less oxygen.

The role of cardiac metabolic imaging for the visualization of cardiac ischemia can be explained in simple terms as visualizing two conditions: one is fatty acid metabolism and the other is carbohydrate metabolism. Fatty acids are the preferred and dominant fuel used by the heart when oxygen is in healthy or sufficient supply. When oxygen supply is insufficient (as in the case of cardiac ischemia), the cells of the heart consume carbohydrates. Cardiac ischemia therefore creates a rapid swing away from fatty acid metabolism over to carbohydrate metabolism. But after an ischemic event, even if blood flow is restored or normalized, there is a prolonged period of reduced fatty acid metabolism that has been referred to as "ischemic memory." This alteration in fatty acid metabolism can be visualized using our product candidate Zemiva, even for a time period after the ischemic event has taken place.

Zemiva is an iodine 123-labeled fatty acid analog, which is delivered to a patient by an intravenous injection. Zemiva is uptaken by and retained in cardiac muscle cells that have a healthy blood supply, but is not uptaken or retained in ischemic heart cells. Because of its high uptake and long retention in healthy heart cells, Zemiva provides higher resolution and better quality images of the heart, supporting better diagnosis of the patient.

Sustained decrease in fatty acid metabolism allows Zemiva to image cardiac muscle function and the integrity of the heart after an ischemic event for up to as many as 30 hours following its occurrence. This was demonstrated in our Phase 2a study that was published in the journal *Circulation* in 2005. Taking advantage of its ischemic memory to image cardiac function is a unique capability of Zemiva, and makes it particularly valuable for cardiac imaging in the acute setting, when stress testing cannot be tolerated, as well as in patients whose symptoms have since subsided.

Zemiva Clinical Trials and Current Clinical Experience

To date, over 800 subjects have received Zemiva in conjunction with our five completed human clinical trials (one Phase 1 and four Phase 2 trials). On August 3, 2009, Molecular Insight met with the FDA to discuss a revised protocol for a Zemiva Phase 3 trial. At this meeting, the FDA continued to indicate that a single Phase 3 trial, with robust results, would be sufficient to support Zemiva's registration. In line with earlier discussions, the

Company and the FDA came to general agreement on the Phase 3 protocol. At the meeting's conclusion, the FDA recommended that the Company proceed with submission of a request for Special Protocol Assessment (SPA) in order to document the formal agreement.

The Phase 2 clinical study (BP-23) trial enrolled 510 patients over 14 months at 50 hospitals throughout North America. The most recently completed BP-23 trial confirms that Zemiva, when combined with the current standard of care for the diagnostic evaluation of a chest pain patient, significantly improves the diagnosis of cardiac ischemic events in that patient. Although key secondary endpoints, including clinical benefit, were met, the initial analysis of the Phase 2 clinical trial primary endpoint did not meet predetermined performance thresholds. The reported results reflected the subsequent analysis of a subset of the sample population with sufficient objective evidence for evaluation of the diagnosis of cardiac ischemia or myocardial infarction. These results and exclusion criteria were determined to be the appropriate conclusion of the Phase 2 program. In this trial, the combination of Zemiva imaging with initial clinical information resulted in improved sensitivity (85%) compared to the sensitivity of the initial clinical diagnosis alone (52.2%) ($p<0.0001$), while maintaining specificity (p=NS) and a significant increase in the negative predictive value ($p<0.001$) to 89.6% for patients with cardiac ischemia when Zemiva was added. This result is up from 72% with standard diagnostic techniques alone. (Negative predictive value is the proportion of patients with negative test results who were correctly diagnosed.) As a stand-alone test, Zemiva imaging provided an increased sensitivity for the diagnosis of cardiac ischemia when compared to the initial clinical diagnosis alone (75.2% vs. 52.2%, $p<0.001$), without loss of specificity, as well as a significant improvement in negative predictive value (84.4% vs. 72%, $p<0.001$). The improved sensitivity was evident even in patients whose chest pain symptoms had subsided up to 30 hours prior to the Zemiva scan. These results were consistent for the subset of patients with acute coronary syndrome (ACS), the most severe form of cardiac ischemia. In patients with ACS, sensitivity (89%) and negative predictive value (93.3%) were significantly ($p<0.001$) improved while specificity was maintained. Significantly, in patients with a negative Zemiva scan, there were no heart attacks or deaths from cardiac causes during the 30-day follow up period. These results demonstrate Zemiva's use in the rapid detection of cardiac ischemia in the emergency room setting.

Zemiva was well tolerated. There were no serious adverse effects associated with the product and no patients discontinued the product due to adverse events. These top-line efficacy results seen in the BP-23-study are consistent with our previously released Phase 2 clinical data (BP-21), which was presented at the 2008 American Heart Association Annual Meeting, showed that Zemiva provides incremental clinical value by improving the detection of cardiac ischemia compared to today's standard of care. Zemiva's safety profile was also consistent with that seen in earlier clinical trials.

We believe that our product candidate Zemiva is the first imaging agent that provides for assessment of an antecedent ischemic event for up to 30 hours after the ischemia actually happened, allowing physicians to manage their patients appropriately even if they show up many hours after their symptoms have resolved. This significantly improves the assessment of chest pain patients, and allow for rapid detection of cardiac ischemia while also reducing the large number of unnecessary hospital admissions due to the uncertainties of the current diagnostic standard of care. In line with our corporate strategy to form collaborations that would extend our internal capabilities and strengths, we hope to maximize the value of Zemiva through a development and marketing collaboration.

Our Proprietary Technology Platforms

We have developed several platform technologies that allow radiochemistry to be integrated into the medicinal chemistry stage of compound discovery. As such, compounds can be screened which are chemically or structurally equivalent to the radiolabeled compound. This integration allows both the rapid synthesis and screening of large numbers of compounds, while it ensures simultaneously that all candidate compounds identified are suitable for radiolabeling using technologies that are also scalable for commercial manufacturing.

Our proprietary platform discovery technologies drive development of our current portfolio and enable the research and development of future molecular imaging pharmaceuticals and targeted radiotherapeutic candidates. Our platform discovery technologies, which can be applied independently and together, include:

- *Ultratrace Platform.* Our Ultratrace platform is a proprietary solid-phase radiolabeling technology that enables the development of ultrapure radiopharmaceuticals. Getting more therapeutic radiation on a carrier compound is desirable as it enhances the specificity and potency of the dose given to the patient. Ultratrace permits better radiolabeling of the compound and it minimizes the presence of nonradioactive (unlabeled) compound, which lacks therapeutic effect and may potentially induce unnecessary side effects. Cold "contaminants" also lower the efficacy of a treatment by competing with the radiolabeled compound for binding to limited numbers of target sites on the cancer cells.

- *SAAC Platform.* The ability to reliably and robustly incorporate medically useful radioactive metals into biologically relevant targeting molecules is critical to the design of successful radiopharmaceuticals for molecular imaging and targeted radiotherapy. Single Amino Acid Chelate, or SAAC, is our unique metal binding chemistry platform technology. It represents a new family of compounds with superior metal binding properties for leading radionuclides used for imaging and therapy, namely technetium-99m, rhenium-186 and rhenium-188. This technology incorporates a metal binding, or chelating, group that can rapidly and efficiently bind to technetium or rhenium for diagnostic and therapeutic applications and an amino acid portion that allows it to be incorporated into any peptide sequence through the use of conventional peptide chemistry.

- *SAACQ Platform.* Two widely employed techniques for visualizing specific biological processes are fluorescence microscopy and radioisotope imaging. Different from current technologies, our fluorescence-based platform called SAACQ enables the visualization of radiopharmaceuticals interacting with cellular structures. This advanced technology promises to accelerate the development of targeted radiotherapeutics and molecular imaging pharmaceuticals by allowing live cell activity to be viewed by fluorescent microscopy.

- *Nanotrace Discovery Platform.* Our Nanotrace Discovery targeting platform technology allows for the rapid creation and screening of new leads for a wide variety of diseases based on molecular targeting strategies for validated therapeutic and diagnostic targets. This technology permits us to create compound libraries of radiolabeled candidates in a relatively short period of time. Nanotrace Discovery is applicable to major disease categories such as cardiovascular disease, oncology and neurology, and it integrates with our proprietary chemistry and microscopy platforms.

Manufacturing

Azedra clinical trial supply is currently manufactured by MDS Nordion at their facility located in Kanata, Canada and post-approval commercial supply will also be accomplished through MDS Nordion as described above.

For Onalta, the edotreotide peptide is currently manufactured by Bachem, AG. We have contracted with EZN to manufacture the Y-90 labeled radiotherapeutic Onalta for its supply in connection with BioMedica's activities in its licensed territories. We believe that the EZN facility is sufficient to provide Onalta for clinical trials, compassionate use and into the commercial phase in connection with BioMedica's activities.

Zemiva is currently manufactured at a commercial manufacturing facility owned by MDS Nordion located in Vancouver, Canada through a contractual commercial manufacturing agreement. We believe that the MDS Nordion facility is sufficient to produce Zemiva required for use through launch. In January 2010, w received a notice from MDS Nordion of its intent to terminate the Zemiva Supply Agreement effective upon the expiration of the initial term on January 12, 2012.

We anticipate that the manufacture of the other products in our development pipeline could be outsourced to experienced current good manufacturing practices or cGMP-compliant medical manufacturing companies.

Strategic Collaboration Agreements

In September 2009, we entered into a Territory License Agreement ("Agreement") with BioMedica to sub-license its Onalta™ 90-Y edotreotide radiotherapeutic in certain countries in Europe, the Middle East, North Africa, Russia and Turkey. This Agreement provides BioMedica an exclusive sub-license to ours and Novartis Pharma AG's ("Novartis") intellectual property rights and know-how with respect to Onalta. We had licensed the rights to edotreotide, the parent compound of Onalta, from Novartis in November 2006. Under this Agreement, BioMedica is expected to perform clinical studies and market, distribute and commercialize Onalta in the specified territories and secure all regulatory approvals. We agreed to provide forty (40) hours of compound radiolabeling technical transfer support services without charge in addition to providing reasonable levels of training, technical and regulatory support services on a time and materials basis at BioMedica's request.

Under the terms of this Agreement, we received an initial, non-refundable payment of $4.4 million, two option grants to have BioMedica assign, transfer and convey to us, a minority shareholder interest in BioMedica, each for 1.5% of the total non-diluted interest in all classes of any issued and authorized outstanding share capital in BioMedica at the time of each exercise, exercisable upon execution of this Agreement and upon the EMEA marketing authorization approval of Onalta and will be eligible to receive more than $10 million in total regulatory milestone payments, net of license payments to Novartis. We will also be eligible to receive milestone and tiered royalties on Onalta sales.

This Agreement also provides that during the term of the Agreement, BioMedica will purchase all of its requirements for Onalta exclusively and solely from us, a third party manufacturer designated by us, and/or a BioMedica-designated third party manufacturer approved by us, the terms and conditions of which are outlined in a definitive supply agreement executed in October 2009 ("Supply Agreement"). The term of the Supply Agreement is for ten (10) years and provides for guaranteed monthly minimum purchases within a defined period of time by BioMedica.

Either BioMedica or we, may terminate the Agreement immediately upon delivery of written notice to the other party upon the insolvency of the other party, the commitment by the other party of a material breach or an uncured material breach (as defined in the Agreement) within sixty (60) days of written notice specifying the breach and requiring its remedy. We may also be forced to terminate the Agreement in the event that Novartis exercises its right to terminate its license agreement with us in the event of a change in control our Company by a direct competitor of Novartis.

Under the terms of the Agreement, unless earlier terminated by either party or Novartis through the exercise of a call-back option as provided under the terms of our license agreement with Novartis, the license extends until the later to occur of the expiration of the last of the licensed Novartis patents to expire, including any extensions in each country covered by such patents or ten (10) years from the first commercial sale of the product.

Competition

We are aiming to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their partners, may develop new product candidates to compete with ours, and these competitors may, and in certain cases do, operate larger research and development programs or have substantially greater financial resources than we do.

If Azedra or Onalta are approved, existing competing products could continue to be the current standard of care, and other companies are or may be engaged in the development and commercialization of other targeted radiotherapeutics and non-radioactive therapeutics for treatment of neuroendocrine cancers that could compete with Azedra and Onalta.

If Trofex is approved, its competition could be the current standard of care in the assessment of metastatic prostate cancer. This standard involves several diagnostic products and radiographic procedures which have limited sensitivity and specificity. A competitive product to Trofex is Prostascint® which is approved for the detection of metastatic prostate cancer on relapsed or high-risk prostate cancer patients. A Prostascint scan requires several days to complete, has marginal sensitivity and bone metastases are not well delineated with this scan.

Currently there is no successful treatment for relapsed metastatic melanoma, and physicians treat the condition with a wide variety of chemotherapeutic and radiation based treatments selected by the physician for the patient. If Solazed is approved, competition from existing therapeutic regimens could continue to be the current standard of care, and other companies are or may be engaged in the development and commercialization of targeted radiotherapeutics and non-radioactive therapeutics for treatment of skin cancers and melanoma, that could compete with Solazed.

If Zemiva is approved, its competition in the emergency department setting could be the current standard of care in the assessment of chest pain patients who present themselves to emergency departments. This standard involves several diagnostic products and procedures, in some cases involving the use of perfusion imaging agents, which in the aggregate may require several hours or days of hospitalization to reach an ultimate diagnosis.

Patents and Proprietary Rights

Our success depends in part on our ability to obtain and maintain a competitive position in the marketplace. This includes obtaining proprietary protection for our product candidates, technology, and know-how; preventing others from infringing our proprietary rights; and operating without infringing the proprietary rights of others. Our strategy is to seek to protect our proprietary position by, among other methods, applying for and obtaining U.S. and foreign patents relating to our proprietary technologies, inventions, and improvements that are important to our business. This includes obtaining patent term extensions or restorations when possible. In addition, we rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary positions. Furthermore, we intend to build brand identity in our company, our technologies and our product candidates, and for this purpose have applied for certain trademarks, as described below.

As of February 28, 2010, we had 13 issued U.S. patents, 19 U.S. pending patent applications, 41 granted foreign patents, 8 pending PCT applications and 57 pending foreign patent applications that have been nationalized in various countries.

Additionally, we have obtained licenses from third parties for the patent rights to U.S. and foreign patents and patent applications to make, use, sell and import certain proprietary technologies and compounds. Patent rights for in-licensed technologies are not included in the above totals.

Patents owned or in-licensed by us that we consider important to our business include the following:

Our Oncology Product Candidates

Azedra — We have in-licensed patents and a pending application from The University of Western Ontario that relate to the precursor material, Ultratrace™ benzyl guanidine, a process of preparing the precursor material, and Ultratrace™ technology used to produce Azedra (Table 1). These patents are set to expire in October 2018.

TABLE 1

Preparation of Radiolabelled Haloaromatics Via Polymer-Bound Intermediates

Country	Appl. Date	Patent No./Application Serial No.
Canada	10/2/1998	2345710
U.S.A.	8/20/2002	7273601
U.S.A.	7/18/2000	6461585
U.S.A.	9/5/2007	7658910

Onalta — We have in-licensed certain patents and patent applications from Novartis Pharma AG and Mallinckrodt relating to certain aspects of Onalta. Tables 2-4 summarize the patents and patent application in-licensed from Novartis Pharma AG. Table 5 summarizes the patents and patent application in-licensed from Mallinckrodt. The patents summarized in Tables 2-5 will expire between March 2010 and September 2017.

TABLE 2

Somatostatin Peptides for In Vivo Imaging of Somatostatin Receptor Positive Tumors and Metastasis

Country	Appl. Date	Patent No.
Korea-South	12/4/1989	156541
Malaysia	3/13/1990	106120
Philippines	5/7/1993	29649
USA	6/6/1995	5753627
USA	6/6/1995	5776894

TABLE 3

Therapeutic Use of Somatostatin Peptides

Country	Appl. Date	Patent No.
Belgium	2/19/1991	1004645
France	2/18/1991	9101993
Germany*		
Great Britain	2/18/1991	2241167
Hong Kong	4/10/1997	43497
Italy	2/19/1991	1244496
Japan	2/21/1991	3288055
Switzerland	2/19/1991	683318-4
USA	6/13/1994	6123916

* Germany: patent application still pending. Filing number: P4104308.1

TABLE 4

Chelated Peptides, Complexes Thereof Pharmaceutical Compositions Containing Them and Their Use as Radiopharmaceuticals

Country	Status	Appl. Date	Appl. No.	Patent No.
Argentina	Granted	9/5/1995	333413	AR256010M
Australia	Granted	9/4/1995	30414/95	703057
Austria	Granted	9/4/1995	95810545.4	714911
Belgium	Granted	9/4/1995	95810545.4	714911
Brazil	Granted	9/5/1995	PI9503936-8	PI9503936-8
Canada	Pending	9/5/1995	2157530	
Chile	Granted	9/5/1995	1351/95	40732
China	Granted	9/5/1995	115610/95	ZL95115610.1
Colombia	Granted	9/5/1995	95040393	27134
Czech Republic	Granted	9/4/1995	PV1995-2263	287012
Denmark	Granted	9/4/1995	95810545.4	714911
Ecuador	Granted	9/5/1995	SP 95-1528	PI 97-1158
Europe	Granted	9/4/1995	95810545.4	714911
Finland	Granted	9/4/1995	4147/95	117424
France	Granted	9/4/1995	95810545.4	714911
Germany	Granted	9/4/1995	69520256.1	714911
Great Britain	Granted	9/4/1995	95810545.4	714911
Greece	Granted	9/4/1995	95810545.4	714911
Hungary	Granted	9/4/1995	2577/95	218284
India	Pending	8/24/1995	1092/MAS/95	
Ireland	Granted	9/4/1995	95810545.4	714911
Israel	Granted	9/4/1995	115154	115154
Italy	Granted	9/4/1995	95810545.4	714911
Japan	Granted	9/5/1995	227906/95	3054346
Korea-South	Granted	9/5/1995	28905/95	364111
Luxemburg	Granted	9/4/1995	95810545.4	714911
Malaysia	Pending	9/5/1995	PI95002626	
Mexico	Granted	9/4/1995	9503785	195731
Netherlands	Granted	9/4/1995	95810545.4	714911
New Zealand	Granted	9/4/1995	272919	272919
Norway	Granted	9/4/1995	19953457	316569
Pakistan	Granted	9/3/1995	467/95	134791
Peru	Granted	9/4/1995	277844	001736
Philippines	Granted	9/4/1995	51237	1-1995-51237
Poland	Granted	9/4/1995	P310274	182434
Portugal	Granted	9/4/1995	95810545.4	714911
Russia	Granted	9/4/1995	95114740	2156774
Singapore	Granted	9/4/1995	9501282-9	50356
Slovak Republic	Granted	9/4/1995	1088/95	283774
Slovenia	Granted	9/4/1995	P9530491	714911
South Africa	Granted	9/6/1995	95/7475	7475/95
Spain	Granted	9/4/1995	95810545.4	714911
Sweden	Granted	9/4/1995	95810545.4	714911
Switzerland	Granted	9/4/1995	95810545.4	714911
Taiwan	Granted	9/8/1995	84-109395	114095
Thailand	Granted	9/4/1995	27824/95	11623
Turkey	Granted	9/6/1995	1094/95	TR199501094B
USA	Granted	6/5/2000	09/609844	6277356
USA	Granted	4/23/1997	08/842125	6183721
Venezuela	Granted	9/6/1995	1572-95	

TABLE 5

Stabilizers to Prevent Autoradiolysis of Radiolabeled Peptides and Proteins

Country	App. Date	Patent No.
US	10/13/1993	5,384,113
EPO	7/31/1992	EP 600 992B1
Austria	7/31/1992	AT 196428T
Germany	7/31/1992	DE 69231469T
Denmark	7/31/1992	DK 600 992
Spain	7/31/1992	ES 2150916T
Greece	7/31/1992	GR 3035067T
Canada	7/31/1992	CA 2113995C
Japan	7/31/1992	JP 6510539T

Trofex — We own patent applications related to the composition and methods of use for MIP-1072 and MIP-1095 (Tables 6-9). No application has been granted. Should any rights be granted in these applications, they would expire between April 2020 and November 2027.

TABLE 6

Heterodimers of Glutamic Acid

Country	Status	Appl. Date	Appl. No.
U.S.A.	Pending	11/7/2007	11/936,659
Taiwan	Pending	11/7/2007	96142019
Australia	Pending	11/7/2007	2007316391
Brazil	Pending	11/7/2007	PI0718700-9
Canada	Pending	11/7/2007	2669127
China	Pending	11/7/2007	200780049490.2
EPO	Pending	11/7/2007	07844938.6
India	Pending	11/7/2007	1787/KOLNP/2009
Japan	Pending	11/7/2007	2009-536459

TABLE 7

Ligands for Metabotropic Glutamate Receptors and Inhibitors of NAALADase

Country	Status	Appl. Date	Appl. No.	Patent No.
Australia	Granted	04/27/2000	46682/00	773915
Canada	Pending	04/27/2000	2367787	
EPO	Granted	04/27/2000	00928441.5	1177200
France	Granted	04/27/2000	1177200	1177200
Germany	Granted	04/27/2000	60020962.8-08	1177200
Italy	Granted	04/27/2000	00928441.5	1177200
Japan	Pending	04/27/2000	2000-614262	
United Kingdom	Granted	04/27/2000	1177200	1177200

TABLE 8

Ligands for Metabotropic Glutamate Receptors

Country	Status	Appl. Date	Appl. No.	Patent No.
United States (US)	Granted	4/27/2000	09/559978	6479470
United States (US)	Granted	9/15/2000	09/662767	6528499
United States (US)	Granted	2/25/2003	10/374765	7381745
United States (US)	Pending	02/11/2008	12/029367	

TABLE 9

Imaging Agents and Methods of Imaging NAALADase or PSMA

Country	Status	Appl. Date	Appl. No.	Patent No.
United States (US)	Pending	01/10/2003	10/340,864	
United States (US)	Pending	01/10/2003	PCT/US03/00680	

Solazed — The patent and patent applications relating to Solazed are provided in Table 10. Patent term for this family expires between March 2024 and March 2025.

TABLE 10

Radiohalogenated Benzamide Derivatives and Their Use in Tumor Diagnosis and Tumor Therapy

Country	Status	Appl. Date	Appl. No.	Patent No.
Argentina (AR)	Pending	3/10/2005	P050100925	
Bolivia (BO)	Pending	3/10/2005	SP-250047	
Chile (CL)	Pending	3/10/2005	0507-2005	
Germany (DE)	Pending	3/10/2004	102004011720.9	
Guatemala (GT)	Pending	3/10/2005	PI-2005-0046	
Malta (MT)	Pending	3/3/2005	2654	
Malaysia (MY)	Pending	3/8/2005	PI20050946	
Panama (PA)	Pending	3/10/2005	86260-01	
Peru (PE)	Pending	3/10/2005	000276-2005	
El Salvador (SV)	Pending	3/10/2005	E-3385-2005	
Thailand (TH)	Pending	3/8/2005	098358	
Taiwan (TW)	Pending	3/10/2005	094107360	
United States (US)	Granted	3/10/2005	11/076023	7427390
United States (US)	Pending	9/10/2008	12/207774	
Uruguay (UY)	Pending	3/10/2005	28801	
Venezuala (VE)	Pending	3/10/2005	2005-000421	

Our Non-Oncology Product Candidate

Zemiva — We own patents directed to specific stereoisomers of Zemiva and the use of these stereoisomers as imaging agents (Table 11). All patents in this family are set to expire in November 2016. We are also pursuing three additional patent families (in the United States and internationally) to provide up to 18 years of new patent-based exclusivity for certain aspects of beta-methyl-iodophenylpentadecanoic acid ("BMIPP") and BMIPP-derivative compositions and their uses, with the patent and patent applications expiring generally in 2023.

TABLE 11

Stereoisomers of Fatty Acid Analogs for Diagnostic Imaging

Country	Status	Appl. Date	Appl. No.	Patent No.
EPO	Granted	11/25/1996	96941503.3	0869821
United Kingdom	Granted	11/25/1996	96941503.3	0869821
Spain	Granted	11/25/1996	96941503.3	0869821
Netherlands	Granted	11/25/1996	96941503.3	0869821
Italy	Granted	11/25/1996	96941503.3	0869821
Germany	Granted	11/25/1996	96941503.3	P69636881.1
France	Granted	11/25/1996	96941503.3	0869821
EPO	Pending	11/25/1996	06025944.7	
Hong Kong	Pending	11/25/1996	07110322.1	
Hong Kong	Granted	11/25/1996	99101613.7	HK1016494
Canada	Granted	11/25/1996	2238860	2238860
Japan	Granted	11/25/1996	09-520669	4272259
Japan	Pending	11/25/1996	2008-006447	
U.S.A.	Granted	05/5/2003	10/429416	7005119
U.S.A.	Granted	11/16/2005	11/274505	7314609
U.S.A.	Pending	4/2/2008	12/061528	

While our patents and patent applications may be important for certain aspects of our business, such as those related to specific product candidates such as BMIPP derivatives whose patents and applications expire between 2016 and 2023, we believe that our success also depends upon innovation, technical expertise, and responsiveness to the medical needs of an aging patient population. While our patented technology may delay or deter a competitor in offering a competing product, we believe our technical capability could allow us to obtain limited market exclusivity in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and abroad through similar legislation.

The original patent protecting the composition of BMIPP expired in 2003. However, we believe that Zemiva or I-123-BMIPP, is a new chemical entity in the United States and Europe and, therefore, could be eligible for market exclusivity under the Food, Drug and Cosmetic Act ("FDCA") as amended by the Hatch-Waxman Act. We are also pursuing three additional patent families (in the United States and internationally) to provide up to 18 years of new patent-based exclusivity for certain aspects of BMIPP and BMIPP-derivative compositions and their uses, with the patent and patent applications expiring generally in 2023.

The Hatch-Waxman Act provides a five-year period of non-patent marketing exclusivity to the first applicant to gain approval of a New Drug Application, or NDA, for a new chemical entity. A drug can be classified as a new chemical entity if the FDA has not previously approved any other new drug containing the same active agent. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug, where the applicant does not own or have a legal right of reference to all the data required for approval. Protection under the Hatch-Waxman Act will not prevent the filing or approval of another full NDA, but the applicant could be required to conduct its own adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplements to existing NDAs if new clinical investigations are essential to the approval of the applications, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent.

The Hatch-Waxman Act also permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an investigational new drug exemption, or IND, and the

submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may consider applying for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond the current expiration date, depending on the expected length of clinical trials and other factors involved in the filing of the relevant NDA.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know with certainty whether any of our patent applications or those patent applications that we license could result in the issuance of any new patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products, or could affect the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us and, to the extent they seek to protect these technologies through patents and such technologies are determined to contain valid and enforceable claims, they could achieve a legal determination that our products or technologies are infringing these third-party patents. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any of our products can be commercialized, any related patent may expire, or that such patent may remain in force for only a short period following commercialization of a product candidate, thereby reducing any advantage of the patent with respect to that product candidate. While patent term restoration is available under the Hatch-Waxman Act and similar laws, we cannot predict whether such patent term restoration could be granted to us or to any particular patent covering such product candidate.

We rely in some circumstances on trade secrets to protect our technology, particularly with respect to certain aspects of our Zemiva manufacturing process. Trade secrets, however, can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors, contract manufacturers and other entities with whom we do business. However, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the proprietary rights or resulting know-how generated in related inventions.

We currently use Molecular Insight™, and the Molecular Insight Pharmaceuticals™ (logo) as trademarks in the United States and other countries. We have sought trademark registration for the Molecular Insight Pharmaceuticals™ logo, Azedra™, Ultratrace™, Nanotrace™, Zemiva™, SAAC™, SAACQ™, Onalta™, Solazed™, and Trofex™, in the United States and in countries outside the United States. We have sought trademark registration for Molecular Insight Pharmaceuticals Pioneers in Medicine, Partners In Care™, Rintara™, Unectra™, and Velepin™ in the United States. We cannot guarantee any of these marks will be approved in the United States or in foreign jurisdictions. However, we have secured registration for AZEDRA® (Japan, South Korea and European Union (CTM)), MOLECULAR INSIGHT® (USA), MOLECULAR INSIGHT PHARMACEUTICALS® (logo; European Union), SOLAZED® (European Union), ONALTA® (European Union, Israel and Turkey), SAAC® (European Union), SAACQ® (European Union), TROFEX® (Japan) and ZEMIVA® (European Union). We have also received protection for the Katakana character form of Azedra in Japan and have an application for the Chinese character form of the mark pending in China.

In addition, we have obtained rights to the following Internet domain names: www.molecularinsight.com, www.zemiva.com, www.zemiva.org, www.zemiva.net, www.velepin.com, www.velepin.org, www.velepin.net, www.ultratrace.org, www.ultratrace.net, www.azedra.com, www.azedra.net, www.solazed.com, www.solazed.org, www.solazed.net, www.onalta.com, www.onalta.net, www.onalta.org, www.rintara.com, www.trofex.net, www.trofex.org, www.xersen.com, www.xersen.net and www.xersen.org.

Government Regulation

Government authorities in the United States and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing and import and export of pharmaceutical products. Our targeted molecular radiotherapeutics and molecular imaging pharmaceuticals in the United States will be subject to FDA regulation as drugs under the FDCA, and require FDA approval prior to commercial distribution. The process of obtaining governmental approvals and complying with ongoing regulatory requirements requires the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations and policies may change and new legislation or regulations may be issued that could delay such approvals. If we fail to comply with applicable regulatory requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

The U.S. regulatory scheme for the development and commercialization of new pharmaceutical products can be divided into three distinct phases: an investigational phase including both preclinical and clinical investigations leading up to the submission of an NDA; a period of FDA review culminating in the approval or refusal to approve the NDA; and the post-marketing period. Each of these phases is described below.

Preclinical Phase

The preclinical phase involves the characterization, product formulation and animal testing necessary to prepare an IND for submission to the FDA. The IND must be reviewed and authorized by the FDA before the drug can be tested in humans. Once a new pharmaceutical agent has been identified and selected for further development, preclinical testing is conducted to confirm pharmacological activity, to generate safety data, to evaluate prototype dosage forms for appropriate release and activity characteristics, and to confirm the integrity and quality of the material to be used in clinical trials. A bulk supply of the active ingredient to support the necessary dosing in initial clinical trials must be secured. Data from the preclinical investigations and detailed information on proposed clinical investigations are compiled in an IND submission and submitted to the FDA before human clinical trials may begin. If the FDA does not formally communicate an objection to the IND within 30 days, the specific clinical trials outlined in the IND may go forward.

Clinical Phase

The clinical phase of drug development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the substance in humans, as well as the ability to produce the substance in accordance with the FDA's cGMP requirements. Data from these activities are compiled in an NDA requesting approval to market the drug for a given use, or indication. Clinical trials must be conducted under the supervision of qualified investigators in accordance with good clinical practice, and according to IND-approved protocols detailing, among other things, the study objectives and the parameters, or endpoints, to be used in assessing safety and efficacy. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board, or IRB, and each trial, with limited exceptions, must include all subjects' informed consent. The clinical evaluation phase typically involves the following sequential process:

Phase 1 clinical trials are conducted in a limited number of healthy subjects to determine the drug's safety, tolerability, and biological performance. The total number of subjects in Phase 1 clinical trials varies, but is generally in the range of 20 to 80 people (or less in some cases, such as drugs with significant human experience).

Phase 2 clinical trials involve administering the drug to subjects suffering from the target disease or condition to evaluate the drug's potential efficacy and appropriate dose. The number of subjects in Phase 2 trials is typically several hundred subjects or less.

Phase 3 clinical trials are performed after preliminary evidence suggesting effectiveness has been obtained and safety, tolerability, and appropriate dosing have been established. Phase 3 clinical trials are intended to gather additional data needed to evaluate the overall benefit-risk relationship of the drug and to provide adequate instructions for its use. Phase 3 trials usually include several hundred to several thousand subjects.

Throughout the clinical testing phase, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, increasingly large-scale production protocols and written standard operating procedures must be developed for each aspect of commercial manufacturing and testing.

The clinical trial phase is both costly and time-consuming, and may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical testing as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, institutional review boards, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

New Drug Application and Review

After the successful completion of Phase 3 clinical trials, the sponsor of the new drug submits an NDA to the FDA requesting approval to market the product for one or more indications. An NDA is a comprehensive, multi-volume application that includes, among other things, the results of all preclinical and clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging, and labeling the drug. In most cases, the NDA must be accompanied by a substantial user fee. FDA has 60 days after submission to review the completeness and organization of the application, and may refuse to accept it for continued review, or refuse to file, if the application is found deficient. After filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use. Drugs that successfully complete NDA review may be marketed in the United States, subject to all conditions imposed by the FDA.

Prior to granting approval, the FDA generally conducts an inspection of the facilities, including outsourced facilities that will be involved in the manufacture, production, packaging, testing and control of the drug product for cGMP compliance. The FDA will not approve the application unless cGMP compliance is satisfactory. If the FDA determines that the marketing application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter.

The length of the FDA's review can range from a few months to several years or more. Once an NDA is in effect, significant changes such as the addition of one or more new indications for use generally require prior approval of a supplemental NDA including additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective.

Fast Track Development

The Food and Drug Administration Modernization Act of 1997, or the Modernization Act, establishes a statutory program for relatively streamlined approval of "Fast Track" products, which are defined under the Modernization Act as new drugs or biologics intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Fast Track status requires an official designation by the FDA.

Abbreviated New Drug Application and Review

An ANDA is a type of NDA that is used for the review and approval of a generic drug product. A generic drug product is one that is the same as a previously approved innovator drug product, which means it has the same active ingredient, dosage form, strength, route of administration, quality, performance characteristics, and intended use. An ANDA is generally not required to include preclinical and clinical data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to the previously approved drug, which means that it performs in the same manner. None of the products currently under development by Molecular Insight will be eligible for ANDA approval, although it is possible that competing products based on our product could be approved by this route at some future time.

Section 505(b)(2) Applications

If a proposed drug product represents only a limited change from a product that has already been approved by the FDA, yet differs in more ways than those permitted under the ANDA requirements, then the applicant may be able to submit a type of NDA referred to as a 505(b)(2) application. This route of approval is potentially applicable to the development of Azedra, as iobenguane, when labeled with diagnostic radionuclides has previously been approved as an imaging agent for pheochromocytoma and neuroblastoma. In effect, a 505(b)(2) applicant is permitted to rely on information in the scientific literature, or previous safety and efficacy determinations by the FDA, rather than submitting the full complement of clinical or other data that could otherwise be required for NDA approval. However, the 505(b)(2) sponsor must provide any additional clinical or other data needed to supplement and/or establish the relevance and applicability of prior findings for the new product formulation.

Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant Orphan Drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. There are similar provisions for orphan drug status in the laws of Europe and in most other countries. We have received Orphan Drug designation from the FDA for Azedra and from the EMEA for Onalta and we may file for Orphan Drug designation for the use of other potential product candidates. However, obtaining FDA approval to market a product with Orphan Drug exclusivity may not provide us with a material commercial advantage.

Orphan Drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Although Orphan Drug designation does not shorten or otherwise convey any advantage in the regulatory approval process, approved Orphan Drugs are granted a seven year period of market exclusivity during which the FDA may not approve any other application to market the same drug for the same indicated disease except in very limited circumstances. These circumstances are an inability to supply the drug in sufficient quantities, or a situation in which a subsequent product has shown superior safety or efficacy. This regulatory-based market exclusivity, however, could also adversely impact approval of our pharmaceutical products if a competitor first obtains Orphan Drug designation and approval of their drug for the same indication.

Post-Approval Phase

Once the FDA has approved a new drug for marketing, the product becomes available for physicians to prescribe in the United States. After approval, we must comply with post-approval requirements, including ongoing compliance with cGMP regulations, delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. We are required to maintain and provide updated safety and efficacy information to the FDA. We are also required to comply with requirements concerning advertising and promotional labeling.

Compliance with post-approval requirements will require us to expend time, money, and effort on an ongoing basis. We use, and will continue to use, third-party manufacturers, including MDS Nordion, to produce certain of our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional clinical studies, known as Phase 4 trials, to evaluate long-term effects.

Other Regulation in the United States

Healthcare Reimbursement

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we do business, including the United States. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products. Government programs, including Medicare and Medicaid, private healthcare insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments. This can create price sensitivity among potential customers for our products. Some third-party payers must also approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the medical devices or therapies. Even though a new medical product may have been cleared for commercial distribution, we may find limited demand for the product until reimbursement approval has been obtained from governmental and private third-party payers.

Environmental Regulation

We are also subject to various environmental laws and regulations both within and outside the United States. Like many other pharmaceutical and medical device companies, our operations involve the use of substances, including hazardous wastes, which are regulated under environmental laws, primarily manufacturing and sterilization processes. We do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position or cash flow. These laws and regulations are all subject to change, however, and we cannot predict what impact, if any, such changes might have on our business, financial condition, results of operations and cash flows.

Our research is also dependent on our maintenance of a Radioactive Materials license from the Massachusetts Department of Public Health and the State of Texas which allows us to acquire, use and store quantities of radioactive isotopes that are critical for the manufacture and testing of research products.

Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval from the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable jurisdiction, clinical trials conducted outside of the United States typically are administered under a three-phase sequential process similar to that discussed above for pharmaceutical products.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the prices which result from the regulatory approval process would be insufficient to generate an acceptable return to us or our collaborators.

Employees

As of December 31, 2009, we had seventy-one full-time employees. Fifty-three of our employees are engaged in research and development, clinical development and regulatory affairs and quality assurance of our product candidates. Eighteen of our employees are classified in general and administrative, which includes operations, finance, accounting, human resources, external communications, facilities management and general administration.

Available Information

We were incorporated in the Commonwealth of Massachusetts in 1997 under the name Imaging Biopharmaceuticals, Inc, changed our name to Biostream, Inc. in 1998, and changed our name again to Molecular Insight Pharmaceuticals, Inc. in 2003. Our principal executive offices are located at 160 Second Street, Cambridge, Massachusetts, 02142, and our telephone number is (617) 492-5554. Our Internet site address is www.molecularinsight.com. Information found on, or that can be accessed through, our website is not incorporated by reference into this annual report on Form 10-K. We make available free of charge on or through our website our filings with the Securities and Exchange Commission, or SEC, including this annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act") as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, a copy of this annual report is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding our filings at www.sec.gov.

ITEM 1A. *RISK FACTORS*

This report contains forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995) that are based on management's current expectations, estimates, forecasts, and projections about the Company and its business. In addition, other written or oral statements which constitute forward-looking statements may be made from time to time by or on behalf of Molecular Insight Pharmaceuticals, Inc. Any statement in this report that is not a statement of historical fact is a forward-looking statement, and in some cases, words such as "believe," "estimate," "project," "expect," "intend," "may," "anticipate," "plans," "seeks," and similar expressions identify forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual outcomes and results to differ materially from the anticipated outcomes or result. These statements are not guarantees of future performance, and undue reliance should not be placed on these statements. Molecular Insight Pharmaceuticals, Inc. undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Factors that could cause actual results to differ materially from what is expressed or forecasted in our forward-looking statements include, but are not limited to, the following:

Risks Related to Our Ability to Continue as a Going Concern and Our Noncompliance with Covenants under Our Bond Indenture

We may not be able to continue as a going concern.

On November 16, 2007, we sold $150,000,000 in Senior Secured Floating Rate Bonds due 2012 ("Bonds") and warrants to purchase 6,021,247 shares of common stock at an exercise price of $5.87 per share ("Bond Warrants") under an indenture ("Bond Indenture"). The terms of our Bond Indenture include various covenants, including, among others, a financial covenant that requires us to maintain a minimum liquidity level on a quarterly basis. The minimum liquidity covenant (as defined in the Indenture and which substantially represents all of our cash, cash equivalents and investments) requires us to maintain a minimum amount of not less than $25.7 million and $29.2 million at September 30, 2010 and December 31, 2010, respectively. Based on our current projections of our cash flow, we expect that we would not be in compliance with this covenant in the third or fourth quarter of 2010, unless we are able to raise sufficient additional capital. Additionally, under the Bond Indenture, we are required to deliver audited annual financial statements to Bond holders which are not subject to a "going concern" or like qualification or exception from our independent auditors. Such anticipated noncompliance of the required minimum liquidity level in the second half of 2010, recurring losses from our operations and net stockholders' capital deficiency, and the uncertainty of our obtaining additional financing on a timely basis raise substantial doubt about our ability to continue as a going concern beyond September 2010. As a result, in the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2009, our independent auditors have included an emphasis of a matter paragraph relating to substantial doubt whether we can continue as a going concern. We cannot guarantee our ability to continue as a going concern unless we can raise additional capital, of which there can be no assurance.

Our obligations under our Bond Indenture may be accelerated due to our noncompliance with the covenants in our Bond Indenture if the grace period (or any extension thereof) of the waiver granted by our Bond holders expires, and we are unable to reach an agreement with Bond holders regarding an additional waiver or an agreement regarding the restructuring of our outstanding debt.

As discussed above, the inclusion of such a "going concern" paragraph in the report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2009 would result in a default by us under the terms of the Bond Indenture that may give rise to an acceleration of our debt obligations under the Bond Indenture, unless waived by the Bond holders.

We discussed with the holders of our Bond the foregoing circumstances and a restructuring of our outstanding debt. On March 15, 2010, we executed a waiver agreement with the holders of at least a majority of the Bonds and the Bond Indenture trustee. Under the terms of the waiver agreement, the Bond holders and Bond Indenture trustee have agreed to waive the noncompliance arising from the inclusion of the "going concern" paragraph in the report of our independent registered public accounting firm on our financial statements and other technical defaults under the Bond Indenture until 12:01 AM Eastern Standard Time on April 16, 2010, subject to earlier termination upon certain circumstances. The waiver is also subject to a number of certain terms and conditions relating to our provision of certain information to the Bond holders, among other conditions and matters. In the event that the waiver expires or terminates prior to the successful restructuring of the outstanding debt, then we will be in default of our obligations under the Bond Indenture and the Bond holders may choose to accelerate the debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations.

We are continuing to negotiate with the Bond holders regarding the restructuring of the outstanding debt in a manner designed to avoid the acceleration of our debt obligations and position us for future growth. There is no assurance that we will reach such an agreement on terms favorable to us, or at all. Moreover, in connection with our discussions with the Bond holders to reach such an agreement, the Bond holders may impose additional

operational or financial restrictions on us or modify the terms of our existing Bond Indenture. These restrictions may limit our ability, among other things, to make necessary capital expenditures or incur additional indebtedness. In addition, the Bond holders may require us to pay additional fees, prepay a portion of our indebtedness, accelerate the amortization schedule for our indebtedness or agree to higher interest rates on our outstanding indebtedness or take other actions that could adversely affect our business. The Bond holders may also require us to raise additional capital concurrently with any restructuring. Any restructuring of the debt obligations could require a significant change in our plans and could require us to undergo a realignment of our cost structure, including a reduction in workforce. Further, we expect that any restructuring of the Bonds will require the approval of holders of more than a majority of the outstanding Bonds and, in some circumstances, unanimous approval will be required. Consequently, we cannot assure you that we will be able to obtain such approval on satisfactory terms or at all. If the waiver grace period (or any extension thereof) expires or terminates, and we are unable to reach an agreement with Bond holders regarding an additional waiver or an agreement regarding the restructuring of our outstanding debt, the Bond holders may choose to accelerate our debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations. If our indebtedness under the Bond Indenture is accelerated or is not restructured on acceptable terms, it is likely that we will be unable to repay our debt and we may seek protection under the U.S. Bankruptcy Code or similar relief.

Our outstanding Bonds are secured by all of our assets, and a default could result in our debt holders taking title to all of our assets in order to satisfy our obligations to them, which could render our common stock valueless, as our debt holders may foreclose on our assets in an effort to be repaid amounts due under the Bonds and force us into bankruptcy.

Our obligations under our existing Bonds are secured by a first priority security interest in all of our assets including our intellectual property. If we are unable to make the payments due on the Bonds, if we default on any of the conditions, restrictions or covenants of the Bonds, or if we become insolvent, the holders of the Bonds have a right to foreclose on, take possession of and liquidate all of our assets. Any such a default and the related foreclosure and liquidation could irreparably harm our financial condition and our ability to operate. As such, our Bond holders could force us into bankruptcy at any time, which could result in the complete failure of our business and stockholders would lose their entire investment in our Company. We currently have very limited assets that would most likely not be sufficient to cover existing debts if we had to liquidate. Consequently, if the Bond holders choose to accelerate our debt obligations under the Bond Indenture and demand immediate repayment in full, we may seek protection under the U.S. Bankruptcy Code or similar relief.

If we are unable to reach an agreement with our Bond holders regarding the restructuring of our outstanding debt obligations and obtain additional financing, we will likely be unable to comply with our Bond Indenture's financial covenants.

We are currently in discussions with our Bond holders regarding the restructuring of our debt obligations under the Bond Indenture and the avoidance of an acceleration of our debt obligations under the Bond Indenture. There is no assurance that we will reach such an agreement on terms favorable to us, or at all. Even though the Bond holders have granted a temporary waiver with respect to the breach of the covenant regarding the inclusion of a "going concern" paragraph in the report of our independent registered public accounting firm on our financial statements and other technical defaults by us, such waiver may expire or terminate without us having reached an agreement with the Bond holders regarding a restructuring. Further, based on our current cash flow projections, it is still likely that we will be in breach of the minimum liquidity covenant contained in the Bond Indenture in the second half of 2010. Consequently, we will need to reach an agreement with the Bond holders regarding a restructuring of our outstanding debt obligations to either remove such requirements or allow us to raise a sufficient amount of additional capital through the issuance of additional debt or equity securities or through asset dispositions or other means to maintain compliance with such requirements. If we are unable to successfully restructure the indebtedness outstanding under the Bond Indenture, we will likely breach the minimum liquidity covenant and the Bond holders may choose to accelerate our debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such

obligations. If our indebtedness under the Bond Indenture is accelerated or is not restructured on acceptable terms, it is likely that we will be unable to repay our debt and we may seek protection under the U.S. Bankruptcy Code or similar relief.

Any uncertainty relating to our ability to restructure our debt could impair our ability to implement our business plan.

As we continue our discussions with the Bond holders regarding a restructuring of our outstanding debt obligations, we will also need to continue to operate our business, maintain our relationships with our key employees, vendors and other third parties. Our key employees may seek opportunities elsewhere due to a lack of certainty regarding our financial situation. Vendors may be reluctant to extend credit as a result of our current financial situation. Similarly, our ability to grow our relationships with our current licensees and potential licensees may be significantly impaired due to the uncertainty regarding our financial situation. If we are unable to maintain our relationships with our key employees and vendors and grow our relationships with our current licensees and potential licensees, our ability to continue to operate and grow our business could be materially impaired.

General Risks Related to Our Bonds and Bond Warrants

Our substantial indebtedness could materially adversely affect our financial condition and our ability to operate our business, and could prevent us from fulfilling our obligations under the Bonds.

Our substantial level of indebtedness under the Bond Indenture could have significant consequences to us, including, but not limited to, limiting our ability to raise additional capital. For example, since we are highly leveraged, we may not be able to sell additional securities or incur additional indebtedness on terms that are favorable to us, if at all. Additionally, we may have difficulty negotiating licensing agreements with potential licensors of our products/programs due to the concerns of potential licensors regarding our ability to continue to operate as a going concern as a result of our substantial level of indebtedness. Since we will require additional financing to continue our research and development programs, service our debt obligations and grow our business, our substantial level of indebtedness could have a materially adverse impact on our ability to operate our business and fulfill our obligations under the Bonds.

Additionally, our substantial level of indebtedness under the Bond Indenture could have the following adverse impacts on our operations:

- it will restrict us from making strategic acquisitions, introducing new products or services, or exploiting business opportunities;
- it may limit our flexibility in planning for, or reacting to, changes in our business and future business opportunities;
- it may place us at a competitive disadvantage with our competitors that are not as highly leveraged; and
- it may make us more vulnerable to a downturn in our business, our industry, or the economy in general than our competitors who have less debt.

In the event that we are able to come to an agreement with the Bond holders regarding the restructuring of our outstanding indebtedness, we will require additional financing to grow our business and service our debt obligations.

We expect to continue to incur significant net losses and negative operating cash flows in the foreseeable future. We have five clinical-stage product candidates in development and will need to spend significant capital to fulfill planned operating goals and continue to conduct clinical and non-clinical trials, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization. We will require substantial funds to continue our research and development programs and our future capital requirements may vary from what we expect. In addition, as our product candidates progress into later-stage clinical development,

we will be required to initiate larger, more costly trials. There are factors, many of which are outside our control, that may affect our future capital requirements and accelerate our need for additional financing.

Furthermore, we have consistently elected to use the payment-in-kind ("PIK") feature of the outstanding Bonds in lieu of making cash interest payments ("PIK Interest") since the issuance of the Bonds. As a result, in each period in which we were entitled to make such an election in lieu of making interest payments on the Bonds, our debt increased by the amount of such interest. Our ability to continue to elect to pay interest in the form of PIK Interest ends in November 2010 and we will be required to make cash payments of interest in order to service the Bonds after such date.

As a result of these factors, we do not expect to be able to achieve and maintain a level of cash flow from operations sufficient to permit us to service our Bonds and fund our operations and planned capital expenditures. Consequently, we will need to raise additional capital.

If we raise additional funds through the issuance of new equity securities, our stockholders may experience substantial dilution, or the new equity securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through debt financings, these financings may involve significant cash payment obligations and covenants that restrict our ability to operate our business and make distributions to our stockholders. We also could elect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain technologies, product candidates or products. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us. We have no current commitments from any persons that they will provide any additional financing.

Due to market conditions and the status of our product development pipeline, additional funding may not be available to us on acceptable terms, or at all. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Our failure to raise additional financing would adversely affect our ability to maintain, develop, enhance or grow our business, take advantage of future opportunities or respond to competitive pressures.

If we are unable to procure additional financing, we could face substantial liquidity problems and we could be forced to reduce or delay capital expenditures or to dispose of material assets or operations to meet our debt service and other obligations. In addition, our Bond Indenture restricts our ability to dispose of assets and could prevent us from undertaking dispositions that become necessary for us to meet our debt service obligations.

If we cannot make scheduled payments on our indebtedness, including the cash payment of interest on the Bonds starting in November of this year, the Bond holders may choose to accelerate our debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations. If our indebtedness under the Bond Indenture is accelerated, it is likely that we will be unable to repay our debt and we may seek protection under the U.S. Bankruptcy Code or similar relief.

We are subject to a number of restrictive financial covenants and redemption provisions under the terms of our Bond Indenture which may restrict and limit our business and financing activities.

The Bond Indenture and other documents governing our outstanding Bonds contain financial covenants requiring that we maintain a minimum liquidity level and contains limits on maximum capital expenditures. In addition, the Bond Indenture contains redemption provisions that, among other things, limit our ability to:

- enter into outbound licensing agreements with third parties;
- borrow money;
- make certain investments;
- use assets as security in other transactions;
- create liens;

- merge or consolidate; and
- transfer and sell assets.

A failure to comply with these redemption provisions and covenants could result in a default under our Bonds. This could cause any or all of our Bonds to become immediately due and payable under acceleration provisions. If our debt were to be accelerated, it is likely that we will be unable to repay our debt and we may seek protection under the U.S. Bankruptcy Code or similar relief.

Our Bonds have a variable interest rate, which makes us vulnerable to increases in interest rates and could cause our interest expense to increase, make our debt service more difficult to manage and decrease cash available for operations and other purposes.

Our indebtedness exposes us to interest rate increases because our Bonds are subject to variable rates. We may incur additional debt in the future that also bears interest at variable rates. Variable rate debt creates higher debt service requirements if market interest rates increase, which would adversely affect our funds from operations. At present, we do not have any derivative financial instruments such as interest rate swaps or hedges to mitigate interest rate variability. The interest rates under our Bond Indenture will be reset at varying periods. These interest rate adjustments could expose our operating results and cash flows to periodic fluctuations. Our annual debt service obligations will increase by approximately $1.9 million per year for each 1% increase in the average interest rate we pay based on the $186.5 million balance of variable rate debt outstanding at December 31, 2009. If interest rates rise in the future, and particularly, if they rise significantly, our ability to service our debt obligations will be negatively affected. Any increase in the interest rates will increase our expenses and reduce funds available for our operations and future business opportunities. Increases in interest rates will also increase the risks resulting from our significant debt levels.

Future issuances of common stock, including issuance of common stock as a result of the restructuring of our outstanding debt, additional financings, or upon exercise of Bond Warrants held by holders of our Bonds, will severely dilute the ownership interest of existing stockholders and may further depress the trading price of our common stock.

Any new issuance of equity securities as a result of the restructuring of our outstanding debt, additional financings, or upon exercise of Bond Warrants held by holders of our Bonds will likely severely dilute the interests of our existing stockholders, and any sales in the public market of any common stock issuable upon such exercise could adversely affect trading prices of our common stock.

Risks Related to Our Business

We have a history of losses and expect to continue to incur losses and may not achieve profitability.

We have incurred net losses every year since our inception in 1997 and have generated no significant revenue from product sales and have received limited revenue from licenses to date. As of December 31, 2009, we had a deficit accumulated of approximately $292.9 million. We expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risk that we may not obtain substantial additional capital needed to support the expenses of developing our technology and commercializing our potential products; develop a market for our potential products; successfully transition from a company with a research focus to a company capable of either manufacturing and selling potential products or profitably licensing our potential products to others; and/or attract and retain qualified management, technical and scientific staff.

If we fail to attract and retain senior management, consultants, advisors and scientific and technical personnel, our product development and commercialization efforts could be impaired.

Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel, particularly Daniel L. Peters, our President and Chief Executive Officer, and John W.

Babich, our Executive Vice-President and Chief Scientific Officer. Although we have entered into employment agreements with certain members of our current senior management, there is no assurance that they will remain in our employ for the entire term of such employment agreements. The loss of the services of any member of our senior management or our scientific or technical staff may significantly delay or prevent the development of our product candidates and other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business, operating results, cash flows and financial condition. We maintain key man life insurance on John Babich.

We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

In addition, it is important that we retain our core executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to retain sufficient scientific, technical and managerial personnel or quickly recruit and attract qualified replacements could limit or delay our product development efforts, which could adversely affect the development of our product candidates and commercialization of our potential products and growth of our business.

A substantial portion of our funding comes from federal government grants and research contracts. We cannot rely on these grants or contracts as a continuing source of funds.

A substantial portion of our revenue to date has been derived from federal government grants and research contracts. As of December 31, 2009, we were awarded in the aggregate, approximately $3.1 million in grants from National Institutes of Health, or NIH and gross proceeds of $2.1 million remained to be received under our various NIH grants, which include potential reimbursements for our employees' time and benefits and other expenses related to performance under various contracts. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them due to their own budgetary constraints. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing grants or contracts may be less than the awarded amounts.

Additionally, significant government investment and allocation of resources to assist the economic recovery of other sectors may reduce the resources available for government grants and related funding for life sciences research and development. Our ability to obtain financing from government grants is subject to the availability of funds under applicable government programs and approval of our applications to participate in such programs. We cannot provide assurances that our efforts to obtain such funds from these government sources will be successful. In the event we are not successful in obtaining any new government grants or extensions to existing grants, we may have to reduce the scope of, or discontinue, some of our programs, which could have a material adverse effect on us.

Our government grants and government contracts are subject to unique risks.

In addition to normal business risks, our contracts with the U.S. government are subject to unique risks, some of which are beyond our control. All of our government contracts contain provisions which make them terminable at the convenience of the government. The government could terminate, reduce or delay the funding under any of our grants at any time without prior notice at its convenience upon payment for work done and commitments made at the time of termination.

Our contract costs are subject to audits by U.S. government agencies. U.S. government representatives may audit the costs we incur on our U.S. government contracts, including allocated indirect costs. Such audits could result in adjustments to our contract costs. Any costs found to be improperly allocated to a specific contract will

not be reimbursed, and such costs already reimbursed must be refunded. If any audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government.

We license patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects could be harmed.

We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our business. In particular, we have obtained the nonexclusive rights from Novartis, for certain radiolabeled somatostatin analogs and the exclusive rights to the particular somatostatin analog compound edotreotide (the parent compound of Onalta), along with know-how related to the manufacture and use of this compound. We may enter into additional licensing agreements to license third-party intellectual property in the future. Our success could depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue with respect to these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we could. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Under the license agreement with Novartis has retained an option to reacquire rights in the compound if annual sales exceed a certain threshold level. If Novartis does exercise this call back option, we will be required to sell to Novartis the rights in the compound which may have a negative effect on our operating results.

We out-license certain of our product candidates to third parties for further development and commercialization. If such licensees fail in their development or commercialization efforts or default under our agreements with them, we will be harmed.

We began out-licensing Onalta to BioMedica in September 2009 for development in certain countries in Europe, the Middle East, North Africa, Russia and Turkey. We plan to explore out-license opportunities for our other products and/or programs, including, but not limited to, Azedra, Trofex or Zemiva. It is possible that we could be unsuccessful in our attempts to out-license these products and/or programs. In the event that we are successful in out-licensing any of these products and/or programs, our revenue from licensing payments from any licensee will depend on whether such licensee is ultimately successful in the development of the products and/or programs. Accordingly, it is possible that we may not receive any substantial financial benefit from any out-license of these products and/or programs in the short term. Our revenue from these licenses will be limited if the licensees are not successful in developing and commercializing products in the licensed territories. Additionally, our licensees may terminate or fail to perform their obligations under our agreements or have internal liquidity issues, in which case our ability to review payments from them will be significantly impaired. There is no guarantee that our licensees will be able to pay fees to us at all.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act requires management's annual review and evaluation of our internal controls and attestations of the effectiveness of new internal controls by our independent auditors. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business.

We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

In addition, our Bonds contain a covenant requirement that we obtain a statement from our auditors that we are in compliance at the end of each fiscal year with the requirements of the Sarbanes-Oxley Act regarding our system of internal control over financial reporting. Failure to be in compliance will result in a default under the Bond Indenture. We cannot provide assurances that we will receive a statement that we are in compliance with the Sarbanes-Oxley Act from our independent auditors, or that we will receive a waiver of the default from our Bondholders.

Risks Related to Our Common Stock

Our stock price has resulted in our failure to meet NASDAQ Global Market continued listing requirements, which could result in NASDAQ delisting of our common stock.

Our common stock is listed on the NASDAQ Global Market. On March 9, 2010, we received a letter from The NASDAQ Stock Market ("NASDAQ") notifying us that for the 30 consecutive business days preceding the date of the letter, we failed to maintain the minimum $50 million Market Value of Listed Securities requirement for continued listing on the NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(b)(2)(A) (the "MVLS Rule"). NASDAQ further advised that in accordance with NASDAQ Listing Rule 5810(c)(3)(C), we have a grace period of 180 calendar days, or until September 7, 2010, to regain compliance with the MVLS Rule. NASDAQ will deem us to have regained compliance with the MVLS Rule if at any time during the 180-day grace period our Market Value of Listed Securities (the "MVLS") closes at $50,000,000 or more for a minimum of 10 consecutive business days.

We will actively monitor our MVLS between now and September 7, 2010, and will consider available options to resolve the deficiency and regain compliance with the MVLS Rule. In the event that we are unable to regain compliance with the MVLS Rule prior to September 7, 2010, we plan to apply to transfer our common stock to the NASDAQ Capital Market provided that we satisfy the requirements for continued listing on that market, otherwise we will receive written notification from Nasdaq that our securities are subject to delisting.

Additionally, in order to maintain our listing, we are required to satisfy other minimum financial and continued listing requirements, including, without limitation, maintaining a $1.00 per share minimum closing bid price for our common stock (the "Minimum Bid Price Rule").

Our common stock has recently traded at a low of $1.05 per share on February 17, 2010. If the closing bid price of our common stock goes below $1.00 for 30 consecutive business days, we would receive another deficiency notice from NASDAQ stating that our common stock fails to meet the Minimum Bid Price Rule. To regain compliance, our common stock would need to close at $1.00 or more for a minimum of 10 consecutive business days during the 180 calendar days following our receipt of such a notice. If we are unable to regain compliance within 180 calendar days with the Minimum Bid Price Rule, we will be subject to delisting unless we apply to transfer our common stock to the NASDAQ Capital Market provided that we satisfy the requirements for continued listing on that market. There can be no assurance that we will be able to reestablish or maintain compliance with listing criteria on either NASDAQ market.

Given current economic conditions and the volatility of our stock price, there is no guarantee that we will regain compliance with the MVLS Rule for continued listing on the NASDAQ Global Market or satisfy the requirements for transferring our listing to the NASDAQ Capital Market. If we are unable to meet either the MVLS Rule or the Minimum Bid Price Rule, or if we fail to satisfy any other continued listing standards under the NASDAQ Global Market rules, NASDAQ may commence delisting proceedings against us. If we were to be delisted, the market liquidity of our common stock and the value of our stock would likely be adversely affected. Although our common stock may be traded over-the-counter or on pink sheets, these types of listings involve more risk and trade less frequently and in smaller volumes than securities traded on NASDAQ. A delisting could also adversely affect our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by our investors, business partners and employees. If we are not listed on The NASDAQ Stock Market and/or if our public float remains below $75 million, we will be limited in our ability to file new shelf registration statements on Form S-3 and/or to fully use one or more registration statements on Form S-3 that have

been filed with the SEC. Any such limitations might have a material adverse effect on our ability to raise the capital we need for the continuation of our operations.

Our stock is subject to short selling, which could cause trading in our common stock and our stock price to be volatile, and the anticipation of a volatile stock price could cause greater volatility.

There has been active shorting on our stock, and from time to time when short sales are covered, this has had the effect of having fluctuations in our stock price. Short selling and possible market price manipulation of our common stock may cause trading in our common stock to be volatile and has a negative effect on the trading price of our common stock. The anticipation of a volatile stock price could cause even greater volatility in our stock trading and could further adversely affect our stock price. The short selling and volatility of our stock may cause the value of a stockholder's investment to decline rapidly.

Our stock price may be highly volatile, and your investment in our stock could decline in value.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- our ability to successfully restructure the Bonds;
- if we restructure the Bonds, the terms of the restructuring, including the debt and its terms and the type and number of equity securities issued in any such restructuring;
- any expiration or termination of the Bond holder waiver relating to the inclusion of a "going concern" paragraph in our auditor's audit opinion prior to any restructuring of the Bonds;
- results from and any delays in the clinical trials programs;
- failure or delays in entering additional product candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- delays in establishing new strategic relationships;
- delays in the development of our product candidates and commercialization of our potential products;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic conditions, including recent adverse changes in the global financial markets;
- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our product candidates or products;
- market acceptance of our products;
- third-party healthcare reimbursement policies;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our product candidates or products;
- additions or departures of key personnel;
- third-party sales of large blocks of our common stock;

- sales of our common stock by our executive officers, directors or significant stockholders; and
- equity sales by us of our common stock to fund our operations.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

A significant portion of our outstanding shares that are restricted as a result of securities law could be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We had outstanding 25,268,327 shares of common stock as of March 12, 2010. The shares that were sold in our IPO may be resold in the public market freely. On May 9, 2008, we registered 4,030,543 shares of common stock owned by certain existing stockholders on a registration statement on Form S-3 with the SEC. These shares may be sold into the public market in the near future. As of March 12, 2010, 8,622,021 shares of our common stock are restricted as a result of securities laws. These restricted shares may be sold by "affiliates" and by non-"affiliates" who have held such shares for less than one year after meeting certain requirements of Rule 144 of the Securities Act of 1933, as amended ("the Securities Act") and may be sold by non-"affiliates" who have held such shares for longer than one year without meeting certain requirements of the Securities Act.

Future sales or other issuances of our common stock could depress the market for our common stock and dilute existing stockholders.

On August 28, 2009, we filed a shelf registration statement on Form S-3 (SEC file No. 333-161601), which was declared effective by the SEC on September 11, 2009. Under this shelf registration statement, which gives us the flexibility to raise funds of up to $250,000,000 through the sale of a variety of securities, we may raise money by the sale of our equity or debt securities or debt, warrants, stock purchase contracts or stock purchase units. However, given uncertain market conditions and the volatility of our stock price, we may not be able to sell our securities in public offerings or private placements at prices and/or on terms that are favorable to us, if at all. Also, if we are able to sell our securities, any sales of large quantities of our securities could reduce the price of our common stock, and, to the extent that we raise additional capital by issuing equity securities pursuant to our effective shelf registration statements or otherwise, our existing stockholders' ownership will be diluted.

Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, and Nasdaq National Market rules are creating uncertainty for public companies. As a result of these new rules, we could incur additional costs associated with our public company reporting requirements. In addition, these new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and this could make it difficult for us to attract and retain qualified persons to serve on our board of directors.

We are constantly evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs. These new or changed laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by

regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Several institutions have large investments in our common stock, bonds and warrants. One, or a combination of, these institutions may be able to exert substantial influence over our management and board of directors and, through them, affect our corporate policies and management's decisions. Their interests may conflict with your interests as an investor in our common stock.

Several institutions have made large investments in our common stock, bonds and/or warrants. As a result, these institutions, operating singly or together, may be able to exert substantial influence over our management and board of directors and, as a result, affect our corporate policies and management's decisions relating to key corporate actions. These institutions may also from time to time acquire and hold interests in businesses that compete directly or indirectly with us, or independently pursue acquisition opportunities that could otherwise be complementary to our business. In addition, our directors may authorize transactions, such as acquisitions, that involve risks to the interests of our Bondholders and common stockholders. These institutions' interests may not be aligned, and may conflict, with your interests as an investor in our common stock, bonds, or warrants.

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

We have not paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business, and we do not anticipate paying any cash dividends on our capital stock for the foreseeable future. In addition, the terms of existing or any future debt facilities may preclude us from paying dividends on our stock. As a result, capital appreciation, if any, of our common stock could be your sole source of gain for the foreseeable future.

Some provisions of our Restated Articles of Organization and Amended and Restated Bylaws may inhibit potential acquisition bids that you may consider favorable.

Our Restated Articles of Organization and Amended and Restated Bylaws contain provisions that may enable our Board of Directors to resist a change in control of our company even if a change in control were to be considered favorable by stockholders. These provisions include:

- the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- advance notice procedures required for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders;
- limitations on persons authorized to call a meeting of stockholders;
- a staggered Board of Directors; and
- supermajority voting requirements to remove directors from office.

These and other provisions contained in our charter and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions which our stockholders might otherwise receive a premium for their shares over then current prices, and may limit the

ability of stockholders to remove our current management or approve transactions that our stockholders may deem to be in their best interest and, therefore, could adversely affect the price of our common stock.

Risks Related to Our Product Candidates

We are largely dependent on the success of our lead product candidates, Azedra, Onalta, Trofex, Solazed, and Zemiva, and we may not be able to successfully commercialize these potential products.

We have incurred and will continue to incur significant costs relating to the development and marketing of our lead product candidates, Azedra, Onalta, Trofex, Solazed, and Zemiva. We have not obtained approval to market these potential products in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize these products successfully. If we fail to successfully commercialize these products, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, results of operations and cash flows will be adversely affected.

We have also been working on identifying and developing product candidates in addition to Azedra, Onalta, Trofex, Solazed, and Zemiva. We do not know whether our planned preclinical development or clinical trials for these other product candidates will begin on time or be completed on schedule, if at all. In addition, we do not know whether any of our clinical trials will result in marketable products. We do not anticipate that any additional product candidates will reach the market for at least several years, if at all.

If we fail to obtain foreign and U.S. regulatory approval of Azedra, Onalta, Trofex, Solazed, or Zemiva, or any of our other current or future product candidates, we will be unable to commercialize these potential products in and outside the United States.

In September 2009, we entered into a Territory License Agreement with BioMedica of Athens, Greece for commercialization of Onalta in certain European countries, the Middle East, North Africa, Russia and Turkey. Under the Agreement, BioMedica is expected to perform clinical studies and to secure all regulatory approvals to market, sell and distribute Onalta within its licensed territories. There are risks and uncertainties related to BioMedica's ability to obtain regulatory approval for Onalta in the specified territories, and the progress, timing, cost, and results of clinical trials and product development by BioMedica.

The development, testing, manufacturing and marketing of our product candidates are subject to extensive regulation by governmental authorities in the United States and throughout the world. In particular, the process of obtaining FDA or EMEA approval is costly and time consuming, and the time required for such approval is uncertain. Our product candidates must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process mandated by the FDA or EMEA. Such regulatory review includes the determination of manufacturing capability and product performance. Generally, only a small percentage of pharmaceutical products are ultimately approved for commercial sale.

There can be no assurance that our current or future product candidates will be approved by the FDA, EMEA or any other governmental body. In addition, there can be no assurance that all necessary approvals will be granted for future product candidates or that review or actions will not involve delays caused by requests for additional information or testing that could adversely affect the time to market for and sale of our product candidates. Further, failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval as well as possible civil and criminal sanctions.

Failure to enroll patients in our clinical trials may cause delays in developing Azedra, Onalta, Trofex, Solazed, or Zemiva, or any of our other current or future product candidates.

We may encounter delays in the development and commercialization, or fail to obtain marketing approval, of Azedra, Onalta, Trofex, Solazed, or Zemiva, or any other future product candidate if we are unable to enroll enough patients to complete clinical trials. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the nature and severity of illness of the population, the size of the patient population, the nature of the clinical protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial and competing clinical trials. In particular, it may be very difficult to find patients to enroll in our

clinical trials of Azedra and Onalta, as we have received the Orphan Drug designation for Azedra and for Onalta. Orphan drug designation is intended to treat a "rare disease or condition" which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Delays in planned patient enrollment may result in increased costs and harm our ability to complete our clinical trials and obtain regulatory approval.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Significant delays in clinical testing could materially increase our product development costs. We have spent all of the net proceeds raised in our initial public offering and utilizing the net proceeds from the subsequent sale of Bonds and Warrants in connection with additional clinical trials for Azedra, Onalta, Trofex, Solazed, and Zemiva. We do not know whether planned clinical trials could begin on time, or require to be restructured or could be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence and continue a study, delays in reaching agreement on acceptable clinical study terms with prospective sites, delays in obtaining institutional review board approval to conduct a study at a prospective site and delays in recruiting patients to participate in a study.

In addition, we typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of these clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not perform their obligations in a timely fashion. Significant delays in testing or regulatory approvals for any of our current or future product candidates, including Azedra, Onalta, Trofex, Solazed, and Zemiva, could prevent or cause delays in the commercialization of such product candidates, reduce potential revenues from the sale of such product candidates and cause our costs to increase.

Our clinical trials for any of our current or future product candidates may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for these product candidates or cease our trials.

We do not know whether our existing or future clinical trials could demonstrate safety and efficacy sufficiently to result in marketable products. Because our clinical trials for Azedra, Onalta, Trofex, Solazed, and Zemiva, and our other product candidates may produce negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for these product candidates or cease our clinical trials. If this occurs, we may not be able to obtain approval for these product candidates or our anticipated time to market these product candidates may be substantially delayed and we may also experience significant additional development costs. We may also be required to undertake additional clinical testing if we change or expand the indications for our product candidates. We could only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA, or the applicable foreign regulatory agency, that the product candidate is safe and effective.

If approved, the commercialization of our product candidates, including Azedra, Onalta, Trofex, Solazed, and Zemiva, may not be profitable due to the need to develop manufacturing, sales, marketing and distribution capabilities, or make arrangements with a third party to perform these functions.

In order for the commercialization of our potential products to be profitable, our products must be cost-effective and economical to manufacture on a commercial scale. Subject to regulatory approval, we expect to incur significant sales, marketing, distribution and, to the extent we do not outsource manufacturing, manufacturing expenses in connection with the commercialization of Azedra, Onalta, Trofex, Solazed, and Zemiva, and our other potential products as we do not currently have a dedicated sales force, and we have no experience in the manufacturing, sales, marketing and distribution of pharmaceutical products. In order to commercialize Azedra, Onalta, Trofex, Solazed, or Zemiva, or any of our other potential products that we develop, we must develop manufacturing, sales, marketing and distribution capabilities or make arrangements with a third party to perform these functions. Developing a sales force is expensive and time-consuming, and we may not be able to develop this capacity. If we are unable to establish adequate manufacturing, sales, marketing

and distribution capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable. Our future profitability will depend on many factors, including, but not limited to:

- the costs and timing of developing and operating a commercial scale manufacturing facility or the costs of outsourcing the manufacturing of Azedra, Onalta, Trofex, Solazed, and Zemiva;
- receipt of FDA approval of Azedra, Onalta, Trofex, Solazed, and Zemiva, and our other product candidates, as applicable;
- the terms of any marketing restrictions or post-marketing commitments imposed as a condition of approval by the FDA or foreign regulatory authorities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish.

Even if we receive regulatory approval for Azedra, Onalta, Trofex, Solazed, or Zemiva, or any of our other product candidates, we may never receive significant revenues from any of them. To the extent that we are not successful in commercializing our potential products, we will incur significant additional losses and the price of our common stock could be negatively affected.

We do not have patent rights to the composition of Zemiva, and if we cannot gain and exploit a period of marketing exclusivity under the Food, Drug & Cosmetic Act, as amended, we may not be able to successfully commercialize Zemiva or our other product candidates.

We do not have patent rights to the composition of Zemiva. The original patent protecting BMIPP, the underlying active molecule in Zemiva, expired in 2003. We believe that Zemiva is a new chemical entity in the United States and could be eligible for market exclusivity under the FDCA, as amended by the Hatch-Waxman Act of 1984. A drug can be classified as a new chemical entity if the FDA has not previously approved any other new drug containing the same active agent. Under sections 505(c)(3)(D)(ii) and 505(j)(5)(D)(ii) of the FDCA, as amended by the Hatch-Waxman Act of 1984, a new chemical entity that is granted regulatory approvals may, in the absence of patent protections, be eligible for five years of marketing exclusivity in the United States following regulatory approval. This marketing exclusivity could protect us from any other applicant utilizing the materials in support of our new drug application, or NDA, during the exclusivity period. However, there is no assurance that Zemiva could be considered a new chemical entity for these purposes or be entitled to the period of marketing exclusivity. If we are not able to gain or exploit the period of marketing exclusivity, we may not be able to successfully commercialize Zemiva or may face significant competitive threats to such commercialization from other manufacturers, including the manufacturers of generic alternatives. Further, even if Zemiva is considered a new chemical entity and we are able to gain five years of marketing exclusivity, another company could also gain such marketing exclusivity under the provisions of the FDCA, as amended by the Hatch-Waxman Act if such company can complete a full NDA with a complete human clinical trial process and obtain regulatory approval of its product.

Our proprietary rights may not adequately protect our intellectual property and product candidates and if we cannot obtain adequate protection of our intellectual property and product candidates, we may not be able to successfully market our product candidates.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies and product candidates. We will only be able to protect our technologies and product candidates from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or other market exclusionary rights apply. Our lead cardiovascular molecular imaging candidate, Zemiva, is not covered by patent rights. We hold the patent rights to our second generation cardiac candidate, a derivative of

Zemiva. Because Zemiva itself is not patented, we depend on obtaining the five year period of marketing exclusivity under the FDCA for Zemiva as a new chemical entity. Failure to obtain this marketing exclusivity right could permit competitors to gain access to the market for Zemiva.

While we have obtained enforceable patents covering our oncology product candidate Trofex, our neurology product candidate which is not in active development and our Ultratrace radiolabeling technology platform, some of our patent rights for these compounds and technologies are still pending patent applications. We cannot guarantee these patent applications will issue as patents. The patent positions of life sciences companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The general patent environment outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. Additionally, life science companies like ours are dependent on creating a pipeline of products. We may not be able to develop additional proprietary technologies or product candidates that produce commercially viable products or that are themselves patentable.

Our issued patents may be subject to challenge and possibly invalidated by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or other countries may diminish the market exclusionary ability of our intellectual property.

In addition, others may independently develop similar or alternative compounds and technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar compounds or radiolabeling technology, this may have an adverse effect on our business.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. In particular, we rely on trade secrets to protect certain manufacturing aspects of our compound Zemiva. Trade secrets, however, are difficult to protect. While we believe that we use reasonable efforts to protect our trade secrets, our own or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements could provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our product candidates, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favor. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed.

Our ability to commercialize our product candidates will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business.

Our ability to commercialize our product candidates will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property in the fields of

cardiology, oncology, neurology, and radiopharmaceutical technologies are complicated, and third-party intellectual property rights in these fields are continuously evolving. We have not performed searches for third-party intellectual property rights that may raise freedom-to-operate issues, and we have not obtained legal opinions regarding commercialization of our product candidates. As such, there may be existing patents that may affect our ability to commercialize our product candidates.

In addition, because patent applications are published 18 months after their filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents.

If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court order prohibiting us from commercializing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our own products to market.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

We may be unable to obtain Orphan Drug marketing exclusivity for certain of our product candidates and if another party obtains Orphan Drug exclusivity instead, approval of our product for the same indication could be prevented for seven years.

Under the Orphan Drug Act, the FDA may grant Orphan Drug designation to drugs intended to treat a rare disease or condition, which is defined by the FDA as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan Drug designation does not shorten the development or regulatory review time of a drug, but does provide limited advantages in the regulatory review and approval process. The company that obtains the first FDA approval for a designated Orphan Drug indication receives marketing exclusivity for use of that drug for that indication for a period of seven years. Moreover, even if we obtain Orphan Drug exclusivity for one or more indications, our exclusivity may be lost if the FDA later determines that the request for designation was materially defective, or if we are unable to assure sufficient commercial quantity of the drug. Orphan Drug exclusivity for Azedra and Onalta also could not prevent a competitor from obtaining approval of a different drug to treat the same Orphan Drug indications.

If our product candidates, including Azedra, Onalta, Trofex, Solazed, and Zemiva, do not gain market acceptance among physicians, patients and the medical community, we may be unable to generate significant revenue, if any.

The products that we develop may not achieve market acceptance among physicians, patients, third-party payers and others in the medical community. If we receive the regulatory approvals necessary for commercialization, the degree of market acceptance could depend upon a number of factors, including:

- limited indications of regulatory approvals;
- the establishment and demonstration in the medical community of the clinical efficacy and safety of our product candidates and their potential advantages over existing diagnostic compounds;

- the prevalence and severity of any side effects;
- our ability to offer our product candidates at an acceptable price;
- the relative convenience and ease of administration of our products;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

The market may not accept Azedra, Onalta, Trofex, Solazed, or Zemiva, based on any number of the above factors. If Trofex is approved, its primary competition could be the current standard of care in the assessment of metastatic prostate cancer. If Zemiva is approved, its primary competition in the emergency department setting could be the then current standard of care, which involves several diagnostic products, and its primary competition in the non-acute setting could be existing perfusion agents such as Cardiolite and Myoview. As of the time that Azedra, Onalta, Trofex, Solazed, and Zemiva are approved, there may be other therapies available which directly compete for the same indications. The market may choose to continue utilizing the existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of any of our product candidates to gain market acceptance could impair our ability to generate revenue, which could have a material adverse effect on our future business, financial condition, results of operations and cash flows.

We have no commercial manufacturing facility currently in production for Azedra, Onalta, Trofex, Solazed, Zemiva or any of our other product candidates and have no experience in manufacturing products for commercial purposes and the failure to find manufacturing partners or create a functioning manufacturing facility ourselves could have an adverse impact on our ability to grow our business.

We currently have no active commercial manufacturing facility in production for Azedra, Onalta, Trofex, Solazed, Zemiva or our other product candidates. In October 2007, we purchased a domestic radiopharmaceutical manufacturing facility in Denton, Texas. As of December 31, 2009, the facility was not yet placed in service. The facility was originally intended to be used for the manufacture of molecular imaging and targeted radiotherapeutic product candidates. Completion of the build-out of the facility was previously deferred until manufacturing requirements for our clinical trials were determined. Concurrent with the change in senior management, research specialists were engaged to evaluate the market potentials of each of our product candidates. Based on the results of these studies, plans with respect to the utilization of the facility have changed and there is no current plan to utilize it.

We are dependent on third parties to supply our product candidates according to our specifications, in sufficient quantities, on time, in compliance with appropriate regulatory standards and at competitive prices.

In October 2009 we contracted with EZN to construct an exclusive suite dedicated to radiolabel Onalta and manufacture and supply Onalta for clinical trials and commercial production outside the United States, however, such facility is not operational yet. The EMEA has reviewed and accepted Onalta's Phase 3 clinical trial protocol design and has granted Onalta Orphan Drug Designation, however we cannot be sure that we will be able to obtain an adequate supply of our Onalta on acceptable terms, or at all. In October 2009, we entered into a Supply Agreement with BioMedica in connection with the BioMedica Territory License Agreement. Our ability to supply Onalta to BioMedica is dependent on manufacture by EZN, and we cannot be sure that we will be able to obtain an adequate supply of Onalta on acceptable terms, or at all, to meet our supply obligations. We are under an obligation to make certain advance payments for construction of the exclusive suite, and if we fail to do so in a timely manner, construction will be delayed or halted. This may affect our ability to secure supplies of Onalta.

In August 2009 we contracted with a Canadian company, MDS Nordion, to construct a dedicated facility to radiolabel Azedra and manufacture and supply Azedra for our clinical trials and commercial production, however, such facility is not operational yet. Although MDS Nordion supplies Azedra in connection with our current clinical trials, we do not have a dedicated functioning commercial manufacturing facility for large scale production of Azedra at MDS Nordion. Azedra has completed a Phase 1 and is commencing recruiting for

pivotal Phase II clinical trials, however we cannot be sure that we will be able to obtain an adequate supply of Azedra on acceptable terms, or at all. We are under an obligation to make certain advance payments for construction of the facility, and if we fail to do so in a timely manner, construction will be delayed or halted. This may affect our ability to secure supplies of Azedra.

We have contracted with MDS Nordion, to radiolabel BMIPP and manufacture and supply Zemiva for our clinical trials and commercial production. We do have a functioning commercial manufacturing facility for Zemiva at MDS Nordion. In January 2010, w received a notice from MDS Nordion of its intent to terminate the Zemiva Supply Agreement effective upon the expiration of the initial term on January 12, 2012. We cannot be sure that we will be able to obtain an adequate supply of our product candidates on acceptable terms, or at all.

Zemiva is BMIPP that has been radiolabeled with I-123. We are currently aware of only one commercial provider of BMIPP, TCI America, in Portland, Oregon. There is no assurance that we will be able to obtain sufficient amounts of BMIPP from this provider to produce adequate quantities of Zemiva. If this provider is unable to meet our demand, we could be required to find alternative sources of BMIPP including producing BMIPP ourselves or contracting with third parties to produce BMIPP. We are not aware of any proprietary or technical reasons prohibiting the manufacture of BMIPP by us or a third party. However finding an alternative source for Zemiva could likely result in unforeseen costs and delays to the commercialization of Zemiva.

Manufacturers supplying biopharmaceutical products must comply with FDA regulations which require, among other things, compliance with the FDA's evolving regulations on cGMPs, which are enforced by the FDA through its facilities inspection program. The manufacture of products at any facility will be subject to strict quality control, testing and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. Since the commercial manufacturing facilities for Azedra, Onalta and Zemiva have not been constructed, the FDA and EMEA have not certified the cGMP compliant manufacture of Azedra, Onalta and Zemiva. We cannot guarantee that the resultant facility will pass FDA and/or EMEA inspection, or that future changes to cGMP manufacturing standards will not also affect the cGMP compliant manufacture of Azedra, Onalta and Zemiva.

Trofex is under preliminary review in connection with an exploratory IND, and Solazed is in preclinical stages, and our other product candidates are in discovery stages. We have no commercial cGMP manufacturing capability for Trofex, Solazed or these other product candidates, and currently no third-party manufacturer for them. As such, we may not be able to obtain sufficient quantities of these product candidates as we develop our pre-clinical or clinical programs for these compounds. We will need to enter into additional manufacturing arrangements for the manufacturing needs for Trofex, Solazed and all other product candidates. We have not yet determined if we will construct our own manufacturing facility for these product candidates. While we have signed an agreement with MDS Nordion for the commercial manufacture and supply of Azedra, we cannot guarantee that MDS Nordion will be contracted to fulfill this role, or if another manufacturer will be sought. We cannot guarantee that a suitable manufacturer for these product candidates will be found, or that we will be able to secure manufacturing agreements on acceptable terms with any of these manufacturers. We also cannot guarantee that such manufacturer will be able to supply sufficient quantities of our product candidates, or that they will meet the requirements for clinical testing and cGMP manufacturing.

Termination of agreements in the Onalta and Azedra supply chains as well as agreements with other third parties can have adverse financial consequences.

Pursuant to our agreement for supply of Azedra with MDS Nordion, we are responsible for certain exit payments following termination of the agreement for any reason other than a material breach by MDS Nordion. These exit payments include facility decommissioning and waste disposal charges, inventory write down charges, and other operational costs of discontinuing Azedra manufacture. If we are unable to meet our monthly minimum purchases of Azedra, or following drug approval if we are unable to meet our monthly reservation fees for the facility, or if we became insolvent or filed for bankruptcy, this agreement could be terminated, which would trigger the above exit payments.

Likewise, pursuant to our agreement for supply of Onalta with EZN, we are responsible for certain payments following termination of the agreement. If we terminate the agreement or following termination by a material breach of the agreement by us, we are obligated to make a substantial one-time payment for purchase of EZN's rights in any intellectual property developed under the agreement. In addition, we are responsible for all costs associated with decommissioning of the dedicated Onalta facility, or we may transfer title to the facility and equipment to EZN, at its option. If we are unable to meet the facility construction payments, or if we became insolvent or filed for bankruptcy, this agreement could be terminated, which would trigger the above termination payments. In addition, termination of the EZN agreement would have direct consequences in our ability to supply Onalta to BioMedica, for purchase and sale of Onalta by BioMedica throughout Europe, North Africa and parts of Asia. Therefore termination of the EZN agreement could cause us to breach our Supply Agreement and Territory License Agreement with BioMedica.

In addition, in the event that we are become insolvent or file for bankruptcy, this may trigger an event of default by us under other agreements we have with third parties and provide termination rights for parties to our agreements and this could have a material adverse effect on our business.

Risks Related to Our Industry

Our competitors may develop products that are less expensive, safer or more effective, which may diminish or eliminate the commercial success of any potential products that we may commercialize.

If our competitors market products that are less expensive, safer or more effective than our future products developed from our product candidates, or that reach the market before our product candidates, we may not achieve commercial success. For example, if approved, Zemiva will compete in the emergency department setting with the current standard of care in the assessment of chest pain patients who present themselves to emergency departments. This standard involves several diagnostic products and procedures, in some cases involving the use of perfusion imaging agents, which in the aggregate may require several hours or days of hospitalization to reach an ultimate diagnosis. If approved, Zemiva's primary competition in the non-acute setting will be perfusion imaging agents such as Cardiolite produced by Bristol-Myers Squibb Medical Imaging, Myoview produced by GE Healthcare, and generic thallium, the primary U.S. supplier being Tyco Healthcare/ Mallinckrodt. The market may choose to continue utilizing the existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of Zemiva or any of our product candidates to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition, results of operations and cash flows.

We expect to compete with several pharmaceutical companies including Bristol-Myers Squibb Medical Imaging, GE Healthcare and Tyco Healthcare/Mallinckrodt, and our competitors may:

- develop and market products that are less expensive or more effective than our future products;
- commercialize competing products before we or our partners can launch any products developed from our product candidates;
- operate larger research and development programs or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations.

In addition, the life sciences industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies.

The use of hazardous materials in our operations may subject us to environmental claims or liabilities.

Our research and development activities involve the use of hazardous materials, including chemicals and biological and radioactive materials. Injury or contamination from these materials may occur and we could be held liable for any damages, which could exceed our available financial resources. This liability could materially adversely affect our business, financial condition, results of operations and cash flows.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We may be required to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition, results of operations and cash flows.

If we fail to comply with extensive regulations enforced by the FDA and other agencies with respect to pharmaceutical products, the commercialization of our product candidates could be prevented, delayed or halted.

Research, preclinical development, clinical trials, manufacturing and marketing of our product candidates are subject to extensive regulation by various government authorities. We have not received marketing approval for Azedra, Onalta, Trofex, Solazed, Zemiva or our other product candidates. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive, and the time required for such approvals is uncertain. The approval process is affected by such factors as:

- the severity of the disease;
- the quality of submission relating to the product candidate;
- the product candidate's clinical efficacy and safety;
- the strength of the chemistry and manufacturing control of the process;
- the manufacturing facility compliance;
- the availability of alternative treatments;
- the risks and benefits demonstrated in clinical trials; and
- the patent status and marketing exclusivity rights of certain innovative products.

Any regulatory approvals that we or our partners receive for our product candidates may also be subject to limitations on the indicated uses for which the product candidate may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The subsequent discovery of previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product candidate and withdrawal of the product candidate from the market.

U.S. manufacturing, labeling, storage and distribution activities also are subject to strict regulating and licensing by the FDA. The manufacturing facilities for our biopharmaceutical products are subject to periodic inspection by the FDA and other regulatory authorities and from time to time, these agencies may send notice of

deficiencies as a result of such inspections. Our failure or the failure of our biopharmaceutical manufacturing facilities, to continue to meet regulatory standards or to remedy any deficiencies could result in corrective action by the FDA or these other authorities, including the interruption or prevention of marketing, closure of our biopharmaceutical manufacturing facilities, and fines or penalties.

Regulatory authorities also could require post-marketing surveillance to monitor and report to the FDA potential adverse effects of our product candidates. Congress or the FDA in specific situations can modify the regulatory process. If approved, any of our product candidates' subsequent failure to comply with applicable regulatory requirements could, among other things, result in warning letters, fines, suspension or revocation of regulatory approvals, product recalls or seizures, operating restrictions, injunctions and criminal prosecutions.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our product candidates and our business could suffer.

In the future, we intend to distribute and sell our potential products outside of the United States, which will subject us to further regulatory risk.

In addition to seeking approval from the FDA for Azedra, Onalta, Trofex, Solazed and Zemiva in the United States, we intend to seek the governmental approval required to market Azedra, Onalta, Trofex, Solazed and Zemiva and our other potential products in European Union countries such as the United Kingdom, France, Germany, Belgium, Holland and Italy through third-parties. We may in the future also seek approvals for additional countries. The regulatory review process varies from country to country, and approval by foreign government authorities is unpredictable, uncertain and generally expensive. Our ability to market our potential products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances. We anticipate commencing the applications required in some or all of these countries following approval by the FDA; however, we may decide to file applications in advance of the FDA approval if we determine such filings to be both time and cost effective. If we export any of our potential products that have not yet been cleared for domestic commercial distribution, such products may be subject to FDA export restrictions. Marketing of our potential products in these countries, and in most other countries, is not permitted until we have obtained required approvals or exemptions in each individual country. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

Market acceptance of our potential products could be limited if users are unable to obtain adequate reimbursement from third-party payers.

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like our product candidates, and our commercial success could depend in part on these third-party payers agreeing to reimburse patients for the costs of our potential products. Even if we succeed in bringing any of our product candidates to market, there is no assurance that third-party payers will consider our potential products cost effective or provide reimbursement in whole or in part for their use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Each of our product candidates is intended to replace or alter existing therapies or procedures. These third-party payers may conclude that our product candidates are less safe, effective or cost-effective than these existing therapies or procedures. Therefore, third-party payers may not approve our products candidates for reimbursement.

If third-party payers do not approve our product candidates for reimbursement or fail to reimburse for them adequately, sales could suffer as some physicians or their patients could opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payers make reimbursement available, these payers' reimbursement policies may adversely affect our ability and the ability of our potential collaborators to sell our potential products on a profitable basis.

The trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products which could adversely affect our business, financial condition, results of operations and cash flows.

In addition, legislation and regulations affecting the pricing of our product candidates may change in ways adverse to us before or after the FDA or other regulatory agencies approve any of our product candidates for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals, they could materially adversely affect our business, financial condition, results of operations and cash flows.

Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our potential products.

In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we could obtain and maintain such insurance on acceptable terms or that we could secure increased coverage if the commercialization of our potential products progresses, or that future claims against us could be covered by our product liability insurance. Moreover, there can be no assurance that the existing coverage of our insurance policy and/or any rights of indemnification and contribution that we may have could offset any future claims. We currently maintain product liability insurance of $10 million per occurrence and in the aggregate for clinical trial related occurrences only. We believe that this coverage is currently adequate based on current and projected business activities and the associated risk exposure, although we expect to increase this coverage as our business activities and associated risks grow. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage and not subject to any indemnification or contribution could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We could be negatively impacted by the application or enforcement of federal and state fraud and abuse laws, including anti-kickback laws and other federal and state anti-referral laws.

We are not aware of any current business practice which is in violation of any federal or state fraud and abuse law. However, continued vigilance to assure compliance with all potentially applicable laws will be a necessary expense associated with product development. For example, all product marketing efforts must be strictly scrutinized to assure that they are not associated with improper remunerations to referral sources in violation of the federal Anti-Kickback Statute and similar state statutes. Remunerations may include potential future activities for our product candidates, including discounts, rebates and bundled sales, which must be appropriately structured to take advantage of statutory and regulatory "safe harbors." From time to time we engage physicians in consulting activities. In addition, we may decide to sponsor continuing medical education activities for physicians or other medical personnel. We also may award or sponsor study grants to physicians from time to time. All relationships with physicians, including consulting arrangements, continuing medical education and study grants, must be similarly reviewed for compliance with the Anti-Kickback Statute to assure that remuneration is not provided in return for referrals. Patient inducements may also be unlawful. Inaccurate reports of product pricing, or a failure to provide product at an appropriate price to various governmental entities, could also serve as a basis for an enforcement action under various theories.

Claims which are "tainted" by virtue of kickbacks or a violation of self-referral rules may be alleged as false claims if other elements of a violation are established. The federal False Claims Act, which includes a provision allowing whistleblowers to bring actions on behalf of the federal government and receive a portion of the

recovery, applies to those who submit a false claim and those who cause a false claim to be submitted. Because our potential customers may seek payments from the federal healthcare programs for our product candidates, even during the clinical trial stages, we must assure that we take no actions which could result in the submission of false claims. For example, free product samples which are knowingly or with reckless disregard billed to the federal healthcare programs could constitute false claims. If the practice was facilitated or fostered by us, we could be liable. Moreover, inadequate accounting for or a misuse of federal grant funds used for product research and development could be alleged as a violation of the False Claims Act or other relevant statutes.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change.

Risks Related to General Economic Conditions

Continued instability in the credit and financial market conditions may negatively impact our business, results of operations, and financial condition.

Financial markets in the United States, Canada, Europe and Asia continues to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be greatly reduced and local governments and many businesses are still in serious difficulty due to the lack of consumer spending and the lack of liquidity in the credit markets. Unemployment rates remain significantly high. As a clinical-stage biopharmaceutical company, we rely on third parties for several important aspects of our business, including the manufacturing and supply of our products for clinical and compassionate use, clinical development of our product candidates, and conduct of our clinical trials. Such third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued instability in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

Facilities

Our principal executive and administrative offices are comprised of two leased facilities located in Cambridge, Massachusetts. We believe that our current facilities will meet our anticipated needs for the remainder of the lease terms. The following summarizes the principal terms of our leases:

(1) On April 8, 2008, we entered into a lease agreement for the lease of approximately 15,555 square feet of office and laboratory space in Cambridge, Massachusetts. The term of the lease is from July 1, 2008 to June 30, 2011. The monthly base rent for the first two years of the lease is $45,369 and for the last year of the lease is $46,665. The Company has an option to extend the term for a two-year period from July 1, 2011 to June 30, 2013.

(2) On April 25, 2008, we entered into a lease agreement for the lease of approximately 19,750 square feet of office space located in Cambridge, Massachusetts. The term of the lease is from April 25, 2008 to March 31, 2010. The monthly base rent from April 25, 2008 to March 31, 2009 is $55,308 and from April 1, 2009 to March 31, 2010 is $56,959. The Company has an option to extend the term twice and each extension is for a period of six months.

(3) We also entered into a five-year lease agreement for an office space in Germany that ends in April 2013.

We own a domestic radiopharmaceutical manufacturing facility located at 3100 Jim Cristal Road, Denton, Texas. The Denton facility is intended to be used for the manufacture of molecular imaging and targeted radiotherapeutic product candidates. This plant provides more than 80,000 square feet of pharmaceutical manufacturing, warehouse, clean room and administrative office space. As of December 31, 2009, the facility was not yet placed in service. Completion of the build-out of the facility was previously deferred until manufacturing requirements for our clinical trials were determined. Plans with respect to the utilization of the facility have changed and there is no current plan to utilize it.

ITEM 3. ***LEGAL PROCEEDINGS***

We are not a party to any material legal proceedings.

ITEM 4. ***[RESERVED]***

PART II

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

Market for Registrant's Common Stock

Our common stock began trading on the NASDAQ Global Market under the symbol "MIPI" on February 2, 2007. The following sets forth, for the fiscal periods ended December 31, 2009 and 2008, respectively the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

	2009	
	High	Low
First Quarter (January 1 through March 31)	$4.50	$1.15
Second Quarter (April 1 through June 30)	7.90	2.42
Third Quarter (July 1 through September 30)	6.69	4.51
Fourth Quarter (October 1 through December 31)	6.50	2.13

	2008	
	High	Low
First Quarter (January 1 through March 31)	$9.38	$6.38
Second Quarter (April 1 through June 30)	8.70	5.30
Third Quarter (July 1 through September 30)	8.90	4.61
Fourth Quarter (October 1 through December 31)	7.95	2.11

Number of Stockholders

As of March 12, 2010, there were approximately 97 stockholders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to fund the development and expansion of our business and, therefore, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend on the terms of our Bond Indenture, our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments, and other factors our board of directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes our outstanding securities and securities available for future issuance under our equity compensation plans as of December 31, 2009 (our last completed fiscal year end).

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights [a]	Weighted-Average Price of Outstanding Options, Warrants, and Rights [b]	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column [a]) [c]
Equity compensation plans approved by stockholders	4,114,853(1)	$5.16	1,116,995
Equity compensation plans not approved by stockholders	320,000(2)	$7.36	—
Total	4,434,853		1,116,995

(1) Includes options issued under the 1997 Stock Option Plan, which terminated on January 9, 2007, and the Amended and Restated 2006 Equity Incentive Plan, which was approved by the stockholders on August 31, 2006, and which has allowed award grants since the effective date of the Company's initial public offering.

(2) Includes warrants for the purchase of 240,000 shares of common stock issued to consultants on September 16, 2008 in payment for their services which expire five years after issuance date and remaining 80,000 of performance-based stock options granted outside the Company's existing equity incentive plan to our President and Chief Executive Officer.

Recent Sales of Unregistered Securities

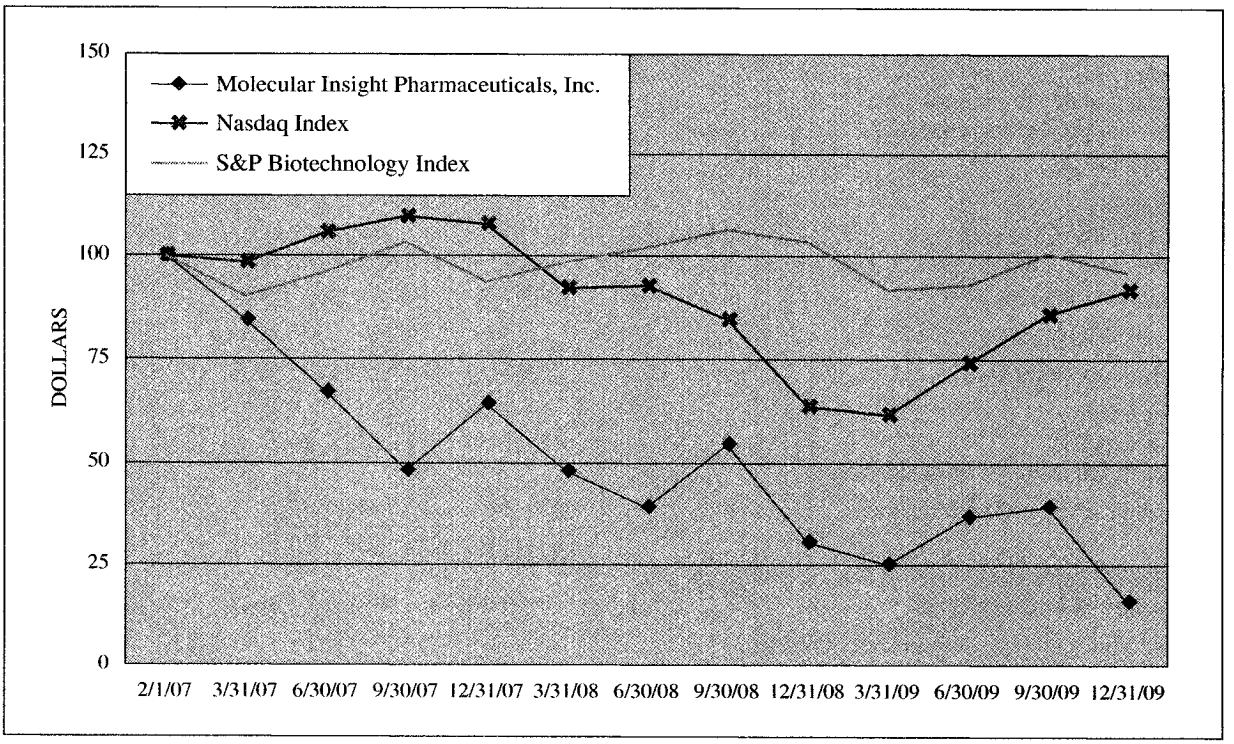
As disclosed in our quarterly report on Form 8-K filed with the SEC on November 16, 2007, we issued the Senior Secured Floating Rate Bonds due 2012 and Warrants to purchase 6,021,247 shares of our common stock at an exercise price of $5.87 per share as disclosed in our filings with the SEC in 2007. The Bonds and Warrants were offered and sold in a private offering only to qualified institutional buyers pursuant to Rule 144A and to persons outside the United States under Regulation S under the Securities Act. Except for the foregoing issuance, we did not issue any other securities that were not registered under the Securities Act during the fiscal year ended December 31, 2007.

As disclosed in our quarterly report on Form 10-Q filed with the SEC on November 14, 2008, we issued a warrant to purchase 240,000 shares of our common stock at an exercise price of $7.91 per share. The warrant has a term of five years and is exercisable at any time on or after September 16, 2008. The warrant was issued in payment for consulting services. We did not receive any cash proceeds from the issuance of the warrant. We did not issue any other securities that were not registered under the Securities Act during the fiscal year December 31, 2008.

As disclosed in our quarterly report on Form 10-Q filed with the SEC on November 9, 2009 and reported in our Current Report on Form 8-K filed on August 11, 2009, we issued to Mr. Daniel L. Peters, our President and Chief Executive Officer, an inducement grant of a non-statutory stock option to purchase up to 125,000 shares of our common stock on August 11, 2009, at an exercise price of $5.70. This option was granted in reliance of NASDAQ Marketplace Rule 4350(i)(1)(A)(iv) and was granted outside the Company's existing equity incentive plan. The option was issued in reliance on the exemption from registration under Section 4(2) of the Securities Act, as amended, which provides an exemption from registration for transactions not involving a public offering. We did not issue any other securities that were not registered under the Securities Act during the fiscal year December 31, 2009.

Stock Performance Graph

The following graph compares the cumulative total return, assuming the investment of $100 on February 1, 2007, the date on which our initial public offering was declared effective (our common stock began trading on the NASDAQ Global Market on February 2, 2007), on an investment in each of our common stock, on the NASDAQ Index and on the S&P Biotechnology Index. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.



	Base Period	Quarter Ended							
		Indexed Returns							
Company/Index	2/1/07	3/31/07	6/30/07	9/30/07	12/31/07	3/31/08	6/30/08	9/30/08	12/31/08
Molecular Insight Pharmaceuticals, Inc.	100	84.26	66.95	48.16	64.26	47.98	39.11	54.51	30.52
Nasdaq Index	100	98.33	105.74	109.66	107.75	92.05	92.61	84.49	63.70
S&P Biotechnology Index	100	90.02	95.97	103.28	93.55	98.45	102.14	106.37	103.42

	Quarter Ended			
	Indexed Returns			
Company/Index	3/31/09	6/30/09	9/30/09	12/31/09
Molecular Insight Pharmaceuticals, Inc.	25.27	36.69	39.25	15.97
Nasdaq Index	61.74	74.12	85.72	91.65
S&P Biotechnology Index	91.77	92.77	100.66	95.91

ITEM 6. *SELECTED FINANCIAL DATA*

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this filing.

	Year Ended December 31,				
	2005	2006	2007	2008	2009
	(In thousands except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Research and development grants	$ 1,232	$ 325	$ 731	$ 475	$ 1,059
License and product revenues(2)	—	—	—	—	4,436
Total revenues	1,232	325	731	475	5,495
Operating expenses:					
Cost of product revenues	—	—	—	—	35
Research and development	8,855	16,635	40,490	38,653	30,206
General and administrative	11,025	10,211	17,915	23,739	21,530
Total operating expenses	19,880	26,846	58,405	62,392	51,771
Loss from operations	(18,648)	(26,521)	(57,675)	(61,917)	(46,276)
Interest income	488	469	2,572	3,583	1,070
Interest expense	(141)	(1,214)	(4,723)	(23,070)	(21,277)
Change in fair value of bond derivative	—	—	—	150	—
Total other (expense) income, net	347	(745)	(2,151)	(19,337)	(20,207)
Net loss	(18,301)	(27,266)	(59,825)	(81,254)	(66,483)
Redeemable convertible preferred stock dividends and accretion of issuance costs	(4,046)	(4,958)	(1,368)	—	—
Net loss attributable to common stockholders	$(22,347)	$(32,224)	$(61,193)	$(81,254)	$(66,483)
Basic and diluted net loss per share attributable to common stockholders	$ (5.30)	$ (7.18)	$ (2.65)	$ (3.25)	$ (2.64)
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders	4,213	4,490	23,054	24,975	25,178

	As of December 31,				
	2005	2006	2007	2008	2009
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents(1)	$ 5,811	$ 8,916	$ 62,115	$ 25,495	$ 15,467
Working capital (deficit)(1)(3)	12,977	598	105,996	89,605	(114,538)
Total assets(1)	19,654	12,934	176,702	119,177	74,606
Long term obligations, net of current portion(1)(3)	3,429	16,382	133,132	155,384	503
Redeemable convertible preferred stock(1)	45,236	48,090	—	—	—
Total stockholders' (deficit) equity	(35,135)	(61,864)	28,556	(47,820)	(110,497)

(1) The significant increase in cash and cash equivalents, working capital (deficit), total assets and long term obligations and decrease in redeemable convertible preferred stock from December 31, 2006 to December 31, 2007 is a result of proceeds received from our November 2007 sale of senior secured floating rate bonds and the Company's initial public offering in February 2007.

(2) For the year ended December 31, 2009, we have recognized license and product revenues of $4,400,000 and $35,814, respectively, under our Territory License Agreement entered into with BioMedica in September 2009. The year ended December 31, 2009 is the first year we have entered into a strategic collaboration.

(3) The long-term bond obligations and related debt issuance costs have been reclassified as current liabilities and current assets at December 31, 2009. See Note 1 to our consolidated financial statements.

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

When you read this section of this Form 10-K, it is important that you also read the financial statements and related notes included elsewhere in this Form 10-K. This section of this annual report contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "should," "could," and similar expressions to identify forward- looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the factors described below and in the "Risk Factors" section of this Form 10-K.

Recent Developments

On November 16, 2007, we sold $150,000,000 in Senior Secured Floating Rate Bonds due 2012 ("Bonds") and warrants to purchase 6,021,247 shares of common stock at an exercise price of $5.87 per share ("Bond Warrants") under an indenture ("Bond Indenture"). Based on our current projections of our cash flow, we will breach the minimum liquidity requirements under the Bond Indenture in the second half of 2010, unless we are able to raise sufficient additional capital. Additionally, under the Bond Indenture, we are required to deliver audited annual financial statements to Bond holders which are not subject to a "going concern" or like qualification or exception from our auditors. In light of recurring losses from our operations and net stockholders' capital deficiency, the uncertainty of our obtaining additional financing on a timely basis, and the fact we will likely not comply with the minimum liquidity requirements under the Bond Indenture if we do not procure such additional financing, as well as other factors described in Note 1 to the financial statements for the year ended December 31, 2009 attached to this Annual Report on Form 10-K, in the report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2009, our independent auditors have included an emphasis of a matter paragraph relating to substantial doubt whether we can continue as a going concern. Consequently, the inclusion of such a "going concern" paragraph would result in a default under the terms of the Bond Indenture, unless waived by the Bond holders.

We discussed with the holders of our Bond the foregoing circumstances and a restructuring of our outstanding debt. On March 15, 2010 we executed a waiver agreement with the holders of at least a majority of the Bonds and the Bond Indenture trustee. Under the terms of the waiver agreement, the Bond holders and Bond Indenture trustee have agreed to waive the default arising from the inclusion of a "going concern" paragraph in the report of our independent registered public accounting firm on our financial statements and other technical defaults under the Bond Indenture until 12:01 AM Eastern Standard Time on April 16, 2010, subject to earlier termination upon certain circumstances. The waiver is also subject to a number of certain terms and conditions relating to our provision of certain information to the Bond holders, among other conditions and matters. In the event that the waiver expires or terminates prior to the successful restructuring of the outstanding debt, then we will be in default of our obligations under the Bond Indenture and the Bond holders may choose to accelerate the debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations.

We are continuing to negotiate with the Bond holders regarding the restructuring of the outstanding debt in a manner designed to avoid the acceleration of our debt obligations. Although our management team remains optimistic regarding the possibility of reaching an agreement with the Bond holders that will allow us to avoid such an acceleration of the debt obligations and position us for future growth through a restructuring of these obligations, there is no assurance that we will reach such an agreement on terms favorable to us, or at all.

In the event that we are able to successfully restructure our outstanding indebtedness, we will also need to actively pursue financing strategies to raise additional funds through private sales of equity and other strategic collaborative arrangements. However, unless the amount of our senior secured indebtedness is significantly reduced, it may prove difficult for us to obtain such additional financing.

Overview

We are a clinical-stage biopharmaceutical company and a pioneer in the emerging field of molecular medicine. We are focused on the discovery, development and commercialization of targeted therapeutic and imaging radiopharmaceuticals for use in oncology.

During the period from inception through September 30, 2009, we were considered to be a development stage company. In the third and fourth quarters of 2009, we entered into a territory license agreement and supply agreement, respectively, and have generated revenues from planned principal operations. We have therefore emerged from the development stage as of December 31, 2009.

We have five clinical-stage candidates in development. Our product candidates and their stages of development as of December 31, 2009 are summarized below:

Program	Primary Indication(s)	Stage of Development
Oncology		
Azedra (Ultratrace iobenguane I 131)	Pheochromocytoma (*and paraganglioma*; together referred to singly as "pheochromocytoma")	In Pivotal Phase 2b
	Neuroblastoma	In Phase 2a
Onalta (Yttrium-90 edotreotide)	Metastatic carcinoid and pancreatic neuroendocrine tumors	Pre-Phase 3 (Europe)
Trofex (MIP-1072)	Metastatic prostate cancer	In Phase 1
Solazed (Ioflubenzamide I 131)	Metastatic melanoma	Initiating Phase 1
Non-Oncology		
Zemiva (Iodofiltic acid I 123)	Acute cardiac ischemia	Completed Phase 2

Clinical Developments Regarding our Product Candidates

Oncology Product Candidates

Azedra

Azedra is our lead radiotherapeutic oncology product candidate. We have received an SPA letter stating that the FDA has reached agreement with the Company regarding the design of the pivotal Phase 2 trial for pheochromocytoma leading to the registration of Azedra™ (Ultratrace™ iobenguane I 131, formerly known as Ultratrace MIBG). An SPA is an agreement between the trial sponsor and the FDA covering the major design features such as patient population, choice of control, primary efficacy endpoint(s), safety monitoring plan, and statistical analysis plan of a clinical trial to be used as the pivotal evidence of safety and efficacy in support of regulatory approval.

We are developing Azedra for the systematic treatment of metastatic neuroendocrine cancers, such as pheochromocytoma and neuroblastoma. In August 2009, we announced the initiation of a single-arm, pivotal Phase 2 clinical trial for Azedra for the treatment of malignant pheochromocytoma in adults. In addition, Azedra has been granted Orphan Drug designation and Fast Track status by the FDA. Under these programs, we plan to file an NDA based on the Phase 2 data and anticipate an expedited FDA review of our application. If successful, Azedra could be the first anti-cancer therapy in the United States indicated for the treatment of pheochromocytoma.

In October 2009, we reported the results of our one-year follow-up data from a Phase 1 dose-escalation clinical study of Azedra™ demonstrating a positive safety profile and durable objective tumor responses in patients with neuroendocrine cancers, pheochromocytoma and paraganglioma. The study was designed to evaluate the safety and identify the maximum tolerated dose of Azedra, as well as to collect clinical data on efficacy. In the 12-month data reported, a single dose of Azedra was shown to be well tolerated by patients, and toxicities were predictable and manageable. The data provides long-term confirmation of preliminary Phase I clinical findings that were presented at the 2008 American Society of Clinical Oncology ("ASCO") Annual Meeting. Planning is underway for a Phase 2b pivotal efficacy study.

Onalta

In May, 2009, we reached an agreement with the EMEA on a proposed Phase 3 protocol design for Onalta that would be suitable to support registration provided the results are compelling. In September 2009, we sub-licensed Onalta™ 90-Y edotreotide to BioMedica. Under the Agreement, BioMedica is expected to perform clinical studies and market, distribute and commercialize Onalta in certain countries in Europe, the Middle East, North Africa, Russia and Turkey and secure all regulatory approvals within the BioMedica territories.

Trofex

Based on our initial results of clinical data in men with prostate cancer, we initiated a Phase 1 Trofex™ imaging study in August 2009 to compare normal men and men with metastatic disease.

Solazed

We are preparing for site initiation and have received an Institutional Review Board ("IRB") approval for a Phase I clinical study to confirm proof of concept in man and to define the pharmacokinetics, normal organ distribution, radiation dosimetry and urinary excretion. This study is primarily supported by grants from the National Cancer Institute.

Our Non-Oncology Product Candidate

Zemiva

We have completed the Phase 2 clinical trial (BP-23) for the diagnosis of cardiac ischemia or myocardial infarction. This study demonstrated that Zemiva, when combined with the current standard of care for the diagnostic evaluation of the chest pain patient, significantly improves the diagnosis of cardiac ischemic events in that patient. We are currently in discussions with the FDA regarding the design of the Phase 3 protocol.

On-Going Clinical Programs

Clinical trial costs are a significant component of our research and development expenses. We contract with third parties to perform certain clinical trial activities on our behalf in the on-going development of our product candidates. As of December 31, 2009, we have four (4) active clinical trials in the area of oncology. Our on-going clinical trials and estimated future remaining costs to be incurred on these clinical trials based on the financial terms of our contracts with clinical sites and contract research organizations are as follows:

Clinical Trial	Indication	Estimated Future Remaining Costs	Estimated Period of Expenditure
Pivotal Phase 2b for Azedra or IB12b	Malignant pheochromocytoma in adults	$9.50 million	End of 2014
Phase 2a for Azedra or IB13	Neuroblastoma in children	$0.20 million	Early 2010
Phase 1 Trofex or TX-P103	Prostate cancer imaging	$0.50 million	End of 2010
Phase 1 Trofex or TX-P102	Prostate cancer imaging	$0.02 million	Early 2010

Financial Operations Overview

Revenue

Licensing Agreement.

In September 2009, we entered into a Territory License Agreement ("Agreement") with BioMedica to sub-license our Onalta™ 90-Y edotreotide radiotherapeutic in certain countries in Europe, the Middle East, North Africa, Russia and Turkey. This Agreement provides BioMedica an exclusive sub-license to ours and Novartis' intellectual property rights and know-how with respect to Onalta. We had licensed the rights to edotreotide, the parent compound of Onalta, from Novartis in November 2006. Under this Agreement, BioMedica is expected to perform clinical studies and market, distribute and commercialize Onalta in the specified territories and secure all regulatory approvals. We agreed to provide forty (40) hours of compound radiolabeling technical transfer support services without charge in addition to providing reasonable levels of training, technical and regulatory support services on a time and materials basis at BioMedica's request.

Under the terms of this Agreement, we received an initial, nonrefundable payment of $4.4 million, two option grants to have BioMedica assign, transfer and convey to us, a minority shareholder interest in BioMedica, each for 1.5% of the total non-diluted interest in all classes of any issued and authorized outstanding share capital in BioMedica at the time of each exercise, exercisable upon execution of this Agreement and upon the EMEA marketing authorization approval of Onalta and will be eligible to receive more than $10 million in total regulatory milestone payments, net of license payments to Novartis. We will also be eligible to receive milestone and tiered royalties on Onalta sales.

This Agreement also provides that during the term of the Agreement, BioMedica will purchase all of its requirements for Onalta exclusively and solely from us, a third party manufacturer designated by us, and/or a BioMedica designated third-party manufacturer approved by us, the terms and conditions of which are outlined in a definitive supply agreement executed in October 2009 ("Supply Agreement"). The term of the Supply Agreement is for ten (10) years and provides for guaranteed monthly minimum purchases within a defined period of time by BioMedica.

Research and Development Grants.

Our revenue to date has been derived from National Institutes of Health, or NIH, grants. We have not had any product sales. In the future, we expect our revenue to consist of product sales and payments from collaborative or strategic relationships, as well as from additional grants. Funding of government grants is subject to government appropriation and all of our government contracts contain provisions which make them terminable at the convenience of the government. The government could terminate, reduce or delay the funding under any of our grants at any time. Accordingly, there is no assurance that we will receive funding of any grants that we may be awarded. As of December 31, 2009, gross proceeds of $2.1 million remained to be received under our various NIH grants, which include potential reimbursements for our employees' time and benefits and other expenses related to performance under various contracts. In the event we are not successful in obtaining any new government grants or extensions to existing grants, we may have to reduce the scope of some of our programs.

The status of our research and development grants is as follows:

Program Title	Agency	Program Total	Total Received Through December 31, 2009	Remaining Amounts to be Received as of December 31, 2009	Contract/ Grant Expiration
Early Clinical Testing for Melanin Targeting Radio-therapeutic Agent in Melanoma(2)	NCI(1)	$ 224,000	$ 74,000	$ 150,000	2009
Targeting Tumor Microenvironment with Radiolabeled Inhibitors of Seprase(2)	NCI(1)	181,000	157,000	24,000	2010
Nanodosing: A Path to Higher Sensitivity and Lower Toxicity Pharmaceuticals(3)	NCI(1)	982,000	501,000	480,000	2010
Systematic Radiotherapy for Metastatic Melanoma: Innovation of a Novel Radiopharma(3)	NCI(1)	1,243,000	174,000	1,069,000	2011
Development of a Molecular Targeting Agent for PSMA to Diagnose Metastatic Prostate Cancer(2)	NCI(1)	488,000	97,000	392,000	2011
Total		$3,118,000	$1,003,000	$2,115,000	

(1) National Cancer Institute ("NCI"), part of the National Institutes of Health.
(2) New contracts awarded in the third quarter ended September 30, 2009.
(3) Contract terms were extended by NCI for another year to the expiration date stated in the table above in the third quarter ended September 30, 2009.

Cost of Product Revenues.

Concurrent with the Supply Agreement entered into with BioMedica in October 2009, we also entered into a ten (10) year Facility Setup and Contract Manufacturing Agreement with EZN, a company with a licensed radiopharmaceutical manufacturing facility in Braunschweig, Germany. Under the terms of the agreement, EZN will manufacture and supply Onalta for compassionate use and registration clinical trials within the BioMedica territories, and for commercial sales, upon the EMEA marketing authorization approval of Onalta. The agreement also provides for EZN to establish an exclusive suite for the manufacture and supply of Onalta which will be funded by us and estimated at a cost of €1.3 million (approximately $1.9 million), including estimated costs of €0.3 million associated with decommissioning of the dedicated suite upon termination. We are also required to make fixed monthly payments to EZN aggregating €2.7 million (approximately $3.9 million) for the initial five (5) years following the effective date of the agreement in addition to product costs.

The monthly payments to EZN are expensed as incurred and recognized as "Cost of product revenues" in the Consolidated Statements of Operations.

Research and Development Expense.

Research and development expense consists of expenses incurred in developing and testing product candidates. These expenses consist primarily of salaries and related expenses for employees, as well as fees from contract research organizations, independent clinical investigators, fees paid to third-party professional service providers for monitoring our clinical trials and for acquiring and evaluating clinical trial data, costs of contract manufacturing services and materials used in clinical trials, depreciation of capital assets used to develop our product candidates, and facilities operating costs. We expense research and development costs as incurred. Certain research and development activities are partially funded by NIH grants described above. All costs related to such grants are included in research and development costs. We believe that significant investment in product development is necessary and plan to continue these investments as we seek to develop our product candidates and proprietary technologies.

We do not know if we will be successful in developing our drug candidates. While we expect that expenses associated with the completion of our current clinical programs could be substantial, we believe that such expenses are not reasonably certain at this time. The future timing and amount of these development expenses is dependent upon the costs associated with potential future clinical trials of our drug candidates, and the related expansion of our research and development organization, regulatory requirements, the advancement of our preclinical programs and product manufacturing costs, many of which cannot be determined with accuracy at this time based on our stage of development. This is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, including regulatory requirements for government approvals, which can vary significantly over the life of a project as a result of unanticipated events arising during clinical development, including:

- the number of clinical sites included in the trial;
- the length of time required to enroll suitable subjects;
- the number of subjects that ultimately participate in the trials;
- the efficacy and safety results of our clinical trials; and
- the number of additional required clinical trials that may be required as part of the government approval process.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals and expenses related to filing, prosecuting, defending or enforcing any patent claims or other intellectual property rights. In addition, we may obtain unexpected or unfavorable results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some drug candidates or focus on others. A change

in the outcome of any of the foregoing variables in the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Additionally, future commercial and regulatory factors beyond our control will evolve over time, which will impact our clinical development programs and plans.

Beyond our lead drug candidates, we could select additional drug candidates and research projects for further development in response to the preclinical and clinical success, as well as the commercial potential of such drug candidates.

As our product candidates advance to late-stage clinical trials, we anticipate incurring increased costs as expanded, larger-scale studies of patients with the target disease or disorder are conducted to obtain more definitive statistical evidence of efficacy and safety of the proposed product and dosing regimen. In particular, we expect to incur increased development costs in connection with our ongoing development efforts and clinical trials. We may incur additional costs to pursue the identification and development of other product candidates, which can be funded through our own resources or through strategic collaborations.

We own a radiopharmaceutical manufacturing facility located in Denton, Texas and have obtained a radioactive materials license from the State of Texas for this facility that expires in May 2018. The facility has more than 80,000 square feet of pharmaceutical manufacturing, warehouse, clean room and administrative office space.

As of December 31, 2009, the facility was not yet placed in service. The facility was originally intended to be used for the manufacture of molecular imaging and targeted radiotherapeutic product candidates. Completion of the build-out of the facility was previously deferred until manufacturing requirements for our clinical trials were determined. Concurrent with the change in our senior management, research specialists were engaged to evaluate the market potentials of each of our product candidates. In the fourth quarter of 2009, based on the results of these studies, plans with respect to the utilization of the facility have changed and there is no current plan to utilize it. An impairment review was undertaken, the outcome of which, indicated a fair value of $1.8 million that is below the carrying value of the building facility as of December 31, 2009 of $3.0 million. The fair value of the facility was determined using the market and cost approach valuation methods as the asset does not have separately identifiable income stream from which to develop reliable estimates of future cash flows. Given that the facility has not been placed into service as of December 31, 2009, we have ascribed more weight to the results of the market approach in determining the fair value of the asset. As a result, an impairment charge of $1.2 million has been recorded and reported within "Research and development expenses" in the Consolidated Statements of Operations for the year ended December 31, 2009.

In early January 2010, we also announced a strategic decision to re-align and re-balance personnel to further reduce operating costs and support the efficient development of our oncology product candidates. A one-time charge of approximately $0.2 million is anticipated to be taken in the first quarter of 2010. We expect to achieve approximately $0.9 million in annualized savings in our research and development expenses as a result of the reduction in personnel.

General and Administrative Expense.

General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, accounting, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense, legal fees relating to patent and corporate matters and fees for accounting and consulting services.

We have experienced a significant reduction in our general and administrative expenses for 2009 due to our cost-cutting initiatives implemented in the latter half of 2008. We expect further reductions in general and administrative expenses for 2010 as we continue to evaluate and implement additional cost-cutting initiatives to maximize our remaining resources.

Other (Expense) Income, Net.

Other (expense) income, net includes interest income, interest expense and the change in fair value of the bond derivative. Interest income consists of interest earned on our cash, cash equivalents and investments. Interest expense consists of interest incurred on debt instruments. Interest expense is a non-cash expense relating to the Bond interest, which includes the paid-in-kind Bonds issued to the bondholders in lieu of cash interest payments, the amortization of Bond financing expenses and discount.

Redeemable Convertible Preferred Stock Dividends and Accretion of Issuance Costs.

Redeemable convertible preferred stock dividends and accretion of issuance costs consists of cumulative, undeclared dividends payable on the securities and accretion of the issuance costs and costs allocated to issued warrants to purchase common stock. The issuance costs on these shares and warrants were recorded as a reduction to the carrying value of the redeemable convertible preferred stock when issued, and are accreted to redeemable convertible preferred stock using the interest method through the earliest redemption dates of each series of redeemable convertible preferred stock (A, B and C) by a charge to additional paid-in capital and net loss attributable to common stockholders. Upon the consummation of the initial public offering of the Company on February 1, 2007, the redeemable convertible preferred stock automatically converted into common stock on a 33-for-1 basis and the cumulative but unpaid dividends (with limited exception) converted into common stock based upon formulas established at each issuance date of the securities. Accordingly, we no longer record dividends and accretion on the redeemable convertible preferred stock.

Recent Accounting Pronouncements

On June 3, 2009, the Financial Accounting Standards Board ("FASB") approved the *FASB Accounting Standards Codification* ("ASC 105-10"), or the Codification, as the single source of authoritative Generally Accepted Accounting Principles, or GAAP, in the United States to be applied by all non-governmental entities. Rules and interpretative releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The Codification supersedes all existing non-SEC accounting and reporting standards. All other accounting literature not included in the Codification will be non-authoritative. The Codification is effective for interim and annual periods ending after September 15, 2009. The adoption of the Codification did not have an impact on the Company's consolidated financial statements.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make judgments, assumptions and estimates that affect our reported amounts of assets, liabilities, revenues and expenses, as well as related disclosures of contingent obligations. On an on-going basis, we evaluate our judgments and estimates, including those related to revenue recognition, the fair value of our Denton Texas facility, establishing amounts of accrued expenses, fair valuation of stock-based awards, valuation of the bond, common stock warrants and derivative financial instruments. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition. We generate revenue from two primary sources: (1) license, product and royalty revenues from collaborative agreements with strategic partners; and (2) government grants for research and development. The timing of cash received from collaborative agreements and government grants differs from revenue recognized. Payments received in advance of costs being incurred are recorded as deferred revenue. Revenue is recognized provided contractual agreements exist, delivery has occurred and risk of loss has passed, the fees are fixed or determinable and the collection is probable. Amounts recognized are limited to amounts due from the collaborative partners and grantor based upon the contract or grant terms.

Collaborative Agreements.

In October 2009, the FASB issued Accounting Standards Update ("ASU") 2009-13 to address the accounting for multiple-deliverable revenue arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. The ASU also establishes a selling price hierarchy for determining the selling price of a deliverable, replaces the term *fair value* in the revenue allocation guidance with *selling price* to clarify that the allocation of revenue is based on entity-specific assumptions rather than assumptions of a marketplace participant. We have elected to early adopt this ASU. No retrospective adjustments were required upon adoption. The adoption of this ASU did not have a significant impact on our financial statements.

From time to time, we may enter into collaborative license, development and supply agreements with biotechnology and pharmaceutical companies for the development and commercialization of our product candidates. The terms of these agreements typically include non-refundable upfront license fee payments and contingent cash payments based upon achievement of: (1) clinical development objectives; and (2) targeted product sale milestones, and royalties on product sales. Our obligations under these agreements may also include research and development activities, manufacturing and supply of product to collaborators for clinical trials and for commercial distribution upon product approval, as well as participation in joint committees established under the agreements.

Under ASU 2009-13, significant judgment is required in determining whether multiple deliverables can be separated and accounted for individually as separate units of accounting as well as determining whether deliverables have stand-alone value and determining the selling price of each of the deliverables for purposes of revenue allocation under the relative selling price method. Significant judgment is also required in determining the period over which we expect to complete our performance obligations under an arrangement. We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value, we are able to determine the selling price for all deliverables, and there are no refund rights relative to the delivered license. Undelivered performance obligations are then accounted for separately as performed. If these conditions are not met, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of performance.

Judgment is also involved in the determination as to whether milestone payments under related arrangements where we have continuing performance obligations meet the conditions and criteria to be considered a substantive milestone. Factors we consider in determining whether a milestone is substantive and can be accounted for separately from an upfront payment include assessing the level of risk and effort in achieving the milestone, the timing of its achievement relative to the upfront payments, and whether the amount of the payment was reasonable in relation to our level of effort. If any of the substantive milestone conditions are not met, the resulting payment would not be considered a substantive milestone. Any resulting payments received would be considered part of the consideration for the single unit of accounting and would be deferred and recognized as revenue over the estimated period of the arrangement.

Government Grants.

We recognize revenue from government grants for research and development as services are performed.

Impairment of Long-Lived Assets. We conduct a review of our long-lived assets for possible impairment when events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Recoverability of assets to be held and used is evaluated by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets as determined by valuation techniques appropriate in the circumstances.

Accrued Expenses. As part of the process of preparing consolidated financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of services performed and the associated cost incurred for such services as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for which we accrue include: professional service fees, such as legal and accounting fees; contract service fees, such as fees paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials; fees paid to contract manufacturers in conjunction with the production of clinical materials; and employee bonuses. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period could be too low or too high. We record adjustments to prior period accrual estimates that increase or decrease operating expenses in future periods when the actual activity level becomes known. Determining the date on which certain services commence, the level of services performed on or before a given date and the cost of such services often involves judgment. We make these judgments in accordance with GAAP based upon the facts and circumstances known to us. We attempt to mitigate the risk of inaccurate estimates, in part, by communicating with our service providers when other evidence of costs incurred is unavailable.

Stock-Based Compensation. We issue stock awards such as options and restricted stock to employees, members of our Board of Directors and consultants for incentive purposes and in lieu of cash consideration for services received. The measurement and recognition of compensation expense for service-based awards made to employees under our Equity Incentive Plans are based on their estimated grant date fair values and compensation costs are recognized over the requisite service period using the straight-line attribution method. Fair values for performance-based awards made to employees are estimated based on the date the performance conditions are established and assessed as probable of being achieved and compensation costs are recognized on a straight-line basis through the period of achievement of the performance conditions. The probability of vesting is reassessed by the Company at each reporting period and compensation costs are adjusted based on its probability assessment. Compensation costs recognized reflect the number of awards that are expected to vest and adjusted to reflect those awards that do ultimately vest.

The estimated fair value of the stock options granted is estimated using the Black-Scholes valuation model. The use of the Black-Scholes option-pricing model requires us to make assumptions with respect to the expected life of the option, the expected volatility of the common stock consistent with the expected life of the option, risk free interest rates and expected dividend yields of our common stock. Higher estimates of volatility and expected life of the option increase the value of an option and the resulting expense.

All stock-based awards to non-employees are accounted for at their fair values and recognized over the period of expected service by the nonemployees (which is generally the vesting period). As the service is performed, we are required to update these assumptions and periodically revalue unvested options and make

adjustments to the stock-based compensation expense using the new valuation. These adjustments are recognized in the consolidated statements of operations in the periods of re-measurement. Ultimately, the final compensation charge for each option grant to nonemployees is unknown until the performance of services is completed. We account for transactions in which services are received in exchange for equity instruments based either on the fair value of such services received from nonemployees or of the equity instruments issued, whichever is more reliably measured. The two factors which most effect charges or credits to operations related to stock-based compensation for nonemployee awards are the fair value of the common stock underlying stock options for which such stock-based compensation is recorded and the volatility of such fair value.

Compensation expense for options and restricted stock granted to employees and nonemployees is classified either as research and development expense or general and administrative expense based on the job function of the individual receiving the grant.

Valuation of Bonds, Common Stock Warrants and Derivative Financial Instruments

Floating Rate Bonds and Embedded Derivative. Our senior secured floating rate Bonds issued in November 2007 constitute a hybrid instrument that includes a debt host contract containing an embedded derivative feature (a contingent mandatory repayment provision) that requires bifurcation and separate accounting as a derivative under GAAP on accounting for derivative instruments and hedging activities. We valued the derivative financial instrument and remeasure it at each reporting period. The initial fair value of the embedded derivative was approximately $200,000 on the date of the issuance of the bonds and did not change materially through September 30, 2008. Based on our periodic evaluation of input assumptions to the valuation model utilized in determining the initial fair value of the embedded derivative, we have determined a remaining fair value of $50,000 at December 31, 2008 and 2009. The embedded derivative is classified in accrued expense in the consolidated balance sheets. Changes in fair value are recorded as either a gain or loss in the consolidated statement of operations in other income (expense). For the year ended December 31, 2008, we recognized a $150,000 gain related to the decrease in fair value of the embedded derivative. The carrying value of the debt is being accreted to its face value of $150 million over its five year term using the effective interest method. Accrued payment-in-kind interest is also included in the carrying value of the Bond.

Common Stock Warrants. We have issued common stock warrants in connection with the issuance of the Bonds. The fair value of the Warrants was determined using the Black Scholes model using assumptions regarding volatility of our common stock price, remaining life of the Warrant, 0% dividend rate and a five year, risk-free interest rate and amounted to $19.5 million. The Warrants are not considered derivative liabilities under GAAP and, accordingly, the fair value of the Warrants has been recorded at the date of issuance in additional paid-in capital.

Results of Operations

Years Ended December 31, 2008 and 2009

Revenues

Research and Development Grants.

Research and development grants revenue increased by approximately $585,000, or 123%, to approximately $1,059,000 for the year ended December 31, 2009 from approximately $475,000 for the year ended December 31, 2008. The Company receives funding under various research and development grants. The increase is primarily due to three new grants obtained at the end of 2008, three new grants received in the current year, an increase in the program total for two grants obtained in 2008 due to contract term extensions and timing of grant-related activities.

Licensing and Product Revenues.

For the year ended December 31, 2009, we have recognized license and product revenues of $4,400,000 and $35,814, respectively, under our Territory License Agreement entered into with BioMedica in September 2009. The year ended December 31, 2009 is the first year we have entered into a strategic collaboration.

We have determined that the Agreement with BioMedica is a revenue arrangement with multiple deliverables. In assessing our performance obligations, we determined that there are three separate deliverables comprising of: (1) the license; (2) training and support services; and (3) the Supply Agreement. We have determined that each of the deliverables in the arrangement has stand alone value to BioMedica. We used our best estimate of selling price for each of the deliverables in the arrangement in allocating the arrangement consideration under the relative selling price method. In estimating the selling price for the deliverables, we considered all of the following: (1) our internal costs; (2) the market and industry pricing practices; and (3) comparative offers received from potential development partners during the business development phase. The arrangement consideration allocable to the delivered license approximates the $4.4 million upfront license fee received and was recognized as license revenue in the Consolidated Statements of Operations. The arrangement consideration allocable to the undelivered support services is immaterial. The arrangement consideration for the Supply Agreement will be recognized as product revenues in the period such products are delivered.

Cost of Product Revenues.

For the year ended December 31, 2009, we have recognized cost of product revenues of $35,235 under our agreement entered into with EZN in October 2009 for the manufacture and supply of Onalta to BioMedica.

Research and Development Expense.

For the periods indicated, research and development expenses for our programs in the development of Azedra, Zemiva, Onalta, Solazed, Trofex and other general R&D programs were as follows:

Program	Years ended December 31, 2008	2009	Increase / (Decrease)
		(in thousands)	
Azedra and Ultratrace platform	$ 8,538	$11,406	$ 2,868
Zemiva	11,003	525	(10,478)
Onalta	2,047	1,626	(421)
Solazed	1,137	136	(1,001)
Trofex	1,680	3,345	1,665
Other platform and general R&D	14,248	13,168	(1,080)
Total	$38,653	$30,206	$ (8,447)

Research and development expenses decreased approximately $8.0 million or 21%, to $30.2 million for the year ended December 31, 2009 from $38.7 million for the year ended December 31, 2008. Key components of this spending decrease were attributed to the following: (1) a decrease of $10.5 million in overall Zemiva program costs due to the completion of our Zemiva Phase 2 (BP-23) clinical trial in December 2008 and true-ups of certain program costs of $1.8 million primarily relating to completed clinical trials in prior years ; (2) reduced clinical activities and costs of $1.4 million for Onalta and Solazed to plan our European and Phase I clinical trials, respectively; and (3) a reduction in other platform and general research and development costs of $1.1 million primarily due to reallocation of $1.5 million in payroll costs to key programs, a decrease in outside services, recruiting and consultants expenses of $0.7 million and a decline in sponsored research of $0.3 million which were offset by an impairment charge of $1.2 million related to our Denton facility and an increase of $0.4 million in stock-based compensation due to a shorter period of vesting coupled with the achievement of certain performance-based stock awards. These spending decreases were offset, in part, by (1) an increase of $2.9 million in the Azedra program primarily due to costs incurred for the build-out of the manufacturing facility

at MDS Nordion and validation of the manufacturing process for the manufacture and supply of Azedra for clinical trials and commercial supply; and (2) an increase of $1.7 million primarily for preclinical animal testing conducted in the current year for Trofex.

General and Administrative Expense.

	Years ended December 31,		Increase / (Decrease)
	2008	2009	
		(in thousands)	
Compensation and personnel-related expense	$ 5,975	$ 5,109	$ (866)
Professional services	13,398	11,785	(1,613)
Insurance	589	608	19
Facility costs	191	357	166
Stock-based compensation expense	1,727	2,381	654
Depreciation and amortization expense	903	940	37
Other	956	351	(605)
Total general and administrative expenses	$23,739	$21,531	$(2,208)

General and administrative expenses decreased $2.2 million or 9%, to $21.5 million for the year ended December 31, 2009 from $23.7 million for the year ended December 31, 2008. This decrease is due primarily to $3.3 million of savings in professional services offset in part by net success fees of $1.7 million incurred on the BioMedica transaction, lower recruiting costs, a reduction in the use of external consultants and outside services to support corporate management, legal, accounting, marketing and communications. In addition, we have realized $0.9 million in savings from the workforce reduction implemented in late 2008. The decrease in other general and administrative expenses of $0.6 million was primarily related to a reduction in meeting and travel costs. These decreases were offset, in part, by an increase in stock-based compensation expense of $0.7 million due to a shorter period of vesting for the annual grant awarded during the quarter ended June 30, 2009, the grant of performance-based awards to executive officers for which certain awards have been achieved and the remainder for which the Company has assessed as probable of being achieved and the re-measurement of stock options related to the modification of options that was undertaken for the former CFO.

Other (Expense) Income, Net.

Other expense, net, increased $0.9 million to $20.2 million for the year ended December 31, 2009 from other expense, net of $19.3 million for the year ended December 31, 2008. During the year ended December 31, 2008 and 2009, interest expense was $23.1 million and $21.3 million, respectively, partially offset by interest income of $3.6 million and $1.1 million, respectively. The decrease in interest expense of $1.8 million in the year ended December 31, 2009 as compared to the year ended December 31, 2008 was due to lower LIBOR interest rates on our $150 million Senior Secured Floating Rate Bonds ("Bonds") and PIK bonds, offset by an increase in the principal base on which interest is accrued. Interest accrued on the Bonds for the first three years from issuance date shall be payable through the issuance of PIK Bonds and shall begin to accrue interest from the date of issuance of such PIK Bonds. The average interest rate was 11.17% and 8.98% for the years ended December 31, 2008 and 2009, respectively. The decrease in interest income of $2.5 million in the current year was the result of lower yields on our investments as well as a decrease in investments. The investments and associated income are utilized to fund current operations.

Years Ended December 31, 2007 and 2008

Revenue — Research and Development Grants.

Revenue decreased by $256,000, or 35%, to $475,000 for the year ended December 31, 2008 from $731,000 for the year ended December 31, 2007. The Company receives funding under various research and development grants and the 2008 decrease from 2007 is primarily attributable to the decreased workload and reimbursable

expenses for 2008 grants as well as the timing of grant related activities. The Company has approximately $0.9 million of NIH grants that had been awarded as of December 31, 2008 that will be recognized as revenue as research services are performed.

Research and Development Expense.

For the periods indicated, research and development expenses for our programs in the development of Azedra, Zemiva, Onalta, Solazed, Trofex and other general R&D programs were as follows (in thousands):

Program	For Years Ended December 31, 2007	2008
Azedra and Ultratrace platform	$ 6,968	$ 8,538
Zemiva	12,312	11,003
Onalta	4,946	2,047
Solazed	2,019	1,137
Trofex	1,252	1,680
Other platform and general R&D	12,993	14,248
Total	$40,490	$38,653

Research and development expenses decreased $1.8 million, or 4.5%, to $38.7 million for the year ended December 31, 2008 from $40.5 million for the year ended December 31, 2007. Year over year incremental reductions are a result of reduced clinical trial and manufacturing spending for Zemiva ($1.3 million) and reduced license fees for both Onalta ($2.9 million) and Solazed ($1.0 million). Offsetting this spending reduction was increased clinical trial spending for Azedra ($0.7 million) and Trofex ($0.5 million), as well as $2.1 million in additional compensation related expense, including stock compensation. Research and development expenditures are dependent on the timing of regulatory applications and approval, and results of our clinical trials.

We in-licensed Onalta and Solazed in November 2006 and January 2007, respectively. R&D development activities began on these two products in 2007.

General and Administrative Expense.

General and administrative expenses increased $5.8 million, or 32%, to $23.7 million for the year ended December 31, 2008 from $17.9 million for the year ended December 31, 2007. The primary increases in 2008 were an increase of $3.2 million in consulting services, including $1.1 million in stock-based compensation cost related to warrants granted for consulting services, increase of $2.4 million for employee related spending which includes severance costs related to terminations, and $0.6 million for accounting fees to support auditing and external reporting to comply with Sarbanes Oxley. Offsetting the increase was a reduction of $0.5 million in legal costs.

Other (Expense) Income, Net.

Other expenses, net, increased by $17.2 million to $19.3 million for the year ended December 31, 2008. The increase was primarily due to an increase in interest expense of $18.3 million on the $150.0 million Senior Secured Floating Rate Bonds which were issued in November 2007. The increase in interest expense was offset by a $1.0 million increase in interest income earned on invested funds obtained from the bond proceeds. Interest expense and income in 2008 was incurred and earned, respectively, for the full year as compared to one-and a half (1.5) months in 2007.

Redeemable Convertible Preferred Stock Dividends and Accretion of Issuance Costs.

There was no Redeemable Convertible Preferred Stock during the year ended December 31, 2008 because those securities were converted to common stock on February 1, 2007 in connection with our Initial Public Offering of common stock. Redeemable Convertible Preferred Stock's first quarter 2007 dividends and accretion of issuance costs were $1.4 million.

Liquidity and Capital Resources

We have funded our operations from inception on January 10, 1997 through December 31, 2009 mainly through the issuance of bonds and warrants, common stock, redeemable convertible preferred stock, convertible notes and other notes, research funding from government grants and upfront license payments from collaborations.

We have incurred significant net losses and negative operating cash flows since inception. At December 31, 2009, we had an accumulated deficit of $292.9 million including the $66.5 million net losses incurred for the year ended December 31, 2009. We currently have five clinical programs in various stages of development and will need to spend significant capital to fulfill planned operating goals and continue to conduct clinical and non-clinical trials, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization. As such, we expect to continue to incur significant net losses and negative operating cash flows in the foreseeable future.

The terms of our Bond Indenture include various covenants, including among others, financial covenants that requires us to maintain a minimum liquidity level on a quarterly basis. The minimum liquidity covenant (as defined in the Indenture and which substantially represents all of our cash, cash equivalents and investments) requires us to maintain a minimum amount of not less than $25.7 million and $29.2 million at September 30, 2010 and December 31, 2010, respectively. Based on our current projections of our cash flow, we expect that we would not be in compliance with this covenant in the third or fourth quarter of 2010, unless we are able to raise sufficient additional capital. Additionally, under the Bond Indenture, we are required to deliver audited annual financial statements to Bond holders which are not subject to a "going concern" or like qualification or exception from our independent auditors. Such anticipated noncompliance of the required minimum liquidity level in the second half of 2010, recurring losses from our operations and net stockholders' capital deficiency, and the uncertainty of our obtaining additional financing on a timely basis, raise substantial doubt about our ability to continue as a going concern beyond September 2010. As a result, in the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2009, our independent auditors have included an emphasis of a matter paragraph relating to substantial doubt whether we can continue as a going concern. Consequently, the inclusion of such a "going concern" paragraph would result in a default under the terms of the Bond Indenture, unless waived by the Bond holders. We cannot guarantee our ability to continue as a going concern unless we can raise additional capital, of which there can be no assurance.

We have executed a waiver agreement and obtained a temporary waiver from the holders of at least a majority of the Bonds and the Bond Indenture trustee. Under the terms of the waiver agreement, the Bond holders and Bond Indenture trustee have agreed to waive the noncompliance arising from the inclusion of the "going concern" paragraph in the report of our independent registered public accounting firm on our financial statements and other technical defaults under the Bond Indenture until 12:01 AM Eastern Standard Time on April 16, 2010, subject to earlier termination upon certain circumstances. The waiver is also subject to a number of certain terms and conditions relating to our provision of certain information to the Bond holders, among other conditions and matters. Notwithstanding the waiver, it is probable that we will continue to fail to meet the same covenant within the next twelve months. Consequently, the long-term bond obligations and related debt issuance costs have been reclassified as current liabilities and current assets, respectively, at December 31, 2009. If the Bond Indenture is restructured in a transaction required to be accounted for as an extinguishment or the outstanding balance of the bond obligations is demanded by the Bond holders, unamortized debt issue costs of $4.5 million would be required to be expensed at the restructuring or demand date.

The consolidated financial statements as of December 31, 2009 have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern. As of December 31, 2009, we had $15.5 million of cash and cash equivalents and $48.5 million of investments.

We are continuing to negotiate with the Bond holders regarding the restructuring of the outstanding debt in a manner designed to avoid the acceleration of our debt obligations and position us for future growth. There is no assurance that we will reach such an agreement on terms favorable to us, or at all. Moreover, in connection with our discussions with the Bond holders to reach such an agreement, the Bond holders may impose additional operational or financial restrictions on us or modify the terms of our existing Bond Indenture. These restrictions may limit our ability, among other things, to make necessary capital expenditures or incur additional indebtedness. In addition, the Bond holders may require us to pay additional fees, prepay a portion of our indebtedness, accelerate the amortization schedule for our indebtedness or agree to higher interest rates on our outstanding indebtedness or take other actions that could adversely affect our business. The Bond holders may also require us to raise additional capital concurrently with any restructuring. If the waiver grace period (or any extension thereof) expires or terminates, and we are unable to reach an agreement with Bond holders regarding an additional waiver or an agreement regarding the restructuring of our outstanding debt, the Bond holders may choose to accelerate our debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations. If our indebtedness under the Bond Indenture is accelerated or is not restructured on acceptable terms, it is likely that we will be unable to repay our debt and we may seek protection under the U.S. Bankruptcy Code or similar relief.

In conjunction with these discussions, we are also actively pursuing financing strategies to raise additional funds through private sales of equity and other strategic collaborative arrangements which are limited under the provisions of the Indenture. If we raise additional funds through the issuance of new equity securities, our stockholders may experience substantial dilution, or the new equity securities may have rights, preferences or privileges senior to those of existing stockholders. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us. We have no current commitments from any persons that they will provide any additional financing. Given the current market conditions and the status of our product development pipeline, obtaining financing may be difficult and may not be available on commercially acceptable terms, or at all.

As discussed in Note 12 to the consolidated financial statements, in September 2009, we entered into a Territory License Agreement with BioMedica to sub-license the Onalta™ 90-Y edotreotide radiotherapeutic in certain countries. Further, in October 2009, we executed an exclusive, 10-year agreement to supply Onalta to BioMedica and entered into an agreement with EZN to manufacture Onalta. We have received $4.4 million of upfront payments from BioMedica and will also be eligible to receive regulatory milestone payments as well as commercial milestones and tiered royalties on Onalta sales upon commercialization in addition to near- and long-term revenues from supplying Onalta for compassionate use, clinical trial supplies and, upon regulatory approval, commercial supply to the licensed BioMedica territories. While the Supply Agreement will provide us with a source of liquidity after net payments for manufacturing costs to EZN of approximately $4.9 million for the first five years, future potential cash receipts from BioMedica, if any, are principally contingent upon the successful completion of contractually defined development and regulatory approval objectives. There is also considerable inherent uncertainty in the successful development and commercialization of products in the pharmaceutical industry.

We continue to evaluate cost efficiencies in the conduct of our research and development programs. In 2009, we were able to reduce cash used in operations by $15.6 million as compared with the year ended 2008. The savings were primarily due to the completion of certain clinical trials and operational efficiencies implemented in general and administrative functions in the latter half of 2008. We believe that our existing cash, cash equivalents and investments, and future cash payments from BioMedica, together with the implementation

of planned additional cost reduction initiatives if necessary, will be sufficient to fund our operations and maintain compliance with our minimum liquidity covenant through at least September 30, 2010. In order to continue operations beyond September 2010, we must raise additional capital. Our failure to raise capital when needed could have a negative impact on our financial condition and our ability to pursue business strategies as well as potentially delay product research and development efforts and potentially require us to reduce the scope of, or eliminate one or more of our ongoing clinical programs or cause us to cease operations. We would also be required to implement further reduction in personnel and related costs and other discretionary expenditures that are within our control. In January 2010, we announced a strategic decision to re-align and re-balance personnel to further reduce operating costs and support the efficient development of our oncology product candidates.

Annual Cash Flows

Summary Cash Flow Information	Years Ended December 31, 2008	Years Ended December 31, 2009	Increase / (Decrease) 2009 vs. 2008
		(in thousands)	
Net cash (used in) provided by:			
Operating activities	$ (56,375)	$(40,766)	$ 15,609
Investing activities	19,698	30,110	10,412
Financing activities	65	633	568
Exchange rate effect on cash and cash equivalents	(8)	(5)	3
Net increase (decrease) in cash and cash equivalents	(36,620)	(10,028)	26,592
Cash and cash equivalents	25,495	15,467	(10,028)
Short and long-term investments	80,291	48,515	(31,776)
Cash, cash equivalents and short-term investments	$105,786	$ 63,982	$(41,804)

Years Ended December 31, 2008 and 2009

Net cash used in operating activities decreased by $15.6 million to $40.8 million for the year ended December 31, 2009, compared to $56.4 million for the year ended December 31, 2008. The decrease in cash used in operations was primarily due to the receipt of $4.4 million upfront payment from BioMedica, decrease of $2.0 million in payments to vendors for prepaid expenses, accounts payable and accrued expenses, and the decrease in net loss of $14.8 million offset by an increase in accounts receivable of $0.7 million due to increased level of grant activity. The decrease in net loss is attributed to the recognition of $4.4 million in license revenue under the BioMedica agreement, reduction in research and development expenses of $8.4 million primarily due to the completion of our clinical trial for Zemiva and operational efficiencies implemented in general and administrative functions which contributed a $2.2 million decrease in net loss. Net cash provided by investing activities increased by $10.4 million to $30.1 million for the year ended December 31, 2009, compared to $19.7 million for the year ended December 31, 2008. The increase was primarily due to liquidation of investments as such are utilized to fund operations. Net cash provided by financing activities related primarily to the exercise of common stock options. We anticipate to further reduce our annual cash burn from operations in 2010 and implement strategies for the efficient development of our oncology pipeline.

Years Ended December 31, 2007 and 2008

Net cash used in operating activities increased by $11.5 million to $56.4 million for the year ended December 31, 2008 compared to $44.9 million for the year ended December 31, 2007. The increase in cash used in operations was due primarily to timing of payments for R&D program related expenditures and other payables. Net cash provided by investing activities was $19.7 million primarily due to investments liquidated to fund operating activities and purchases of property and equipment. Net cash provided by financing activities related to the exercise of stock options. We do not expect to incur capital expenditure in excess of the limits required under our indenture of $5 million for the year ending December 31, 2009.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2009:

Contractual Obligations	Payments Due by Period				
	Total	Within 1 Year	Over 1 to 3 Years	Over 3 to 5 Years	More Than 5 Years
			(In thousands)		
Operating leases	$ 1,103	$ 766	$ 337	$ —	$—
Licensing, clinical, development and manufacturing obligations(1)(2)	24,857	11,012	9,877	3,968	—
Severance	640	640	—	—	—
Bonds payable(4)	150,000	150,000	—	—	—
Estimated interest on bonds payable(4)	83,356	53,923	29,433	—	—
Total contractual obligations	$259,956	$216,341	$39,647	$3,968	$—

(1) We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our business. Under those licenses, we are obligated to pay to the third parties, royalties and potential future milestone payments of up to approximately $18.9 million. The future milestone payments disclosed excludes additional milestone payments of $162.5 million should one of our licensors decides not to exercise its call-back option upon achievement of targeted sales objectives as such obligation would be offset by an equal amount of milestone payment from our licensee to us. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2009, such contingencies have not been recorded in our financial statements or included in the Contractual Obligations table above.

(2) Excludes minimum annual license fees of $0.1 million after five years which are required through the date of the last patent expiration or until the first commercial sale of the licensed technology. As a result of pending patents, we are currently unable to determine the length of this period.

(3) See Note 8 "Debt" to the Consolidated Financial Statements.

(4) Assumes paid-in-kind ("PIK") interest for the first three years from issuance date. Amount disclosed include accrued interest at December 31, 2009 of $36.5 million and projected interest using an estimated interest rate of 9% from January 1, 2010 through November 15, 2012. The long-term bond obligations and related estimated interest on bonds payable have been reclassified as current liabilities at December 31, 2009. See Note 1 to our consolidated financial statements.

Operating Leases

Our principal executive and administrative offices are comprised of two leased facilities located in Cambridge, Massachusetts. We believe that our current facilities will meet our anticipated needs for the remainder of the lease terms. The following summarizes the principal terms of our leases:

(1) On April 8, 2008, we entered into a lease agreement for the lease of approximately 15,555 square feet of office and laboratory space in Cambridge, Massachusetts. The term of the lease is from July 1, 2008 to June 30, 2011. The monthly base rent for the first two years of the lease is $45,369 and for the last year of the lease is $46,665. The Company has an option to extend the term for a two-year period from July 1, 2011 to June 30, 2013.

(2) On April 25, 2008, we entered into a lease agreement for the lease of approximately 19,750 square feet of office space located in Cambridge, Massachusetts. The term of the lease is from April 25, 2008 to March 31, 2010. The monthly base rent from April 25, 2008 to March 31, 2009 is $55,308 and from April 1, 2009 to March 31, 2010 is $56,959. The Company has an option to extend the term twice and each extension is for a period of six months.

(3) We also entered into a five-year lease agreement for an office space in Germany that ends in April 2013.

Capital Leases

As of December 31, 2009, we had no capital leases.

Off-Balance Sheet Arrangements

We do not engage in off-balance sheet financing arrangements.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK*

Interest Rate Risk due to Variable Interest Rates on Bonds

We are exposed to interest rate risk from changes in the three month LIBOR (London Inter-Bank Offer Rate) rate that is the base rate of our $150,000,000 outstanding Bonds. The Bonds have a five-year maturity date and bear an interest rate equivalent to the LIBOR plus eight percent, determined on a quarterly basis. The interest rate at December 31, 2009 was 8.28%. A one percent (100 basis points) increase in the three month LIBOR interest rate could add approximately $1.9 million in annual interest expense on the principal amount of the bonds that includes the PIK interest at December 31, 2009. During the first three years that the Bonds are outstanding, interest payments not paid in cash may be paid by issuing additional Bonds, which increases the Company's overall debt levels. An increase in the LIBOR rate on our debt levels could affect operating results as well as our financial position and cash flows.

Although we have not at the present time employed derivative financial instruments to limit the impact on cash flows of the volatility in the LIBOR interest rate, we may in the future employ derivative financial instruments such as swaps, collars, forwards, options or other instruments to limit the volatility to earnings and cash flows generated by this exposure. Derivative financial instruments will be executed solely as risk management tools and not for trading or speculative purposes. We may employ derivative contracts in the future which are not designated for hedge accounting treatment, which may result in volatility to earnings depending upon fluctuations in the underlying markets.

We principally invest our cash in money market instruments and securities issued by the US government and its agencies. These investments are subject to interest rate risk and could decline in value if interest rates fluctuate.

Foreign Currency Risk

We have entered into agreements with suppliers that require payment in foreign currencies. As a result, our financial position, results of operations and cash flows can be affected by market fluctuations in foreign exchange rates, primarily with respect to the Euro and Canadian dollar. We have not entered into any hedging agreements relating to this risk. We do not believe that a 10% change in foreign currency exchange rates would have a material impact on our financial position, results of operations and cash flows.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA*

The financial statements required by this item are located beginning on page F-1 of this report.

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

Our Chief Executive Officer and Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this annual report. The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2009.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended). 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. Our system of 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 our assets; (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 our receipts and expenditures are being made only in accordance with the authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

The Company's management has used the criteria established in the "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), to evaluate the effectiveness of the Company's internal control over financial reporting. Management has selected the COSO framework for its evaluation as it is a control framework recognized by the SEC and the Public Company Accounting Oversight Board, that is free from bias, permits reasonably consistent qualitative and quantitative measurement of the Company's internal controls, is sufficiently complete so that relevant controls are not omitted, and is relevant to an evaluation of internal controls over financial reporting.

Based on our assessment, management has concluded that our internal control over financial reporting, based on criteria established in "Internal Control-Integrated Framework" issued by COSO was effective as of December 31, 2009.

Deloitte & Touche LLP, an independent registered public accounting firm that audited our consolidated financial statements for the year ended December 31, 2009, included in this annual report, has issued an attestation report on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Molecular Insight Pharmaceuticals, Inc.
Cambridge, Massachusetts

We have audited the internal control over financial reporting of Molecular Insight Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2009, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control Over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel 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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2009 of the Company and our report dated March 16, 2010 expressed an unqualified opinion on those financial statements and included an explanatory paragraph relating to substantial doubt about the Company's ability to continue as a going concern.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 16, 2010

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

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

The information in response to this item is hereby incorporated by reference to the information under the caption "DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE" presented in our definitive proxy statement to be filed with the Securities and Exchange Commission and used in connection with the solicitation of proxies for the Company's 2010 Annual Meeting of Shareholders (the "Proxy Statement").

The Company's shareholders are strongly advised to read the proxy statement and the accompanying WHITE proxy card when they become available, as they will contain important information.

ITEM 11. ***EXECUTIVE COMPENSATION***

The information in response to this item is hereby incorporated by reference to the information under the caption "COMPENSATION OF EXECUTIVE OFFICERS" presented in the Company's Proxy Statement. Information appearing in the Proxy Statement under the headings "REPORT ON EXECUTIVE COMPENSATION BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS," "COMMON STOCK PERFORMANCE" and "REPORT OF AUDIT COMMITTEE" is not incorporated herein and should not be deemed to be included in this annual report for any purposes.

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

The information in response to this item is hereby incorporated by reference to the information under the caption "SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS" presented in the Company's Proxy Statement.

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

The information in response to this item is hereby incorporated by reference to the information under the caption "CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE" presented in the Company's Proxy Statement.

ITEM 14. ***PRINCIPAL ACCOUNTANTS FEES AND SERVICES***

The information required by this item is incorporated by reference to the section entitled "PRINCIPAL ACCOUNTANT FEES AND SERVICES" presented in the Company's Proxy Statement.

PART IV

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

(a) The following documents are filed as part of this Report:

(1) *Financial Statements*

See Index to Financial Statements on page F-1.

(2) *Supplemental Schedules*

All other schedules have been omitted because the required information is not present in amounts sufficient to require submission of the schedule, or because the required information is included in the consolidated financial statements or notes thereto.

(3) *Exhibits*

See the Index to Exhibits attached to this report.

(b) The exhibits listed in the Index to Exhibits attached to this annual report are filed as part of, or incorporated by reference into, this annual report on Form 10-K.

SIGNATURES

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

MOLECULAR INSIGHT PHARMACEUTICALS, INC.

By: /s/ DANIEL L. PETERS
Daniel L. Peters
President and Chief Executive Officer
(principal executive officer)

By: /s/ CHARLES H. ABDALIAN, JR.
Charles H. Abdalian, Jr.
Chief Financial Officer
(principal financial officer)

Date: March 16, 2010

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 Company and in the capacities and as of the date indicated:

Signature	Title	Date
By: /s/ DANIEL L. PETERS Daniel L. Peters	Director; President and Chief Executive Officer (principal executive officer)	March 16, 2010
By: /s/ JOHN W. BABICH, PH.D. John W. Babich, Ph.D.	Director; Executive Vice-President, Chief Scientific Officer and President of Research and Development	March 16, 2010
By: /s/ CHARLES H. ABDALIAN, JR. Charles H. Abdalian, Jr.	Chief Financial Officer (principal financial officer and principal accounting officer)	March 16, 2010
By: /s/ JOSEPH M. LIMBER Joseph M. Limber	Director; Chairman of the Board of Directors	March 16, 2010
By: /s/ DANIEL FRANK Daniel Frank	Director	March 16, 2010
By: /s/ SCOTT GOTTLIEB, M.D. Scott Gottlieb, M.D.	Director	March 16, 2010
By: /s/ LIONEL STERLING Lionel Sterling	Director	March 16, 2010
By: /s/ DAVID M. STACK David M. Stack	Director	March 16, 2010
By: /s/ HARRY STYLLI, PH.D. Harry Stylli, Ph.D.	Director	March 16, 2010

MOLECULAR INSIGHT PHARMACEUTICALS, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Molecular Insight Pharmaceuticals, Inc.
Cambridge, Massachusetts

We have audited the accompanying consolidated balance sheets of Molecular Insight Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2008 and 2009, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Molecular Insight Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements for the year ended December 31, 2009 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company would not have been in compliance with a covenant of its bond indenture had the lender not temporarily waived the covenant and future covenant violations are expected in the upcoming year. The Company's difficulties in meeting its bond indenture covenants and its recurring losses from operations raise substantial doubt about its ability to continue as a going concern. Management's plans concerning 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2009, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2010 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 16, 2010

MOLECULAR INSIGHT PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2008	2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,494,834	$ 15,467,048
Investments	74,180,919	48,514,855
Accounts receivable	124,760	651,094
Prepaid expenses and other current assets	1,417,496	902,045
Debt issuance costs — net	—	4,526,855
Total current assets	101,218,009	70,061,897
Property and equipment — net	5,452,180	4,044,488
Debt issuance costs — net	5,896,952	—
Restricted cash	500,000	500,000
Investments	6,109,814	—
Total assets	$ 119,176,955	$ 74,606,385
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 784,419	$ 1,720,756
Accrued expenses	10,452,419	8,041,130
Accounts payable and accrued expenses — related parties	351,581	—
Bonds payable — net of discount	—	174,838,383
Total current liabilities	11,588,419	184,600,269
Bonds payable — net of discount	154,931,479	—
Asset retirement obligation	276,693	294,637
Deferred revenue — net of current portion	25,000	25,000
Other long term liabilities	175,790	183,075
Commitments and contingencies (Note 13)		
Stockholders' deficit:		
Common stock, $0.01 par value; authorized, 100,000,000 shares at December 31, 2008 and 2009; issued and outstanding, 25,069,406 and 25,268,327 shares at December 31, 2008 and 2009, respectively	250,694	252,683
Additional paid-in capital	177,878,193	182,142,165
Accumulated other comprehensive income (loss)	457,834	(540)
Accumulated deficit	(226,407,147)	(292,890,904)
Total stockholders' deficit	(47,820,426)	(110,496,596)
Total liabilities and stockholders' (deficit)	$ 119,176,955	$ 74,606,385

See notes to consolidated financial statements.

MOLECULAR INSIGHT PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2007	2008	2009
Revenues:			
Research and development grants	$ 730,672	$ 474,559	$ 1,059,259
License and product	—	—	4,435,814
Total revenues	730,672	474,559	5,495,073
Operating expenses:			
Cost of product revenues	—	—	35,235
Research and development	40,490,409	38,653,211	30,205,599
General and administrative	14,815,829	20,916,939	19,822,351
General and administrative — related parties	3,099,039	2,821,678	1,708,323
Total operating expenses	58,405,277	62,391,828	51,771,508
Loss from operations	(57,674,605)	(61,917,269)	(46,276,435)
Other (expense) income:			
Interest income	2,572,103	3,583,174	1,069,679
Interest expense	(4,722,679)	(23,069,837)	(21,277,001)
Change in fair value of bond derivative	—	150,000	—
Total other (expense) income — net	(2,150,576)	(19,336,663)	(20,207,322)
Net loss	(59,825,181)	(81,253,932)	(66,483,757)
Redeemable convertible preferred stock dividends and accretion of issuance costs	(1,368,037)	—	—
Net loss attributable to common stockholders	$(61,193,218)	$(81,253,932)	$(66,483,757)
Basic and diluted net loss per share attributable to common stockholders	$ (2.65)	$ (3.25)	$ (2.64)
Weighted average shares used to compute basic and diluted loss per share attributable to common stockholders	23,053,719	24,974,704	25,178,376

See notes to consolidated financial statements.

MOLECULAR INSIGHT PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY

	Redeemable Convertible Preferred Stock, $0.01 Par Value		Common Stock $0.01 Par Value							
	Number of Shares	Carrying Value	Number of Shares	Par Value	Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' (Deficit)-Equity	Total Comprehensive Loss
Balance at January 1, 2007	315,570	$ 48,089,941	4,637,493	$ 46,375	$ 23,770,599	$(352,224)	$ (520)	$ (85,328,034)	$ (61,863,804)	
Issuance of common stock on initial public offering, net of issuance costs of $7,405,060	—	—	5,000,000	50,000	62,544,940	—	—	—	62,594,940	
Issuance of common stock on exercise of warrants	—	—	444,981	4,449	1,388,001	—	—	—	1,392,450	
Preferred stock dividends and accretion of issuance costs	—	1,368,037	—	—	(1,368,037)	—	—	—	(1,368,037)	
Issuance of common stock on conversion of preferred stock	(315,570)	(49,457,978)	12,566,608	125,666	49,332,312	—	—	—	49,457,978	
Issuance of common stock on conversion of convertible debt	—	—	2,029,233	20,290	15,894,180	—	—	—	15,914,470	
Issuance of common stock on exercise of options	—	—	274,831	2,750	425,138	—	—	—	427,888	
Deferred stock-based compensation	—	—	—	—	—	187,999	—	—	187,999	
Stock-based compensation for non-employees awards	—	—	—	—	175,154	—	—	—	175,154	
Stock-based compensation for employee awards	—	—	—	—	1,874,863	—	—	—	1,874,863	
Warrants issued in connection with Bond financing	—	—	—	—	19,541,000	—	—	—	19,541,000	
Unrealized holding gain on available-for-sale securities	—	—	—	—	—	—	46,642	—	46,642	$ 46,642
Net loss	—	—	—	—	—	—	—	(59,825,181)	(59,825,181)	(59,825,181)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(59,778,539)
Balance at December 31, 2007	—	—	24,953,146	249,530	173,578,150	(164,225)	46,122	(145,153,215)	28,556,362	
Issuance of common stock on exercise of options	—	—	116,260	1,164	401,539	—	—	—	402,703	
Issuance of common stock warrant for services provided	—	—	—	—	1,127,920	—	—	—	1,127,920	
Amortization of deferred stock-based compensation	—	—	—	—	—	164,225	—	—	164,225	
Stock-based compensation for non-employee awards	—	—	—	—	191,660	—	—	—	191,660	
Stock-based compensation for employee awards	—	—	—	—	2,578,924	—	—	—	2,578,924	
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	419,790	—	419,790	419,790
Currency translation adjustment	—	—	—	—	—	—	(8,078)	—	(8,078)	(8,078)
Net loss	—	—	—	—	—	—	—	(81,253,932)	(81,253,932)	(81,253,932)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(80,842,220)
Balance at December 31, 2008	—	—	25,069,406	250,694	177,878,193	—	457,834	(226,407,147)	(47,820,426)	
Issuance of common stock on exercise of options	—	—	143,671	1,437	293,516	—	—	—	294,953	
Issuance of restricted stock	—	—	55,250	552	135	—	—	—	687	
Stock-based compensation	—	—	—	—	3,970,321	—	—	—	3,970,321	
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	(453,190)	—	(453,190)	(453,190)
Currency translation adjustment	—	—	—	—	—	—	(5,184)	—	(5,184)	(5,184)
Net loss	—	—	—	—	—	—	—	(66,483,757)	(66,483,757)	(66,483,757)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	$(66,942,131)
Balance at December 31, 2009	—	$ —	25,268,327	$252,683	$182,142,165	$ —	$ (540)	$(292,890,904)	$(110,496,596)	

See notes to consolidated financial statements.

MOLECULAR INSIGHT PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2007	2008	2009
Cash flows from operating activities:			
Net loss	$ (59,825,181)	$(81,253,932)	$(66,483,757)
Adjustments to reconcile net loss to cash used in operating activities, net of acquisition:			
Noncash interest expense and accretion	4,097,688	23,079,796	21,294,945
Impairment charges	—	—	1,210,000
Depreciation and amortization	721,887	902,593	940,182
Stock-based compensation expense	2,238,016	4,062,729	3,970,321
Deferred rent	(22,568)	—	—
Change in fair value of bond derivative	—	(150,000)	—
Changes in assets and liabilities, net of the acquisition of Zebra Pharmaceuticals, Inc.			
Accounts receivable	(196,404)	199,568	(526,334)
Prepaid expenses and other current assets	996,631	401,561	177,955
Other assets	7,291	—	—
Accounts payable	1,202,157	(1,936,344)	889,119
Accrued expenses and other	5,419,022	(852,636)	(1,886,391)
Accounts payable and accrued expenses — related parties	495,812	(828,474)	(351,581)
Net cash used in operating activities	(44,865,649)	(56,375,139)	(40,765,541)
Cash flows from investing activities:			
Purchase of investments	(140,810,528)	(47,590,606)	(57,225,312)
Proceeds from matured investments	39,976,834	68,900,000	88,248,000
Purchase of property and equipment	(4,905,234)	(1,111,807)	(912,885)
Loss on disposal of assets	337,441	—	—
Restricted cash	—	(500,000)	—
Net cash provided by (used in) investing activities	(105,401,487)	19,697,587	30,109,803
Cash flows from financing activities:			
Proceeds from issuance of bonds and warrants — net of issuance costs of $7,321,670	142,678,330	—	—
Payment on notes payable	(3,627,072)	—	—
Proceeds from exercise of common stock options and warrants	1,820,338	65,207	632,449
Proceeds from sale of common stock and warrants, net of issuance costs	62,594,940	—	—
Proceeds from sale of restricted stock	—	—	687
Net cash provided by financing activities	203,466,536	65,207	633,136
Effect of foreign exchange rate changes on cash and cash equivalents	—	(8,078)	(5,184)
Net increase (decrease) in cash and cash equivalents	53,199,400	(36,620,423)	(10,027,786)
Cash and cash equivalents — beginning of period	8,915,857	62,115,257	25,494,834
Cash and cash equivalents — end of period	$ 62,115,257	$ 25,494,834	$ 15,467,048
Supplemental disclosures of cash flows information:			
Cash paid for interest	$ 211,353	$ —	$ —
Noncash investing and financing activities:			
Payable for purchases of property and equipment	—	243,542	73,147
Capitalized initial fair value of asset retirement obligation	—	266,735	—
Receivable for exercise of stock options	—	337,496	—
Payment-in-kind bonds in lieu of cash interest payments	2,414,531	18,060,895	16,058,218

See notes to consolidated financial statements.

MOLECULAR INSIGHT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND OPERATIONS

Nature of Business — Molecular Insight Pharmaceuticals, Inc. (the "Company") was incorporated in January 1997 and is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted therapeutic and imaging radiopharmaceuticals for use in oncology. Product candidates are designed to improve patient diagnosis, treatment and management. The Company's research programs are conducted both internally and through strategic collaborations. The Company is based in Cambridge, Massachusetts and conducts its operations and manages its business as one operating segment.

During the period from inception through September 30, 2009, the Company was considered to be a development stage company. In the third and fourth quarters of 2009, the Company entered into a territory license agreement and supply agreement, respectively, and has generated revenues from planned principal operations. The Company has therefore emerged from the development stage as of December 31, 2009.

Risks and Uncertainties — The Company is subject to the risks of a highly leveraged, clinical-stage company, such as developing saleable products, building up the research, manufacturing, administrative personnel, and organization structures to support growth, dependence on strategic partners, licensors and third-party contractors to successfully research, develop, manufacture and commercialize its product candidates based on the Company's technologies, maintaining compliance with the Bond Indenture's covenants, and obtaining future financing when required. In addition, the Company is also subject to risks common to companies in the biopharmaceutical industry including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and approval requirements, commercialization of its potential products, uncertainty of market acceptance of products, competition from larger companies, and its ability to reach commercial production of its product candidates.

Going Concern, Liquidity and Management's Plans — The Company has incurred significant net losses and negative operating cash flows since inception. At December 31, 2009, the Company had an accumulated deficit of $292.9 million, including the $66.5 million net losses incurred for the year ended December 31, 2009. The Company has five clinical-stage product candidates in development and will need to spend significant capital to fulfill planned operating goals and continue to conduct clinical and non-clinical trials, achieve regulatory approvals and, subject to such approvals, successfully produce products for commercialization. As such, the Company expects to continue to incur significant net losses and negative operating cash flows in the foreseeable future.

The terms of the Company's Bond Indenture include various covenants, including among others, financial covenants that requires the Company maintain a minimum liquidity level on a quarterly basis. The minimum liquidity covenant (as defined in the Indenture and which substantially represents all of the Company's cash, cash equivalents and investments) requires the Company to maintain a minimum amount of not less than $25.7 million and $29.2 million at September 30, 2010 and December 31, 2010, respectively. Based on the Company's current projections of cash flow, the Company expects that it would not be in compliance with this covenant in the third or fourth quarter of 2010, unless it is able to raise sufficient additional capital. Additionally, under the Bond Indenture, the Company is required to deliver audited annual financial statements to Bond holders which are not subject to a "going concern" or like qualification or exception from its independent auditors. Such anticipated noncompliance of the required minimum liquidity level in the second half of 2010, recurring losses from its operations and net stockholders' capital deficiency, and the uncertainty of the Company obtaining additional financing on a timely basis, raise substantial doubt about its ability to continue as a going concern beyond September 2010. As a result, in the report of the independent registered public accounting firm on the Company's financial statements as of and for the year ended December 31, 2009, the independent auditors have included an emphasis of a matter paragraph relating to substantial doubt whether the Company can continue as a going concern. Consequently, the inclusion of such a "going concern" paragraph would result in a default under the terms of the Bond Indenture, unless waived by the Bond holders. The Company cannot guarantee its ability to continue as a going concern unless it can raise additional capital, of which there can be no assurance.

The Company has executed a waiver agreement and obtained a temporary waiver from the holders of at least a majority of the Bonds and the Bond Indenture trustee. Under the terms of the waiver agreement, the Bond holders and Bond Indenture trustee have agreed to waive the noncompliance arising from the inclusion of the "going concern" paragraph in the report of the independent registered public accounting firm on the Company's financial statements and other technical defaults under the Bond Indenture until 12:01 AM Eastern Standard Time on April 16, 2010, subject to earlier termination upon certain circumstances. The waiver is also subject to a number of certain terms and conditions relating to the Company's provision of certain information to the Bond holders, among other conditions and matters. Notwithstanding the waiver, it is probable that the Company will continue to fail to meet the same covenant within the next twelve months. Consequently, the long-term bond obligations and related debt issuance costs have been reclassified as current liabilities and current assets, respectively, at December 31, 2009. If the Bond Indenture is restructured in a transaction required to be accounted for as an extinguishment or the outstanding balance of the bond obligations is demanded by the Bond holders, unamortized debt issue costs of $4.5 million would be required to be expensed at the restructuring or demand date.

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern. As of December 31, 2009, the Company had $15.5 million of cash and cash equivalents and $48.5 million of investments.

The Company is continuing to negotiate with the Bond holders regarding the restructuring of the outstanding debt in a manner designed to avoid the acceleration of its debt obligations and position the Company for future growth. The Company cannot be assured that it will reach such an agreement on terms favorable to the Company, or at all. Moreover, in connection with the discussions with the Bond holders to reach such an agreement, the Bond holders may impose additional operational or financial restrictions on the Company or modify the terms of our existing Bond Indenture. These restrictions may limit the Company's ability, among other things, to make necessary capital expenditures or incur additional indebtedness. In addition, the Bond holders may require the Company to pay additional fees, prepay a portion of its indebtedness, accelerate the amortization schedule for its indebtedness or agree to higher interest rates on its outstanding indebtedness or take other actions that could adversely affect the Company's business. The Bond holders may also require the Company to raise additional capital concurrently with any restructuring. If the waiver grace period (or any extension thereof) expires or terminates, and the Company is unable to reach an agreement with Bond holders regarding an additional waiver or an agreement regarding the restructuring of its outstanding debt, the Bond holders may choose to accelerate its debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations. If its indebtedness under the Bond Indenture is accelerated or is not restructured on acceptable terms, it is likely that the Company will be unable to repay its debt and it may seek protection under the U.S. Bankruptcy Code or similar relief.

In conjunction with these discussions, the Company is also actively pursuing financing strategies to raise additional funds through public or private sales of equity and other strategic collaborative arrangements which are limited under the provisions of the Indenture. If the Company raises additional funds through the issuance of new equity securities, its stockholders may experience substantial dilution, or the new equity securities may have rights, preferences or privileges senior to those of existing stockholders. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or its product candidates or grant licenses on terms that are not favorable to the Company. The Company has no current commitments from any persons that they will provide any additional financing. Given the current market conditions and the status of the Company's product development pipeline, obtaining financing may be difficult and may not be available on commercially acceptable terms, or at all.

In September 2009, the Company entered into a Territory License Agreement with BioMedica Life Sciences, S.A. ("BioMedica") to sub-license its Onalta™ 90-Y edotreotide radiotherapeutic in certain countries. Further, in October 2009, the Company executed an exclusive 10-year agreement to supply Onalta to BioMedica and entered into an agreement with Eckert & Ziegler Nuclitec GmbH ("EZN") to manufacture Onalta. The Company has received $4.4 million of upfront payments from BioMedica and will also be eligible to receive regulatory milestone payments, as well as commercial milestones and tiered royalties on Onalta sales upon commercialization in addition to near- and long-term revenues from supplying Onalta for compassionate use, clinical trial supplies and, upon regulatory approval, commercial supply to the licensed BioMedica territories. While the Supply Agreement will provide the Company with a source of liquidity after net payments for manufacturing costs to EZN of approximately $4.9 million for the first five years, future potential cash receipts from BioMedica, if any, are principally contingent upon the successful completion of contractually defined development and regulatory approval objectives. There is also considerable inherent uncertainty in the successful development and commercialization of products in the pharmaceutical industry.

The Company continues to evaluate cost efficiencies in the conduct of its research and development programs. In 2009, the Company was able to reduce cash used in operations by $15.6 million, as compared with the year ended December 31, 2008. The savings were primarily due to the completion of certain clinical trials and operational efficiencies implemented in general and administrative functions in the latter half of 2008. The Company believes that its existing cash, cash equivalents and investments, and future contractual cash payments from BioMedica, together with the implementation of planned additional cost reduction initiatives if necessary, will be sufficient to fund its operations and maintain compliance with its minimum liquidity covenant through at least September 30, 2010. In order to continue operations beyond September 2010, the Company must raise additional capital. The Company's failure to raise capital when needed could have a negative impact on its financial condition and its ability to pursue business strategies as well as potentially delay product research and development efforts and potentially require the Company to reduce the scope of, or eliminate one or more of its ongoing clinical programs or cause the Company to cease operations. The Company would also be required to implement further reduction in personnel and related costs and other discretionary expenditures that are within the Company's control. In January 2010, the Company announced a strategic decision to re-align and re-balance personnel to further reduce operating costs and support the efficient development of its oncology product candidates.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation — The consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries, namely Molecular Insight Limited, based in the United Kingdom, Molecular Insight Pharmaceuticals GmbH, based in Germany, and Biostream Therapeutics, Inc. ("BTI"). Intercompany accounts and transactions for all subsidiaries have been eliminated in consolidation.

Use of Estimates — The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and use assumptions that affect reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. Significant estimates reflected in these financial statements include the estimated fair values of the Company's Denton Texas facility, common stock warrants, derivative financial instruments, certain accruals and reserves, revenues, stock-based compensation and the valuation allowance recognized on the deferred tax assets.

Revenue Recognition — The Company generates revenue from two primary sources: (1) license, product and royalty revenues from collaborative agreements with strategic partners, and (2) government grants for research and development. The timing of cash received from collaborative agreements and government grants

differs from revenue recognized. Payments received in advance of costs being incurred are recorded as deferred revenue. Revenue is recognized provided contractual agreements exist, delivery has occurred and risk of loss has passed, the fees are fixed or determinable and the collection is probable. Amounts recognized are limited to amounts due from the collaborative partners and grantor based upon the contract or grant terms.

Collaborative Agreements

In October 2009, the Financial Accounting Standards Board ("FASB") issued ASU 2009-13 to address the accounting for multiple-deliverable revenue arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. The ASU also establishes a selling price hierarchy for determining the selling price of a deliverable, replaces the term *fair value* in the revenue allocation guidance with *selling price* to clarify that the allocation of revenue is based on entity-specific assumptions rather than assumptions of a marketplace participant. The Company has elected to early adopt this ASU. No retrospective adjustments were required upon adoption. The adoption of this ASU did not have a significant impact on the Company's financial statements.

Under ASU 2009-13, Multiple deliverables are separated and may be accounted for individually as separate units of accounting if they have stand-alone value. The Company must determine the selling price of each of the deliverables for purposes of revenue allocation under the relative selling price method. The Company must also determine the period over which it is expected to complete its performance obligations under an arrangement. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value, the Company is able to determine the selling price for all deliverables, and there are no refund rights relative to the delivered license. Undelivered performance obligations are then accounted for separately as performed. If these conditions are not met, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations would be recognized as revenue over the estimated period of performance.

The Company must also determine whether milestone payments under arrangements where the Company has continuing performance obligations meet the conditions and criteria to be considered a substantive milestone. Factors the Company considers in determining whether a milestone is substantive and can be accounted for separately from an upfront payment include assessing the level of risk and effort in achieving the milestone, the timing of its achievement relative to the upfront payments, and whether the amount of the payment was reasonable in relation to the Company's level of effort. If any of the substantive milestone conditions are not met, the resulting payment would not be considered a substantive milestone. Any resulting payments received would be considered part of the consideration for the single unit of accounting and would be deferred and recognized as revenue over the estimated period of the arrangement.

Government Grants

The Company recognizes revenue from government grants for research and development as services are performed.

The Company has been awarded government grants from the National Institutes of Health ("NIH") to provide research services related to certain areas of the Company's research. Such grants are generally on a cost sharing basis with the Company also contributing to the costs of research.

Under the terms of the NIH grants, the Company has all right, title and interest in its patents, copyrights and data pertaining to its product development, subject to certain rights of the government. Under existing regulations, the government receives a royalty-free license for federal government use for all patents developed

under a government grant. In addition, under certain circumstances the government may require the Company to license technology resulting from the government-funded projects to third parties and may require that the Company manufacture its product in the United States. However, ownership in such technology remains with the Company.

Funding of government grants is subject to government appropriation and all of these grants contain provisions which allow for termination at the convenience of the government. These grants require the Company to comply with certain government regulations. Management believes that the Company has complied with all regulations that, if not met, could have a material adverse impact on the Company's consolidated financial statements or the Company's eligibility for future grant awards.

The U.S. government was responsible for 100%, 100% and 19% of the Company's consolidated revenues for the years ended December 31, 2007, 2008 and 2009, respectively. Revenues from BioMedica accounted for 81% of the Company's consolidated revenues for the year ended December 31, 2009. The Company's management does not believe significant risk exists in connection with its concentrations of credit related to accounts receivable at December 31, 2009, since its customers are primarily government agencies and the Company requires advance payments from BioMedica for product sales.

Research and Development — Research and development expense consists of expenses incurred in developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital assets used to develop products and costs of facilities. Research and development costs, including those incurred and supported with government grants, are expensed as incurred and included under such caption in the accompanying consolidated statements of operations. Certain research and development activities are partially funded with government grants, which are recognized as revenue.

Cash Equivalents and Investments — Cash equivalents were money market accounts invested in U.S. Treasury bills and purchased with maturities less than 90 days. The Company's investments were held in U.S. Treasury bills with maturities over 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities with any unrealized gains or losses reported as a separate component of stockholders' deficit. Investments classified as short-term have maturities of less than one year. Investments classified as long-term have maturities of 1 to 2 years and it is management's intent to hold such investments beyond one year, although these funds are available for use and therefore classified as available-for-sale. The Company uses the specific identification method in determining gains and losses reclassified out of accumulated other comprehensive income into earnings. Cash and cash equivalents, and investments are held at two financial institutions, of which substantially all amounts were held in one institution.

The amortized cost, gross unrealized gains and losses, and fair value of investments are as follows:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
December 31, 2009				
Short-term	$48,502,133	$ 18,458	$5,736	$48,514,855
Long-term	$ —	$ —	$ —	$ —
December 31, 2008				
Short-term	$73,468,987	$711,932	$ —	$74,180,919
Long-term	$ 6,055,834	$ 53,980	$ —	$ 6,109,814

No realized gains or losses were recognized in Other Income or Expense for the years ended December 31, 2009, 2008 and 2007.

Property and Equipment — Property and equipment are recorded at cost. Depreciation and amortization is provided using the straight-line method over the estimated lives of the related assets or over the term of the lease (for leasehold improvements and leased equipment), if shorter as follows: lab and other equipment — 3 years; furniture and fixtures — 5 years; leasehold improvements — life of lease.

Impairment of Long-Lived Assets — The Company reviews its long-lived assets for possible impairment when events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Recoverability of assets to be held and used is evaluated by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets as determined by valuation techniques appropriate in the circumstances.

Debt Issuance Costs — Debt issuance costs were incurred in connection with the $150 million November 9, 2007 bond and warrant sale (see Note 8), which are being amortized as a component of interest expense using the effective interest method over the five year term of the bond. Amortization of debt issuance costs included in interest expense for the years ended December 31, 2007, 2008 and 2009 were $153,970, $1,270,749 and $1,370,097, respectively.

Income Taxes — Deferred tax assets and liabilities relate to temporary differences between financial reporting and income tax bases of assets and liabilities and are measured using enacted tax rates and laws expected to be in effect at the time of their reversal. Valuation allowances are established, when necessary, to reduce the net deferred tax asset to the amount more likely than not to be realized. The financial statements includes recognition of expected future tax consequences of uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not file a return in a particular jurisdiction) presuming the taxing authorities' full knowledge of the position and all relevant facts. The Company has not recognized any adjustment in the liability for unrecognized income tax benefits because of the Company's full valuation allowance. Interest and penalties related to uncertain tax positions are recognized in income tax expense.

Stock-Based Compensation — In 1997, the Company's stockholders' and Board of Directors approved the 1997 *Stock Option Plan* (the "1997 Plan"). Under the 1997 Plan, the Board of Directors may grant incentive stock options and nonqualified stock options to officers, directors, other key employees of the Company and its subsidiaries, non-employees and consultants. The 1997 Plan permits the Board of Directors to determine the number of options, the exercise price, the vesting schedule and the expiration date of stock options. The 1997 Plan provides that the exercise price of each incentive stock option must be at least equal to 100% of the estimated fair market value of the common stock on the grant date (110% of fair market value in the case of stockholders who, at the time the option is granted, own more than 10% of the total outstanding common stock), and requires that all such options have an expiration date before the tenth anniversary of the grant date of such options (or the fifth anniversary of the date of grant in the case of 10% stockholders). Options typically expire 10 years from the date of grant and generally vest over a period of four years from the date of grant. In May 2006, the Board of Directors voted to amend the 1997 Plan by increasing the reserved shares by 666,667, which was subsequently approved by stockholders in August 2006, to allow for a total of 2,833,333 shares issuable under the 1997 Plan. There are no remaining available share awards that can be issued under the 1997 Plan, which was subsequently terminated on January 9, 2007. On August 31, 2006 the stockholders approved 2,300,000 shares for issuance under the Amended and Restated 2006 Equity Incentive Plan (the "2006 Plan"). Pursuant to the annual automatic increase provisions of the 2006 Plan, an additional 998,126 shares in 2008 and 1,002,776 shares in 2009 have been reserved under the 2006 Plan to allow for a total of 4,300,902 shares issuable for share awards.

The 2006 Plan allows awards to be granted after February 1, 2007, the effective date of the Company's initial public offering. The Company satisfies share option exercises and issuance of share awards through the issuance of new shares.

The measurement and recognition of compensation expense for service-based awards made to employees under the Company's Equity Incentive Plans are based on their estimated grant date fair values and compensation costs are recognized over the requisite service period using the straight-line attribution method. Fair values for performance-based awards made to employees are estimated based on the date the performance conditions are established and assessed as probable of being achieved and compensation costs are recognized on a straight-line basis through the expected period of achievement of the performance conditions. The probability of vesting is reassessed by the Company at each reporting period and compensation costs are adjusted based on its probability assessment. Compensation costs recognized reflect the number of awards that are expected to vest and adjusted to reflect those awards that do ultimately vest.

The estimated fair value of the stock options granted is estimated using the Black-Scholes valuation model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected life of the option, the expected volatility of the common stock consistent with the expected life of the option, risk free interest rates and expected dividend yields of our common stock. Higher estimates of volatility and expected life of the option increase the value of an option and the resulting expense.

All stock-based awards to non-employees are accounted for at their estimated fair values and recognized over the period of expected service by the nonemployees (which is generally the vesting period). As the service is performed, the Company updates its fair value assumptions and periodically revalue unvested options and make adjustments to the stock-based compensation expense using the new valuation. These adjustments are recognized in the consolidated statements of operations in the periods of re-measurement. Ultimately, the final compensation charge for each option grant to nonemployees is unknown until the performance of services is completed. The Company accounts for transactions in which services are received in exchange for equity instruments based either on the fair value of such services received from nonemployees or of the equity instruments issued, whichever is more reliably measured. The two factors which most effect charges or credits to operations related to stock-based compensation for nonemployee awards are the fair value of the common stock underlying stock options for which such stock-based compensation is recorded and the volatility of such fair value.

Compensation expense for options and restricted stock granted to employees and nonemployees is classified either as research and development expense or general and administrative expense based on the job function of the individual receiving the grant.

Floating Rate Bonds and Embedded Derivative — The senior secured floating rate bonds issued in November 2007 (the "Bonds") constitute a hybrid instrument that includes a debt host contract containing an embedded derivative feature (a contingent mandatory repayment provision) that requires bifurcation and separate accounting as a derivative instrument pursuant to GAAP, The carrying value of the debt is being accreted to its face value of $150 million over its five year term using the effective interest method.

Effective January 1, 2009, the Company implemented new required disclosures about derivative instruments and hedging activities to improve financial reporting about derivative instruments and hedging activities by enhanced disclosures to better understand their effects on a company's financial position, results of operations and cash flows. The new disclosure requirements did not have a significant impact on the Company's financial statements.

Net Loss Per Share — Basic and diluted net loss per common share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of unrestricted common shares outstanding during the periods. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are anti-dilutive for all periods presented. Anti-dilutive securities, which consist of

redeemable convertible preferred stock (through February 7, 2007), common stock issuable upon conversion of accrued cumulative dividends on preferred stock, stock options, restricted common stock, warrants and convertible debt that are not included in the diluted net loss per share calculation, aggregated 9,006,808, 9,893,660 and 10,832,600 potential common shares as of December 31, 2007, 2008, and 2009, respectively. In addition, unvested common stock pursuant to restricted stock awards are excluded from the calculation of basic loss per share until such shares vest but are included in diluted net loss per share if inclusion is not anti-dilutive.

Prior to their February 7, 2007 conversion, the Company's redeemable convertible preferred stock accrued dividends (see Note 10) were paid in cash or in common stock at the election of the holder. If conversion was elected, the number of shares into which the dividends could be converted was based upon the conversion ratio for the redeemable convertible preferred stock and may result in the holders of the redeemable convertible preferred stock receiving common stock with a fair value that is greater than the recorded amount of accrued dividends. If the conversion feature of the accrued dividends had an intrinsic value greater than the dividend earned, the beneficial conversion feature was recognized and treated as a distribution to preferred stockholders for purposes of net loss per share calculations. Redeemable convertible preferred stock dividends and accretion of issuance costs amounted to $39,610 and $1,328,427, respectively for the year ended December 31, 2007.

Guarantees: Indemnified Obligations — The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, typically with contractors, clinical sites and customers and under the Company's office lease arrangements (see Note 13). Under these provisions, the Company generally indemnifies and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred any material costs or settled claims related to these indemnification provisions, and consequently, concludes that the estimated fair value of these agreements is minimal. Accordingly, no liabilities have been recorded under these agreements as of December 31, 2009.

Fair Value of Financial Instruments — The carrying amounts of the Company's financial instruments, which include cash equivalents, investments, accounts receivable, accounts payable and accrued expenses, except for the embedded derivative, approximate their fair values due to their short-term nature. The embedded derivative is recorded at its estimated fair value. Management, using the best information available, has estimated, the fair value of the Company's bond obligations, including accrued interest which are paid-in-kind and issued as additional bonds to bond holders, to be approximately $153.0 million and $150.6 million at December 31, 2008 and 2009, respectively. The fair value was required to be estimated due to the fact that the Bond Indenture is not publicly traded and contains characteristics that are not widely observed in similar debt instruments.

Effective January 1, 2009, the Company implemented new required fair value measurements and disclosures for its non-financial assets and liabilities that are remeasured at fair value on a non-recurring basis. The new requirements did not have a material effect on the Company's consolidated financial statements upon adoption.

Effective, September 30, 2009, the Company implemented Accounting Standards Update ("ASU") 2009-05, issued by the FASB in August 2009. ASU 2009-05 supplements and amends previous guidance for fair value measurements and disclosures, to clarify how an entity should measure the fair value of liabilities. Alternative valuation methods and a hierarchy for their use are also outlined in the ASU. The ASU also clarifies that restrictions preventing the transfer of a liability should not be considered as a separate input or adjustment in the measurement of its fair value. ASU 2009-05 is effective in the first reporting period (including interim periods) after August 26, 2009. The adoption of this ASU did not have a significant impact on the Company's financial statements.

The Company carries its investments and its embedded derivative related to the bond financing agreement at fair value. The Company determines fair value of its investments based upon quoted prices when available or through the use of alternative approaches, such as model pricing, when market quotes of its investments are not readily accessible or available. In determining the fair value various factors are considered including: closing exchange or over-the-counter market price quotations; time value and volatility factors underlying options and derivatives; price activity for equivalent instruments; and the Company's product candidates.

The Company records cash equivalents, which are held in money market funds and invested U.S. treasuries, at fair value (level 1) as quoted prices and an active market exists.

The Company measures and records the fair value of its available-for-sale securities at the closing market price at period end for these investment instruments and the balance sheet valuation reflects the aggregate fair market value of all available-for-sale securities. Unrealized changes in such fair values are recorded in accumulated other comprehensive income.

The Company measures the fair value of the embedded derivative (contingent mandatory redemption feature — see Note 8) through the use of unobservable inputs which include adjustable interest rates, fixed budgeted research spending based on a pre-determined timeline (as defined by the Company's bond financing agreement), discount rate determined using an appropriate risk-free rate plus a credit spread, success factor probabilities for key product candidates at each phase of development and the likelihood that bond holders will allow for reinvestment in an alternative product upon occurrence of a product material adverse event ("MAE"). Contingent mandatory redemption amounts approximate the remaining budgeted research spending in the period in which a product MAE on a primary product is determined to have occurred. The fair value of the embedded derivative declines as product development proceeds over time. Changes in the product development timeline would also have an effect on the fair value of the embedded derivative as potential repayments on the bond declines with the passage of time. In evaluating the assumptions utilized in the valuation model, the Company considered the progress and results of clinical trials conducted on its primary products and potential alternative products in the Company's pipeline in the event of a product MAE. The Company has assigned success factor probabilities ranging from 78%-100% and deems that it is highly unlikely that: (1) a product MAE would occur in the time periods outlined in the bond financing agreement; and (2) bond holders would not allow for reinvestment of budgeted research spending in alternative products in the case of a product MAE. The Company had no purchases, sales, issuances, or settlements that would otherwise have an impact on the fair value of the embedded derivative.

The fair value of the Company's building facility (Denton facility) was determined using the market and cost approach valuation methods as the asset does not have separately identifiable income stream from which to develop reliable estimates of future cash flows. Given that the building facility has not been placed into service as of December 31, 2009, the Company has ascribed more weight to the results of the market approach in determining the fair value of the asset. The Company's building facility with a carrying amount of $3,009,544 was written down to its estimated fair value of $1,799,544, resulting in an impairment charge of $1,210,000, which was included in research and development expenses for the year ended December 31, 2009.

These valuation techniques may be based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two types of inputs create the following fair value hierarchy:

- Level 1 — Quoted prices for identical instruments in active markets.
- Level 2 — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.
- Level 3 — Instruments whose significant value drivers are unobservable.

The following tables present the Company's assets and liabilities that are measured at fair value and the related hierarchy levels:

	December 31, 2009	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Measured at Fair Value on a Recurring Basis				
Assets:				
Cash equivalents	$14,826,040	$14,826,040	$—	$ —
Available-for-sale securities	$48,514,855	$48,514,855	$—	$ —
Liabilities:				
Embedded derivative	$ 50,000	$ —	$—	$ 50,000
Measured at Fair Value on a Non-Recurring Basis				
Long-lived assets	$ 1,799,544	$ —	$—	$1,799,544

	December 31, 2008	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Measured at Fair Value on a Recurring Basis				
Assets:				
Cash equivalents	$25,078,194	$25,078,194	$—	$ —
Available-for-sale securities	$80,290,733	$80,290,733	$—	$ —
Liabilities:				
Embedded derivative	$ 50,000	$ —	$—	$50,000

The table below provides a reconciliation of the fair value of the embedded derivative measured on a recurring basis for which the Company used Level 3 for the years ended December 31, 2008 and 2009:

	2008	2009
Balance at January 1	$ 200,000	$50,000
Realized gain included in other income	(150,000)	—
Purchases, issuances and settlements	—	—
Transfers in/out of Level 3	—	—
Balance at December 31	$ 50,000	$50,000

The table below provides a reconciliation of the fair value of long-lived assets measured on a non-recurring basis for which the Company used Level 3 for the year ended December 31, 2009:

	2009
Balance at January 1	$ 3,009,544
Realized loss included in research and development costs	(1,210,000)
Purchases, issuances and settlements	—
Transfers in/out of Level 3	—
Balance at December 31	$ 1,799,544

Recent Accounting Pronouncements

On June 3, 2009, the FASB approved the *FASB Accounting Standards Codification* ("ASC 105-10"), or the Codification, as the single source of authoritative Generally Accepted Accounting Principles, or GAAP, in the United States to be applied by all non-governmental entities. Rules and interpretative releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The Codification supersedes all existing non-SEC accounting and reporting standards. All other accounting literature not included in the Codification will be non-authoritative. The Codification is effective for interim and annual periods ending after September 15, 2009. The adoption of the Codification did not have an impact on the Company's consolidated financial statements.

3. ASSET RETIREMENT OBLIGATION

In June 2008 the State of Texas granted the Company a radioactive materials license for its manufacturing operation in Denton, TX. Under the terms of the license it is a requirement for the Company to provide for future decommissioning and environmental remediation of the site. The license terms required the Company to post an irrevocable letter of credit ("LOC") for $500,000 to the State of Texas as collateral to fund the future decommissioning costs of the manufacturing site. The issuing bank of the LOC requires the Company to maintain a $500,000 certificate of deposit as collateral for the LOC which has been classified as restricted cash on the balance sheet. The Company determined the Asset Retirement Obligation ("ARO") through the use of a present value calculation. Key assumptions utilized include a term of ten years and a risk adjusted interest rate of 6.3%. Coincident with the grant of the license is the recognition of a future ARO.

The following is a summary of the changes in the Company's ARO for the years ended December 31, 2008 and 2009:

	2008	2009
Asset retirement obligation as of January 1	$ —	$276,693
Liabilities incurred	266,735	—
Accretion expense on discounted obligation	9,958	17,944
Asset retirement obligation as of December 31	$276,693	$294,637

4. STOCK-BASED COMPENSATION

Employees — The estimated fair value of stock options granted was determined using the Black-Scholes option pricing model. In using the Black-Scholes option pricing model, the Company makes certain assumptions with respect to the estimated lives of the awards, expected volatility of the common stock consistent with the expected option life, risk free interest rates, and dividend rates.

The Company assumed the following for the years ended December 31:

	2007	2008	2009
Risk free interest rates	3.9% to 4.8%	2.8 to 3.4%	1.75 to 3.01%
Expected dividend yield	0%	0%	0%
Expected life (non-performance-based options)	6.25 years	6.25 years	5.50-6.25 years
Expected life (performance-based options)	6.25 years	6.25 years	4.0 years
Expected volatility	62.9% to 64.9%	65.0% to 77.0%	82.0% to 101.0%

The weighted average expected option term reflects the application of the simplified method set forth in the Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 107, issued in March 2005 and SAB No. 110, issued in December 2007. The simplified method defines the life as the average of the contractual

term of the options and the weighted average vesting period for all option tranches. The Company calculated the weighted average expected life of the non-performance-based options using the simplified method and this decision was based on the lack of relevant historical data due to the Company's limited operating experience as a public company.

The Company based its estimate of expected volatility using volatility data from comparable public companies in similar industries and markets, and available historical information regarding the volatility of its own share price because there was no public market for the Company's common stock prior to February 2007. The Company intends to continue to consistently apply this process using the same or similar entities until a sufficient amount of historical information regarding the volatility of its own share price becomes available, or unless circumstances change such that the identified entities are no longer similar to the Company. The risk free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company does not pay cash dividends on its common stock and does not anticipate doing so for the foreseeable future. Accordingly, the expected dividend yield is zero.

Information concerning all stock option activity for the year ended December 31, 2009 is summarized as follows:

	2009		
	Number of Shares	Weighted Average Exercise Price per Share	Weighted Remaining Contractual Life (Years)
Options outstanding at beginning of period	3,195,070	$5.91	
Granted	2,099,780	4.24	
Exercised	(143,671)	2.05	
Forfeitures	(1,036,326)	6.04	
Options outstanding at end of period	4,114,853	5.16	7.44
Options exercisable	1,729,496	5.20	5.54
Options vested and expected to vest	3,128,797	5.18	7.00
Options available for grant	1,116,995		
Weighted average fair value of options granted		$3.11	

During the year ended December 31, 2009, the Compensation Committee of the Board of Directors awarded the following performance-based share awards which will vest upon achievement of certain performance milestones:

- the Chief Executive Officer ("CEO") and the Chief Scientific Officer were granted 125,000 and 50,000 stock options, respectively, having an aggregate fair value of approximately $615,000. The Company has assessed certain of the milestones as probable of being achieved. The award to the CEO was granted as an employee inducement grant and was granted outside of the Company's Amended and Restated 2006 Equity Incentive Plan; and
- the Chief Financial Officer ("CFO") was granted 50,000 stock options with an aggregate fair value of approximately $139,000 and which the Company has assessed as probable of being achieved.

Also during the year ended December 31, 2009, pursuant to the terms of the Severance Agreement entered into with the Company's former CFO, in connection with the termination of his employment with the Company, the Company agreed to accelerate 37,500 of unvested stock options and extend the exercise period of such

accelerated options and other vested options. The fair value of fully vested and exercisable stock options accelerated was approximately $112,000 and the incremental fair value of modified stock options of approximately $233,000 was recognized immediately as compensation expense.

In the Company's annual award of stock options for 2009, a total of 978,113 stock options were awarded to employees and executive officers vesting over a period of two years, 8,333 fully vested stock options were awarded to an executive officer, and 125,000 stock options were awarded to non-employee directors vesting over a period of one year. In addition, 500,000 stock options were granted to the Company's CEO which vests over a period of four years from his employment start date.

During the year ended December 31, 2009, the Compensation Committee also granted 302,500 stock options to new hires which include the award to the Company's newly hired CFO of 175,000 stock options, 30,000 stock options to an executive officer on promotion, 8,334 fully vested stock options to an executive officer, and 10,000 stock options to a non-employee. These stock options vest over a period of four years.

The weighted average fair value of options granted during 2007 and 2008 was $5.58 and $6.79, respectively.

The intrinsic values of outstanding options, exercisable options, and options vested and expected to vest as of December 31, 2009 were the same at $965,461.

The intrinsic value of options exercised during the years ended December 31, 2007, 2008 and 2009 was $1,999,380, $243,420 and $232,264, respectively.

The total grant date fair value of stock option awards vested during the years ended December 31, 2007, 2008 and 2009 was $413,178, $2,518,956 and $3,049,440.

Restricted Stock — On May 20, 2008 the Company awarded shares of common stock to certain executives of the Company constituting a Restricted Stock award under the Company's Amended and Restated 2006 Equity Incentive Plan. The shares vest on the fourth anniversary of the award and are subject to accelerated vesting on accomplishment of certain performance milestones. Unvested shares are subject to forfeiture upon termination of employment. Information concerning unvested restricted stock activity for the year ended December 31, 2009 is summarized as follows:

	2009	
	Number of Shares	Grant Date Fair Value
Nonvested shares at beginning of period	93,750	$7.78
Granted	—	—
Vested	(22,343)	7.78
Forfeited	(38,500)	7.78
Nonvested shares at end of period	32,907	$7.78

The total grant date fair value of restricted stock awards vested during the year ended December 31, 2009 was $173,605.

Certain of the Company's option agreements provide that in the event of a change in control of the Company, as defined, any unvested options will become immediately vested and exercisable.

Stock-based compensation expense, including awards granted to non-employees for stock options and warrants for each period presented in the accompanying consolidated statements of operations is as follows:

	December 31,		
	2007	2008	2009
Stock-based compensation charged to:			
Research and development	$ 859,133	$1,208,262	$1,589,132
General and administrative	1,378,883	2,854,467	2,381,189
Stock based compensation expense	$2,238,016	$4,062,729	$3,970,321

Non-employees — During the year ended December 31, 2009, 10,000 stock options were granted to a Scientific Advisory Board ("SAB") member. There were no grants awarded to SAB members for the years ended December 31, 2007 and 2008. Stock-based compensation expense charged to research and development expenses related to awards granted prior to 2007 and awards granted in 2009 for the years ended December 31, 2007, 2008 and 2009 amounted to $175,154, ($83,644) and $22,675, respectively.

On November 18, 2008, the Company granted 120,000 options with a five year contractual term and immediate vesting provisions to two consultants for their services. The total fair value of the awards at grant date of $275,304 was estimated using the Black-Scholes pricing model with the following assumptions: expected term of five years, estimated volatility of 78%, risk-free rate of 2.18% and expected dividend yield of 0%. This amount was recognized in full in 2008 and is included under general and administrative expense.

Further, on September 16, 2008 the Company issued a fully vested warrant to purchase 240,000 shares of the Company's common stock for $7.91 per share with a fair value of $1,127,920 in payment for consulting services. The fair value was determined using Black-Scholes option pricing model (including the following assumptions: life of five years (full term), volatility of 69.9% and a risk-free rate of 2.64%). This amount was recognized in full in 2008 and is included under general and administrative expense (see Note 11).

As of December 31, 2009, the unamortized compensation expense of all employee stock option and restricted stock awards granted under the Company's Plan, net of estimated forfeitures was $4,064,357 and $144,673 respectively. These amounts will be amortized over an estimated weighted average period of 2.18 and 2.38 years, respectively. The remaining unamortized compensation expense for the CEO inducement award was $40,877, which amount will be amortized over an estimated weighted average period of 0.25 years based on the assumption that the performance milestones will be achieved.

5. PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	As of December 31,	
	2008	2009
Lab and other equipment	$ 3,024,639	$ 3,737,526
Furniture and fixtures	451,306	454,466
Building	3,005,351	1,799,544
Leasehold improvements	903,654	925,904
Land	427,059	427,059
Total property and equipment, at cost	7,812,009	7,344,499
Less accumulated depreciation and amortization	(2,359,829)	(3,300,011)
Property and equipment, net	$ 5,452,180	$ 4,044,488

On October 1, 2007, the Company completed the purchase of a commercial-scale radiopharmaceutical manufacturing facility located in Denton, Texas for $3.0 million and has obtained a radioactive materials license from the State of Texas for this facility that expires in May 2018. The facility has more than 80,000 square feet of pharmaceutical manufacturing, warehouse, clean room and administrative office space. As of December 31, 2009, the facility was not yet placed in service. The facility was originally intended to be used for the manufacture of molecular imaging and targeted radiotherapeutic product candidates. Completion of the build-out of the facility was previously deferred until manufacturing requirements for the Company's clinical trials were determined. Concurrent with the change in senior management, research specialists were engaged to evaluate the market potentials of each of the Company's product candidates. In the fourth quarter of 2009, based on the results of these studies, plans with respect to the utilization of the facility have changed and there is no current plan to utilize it. An impairment review was undertaken, the outcome of which, indicated a fair value of $1,799,544 that is below the carrying value of the building as of December 31, 2009 of $3,009,544. As a result, an impairment charge of $1,210,000 has been recorded and reported within "Research and development expenses" in the Consolidated Statements of Operations for the year ended December 31, 2009.

Depreciation and amortization expense was $721,887, $902,593, and $940,182 for the years ended December 31, 2007, 2008, and 2009, respectively.

6. ACCRUED EXPENSES

Accrued expenses consist of the following:

	As of December 31,	
	2008	2009
Accrued payroll, bonuses, severance and vacation	$ 1,477,554	$2,327,866
Clinical trials	5,876,255	2,120,123
Commercial manufacturing	868,114	650,104
Professional fees	608,083	2,355,322
Sponsored research and license agreements	565,620	385,680
Deferred tax liability	300,000	—
Other	756,793	202,035
Total accrued expenses	$10,452,419	$8,041,130

During 2009, the Company decreased its clinical trial accruals and research and development costs by $1,822,000 due to true-ups of estimates for various program costs.

Accounts payable and accrued expenses payable to related parties recorded on the December 31, 2008 consolidated balance sheet consisted of professional fees owed to a law firm representing the Company as legal counsel. The law firm was considered a related party due to its affiliation with a former executive officer and significant investor of the Company through July 31, 2009.

7. EMPLOYEE BENEFIT PLAN

Effective January 1, 2001, the Company adopted an employee savings and retirement plan, or 401(k) plan (the "Plan"), that covers all employees of the Company who meet certain defined requirements. Under the terms of the Plan, employees may elect to make tax-deferred contributions through payroll deductions within statutory and plan limits. The Company may elect to make discretionary matching contributions to the Plan, but has not made any since plan inception through December 31, 2009.

8. DEBT

Senior Secured Floating Rate Bonds, due 2012

On November 9, 2007, the Company entered into a purchase agreement (the "Purchase Agreement") pursuant to which the Company agreed to sell $150,000,000 in senior secured floating rate bonds due 2012 (the "Bonds" or "original Bonds") and warrants to purchase 6,021,247 shares of common stock of the Company (the "Warrants") for an aggregate total of $150,000,000 for the Bonds and Warrants. The closing of the sale of the Bonds and Warrants occurred on November 16, 2007. The Bonds and Warrants were offered and sold only to qualified institutional buyers under Rule 144A of the Securities Act of 1933 (the "Securities Act"), as amended, and to persons outside the United States under Regulation S of the Securities Act. The Bonds and Warrants have not been registered under the Securities Act. The Bonds are governed by an Indenture (the "Indenture"), dated as of November 16, 2007, between the Company and The Bank of New York Trust Company, N.A. as trustee and collateral agent.

The Bonds have a five-year maturity date and bear a coupon interest rate equivalent to the three month LIBOR (London Inter-Bank Offer Rate) plus 8%, determined on a quarterly basis beginning on November 16, 2007. The average interest rate was 12.88%, 11.17% and 8.98% for the years ended December 31, 2007, 2008 and 2009, respectively. Interest accrued on the Bonds on any quarterly interest payment date between and including November 16, 2007 and November 16, 2010, shall be payable through the issuance of PIK ("paid-in-kind") Bonds. Such PIK Bonds shall be part of the same class, and shall have the same terms and rights, as the original Bonds except that interest on such PIK Bond shall begin to accrue from the date of issuance of such PIK Bond. Upon certain events of default, the principal and accrued interest on the Bonds can be accelerated, and will become immediately payable.

The Warrants have an exercise price of $5.87, which was the bid price of the Company's common stock as of the close of trading on November 8, 2007. The Warrants may be exercised by payment of the exercise price or by a cashless exercise at anytime through five years from the date of issuance.

In connection with the sale of the Bonds and the Warrants, the Company entered into an Amended and Restated Registration Rights Agreement (the "Registration Rights Agreement"), dated as of November 16, 2007 with the initial purchasers of the Bonds and Warrants and certain holders of the former Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of the Company, and certain holders of former convertible promissory notes in the Company. Under the Registration Rights Agreement, the Company provides such parties with certain demand registration rights, S-3 registration rights and piggy-back registration rights.

In connection with the sale of the Bonds and the Warrants, the Company also entered into a Pledge and Security Agreement (the "Pledge and Security Agreement") with The Bank of New York Trust Company, N.A. as collateral agent (the "Collateral Agent") dated as of November 16, 2007. Pursuant to the Pledge and Security Agreement, the Company and its subsidiaries that are a party to such agreement from time to time agree to pledge their rights to certain collateral to the Collateral Agent as security for the obligations of the Company under the Indenture. All of the Company's assets are pledged as security as of December 31, 2009.

The Bonds have been recorded net of the relative fair value of the related Warrants of $19,541,000 on the date of issuance and the fair value of the embedded derivative (see Note 2). The Black-Scholes calculation for the fair value of the Bond Warrants used the following assumptions: life of five years, volatility of 61.6%, 0% dividend rate and a risk-free rate of interest of 3.68%, which resulted in a total fair value of the Warrants of $19,540,523. The annualized volatility of 61.6% was the last five years average volatility of three comparable companies. The Company's 2007 stock price data was not used due to the limited time frame since the public offering. The fair value of the Warrants was accounted for as a Bond discount with an offset to additional paid in capital. The Bond discount is being amortized monthly using the effective interest method over the five year life of the Bonds.

Redemption of Bonds

The Indenture requires mandatory redemption of some or all of the Bonds upon defined events, such as the disposition of certain assets or property, disposition of or sale of any non-primary product, disposition of any product consisting of outbound licensing arrangements, the issuance of indebtedness (other than the PIK Bonds), the sale of securities in an equity financing, receipt by the Company of funds constituting extraordinary receipts, in the event of excess free cash flow over specified levels, and in the event of a product material adverse event (as defined in the Indenture).

The contingent mandatory redemption feature related to a product material adverse event is an embedded derivative. The Company valued the derivative financial instrument at date of issue and will continue to re-measure it at each reporting period at its fair value. The initial fair value of the embedded derivative was approximately $200,000 on the date of the issuance of the bonds and did not change materially through September 30, 2008. Based on a periodic evaluation of input assumptions to the valuation model utilized in determining the initial fair value of the embedded derivative, the Company has determined a remaining fair value of $50,000 at December 31, 2008 and 2009. The embedded derivative is classified in accrued expenses in the consolidated balance sheets. Changes in fair value are recorded as either a gain or loss in the consolidated statement of operations in other income (expense). For the year ended December 31, 2008, the Company recognized a $150,000 gain related to the decrease in fair value of the embedded derivative.

The Bonds become subject to redemption upon a change in control (defined as a person acquiring 30% or more of the voting securities of the Company). The Company may redeem the Bonds at its option and with a premium, beginning November 16, 2007. If redeemed at the following dates, the redemption price would be equal to the following:

From	To	Price
November 1, 2009	October 31, 2010	104% of principal plus unpaid interest
November 1, 2010	October 31, 2011	102% of principal plus unpaid interest
Thereafter		100% of principal plus unpaid interest

Debt Covenants

The Indenture contains various covenants with which the Company must comply, including, without limitation, the timely payment of interest and principal when due, the provisions of quarterly and annual financial statements and other reports, the maintenance of a minimum liquidity level and a requirement that capital expenditures not exceed certain annual amounts. The provisions of the Bond Indenture also require that the report on the audit of the Company's consolidated financial statements by the Company's independent registered public accounting firm not be subject to a "going concern" or like qualification or exception. The Company is also prohibited from paying cash dividends on its common stock.

Under the Indenture, the Company is required to maintain a Minimum Liquidity (as defined in the Indenture and which substantially represents all of the Company's cash, cash equivalents and investments) of at least the sum of $35.2 million for year ended December 31, 2009 (the "minimum amount") and any contingent mandatory redemption amounts due in the case of a product material adverse event less any amounts already paid with respect to such mandatory redemption amounts and amounts not held on deposit with the Trustee. The minimum amount decreases on a monthly basis to $29.2 million for the period from October 1, 2010 to December 31, 2010 (the lowest minimum amount is $21.1 million for the period from January 1, 2010 to March 31, 2010); after which the amount increases to $45.0 million for the period from July 1, 2011 and through the maturity date. The Company expects to be in violation of this covenant in the third or fourth quarter of 2010 (see Note 1). The Company had Minimum Liquidity in excess of the required amount by approximately $28.7 million at December 31, 2009.

The financial covenants in the Indenture also set limits on the Company's capital expenditures in any year. Under the Indenture, capital expenditures may not exceed $5.0 million in year 2009, $3.0 million in year 2010, $5.0 million in year 2011, and $6.0 million in 2012. These maximum capital expenditure limits may be adjusted upwards in any given year, up to an additional $1.5 million, if the preceding year's capital expenditures were less than the maximum level. In any year when a cyclotron is purchased, the maximum capital expenditure level is increased by the cost of the cyclotron, up to a maximum of $10.0 million.

A failure to comply with the covenants of the Indenture which is not cured within applicable cure or grace periods would constitute an event of default under the Indenture. Such events of default would include the failure to pay interest and principal when due, the failure to provide financial statements and other required reports when due, the failure to maintain Minimum Liquidity levels, and the failure to limit annual capital expenditures to the maximum levels permitted under the Indenture. Because of the covenant violation described in Note 1, the Company has reclassified the bonds payable and related issuance costs as current in the consolidated balance sheet as of December 31, 2009.

The carrying amounts of the Senior Secured Floating Rate Bonds, due 2012, at December 31, 2008 and 2009 were as follows:

	2008	2009
Bond principal	$150,000,000	$150,000,000
PIK interest	20,475,426	36,533,644
Bond discount	(15,543,947)	(11,695,261)
	$154,931,479	$174,838,383

As of December 31, 2009, future payments of principal and PIK Interest on all existing debt due in November 2012 was $186,533,644.

9. INCOME TAXES

The Company uses an asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The tax authorities could challenge tax positions taken by the Company for the periods for which there are open tax years. The Company is open to challenge for the periods of 1998 through 2009 from federal and the Commonwealth of Massachusetts jurisdictions.

The Company has recorded no provision or benefit for income taxes for any period presented due to its net operating losses (the "NOL") and doubt as to the realizability of the resulting carryforwards of those losses and other deferred tax assets. Deferred tax assets consisted of the following as of December 31:

	2008	2009
Deferred tax assets:		
Net operating loss carryforwards	$70,317,000	$ 96,972,000
Deferred research and development costs	929,000	743,000
Research and development tax credits	2,216,000	3,375,000
Property and equipment	370,000	892,000
Accrued expenses	6,917,000	6,331,000
Gross deferred tax assets, before valuation allowance	80,749,000	108,313,000
Valuation allowance	80,749,000	108,313,000
Net deferred tax asset	$ —	$ —
Deferred tax liability (included in accrued expenses):		
Unrealized gain on investments	$ 300,000	$ —

	2007	2008	2009
Tax benefit at U.S. Statutory Rates	(34.0)%	(34.0)%	(34.0)%
State tax benefit	(6.3)	(6.3)	(6.2)
Permanent differences	0.4	0.3	0.1
Research and development credits	(0.6)	(1.3)	(1.7)
Other	0.7	1.6	0.3
Valuation allowance	39.8	39.7	41.5
	0%	0%	0%

As of December 31, 2009, the Company had net operating loss carryforwards totaling approximately $248.3 million (federal) and $229.8 million (state), which expire at various dates from 2012 through 2029 (federal) and from 2010 through 2014 (state). The Company had research and development tax credits totaling approximately $2.6 million (federal) and $1.2 million (state), which are available to offset future tax liabilities when incurred, which begin to expire in 2012 for federal and 2018 for state and fully expire in 2029 (federal) and 2024 (state).

The Company has recorded a full valuation allowance against its deferred tax assets since the Company believes it is more likely than not, that it will not be able to realize the assets. During the years ended December 31, 2007, 2008 and 2009, the valuation allowance increased by approximately $21,206,000, $32,236,000 and $27,564,000, respectively. The change in the valuation allowance in each period is due to the net increase in deferred tax assets each period (primarily from the net operating loss carryforwards and research and development tax credits) and the Company providing a full valuation against the asset for the reason stated above.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, due to changes in ownership of the Company that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company does not expect to have taxable income for the foreseeable future. Future ownership changes could affect such limitations.

As of December 31, 2009, the Company has not recognized any interest and penalties related to any uncertain tax positions. The total amount of unrecognized tax benefits that would affect the Company's effective tax rate if recognized is approximately $2.7 million as of December 31, 2009, assuming there was no valuation allowance. The Company's U.S. federal income tax returns remain subject to examination, and its state income tax returns for all years through 2009 remain subject to examination.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2008 and 2009:

	2007	2008	2009
Beginning uncertain tax benefits	$2,782,000	$2,782,000	$2,661,000
Current year — increases	—	—	—
Current year — decreases	—	(121,000)	—
Settlements	—	—	—
Expire statutes	—	—	—
Ending uncertain tax benefits	$2,782,000	$2,661,000	$2,661,000

10. REDEEMABLE CONVERTIBLE PREFERRED STOCK

The Company in prior periods authorized 359,515 shares of preferred stock for issuance, of which certain shares were designated as Series A redeemable convertible preferred stock ("Series A"), Series B redeemable convertible preferred stock ("Series B") and Series C redeemable convertible preferred stock ("Series C"). The Company first issued redeemable convertible preferred stock in 2003.

Upon the consummation of the initial public offering of the common stock of the Company on February 7, 2007, the redeemable convertible preferred stock was automatically converted into common stock on a 33-for-1 basis, and the cumulative but unpaid dividends (with limited exception) converted into common stock based upon formulas established at each issuance date of the securities. All outstanding shares of Series A, B and C Convertible Preferred Stock were converted into common stock shares of 4,010,539, 1,788,758 and 4,719,652, respectively. An additional 1,340,624, 258,851 and 448,184 shares of common stock were issued in satisfaction of the then accrued but unpaid dividends on the Series A, B and C Convertible Preferred Stock, respectively. Warrants to purchase common stock were exercised for 396,092 shares of the Company's common stock at an average price of $3.45 per share.

After the conversion to common stock, the Company no longer records dividends and accretion on the redeemable convertible preferred stock. Previously, redeemable convertible preferred stock dividends and accretion of issuance costs, consisted of cumulative, undeclared dividends payable on the preferred securities and accretion of the issuance costs, and costs allocated to issue warrants to purchase common stock. The issuance costs on these shares and warrants were recorded as a reduction to the carrying value of the redeemable convertible preferred stock when issued, and were accreted to redeemable convertible preferred stock, using the interest method, through the earliest redemption dates of each series of redeemable convertible preferred stock by a charge to additional paid-in capital and net loss attributable to common stockholders.

11. STOCKHOLDERS' DEFICIT

Common Stock

100,000,000 shares of $.001 par value Common Stock have been authorized, of which 25,069,406 shares were issued and outstanding at December 31, 2008, and 25,268,327 shares were issued and outstanding as of December 31, 2009. Common Stock shares issued and outstanding do not include the potential shares that may be issued for the conversion of warrants for Common Stock, and shares that may be issued under the Stock Option Plan, which are listed below.

Reserved Shares — The following is a summary of common stock reserved for the following identified purposes at December 31:

	2008	2009
Common stock options	3,288,820	4,194,853
Warrants and Bond Warrants on common stock	6,604,840	6,604,840
	9,893,660	10,799,693

On February 1, 2007, the Company's initial public offering of 5,000,000 shares of its common stock registered on the registration statement on Form S-1, as amended was declared effective by the SEC. All registered shares were sold at the initial public offering price of $14.00 per share. Certain warrants were exercised upon the initial public offering. Net proceeds to the Company were approximately $62.6 million after deducting underwriting discounts and commissions and estimated offering expenses totaling approximately $7.4 million.

Common Stock Warrants — On August 18, 2008, the Company engaged CRT Capital Group LLC ("CRT") to act as its lead financial advisor in connection with assisting and reviewing the Company's strategic, potential capital market and financing transactions ("Transaction") as defined in the engagement letter. In consideration of such services and through December 31, 2008, the Company issued a warrant to purchase 240,000 shares of the Company's common stock for $7.91 per share and has paid and incurred a total of $327,500 in 2008 and $163,750 in 2009, and is obligated to pay CRT, a tiered rate divestiture fee based on the aggregate Transaction value of future consummated Transactions, if any, as provided for in the engagement letter and for a period of twelve (12) months after its termination. The engagement was terminated by the Company on March 6, 2009 upon written notice to CRT.

As of December 31, 2009, the Company had the following warrants outstanding, which are fully vested and exercisable, to purchase shares of the Company's common stock:

	Shares	Exercise Price	Term
Issued in 2006 in connection with convertible note payable	343,593	$7.80	5(a)
Issued in 2007 in connection with sale of Bonds	6,021,247	5.87	5(b)
Issued in 2008 in connection with purchased services	240,000	7.91	5(c)
Total warrants outstanding at December 31, 2009	6,604,840		

(a) expires September 28, 2011
(b) expires November 16, 2012
(c) expires September 16, 2013

Amended and Restated Registration Rights Agreement

In connection with the sale of the Bonds and the Warrants, the Company, entered into an Amended and Restated Registration Rights Agreement (the "Registration Rights Agreement"), dated as of November 16, 2007, with the initial purchasers of the Bonds and Warrants and certain former holders of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of the Company, and certain former holders of convertible promissory notes in the Company. Under the Registration Rights Agreement, the Company provides such parties with certain demand registration rights, S-3 registration rights and piggy-back registration rights. Additionally, the employment agreements for several executive officers of the Company provide that they shall each have piggy-back registration rights for shares held by them equal to the most favorable piggy-back registration rights granted by the Company to its stockholders. Accordingly, these executive officers have the same piggy-back registration rights. The shares of common stock subject to these rights at December 31, 2009 were 185,906.

These parties may demand registration of the underlying securities at any time. The Company shall file the registration statement including the securities covered by such demand notice within 30 days after receipt thereof and shall use its best efforts to effect the registration under the Securities Act as soon as practicable, and in any event within 180 days after receipt of such demand notice. If a Registration Statement is not (i) filed with the Commission on or prior to the applicable filing deadline, or (ii) declared effective by the applicable effectiveness deadline, then the Company shall make pro rata payments to each investor whose securities are to be included in such Registration Statement, as liquidated damages, in an amount equal to 1.5% of the aggregate Market Price of the investor's securities to be included in such Registration Statement for each 30-day period or pro rata for any portion thereof.

Shareholder Rights Plan

On January 30, 2009 the Board of Directors adopted a shareholder rights plan which provides for a dividend of one common stock purchase right on each outstanding share of Molecular Insight's common stock. The issuance of the rights under the rights agreement was made on February 27, 2009 to shareholders of record as of the close of business on February 13, 2009.

The rights are designed to enable all of the Company's shareholders to realize the full long-term value of their investment and to provide for fair and equal treatment of all shareholders in the event that an unsolicited or unfair attempt is made to acquire the Company. The Company believes that the rights agreement will help protect shareholders against abusive or unfair takeover tactics that may be used to gain control of the Company without paying a price that is in the best interest of all shareholders. The rights agreement was not adopted in response to any known offers to acquire the Company and is similar to rights agreements adopted by many other companies.

The rights will be exercisable only if a person or group acquires 20% or more of the Company's outstanding common stock or announces a tender offer, the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock.

Each right will initially entitle its holder to buy one-half of one share of the Company's common stock at an initial exercise price of $35.00 per one full share of common stock, subject to adjustment. If any person becomes a 20% or more shareholder of the Company, then each right (subject to certain limitations) will entitle its holder to purchase, at the right's then-current exercise price, a number of shares of common stock of the Company or the acquirer having a market value at the time of twice the right's full share exercise price.

The Company's Board of Directors may redeem the rights for $0.001 per right at any time prior to the time when the rights become exercisable. Unless the rights are redeemed, exchanged or terminated earlier, they will expire on January 30, 2019.

12. BIOMEDICA STRATEGIC COLLABORATION AGREEMENTS

In September 2009, the Company entered into a Territory License Agreement ("Agreement") with BioMedica to sub-license its Onalta™ 90-Y edotreotide radiotherapeutic in certain countries in Europe, the Middle East, North Africa, Russia and Turkey. The Agreement provides BioMedica an exclusive sub-license to intellectual property rights and know-how of the Company and Novartis Pharma AG ("Novartis") with respect to Onalta. The Company had licensed the rights to edotreotide, the parent compound of Onalta, from Novartis in November 2006. Under the Agreement, BioMedica is expected to perform clinical studies and market, distribute and commercialize Onalta in the specified territories and secure all regulatory approvals. The Company agreed to provide forty (40) hours of compound radiolabeling technical transfer support services without charge in addition to providing reasonable levels of training, technical and regulatory support services on a time and materials basis at BioMedica's request.

Under the terms of the Agreement, the Company received an initial, nonrefundable payment of $4.4 million, two option grants to have BioMedica assign, transfer and convey to the Company, a minority shareholder interest in BioMedica of up to 1.5% of the total non-diluted interest in all classes of any issued and authorized outstanding share capital in BioMedica at the time of each exercise, exercisable upon the execution of the Agreement and upon the European Medicines Agency (EMEA) marketing authorization approval of Onalta and will be eligible to receive more than $10 million in total regulatory milestone payments, net of license payments to Novartis. The Company will also be eligible to receive milestone and tiered royalties on Onalta sales.

The Agreement also provides that during the term of the Agreement, BioMedica will purchase all of its requirements for Onalta exclusively and solely from the Company, a Company-designated third party manufacturer, and/or a BioMedica-designated third party manufacturer approved by the Company, the terms and conditions of which are outlined in a definitive supply agreement executed in October 2009 ("Supply Agreement"). The term of the Supply Agreement is for ten (10) years and provides for guaranteed monthly minimum purchases within a defined period of time by BioMedica.

Either BioMedica or the Company may terminate the Agreement immediately upon delivery of written notice to the other party upon the institution by or against the other party of insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of the other party's debts, the commitment by the other party of a material breach or an uncured material breach (as defined in the Agreement) within sixty (60) days of written notice specifying the breach and requiring its remedy. The Company may also be forced to terminate the Agreement in the event that Novartis exercises its right to terminate its license agreement with the Company in the event of a change in control of the Company by a direct competitor of Novartis.

Under the terms of the Agreement, unless earlier terminated by either party or Novartis through the exercise of a call-back option as provided under the terms of the Company's license agreement with Novartis, the license extends until the later to occur of the expiration of the last of the licensed Novartis patents to expire, including any extensions in each country covered by such patents or ten (10) years from the first commercial sale of the product.

The Company has determined that the Agreement with BioMedica is a revenue arrangement with multiple deliverables. In assessing it's performance obligations, the Company determined that there are three separate deliverables comprising of: (1) the license; (2) training and support services; and (3) the Supply Agreement. The Company has determined that each of the deliverables in the arrangement has stand alone value to BioMedica. The Company used its best estimate of selling price for each of the deliverables in the arrangement in allocating the arrangement consideration under the relative selling price method. In estimating the selling price for the deliverables, the Company considered all of the following: (1) its internal costs; (2) the market and industry pricing practices; and (3) comparative offers received from potential development partners during the business development phase. The arrangement consideration allocable to the delivered license approximates the $4.4

million upfront license fee received and was recognized as license revenue in the Consolidated Statements of Operations. The arrangement consideration allocable to the undelivered support services is immaterial. The arrangement consideration for the Supply Agreement will be recognized as product revenues in the period such products are delivered.

As part of the consideration received, the fair value attributed to the option grant to purchase an equity interest in BioMedica was estimated to be insignificant.

13. COMMITMENTS AND CONTINGENCIES

A. PRODUCT MANUFACTURING AND SUPPLY AGREEMENTS

ONALTA

Concurrent with the Supply Agreement entered into with BioMedica in October 2009, the Company also entered into a ten (10)-year Facility Setup and Contract Manufacturing Agreement with EZN, a company with a licensed radiopharmaceutical manufacturing facility in Braunschweig, Germany. Under the terms of the agreement, EZN will manufacture and supply Onalta for compassionate use and registration clinical trials within the BioMedica territories, and for commercial sales, upon the EMEA marketing authorization approval of Onalta. The agreement also provides for EZN to establish an exclusive suite for the manufacture and supply of Onalta which will be funded by the Company and estimated at a cost of €1.3 million (approximately $1.9 million), including estimated costs of €0.3 million associated with decommissioning of the dedicated suite upon termination. The Company is also required to make fixed monthly payments to EZN aggregating €2.7 million (approximately $3.9 million) for the initial five (5) years following the effective date of the agreement in addition to product costs. Further, the terms of the agreement with EZN are subject to a pricing renegotiation prior to the end of the fifth year and can be terminated by either party by giving a written notice to the other party at least twelve (12) months prior to the fifth anniversary of the effective date of the agreement. In case of termination by the Company during the renegotiation period or in case of termination by EZN due to material breach by the Company, the Company shall pay EZN a lump sum amount of €0.5 million (approximately $0.7 million) for the assignment of EZN's intellectual property rights in all improvements conceived, written, created, developed, or first reduced to practice in and related to the performance of the agreement.

The monthly payments to EZN under the agreement are expensed as incurred. For the year ended December 31, 2009, the Company recognized $35,235 as "Cost of product revenues" in the Consolidated Statements of Operations.

AZEDRA

Phase III Clinical Trial and Commercial Supply Facility Agreement with MDS Nordion ("MDS"),a division of MDS (Canada), Inc. — In August 2009, the Company entered into a five-year, renewable Commercial Facility and Supply Agreement with MDS to establish a facility in Ottawa, Canada, in which to perform the process development for the manufacture and supply of Azedra for clinical trials and commercial supply upon U.S. regulatory approval. This agreement provides for an estimated aggregate facility cost of approximately C$4.1 million (approximately $3.8 million), portions of which are to be paid in advance of each project phase and provides for, among others, minimum purchase obligations during the term of the agreement and commencing with the first full month after completion of the facility; initial pricing and unit dose cost for each batch; and a monthly facility reservation fee during temporary suspensions of minimum purchase obligations which shall not be reimbursable or refundable but shall be credited in a given month only toward amounts owed by the Company for the purchase of batches in such month. Payments made are non-refundable once a phase has commenced. Upon termination of this agreement for any reason, except a material breach by MDS, the Company

shall reimburse MDS for any reasonable expenses incurred in employee(s) severance as a result of or arising from discontinuation of the manufacture of Azedra, inventory write-down, facility decommissioning and any related waste disposal costs, however, such reimbursement shall not apply in the event the Company meets its minimum purchase obligations during the first three (3) years of the commercial supply of Azedra commencing after NDA regulatory approval has been received from the FDA. The project is expected to be ready for commercial production in the second half of 2010. Project costs incurred of $3.2 million for the year ended December 31, 2009 have been charged to research and development expenses.

Under a prior interim clinical trial manufacturing facility and clinical trial supply agreement with MDS entered into in July 2007, approximately $150,000 and $1,078,000 was charged to Research and Development expense in 2006 and 2007, respectively, for all amounts due to MDS.

ZEMIVA

Commercial Manufacture and Supply Agreement with MDS — On January 12, 2006, the Company entered into a six-year, renewable agreement with MDS for the commercial manufacture and supply of Zemiva (the "Zemiva Supply Agreement"). Under the Zemiva Supply Agreement, the Company paid $725,000 as an up-front payment and was obligated to make additional payments totaling $1.4 million upon MDS reaching certain manufacturing preparation milestones. A percentage of each milestone payment was due upon commencement of various phases of construction and process validation, and the remainder of each milestone payment was due upon facility commissioning and demonstration of production capability. As of December 31, 2007, the Company had paid the entire $1.4 million of additional manufacturing milestone payments required under this Zemiva Supply Agreement, of which approximately $358,000 were recorded as research and development expenses in the accompanying consolidated statement of operations for the year ended December 31, 2007. Effective July 2008, the Company was also obligated to pay a monthly facility reservation fee of $24,000 which can be offset against purchases made for that month. The Zemiva Supply Agreement establishes the initial pricing for each batch and cost per dose maximums of Zemiva to be supplied to the Company. In January 2010, the Company received a notice from MDS of its intent to terminate the Zemiva Supply Agreement effective upon the expiration of the initial term on January 12, 2012.

B. IN-LICENSING AGREEMENTS

Schering — On January 15, 2007, the Company executed an agreement with Schering Aktiengesellschaft for an exclusive, worldwide, royalty-bearing license under the Schering Patents and Schering Know-How to develop and commercialize specific products within a field and territory as defined in the agreement. This agreement relates to the Company's oncology product candidate Solazed. Under the agreement, the Company paid a license fee of $1.0 million in the first quarter of 2007 which is included in Research and Development expense in the consolidated statement of operations. Additionally, the Company is obligated to pay a royalty on net sales of the product, for a term defined as the longer of the life of the patents, or ten years following first commercial sale. The Company is also obligated to pay milestone payments, totaling $9.0 million, upon the commencement of clinical trials and the attainment of certain approvals in the regulatory process. The Company has made no additional payments under this agreement.

Novartis — In November 2006, the Company executed an agreement with Novartis Pharma AG (Novartis), for the nonexclusive license of technology under a general patent, as well as the exclusive license of technology under a Novartis specific patent. This agreement relates to certain aspects of the Company's oncology product candidate Onalta. The agreement allows the Company to use this technology for the worldwide development and commercialization of OctreoTher. The Company is obligated to pay royalties based on net sales of the product, for the life of the patents, or alternatively, for a term following first commercial sale, whichever is longer. Sales

of products subject to such license agreements through December 31, 2009 amount to approximately $36,000. The Company is also obligated to pay milestone payments totaling $4.0 million upon the attainment of certain approvals in the regulatory process. None have been achieved as of December 31, 2009. Milestone payments are partially creditable against future royalty payments. The Company paid a license fee of $1.0 million in 2007 which was charged to Research and Development expense.

In December 2006, the Company executed an addendum to the Novartis agreement allowing for an exclusive license of the technology under the general patent. The addendum calls for additional license fees, milestone payments totaling $600,000, and royalty payments to a third-party, Dr. Eric P. Krenning. There have been no sales of products subject to such license agreements and none of the relevant milestones have been achieved through December 31, 2009. The Company paid a license fee of $600,000 under this addendum in 2007.

Either Novartis or the Company may terminate this agreement immediately upon delivery of written notice to the other party upon the institution by or against the other party of insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of the other party's debts, the commitment by the other party of a material breach or an uncured material breach (as defined in the agreement) within sixty (60) days of written notice specifying the breach and requiring its remedy. The Company may also be forced to terminate the agreement in the event that Novartis exercises its right to terminate its license agreement with the Company in the event of a change in control of the Company by a direct competitor of Novartis.

In December 2006, the Company executed an agreement with Tyco Inc. / Mallinckrodt Medical, Inc (Mallinckrodt), whereby Mallinckrodt will transfer the technology and materials necessary for the manufacture of OctreoTher. This agreement relates to the Company's oncology product candidate Onalta, and it complements the rights obtained in the agreement with Novartis Pharma, AG, by providing manufacturing rights and production know-how for Onalta. Under this agreement, the Company is obligated to make an upfront payment and various payments for phases in the technology transfer process. The Company was also obligated to make a one-time purchase of certain existing quantities of production supplies from Mallinckrodt. The term of this agreement is for as long as the Company manufactures and sells Onalta, on a country-by-country basis. The Company paid $1.2 million under this agreement in 2007 which was charged to Research and Development expense.

Georgetown University — Three of the Company's license agreements are with Georgetown University. In addition to royalty obligations, the agreements provide for the Company to pay up to $2.5 million in milestone payments upon the attainment of certain approvals in the regulatory process and other clinical milestones. Certain milestone payments may be reduced by up to 50% for subsequent new drug applications submitted for new uses of the same compound. If paid, these milestone payments would be creditable against future royalty payments. Annual license fees of $5,000 under these agreements are recognized and charged to Research and Development expense.

McMaster University — In December 2006, the Company entered into an exclusive license agreement with McMaster University for worldwide rights to certain platform technology used for radiolabeling compounds. This technology platform is not currently used with any of the Company's existing product candidates, but the Company is exploring the applicability of radiolabeling to its oncology product candidates. The Company has the right to sublicense these rights and also has an obligation to maintain the related patent rights. In exchange for this exclusive license, the Company is obligated to pay an upfront, nonrefundable licensing fee of $10,000, future royalties on any products that are radiolabeled using the licensed technology for the term of the patent rights, minimum annual royalties (that are creditable against royalties) and future milestone payments totaling $575,000 relative to clinical trials for particular indications and certain stages of the regulatory process. The term of this agreement is through the last to expire of the patent rights and the Company has the right to terminate the

agreement upon providing ninety days written notice. There have been no sales of products subject to such license agreements and none of the relevant milestones have been achieved through December 31, 2009. The upfront license fee and minimum annual royalties under these agreements are recognized and charged to Research and Development expense.

Other Licensing Agreements — The Company has exclusively licensed certain of its patent rights from third-parties. In exchange for the exclusive rights, the Company is obligated to pay the licensors' patent expenses and a royalty on net sales of future products ranging from 1% to 4% of net sales, depending on the license agreement. There have been no sales of products subject to such license agreements through December 31, 2009. In addition, some of the license agreements require the Company to pay certain lump sum payments upon attainment of certain clinical milestones, none of which has been achieved through December 31, 2009. In addition, in exchange for access to non-patented, confidential clinical information from one of the third-parties on one of its potential products, the Company has entered into an agreement with this third-party which requires the Company to pay the third-party a royalty which ranges from 2% to 7% on net sales of a defined future product for the first indication, depending on the extent to which the third-party's clinical data expedites U.S. regulatory approval of the defined product. There have been no sales of product through December 31, 2009.

C. CLINICAL TRIAL AGREEMENTS

PPD Development, LP — On August 30, 2007, the Company entered into a Master Services Agreement with PPD (the "MSA) under which PPD will provide, from time to time, clinical development services in connection with certain clinical research programs sponsored by the Company (the "Projects"). The details of each Project would be mutually agreed upon in a written addendum (the "Project Addendum") to the MSA and incorporated therein by reference. On September 18, 2007, the Company and PPD entered into a Project Addendum for PPD to provide certain clinical research services in connection with the Company's clinical research program entitled "A Phase I-II Study Evaluating the Maximum Tolerated Dose, Safety, and Efficacy of Ultratrace Iobenguane I 131 in Patients with Malignant Pheochromocytoma/Paraganglioma". In March 2009, the Company entered into an amendment to the MSA with PPD to reduce its scope of services and the amended estimated not-to-exceed aggregate costs for the Project has been reduced to approximately $7.1 million. The Company is in the process of further negotiating an amendment to the MSA with PPD to reduce total costs for the Project. As of December 31, 2009, the Company has made incurred approximately $5.1 million pursuant to the Project Addendum, which were charged to research and development expense.

D. PROFESSIONAL AND CONSULTING AGREEMENTS

In March 2009, the Company engaged a consultant to advise the Company on business development activities through January 31, 2010, unless earlier terminated. In consideration for such services, the Company agreed to pay the consultant a monthly retainer fee of $67,500 and success fees based on the total Transaction Value (as defined in the engagement letter) of any successful project undertaken by the consultant as part of their services and for a period of twelve (12) months after the termination of its engagement or fifteen (15) months, in the event of an on-going project at the time of the termination of their engagement. Under the terms of the engagement, the consultant is eligible to receive a maximum success fee of $1,950,000 less $270,000 of creditable monthly retainer fee payments in connection with execution of the Territory License Agreement with BioMedica as discussed in Note 12 to the consolidated financial statements. The Company has elected a policy decision to expense the net fee of $1,680,000 during 2009 in "General and administrative expense" rather than defer direct business acquisition costs as it is reasonably probable that such amount may be paid. At December 31, 2009, $1,180,000 remains unpaid and is included in accrued professional fees.

In December 2009, the Company engaged the services of a consultant to act as a financial advisor for the Company in connection with ongoing discussions with the Company's Bond holders and such other financial matters. The engagement can be terminated at any time with or without cause upon fifteen (15) days written notice to the other party. In consideration of such services, the Company incurred and expensed an upfront fee of $200,000 and is obligated to pay a monthly retainer of $50,000 through the termination of the services. A completion fee of $500,000 is also due upon consummation of a restructuring.

E. OPERATING LEASES

The Company's principal executive and administrative offices are comprised of two leased facilities located in Cambridge, Massachusetts. The following summarizes the principal terms of the leases:

On April 8, 2008, the Company entered into a lease agreement for the lease of approximately 15,555 square feet of office and laboratory space in Cambridge, Massachusetts. The term of the lease is from July 1, 2008 to June 30, 2011. The monthly base rent for the first two years of the lease is $45,369 and for the last year of the lease is $46,665. The Company has an option to extend the term for a two-year period from July 1, 2011 to June 30, 2013.

On April 25, 2008, the Company entered into a lease agreement for the lease of approximately 19,750 square feet of office space located in Cambridge, Massachusetts. The term of the lease is from April 25, 2008 to March 31, 2010. The monthly base rent from April 25, 2008 to March 31, 2009 was $55,308 and from April 1, 2009 to March 31, 2010 is $56,959. The Company has an option to extend the term twice and each extension is for a period of six months.

The Company also entered into a five-year lease agreement for an office space in Germany that ends in April 2013.

Total rent expense under these arrangements was $567,046, $1,283,124 and $1,490,662 in 2007, 2008 and 2009, respectively.

As of December 31, 2009, minimum annual payments under all lease arrangements were as follows:

Year	Amount
2010	$ 765,983
2011	311,166
2012	19,434
2013	6,478
2014	—
Total	$1,103,061

In addition to the minimum payments, the Company pays the landlord for allocated taxes and common area usage.

F. EMPLOYMENT AGREEMENTS

The Company has employment agreements with certain of its officers that continue until terminated in accordance with the provisions of the agreements. Pursuant to the terms, the officers will receive annual base salaries. The annual base salaries, as periodically adjusted, aggregate approximately $2.0 million per all agreements, for calendar years after December 31, 2009. The officers are also eligible to earn bonuses based on the discretionary accomplishment of goals set by the Board of Directors. Either the Company or the officer may

terminate their employment agreement at any time, with or without cause. In the event the Company terminates the employment agreement without cause or the officer terminates his employment for good reason, as defined, the officer may be entitled to receive severance pay up to one year's base salary. Severance payments under these employment agreements amounted to approximately $634,000 $1,245,000 and $626,000 for the years ended December 31, 2007, 2008 and 2009, respectively. In addition, each agreement provides that in the event of a change in control of the Company, as defined, any unvested options and restricted stock awards that the officer may hold will become immediately vested and exercisable. The total of such unvested options and restricted stock awards as of December 31, 2009 was 805,083.

14. OTHER RELATED-PARTY TRANSACTIONS AND RELATIONSHIPS

The Company's former CEO served as Chairman and a member of the Company's Board of Directors from 2000 through September 2008 and December 2008, respectively, and as Chief Executive Officer from 2003 through September 2008. During this period and continuing, his brother has been a partner in the law firm representing the Company as legal counsel but has not provided any direct service to the Company. During the years ended December 31, 2007 , 2008 and 2009, fees billed by such firm (including costs related to the issuances of capital stock in 2006) were $3,099,039, $2,821,678 and $1,708,323, respectively.

Further, included under "Prepaid and Other Current Assets account" of the consolidated balance sheets, was a receivable of $337,496 at December 31, 2008 for the exercise of the former CEO's options. The receivable was collected in full by January 5, 2009.

15. SUBSEQUENT EVENTS

Due to the circumstances described in Note 1, on March 15, 2010, the Company executed a waiver agreement with the holders of at least a majority of the Bonds and the Bond Indenture trustee. Under the terms of the waiver agreement, the Bond holders and Bond Indenture trustee have agreed to waive the default arising from the inclusion of a "going concern" paragraph in the report of the independent registered public accounting firm on the Company's financial statements and other technical defaults under the Bond Indenture until 12:01 AM Eastern Standard Time on April 16, 2010, subject to earlier termination upon certain circumstances. The waiver is also subject to a number of certain terms and conditions relating to the Company's provision of certain information to the Bond holders, among other conditions and matters. In the event that the waiver expires or terminates prior to the successful restructuring of the Company's outstanding debt, then the Company will be in default of its obligations under the Bond Indenture and the Bond holders may choose to accelerate the debt obligations under the Bond Indenture and demand immediate repayment in full and seek to foreclose on the collateral supporting such obligations. If the Company's debt obligations under the Bond Indenture are accelerated or are not restructured on acceptable terms, it is likely the Company will be unable to repay such obligations and may seek protection under the U.S. Bankruptcy Code or similar relief.

On March 9, 2010, the Company received a letter from The NASDAQ Stock Market ("NASDAQ") notifying that for the 30 consecutive business days preceding the date of the letter, the Company failed to maintain the minimum $50 million Market Value of Listed Securities requirement for continued listing on the NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(b)(2)(A) (the "MVLS Rule"). NASDAQ further advised the Company that in accordance with NASDAQ Listing Rule 5810(c)(3)(C), the Company has a grace period of 180 calendar days, or until September 7, 2010, to regain compliance with the MVLS Rule. NASDAQ will deem the Company to have regained compliance with the MVLS Rule if at any time during this grace period the Company's Market Value of Listed Securities closes at $50,000,000 or more for a minimum of ten consecutive business days.

16. UNAUDITED QUARTERLY FINANCIAL DATA

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	Revenues	Loss from Operations	Net Loss Attributable to Common Stockholders	Basic and Diluted Net Loss per Share Attributable to Common Stockholders
Year Ended December 31, 2009				
First Quarter	$ 211,859	$(10,236,889)	$(15,255,918)	$(0.61)
Second Quarter	137,274	(11,615,955)	(16,618,567)	(0.66)
Third Quarter	101,239	(16,317,410)	(21,382,213)	(0.85)
Fourth Quarter	5,044,701	(8,106,181)	(13,227,059)	(0.52)
Year Ended December 31, 2008				
First Quarter	$ 88,265	$(15,135,057)	$(19,743,901)	$(0.79)
Second Quarter	88,031	(16,343,653)	(21,010,055)	(0.84)
Third Quarter	61,887	(19,755,671)	(24,678,278)	(0.99)
Fourth Quarter	236,376	(10,682,888)	(15,821,698)	(0.63)

INDEX TO EXHIBITS

Number	Description of Document
3.1**	Restated Articles of Organization, filed May 30, 2006, as amended by Articles of Amendment, filed September 7, 2006.
3.2**	Amended and Restated Bylaws.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate *(incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q filed on November 9, 2009).*
4.3	Form of Warrant *(incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on November 16, 2007).*
4.4	Indenture between the Company and the Bank of New York dated as of November 16, 2007 *(incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on November 16, 2007).*
4.5	Pledge and Security Agreement dated as of November 16, 2007 *(incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K filed on November 16, 2007).*
4.6	Rights Agreement, dated as of January 30, 2009, between the Company and American Stock Transfer & Trust Company, LLC (*incorporated by reference to Exhibit 4.1 to the Registration Statement on Form 8-A filed February 2, 2009*).
10.1**	Unit Purchase Agreement for the Purchase of Shares of Series B Preferred Stock of the Company dated as of February 23, 2004.
10.2**	Stock Purchase Agreement for the Purchase of Series C Preferred Stock of the Company dated as of March 29, 2005.
10.3**	Amended and Restated Voting Agreement by and among the Company and certain holders of Common Stock and Series A Preferred Stock, the holders of Series B Preferred Stock and the holders of Series C Preferred Stock dated as of March 29, 2005.
10.4**	Investors Rights Agreement by and between the Company and the holders of Series C Preferred Stock dated as of March 29, 2005.
10.5**	Registration Rights Agreement by and among the Company and certain holders of Common Stock and Series A Preferred Stock, the holders of Series B Preferred Stock, and the holders of Series C Preferred Stock, dated as of March 29, 2005.
10.6**	Lease Agreement dated as of June 19, 2003 by and between the Company and RayJoe Limited Partnership.
10.7**	Employment Agreement dated as of January 1, 2003 by and between the Company and John Babich.
10.8**	Employment Agreement dated as of February 7, 2003 by and between the Company and David Barlow.
10.9**	Employment Agreement dated as of March 3, 2003 by and between the Company and John McCray.
10.10**	Employment Agreement dated as of May 1, 2004 by and between the Company and Nicholas Borys.
10.11**	Employment Agreement dated as of July 1, 2005 by and between the Company and Bob Gallahue.
10.12**	License Agreement, dated as of October 25, 1999, between the Company and Nihon Medi-Physics Co. Ltd.
10.13**	Development, Manufacturing and Supply Agreement, dated June 14, 2004, as amended by Amendment No. 1, between the Company and MDS Nordion, a division of MDS (Canada) Inc.
10.14**	Exclusive License Agreement, dated as of December 29, 1997, between the Company and Georgetown University.

Number	Description of Document
10.15**	Exclusive License Agreement, dated as of March 1, 2000, between the Company and Georgetown University.
10.16**	License Agreement, dated as of December 15, 2000, between the Company and The Board of Governors of the University of Western Ontario.
10.17**	License Agreement, dated as of September 5, 2003, between the Company and The Board of Governors of the University of Western Ontario.
10.18**	1997 Stock Option Plan.
10.19**	Amended and Restated 2006 Equity Incentive Plan.
10.20**	Consulting Agreement dated as of January 1, 2005 by and between the Company and William Eckelman.
10.21**	Exclusive License Agreement, dated as of December 28, 2005, between the Company, Georgetown University and Johns Hopkins University.
10.22**	Employment Agreement dated June 23, 2005 by and between the Company and James A. Wachholz.
10.23**	BMIPP Supply Agreement, dated as of January 12, 2006, between the Company and MDS Nordion, a division of MDS (Canada) Inc.
10.24**	Agreement, dated as of March 22, 2006, as amended, between the Company and MDS Nordion, a division of MDS (Canada) Inc.
10.25**	Amendment No. 2, dated May 9, 2006, between the Company and MDS Nordion to Development, Manufacturing and Supply Agreement, dated June 14, 2004, and Amendment No. 1, dated May 9, 2006, between the Company and MDS Nordion to BMIPP Supply Agreement, dated January 12, 2006.
10.26**	Amendment No. 3, dated November 26, 2006, between the Company and MDS Nordion to Development, Manufacturing and Supply Agreement, dated June 14, 2004.
10.27**	License Agreement, dated as of November 3, 2006, between the Company and Novartis Pharma AG.
10.28**	License Agreement, dated as of December 6, 2006, between the Company and McMaster University.
10.29**	First Amendment, dated January 4, 2007, between the Company and Novartis Pharma AG to the License Agreement dated November 3, 2006.
10.30**	Technology Transfer Agreement, dated December 20, 2006, between the Company and Mallinckrodt Inc.
10.31**	License, Development and Commercialization Agreement, dated January 15, 2007, between the Company and Bayer Schering Pharma Aktiengesellschaft.
10.32**	Securities Purchase Agreement, dated September 28, 2006, among the Company and the Purchasers of Convertible Notes and Common Stock Warrants.
10.33**	Amendment No. 1 to Registration Rights Agreement, dated September 28, 2006, among the Company and certain holders of Common Stock and Series A Preferred Stock, the holders of Series B Preferred Stock, the holders of Series C Preferred Stock, and the holders of Convertible Notes.
10.34**	Amendment No. 1 to Employment Agreement between the Company and John Babich, dated November 14, 2005.
10.35**	Amendment No. 1 to Employment Agreement between the Company and David Barlow, dated November 14, 2005.
10.36**	Amendment No. 1 to Employment Agreement between the Company and John McCray, dated November 14, 2005.

Number	Description of Document
10.37**	Amendment No. 1 to Employment Agreement between the Company and Nicholas Borys, dated November 14, 2005.
10.38**	Amendment No. 1 to Employment Agreement between the Company and Bob Gallahue, dated November 14, 2005.
10.39	Employment Agreement dated August 13, 2007 by and between the Company and Donald Wallroth *(incorporated by reference to Exhibit 10.1 on our Current Report on Form 8-K filed on September 11, 2007).*
10.40	Contract of Purchase and Sale between the Company and NeoRx Manufacturing Group, Inc., an unaffiliated third party, for the purchase of certain real property and personal property located at 3100 Jim Cristal Road, Denton, Texas *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 17, 2007).*
10.41	Amended and Restated Registration Rights Agreement by and among the Company and certain holders of Common Stock and Series A Preferred Stock, the holders of Series B Preferred Stock, the holders of Series C Preferred Stock, the holders of Convertible Notes and the holders of Bond Warrants dated as of November 16, 2007 *(incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed on November 16, 2007).*
10.42	Separation Agreement between the Company and Robert E. Gallahue, effective as of June 26, 2007 *(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 29, 2007).*
10.43	Seventh Amendment to Greenworks Lease, dated January 18, 2008, between the Company and RayJoe Limited Partnership *(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 25, 2008).*
10.44	Lease Agreement, dated as of April 8, 2008, between the Company and RayJoe Limited Partnership *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 8, 2008).*
10.45	Lease Agreement, dated as of April 25, 2008, between the Company and ARE-MA Region No. 35, LLC *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 8, 2008).*
10.46	Form of Incentive Stock Option Award *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 2, 2007).*
10.47	Form of Nonqualified Stock Option Award *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 2, 2007).*
10.48	Form of Restricted Stock Award *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 21, 2008).*
10.49	Inducement Grant Option Award Agreement, between the Company and Daniel L. Peters, dated August 11, 2009 *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 11, 2009)*
10.50	Severance Agreement by and between the Company and Donald E. Wallroth, effective September 2, 2009 *(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 4, 2009)*
10.51†	Azedra Commercial Facility and Supply Agreement, dated August 6, 2009, by and between the Company and MDS Nordion, a division of MDS (Canada), Inc. *(incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on November 9, 2009 and Amendment No. 1 thereto on Form 10-Q/A filed on March 10, 2010)*
10.52†	Territory License Agreement, dated September 1, 2009, by and between the Company and BioMedica Life Sciences, S.A. *(incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q filed on November 9, 2009 and Amendment No. 1 thereto on Form 10-Q/A filed on March 10, 2010)*

Number	Description of Document
10.53†	Supply Agreement, dated October 19, 2009, by and between the Company and BioMedica Life Sciences, S.A. (*incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q filed on November 9, 2009 and Amendment No. 1 thereto on Form 10-Q/A filed on March 10, 2010*)
10.54†	Facility Setup and Contract Manufacturing Agreement, dated October 20, 2009, by and between the Company and Eckert & Ziegler Nuclitec GmbH. (*incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q filed on November 9, 2009 and Amendment No. 1 thereto on Form 10-Q/A filed on March 10, 2010*)
14.1	Code of Business Conduct (adopted on September 16, 2008 and posted on the Company's website at www.molecularinsight.com).
21.1	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP
31.1	Rule 13a-14(a)/15d-14(a) Certifications by the Registrant's Chief Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications by the Registrant's Chief Financial Officer
32	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

** Incorporated herein by reference to the exhibits under the same exhibit numbers previously filed with the Registrant's Registration Statement on Form S-1 filed with the Commission, as amended (Registration No. 333-129570), as declared effective on February 1, 2007.

† Portions of this exhibit have been omitted and filed separately with the Secretary of the Securities and Exchange Commission pursuant to a confidential treatment request.