

NEKTAR THERAPEUTICS  
Form 10-K  
February 29, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**Form 10-K**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**  
For the fiscal year ended December 31, 2011

December 31, 2011

or

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

Commission File Number: 0-24006

**NEKTAR THERAPEUTICS**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

94-3134940  
(IRS Employer  
Identification No.)

455 Mission Bay Boulevard South  
San Francisco, California 94158

(Address of principal executive offices and zip code)

415-482-5300

(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, \$0.0001 par value	NASDAQ Global Select Market
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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer  Accelerated filer   
 Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
 Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2) Yes  No

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The approximate aggregate market value of voting stock held by non-affiliates of the registrant, based upon the last sale price of the registrant's common stock on the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2011 (based upon the closing sale price of the registrant's common stock listed as reported on the NASDAQ Global Select Market), was approximately \$827,788,677. This calculation excludes approximately 441,119 shares held by directors and executive officers of the registrant. Exclusion of these shares does not constitute a determination that each such person is an affiliate of the registrant.

As of February 24, 2012, the number of outstanding shares of the registrant's common stock was 114,530,745.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of registrant's definitive Proxy Statement to be filed for its 2012 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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### **Forward-Looking Statements**

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical fact are forward-looking statements for purposes of this annual report on Form 10-K, including any projections of earnings, revenue or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, pre-clinical development, clinical trials and manufacturing), any statements concerning proposed drug candidates, any statements regarding future economic conditions or performance, any statements regarding the success of our collaboration arrangements, any statements regarding our plans and objectives to initiate clinical studies, and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential or continue, negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part I, Item 1A Risk Factors below and for the reasons described elsewhere in this annual report on Form 10-K. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this annual report on Form 10-K, the Company, Nektar, we, us, and our refer to Nektar Therapeutics, a Delaware corporation, and, where appropriate, its subsidiaries.

### **Trademarks**

The Nektar brand and product names, including but not limited to Nektar®, contained in this document are trademarks, registered trademarks or service marks of Nektar Therapeutics in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

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**PART I**

**Item 1. Business**

We are a clinical-stage biopharmaceutical company developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms, which are designed to improve the benefits of drugs for patients. Our current proprietary pipeline is comprised of drug candidates across a number of therapeutic areas including oncology, pain, anti-infectives, anti-viral and immunology. Our research and development activities involve small molecule drugs, peptides and other potential biologic drug candidates. We create our innovative drug candidates by using our proprietary advanced polymer conjugate technologies and expertise to modify the chemical structure of drugs to create new molecular entities. Polymer chemistry is a science focused on the synthesis or bonding of polymer architectures with drug molecules to alter the properties of a molecule when it is bonded with polymers. Additionally, we may utilize established pharmacologic targets to engineer a new drug candidate relying on a combination of the known properties of these targets and our proprietary polymer chemistry technology and expertise. Our drug candidates are designed to improve the pharmacokinetics, pharmacodynamics, half-life, bioavailability, metabolism or distribution of drugs and improve the overall benefits and use of a drug for the patient. Our objective is to apply our advanced polymer conjugate technology platform to create new drug candidates in multiple therapeutic areas that address large potential markets.

Our most advanced proprietary drug candidate, NKTR-118, is an oral peripherally-acting opioid antagonist, currently in Phase 3 clinical studies for the treatment of opioid-induced constipation (OIC) in patients with non-cancer pain and cancer pain. OIC is a common side effect of prescription opioids when used for chronic pain management. In September 2009, we entered into a global license agreement with AstraZeneca AB (AstraZeneca) for the global development and commercialization of NKTR-118 and NKTR-119. NKTR-119 is an early stage research and development program that is designed to combine various opioids with NKTR-118. AstraZeneca is responsible for all clinical, regulatory and commercialization costs for NKTR-118 and NKTR-119.

Our second most advanced drug candidate, NKTR-102, is a next-generation topoisomerase I inhibitor, currently being evaluated as a single-agent therapy in a Phase 3 clinical study in patients with metastatic breast cancer. This Phase 3 clinical study, which we call the BEACON study (BrEAsT Cancer Outcomes with NKTR-102), was initiated by us in December 2011. The BEACON study is designed to enroll approximately 840 women with metastatic breast cancer who have had prior treatment with anthracycline, taxane and capecitabine in either the adjuvant or metastatic setting. Patients in the BEACON study will be randomized on a 1:1 basis to receive either single-agent NKTR-102 or a single agent of physician's choice. The primary endpoint of the BEACON study will be overall survival, and secondary endpoints will include progression-free survival and objective tumor response rate.

NKTR-102 is also being evaluated in a Phase 2 clinical study in patients with platinum-resistant ovarian cancer and a Phase 2 clinical study in patients with metastatic colorectal cancer. The Phase 2 clinical study of NKTR-102 in patients with platinum-resistant ovarian cancer completed enrollment of 71 patients in 2009. The study was further expanded to enroll up to 110 additional women with platinum-resistant ovarian cancer whose disease had progressed after prior treatment with Doxil<sup>®</sup> (doxorubicin HCl liposome injection). In November 2011, we announced that enrollment in this expanded Phase 2 study had significantly slowed due to a shortage of Doxil<sup>®</sup> resulting from serious manufacturing issues being experienced by the manufacturer and supplier of Doxil<sup>®</sup>. As of February 2012, approximately 94 of the planned 110 patients had been enrolled in the study. We are currently in the process of compiling the data from this expanded study and performing verification procedures on preliminary interim results from the patients enrolled to date. Results from this study and communication with government health authorities in both the United States and European Union (E.U.) will guide our future development and regulatory strategy for NKTR-102 in ovarian cancer. A Phase 2 clinical trial in patients with metastatic colorectal cancer is still enrolling patients, and a Phase 1 study of NKTR-102 in combination with F-fluorouracil/leucovorin is also continuing to enroll patients.

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We also have several proprietary pre-clinical and clinical drug candidates that are in the pain therapeutic area. NKTR-181 is an orally-available mu-opioid analgesic molecule with a long-acting profile to treat chronic pain that has been designed with the objective of addressing serious CNS-related side effects associated with standard opioid therapies. These CNS-related side effects include abuse liability, sedation and respiratory depression. We have completed two separate Phase 1 clinical studies for NKTR-181 and we are currently preparing for a Phase 2 clinical study that we plan to initiate in mid-2012. The Phase 2 clinical study design is a randomized, double-blind, efficacy and safety study of NKTR-181 as compared to placebo in patients with chronic pain. NKTR-192 is an orally available mu-opioid analgesic molecule with a short-acting profile to treat acute pain that has been designed with the objective to also address the serious CNS-related side effects associated with standard short-acting opioid therapies. NKTR-192 completed preclinical work in 2011 and we plan to begin a Phase 1 clinical study in 2012 subject to our investigational new drug application (IND) clearing the FDA review period.

We also have a number of license, manufacturing and supply agreements with leading biotechnology and pharmaceutical companies, including Affymax, Inc., Amgen Inc., Baxter Healthcare, MAP Pharmaceuticals, Inc., Merck & Co., Inc. (through its acquisition of Schering Plough), Pfizer Inc., F. Hoffmann-La Roche Ltd (Roche), and UCB Pharma. A total of seven products using our PEGylation technology have received regulatory approval in the U.S. or EU, and are currently marketed by our collaboration partners. There are also a number of other products in clinical development that incorporate our advanced PEGylation and advanced polymer conjugate technologies.

We have a significant collaboration with Baxter Healthcare to identify and develop PEGylated drug candidates with the objective of providing new long-acting therapies for hemophilia patients. We are providing our PEGylation technology and expertise. Baxter is responsible for all clinical development. The first drug candidate in this collaboration, BAX 855, is a longer-acting (PEGylated) form of a full-length recombinant factor VIII (rFVIII) protein in Phase 1 clinical development in patients with hemophilia A. In addition to incorporating our PEGylation technology, BAX 855 is also based on Baxter's ADVATE [Antihemophilic Factor (Recombinant) Plasma/Albumin-Free Method] full-length rFVIII molecule and plasma/albumin-free (PAF) manufacturing process. The Phase 1 clinical study is a prospective, open-label study that will assess the safety, tolerability and pharmacokinetics of BAX 855 in previously-treated patients aged 12 years or older with severe hemophilia A. When used for prophylaxis, Baxter's ADVATE requires patients to infuse every two to three days to reduce the occurrence of bleeding episodes. This Phase 1 clinical study is the first step in assessing whether BAX 855 can be infused less frequently in patients while achieving a similar efficacy and safety profile. If the Phase 1 clinical study is successful, Baxter plans to then initiate Phase 3 studies for BAX 855.

We also have a significant collaboration with Bayer Healthcare LLC (Bayer) to develop BAY41-6551 (NKTR-061, Amikacin Inhale), which is an inhaled solution of amikacin, an aminoglycoside antibiotic. We originally developed the liquid aerosol inhalation platform and NKTR-061 drug candidate and entered into a collaboration agreement with Bayer in August 2007 to further advance the drug candidate's development and potential commercialization. Under the collaboration agreement, we are responsible for all future development of the nebulizer device and clinical and commercial manufacturing and supply of the device. BAY41-6551 completed Phase 2 development and we and Bayer are currently preparing for the start of a Phase 3 clinical study. Bayer and Nektar have been working together to prepare for Phase 3 clinical program for BAY41-6551 following the consummation of the collaboration in August 2007. This program is significantly behind schedule due to the fact that Bayer and Nektar decided to finalize the design of the device for commercial manufacturing prior to initiating Phase 3 clinical development. In 2011, Bayer received agreement with the FDA on the design of the planned Phase 3 clinical studies of BAY41-6551 under the Special Protocol Assessment process that is intended to support the submission of a New Drug Application (NDA) if the planned Phase 3 clinical study is successful.

On December 31, 2008, we completed the sale and transfer of certain pulmonary technology rights, certain pulmonary collaboration agreements and approximately 140 of our dedicated pulmonary personnel and operations to Novartis Pharma AG. We retained all of our rights to BAY41-6551 and certain rights to receive

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royalties on net sales of the Cipro Inhale (also known as Ciprofloxacin Inhaled Powder or CIP) program with Bayer Schering Pharma AG that we transferred to Novartis as part of the transaction. We also retained certain rights to patents specific to inhaled insulin.

## **Corporate Information**

We were incorporated in California in 1990 and reincorporated in Delaware in 1998. We maintain our executive offices at 455 Mission Bay Boulevard South, San Francisco, California 94158, and our main telephone number is (415) 482-5300. Our website is located at [www.nektar.com](http://www.nektar.com). The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report.

## **Our Technology Platform**

As a leader in the PEGylation field, we have advanced our technology platform to include first-generation PEGylation technology as well as new advanced polymer conjugate chemistries that can be tailored in very specific and customized ways with the objective of optimizing and significantly improving the profile of a wide range of molecules including many classes of drugs useful in many disease areas. PEGylation has been a highly effective technology platform for the development of therapeutics with significant commercial success, such as Roche's PEGASYS® (PEG-interferon alfa-2a) and Amgen's Neulasta® (pegfilgrastim). Nearly all of the PEGylated drugs approved over the last fifteen years were enabled with our PEGylation technology through our collaborations and licensing partnerships with a number of biotechnology and pharmaceutical companies. PEGylation is a versatile technology as a result of polyethylene glycol (PEG) being a water soluble, amphiphilic, non-toxic, non-immunogenic compound that is safely cleared from the body. Its primary use to date has been in currently approved biologic drugs to favorably alter their pharmacokinetic or pharmacodynamic properties. However, in spite of its widespread success in commercial drugs, there are limitations with the first-generation PEGylation approaches that have been used with biologics. Earlier PEGylation technology applications were limited, in that they could not be used successfully to improve small molecule drugs, antibody fragments and peptides, all of which could potentially benefit from the application of the technology. Other limitations of the early applications of PEGylation technology include sub-optimal bioavailability and bioactivity, and its limited ability to be used to fine-tune properties of the drug, as well as its inability to be used to create oral drugs.

With our expertise and proprietary technology in PEGylation, we have created the next generation of PEGylation technology. Our advanced polymer conjugate technology platform is designed to overcome the limitations of the first generation of the technology platform and allow the platform to be utilized with a broader range of molecules across many therapeutic areas.

Both our PEGylation and advanced polymer conjugate technology platforms have the potential to offer one or more of the following benefits:

improve efficacy or safety in certain instances as a result of better pharmacokinetics, pharmacodynamics, longer half-life and sustained exposure of the drug;

improve targeting or binding affinity of a drug to its target receptors with the potential to improve efficacy and reduce toxicity or drug resistance;

improve solubility of a drug;

enable oral administration of parenterally-administered drugs, or drugs that must be administered intravenously or subcutaneously, and increase oral bioavailability of small molecules;

prevent drugs from crossing the blood-brain barrier, or reduce their rate of passage into the brain, thereby limiting undesirable central nervous system effects;



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reduce first-pass metabolism effects of certain drug classes with the potential to improve efficacy, which could reduce the need for other medicines and reduce toxicity;

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reduce the rates of drug absorption and of elimination or metabolism by improving stability of the drug in the body and providing it with more time to act on its target; and

reduce immune response to certain macromolecules with the potential to prolong their effectiveness with repeated doses.

We have a broad range of approaches that we may use when designing our own drug candidates, some of which are outlined below:

### ***Small Molecule Stable Polymer Conjugates***

Our customized approaches for small molecule polymer conjugates allows for the fine-tuning of the physicochemical and pharmacological properties of small molecule oral drugs to potentially increase their therapeutic benefit. In addition, this approach can enable oral administration of subcutaneously or intravenously delivered small molecule drugs that have low bioavailability when delivered orally. The benefits of this approach can also include: improved potency, modified biodistribution with enhanced pharmacodynamics, and reduced transport across specific membrane barriers in the body, such as the blood-brain barrier. A primary example of reducing transport across the blood-brain barrier is NKTR-118, an orally-available peripheral opioid antagonist that is in Phase 3 clinical studies with our partner AstraZeneca. An additional example of the application of membrane transport, specifically slowing transport across the blood-brain barrier is NKTR-181, an orally-available mu-opioid analgesic molecule that has completed Phase 1 clinical development. An example of a drug candidate that uses this approach to avoid first-pass metabolism is NKTR-140, a protease inhibitor that is in the early stages of discovery research.

### ***Small Molecule Pro-Drug Releasable Polymer Conjugates***

The pro-drug polymer conjugation approach can be used to optimize the pharmacokinetics and pharmacodynamics of a small molecule drug to substantially increase both its efficacy and side effect profile. We are currently using this platform with oncolytics, which typically have sub-optimal half-lives that can limit their therapeutic efficacy. With our technology platform, we believe that these drugs can be modulated for programmed release within the body, optimized bioactivity and increased sustained exposure of active drug to tumor cells in the body. We are using this approach with the oncolytic drug candidate in our pipeline, NKTR-102, a next-generation topoisomerase I-inhibitor, currently in Phase 3 clinical development in metastatic breast cancer, and Phase 2 development in ovarian and colorectal cancers.

### ***Large Molecule Polymer Conjugates (Proteins and Peptides)***

Our customized approaches with large molecule polymer conjugates have enabled numerous successful PEGylated biologics on the market today. We are using our advanced polymer conjugation technology-based approach to enable peptides, which are much smaller in size than other biologics, such as proteins and antibody fragments. We are in the early stages of discovery research with a number of peptides that utilize this proprietary approach. Peptides are important in modulating many physiological processes in the body. Some of the benefits of working with peptides are: they are small, more easily optimized, and can be rapidly investigated for therapeutic potential. However, peptide drug discovery has been slowed by the extremely short half-life and limited bioavailability of these molecules.

Based on our knowledge of the technology and biologics, our scientists have designed novel hydrolyzable linkers that in many cases can be used to optimize bioactivity. Through rational drug design, a protein or peptide's pharmacokinetics and pharmacodynamics can be substantially improved and its half-life can be significantly extended. An example of this is BAX 855, a longer-acting (PEGylated) form of a full-length recombinant factor VIII (rFVIII) protein, which is currently being evaluated in Phase 1 clinical development by our partner Baxter for the treatment of hemophilia A. An additional example includes peginesatide, a synthetic,

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PEGylated peptidic compound that binds to and stimulates the erythropoietin receptor and thus acts as an erythropoiesis stimulating agent. Peginesatide has completed Phase 3 clinical studies and has been filed for approval with the FDA to treat renal anemia in patients with chronic kidney disease on dialysis by our partner Affymax, Inc.

### ***Antibody Fragment Polymer Conjugates***

This approach uses a large molecular weight PEG conjugated to antibody fragments in order to potentially improve their toxicity profile, extend their half-life and allow for ease of synthesis with the antibody. The specially designed PEG replaces the function of the Fc domain of full length antibodies with a branched architecture PEG with either stable or degradable linkage. This approach can be used to reduce antigenicity, reduce glomerular filtration rate, enhance uptake by inflamed tissues, and retain antigen-binding affinity and recognition. There is currently one approved product on the market that utilizes our technology with an antibody fragment, CIMZIA<sup>®</sup> (certoluzimab pegol), which was developed by our partner UCB Pharma and is approved for the treatment of Crohn's Disease in the U.S. and rheumatoid arthritis in the U.S. and E.U.

### **Our Strategy**

The key elements of our business strategy are described below:

#### ***Advance Our Proprietary Internal Clinical Pipeline of Drug Candidates that Leverage Our PEGylation and Advanced Polymer Conjugate Chemistry Platform***

Our objective is to create value by advancing our lead drug candidates through various stages of clinical development. To support this strategy, over the past four years we have significantly expanded and added expertise to our internal clinical development and regulatory departments. A key component of our development strategy is to potentially reduce the risks and time associated with drug development by capitalizing on the known safety and efficacy of approved drugs as well as established pharmacologic targets and drugs directed to those targets. For many of our novel drug candidates, we may seek to study the drug candidates in indications for which the parent drugs have not been studied or approved. We believe that the improved characteristics of our drug candidates will provide meaningful benefit to patients compared to the existing therapies. In addition, in certain instances we have the opportunity to develop new treatments for patients for which the parent drugs are not currently approved.

#### ***Ensure Future Growth of our Proprietary Internal Pipeline through Internal Research Efforts and Advancement of our Preclinical Drug Candidates into Clinical Trials***

We believe it is important to maintain a diverse pipeline of new drug candidates to continue to build on the value of our business. Our discovery research organization is identifying new drug candidates by applying our technology platform to a wide range of molecule classes, including small molecules and large proteins, peptides and antibodies, across multiple therapeutic areas. We continue to advance our most promising research drug candidates into preclinical development with the objective to advance these early stage research programs to human clinical studies over the next several years.

#### ***Enter into Strategic and High-Value Partnerships to Bring Certain of Our Drug Candidates to Market***

We decide on a drug candidate-by-drug candidate basis how far to advance clinical development (e.g. Phase 1, 2 or 3) and whether to commercialize products on our own, or seek a partner, or pursue a combination of these approaches. For example, in December 2010, we decided that we would move NKTR-102 into Phase 3 development in metastatic breast cancer prior to completing a collaboration partnership for this drug candidate. When we determine to seek a partner, our strategy is to enter into collaborations with leading pharmaceutical and biotechnology companies to fund further clinical development, manage the global regulatory filing process, and market and sell drugs in one or more geographies. The options for future collaboration arrangements range from

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comprehensive licensing and commercialization arrangements to co-promotion and co-development agreements with the structure of the collaboration depending on factors such as the structure of economic risk sharing, the cost and complexity of development, marketing and commercialization needs, therapeutic area and geographic capabilities.

***Continue to Build a Leading Intellectual Property Estate in the Field of PEGylation and Polymer Conjugate Chemistry across Therapeutic Modalities***

We are committed to continuing to build on our intellectual property position in the field of PEGylation and polymer conjugate chemistry. To that end, we have a comprehensive patent strategy with the objective of developing a patent estate covering a wide range of novel inventions including among others, polymer materials, conjugates, formulations, synthesis, therapeutic areas and methods of treatment.

**Nektar Proprietary Internal Drug Candidates in Clinical Development**

The following table summarizes our proprietary Nektar-discovered drug candidates that are being developed by us or in collaboration with other pharmaceutical companies. The table includes the type of molecule or drug, the target indications for the drug candidate, and the status of the clinical development program.

<b>Drug Candidate/Program</b>	<b>Target Indications</b>	<b>Status(1)</b>
NKTR-118 (orally available peripheral opioid antagonist)	Opioid-induced constipation	Phase 3 (Partnered with AstraZeneca AB)
NKTR-102 (next-generation topoisomerase I inhibitor)	Metastatic breast cancer	Phase 3
BAY41-6551 (Amikacin Inhale, formerly NKTR-061)	Gram-negative pneumonias	Completed Phase 2 (Partnered with Bayer Healthcare LLC)*
NKTR-102	Platinum-resistant/refractory ovarian cancer	Phase 2
NKTR-102	Second-line metastatic colorectal cancer in patients with the KRAS gene mutation	Phase 2
NKTR-181 (orally-available mu-opioid analgesic molecule)	Chronic pain	Phase 1
NKTR-102 (in combination with F-fluorouracil/leucovorin)	Metastatic Colorectal cancer	Phase 1
NKTR-119 (opioid/NKTR-118 combinations)	Pain	Research/Preclinical (Partnered with AstraZeneca AB)
NKTR-192 (orally-available mu-opioid analgesic molecule)	Acute pain	Research/Preclinical
NKTR-171	Neuropathic pain	Research/Preclinical
NKTR-140	HIV	Research/Preclinical

(1) Status definitions are:

*Phase 3 or Pivotal* a drug candidate in large-scale clinical trials conducted to obtain regulatory approval to market and sell the drug (these trials are typically initiated following encouraging Phase 2 trial results).

*Phase 2* a drug candidate in clinical trials to establish dosing and efficacy in patients.

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*Phase 1* a drug candidate in clinical trials, typically in healthy subjects, to test safety. In the case of oncology drug candidates, Phase 1 clinical trials are typically conducted in cancer patients.

*Research/Preclinical* a drug candidate being studied in research by way of in-vitro studies and/or animal studies.

\* This drug candidate uses a liquid aerosol technology platform that was transferred to Novartis by us in the pulmonary asset sale transaction that was completed on December 31, 2008. As part of that transaction, we retained an exclusive license to this technology for the development and commercialization of this drug candidate originally developed by us.

**Approved Drugs and Drug Candidates Enabled By Our Technology through Licensing Collaborations**

The following table outlines our collaborations with a number of pharmaceutical companies that license our intellectual property. A total of seven products using our PEGylation technology have received regulatory approval in the U.S. or Europe. There are also a number of other candidates that have been filed for approval or are in various stages of clinical development. These collaborations generally contain one or more elements including a license to our intellectual property rights and manufacturing and supply agreements under which we may receive manufacturing revenue, milestone payments, and/or royalties on commercial sales of drug products.

<b>Drug</b>	<b>Primary or Target Indications</b>	<b>Drug Marketer/Partner</b>	<b>Status(1)</b>
Neulasta® (pegfilgrastim)	Neutropenia	Amgen Inc.	Approved
PEGASYS® (peginterferon alfa-2a)	Hepatitis-C	F. Hoffmann-La Roche Ltd	Approved
Somavert® (pegvisomant)	Acromegaly	Pfizer Inc.	Approved
PEG-INTRON® (peginterferon alfa-2b)	Hepatitis-C	Merck (formerly Schering-Plough Corporation)	Approved
Macugen® (pegaptanib sodium injection)	Age-related macular degeneration	Eyetech, Inc.	Approved
CIMZIA® (certolizumab pegol)	Rheumatoid arthritis	UCB Pharma	Approved in U.S., EU and Switzerland; filed in Japan*
CIMZIA® (certolizumab pegol)	Crohn's disease	UCB Pharma	Approved in the U.S. and Switzerland*
MIRCERA® (C.E.R.A.) (Continuous Erythropoietin Receptor Activator)	Anemia associated with chronic kidney disease in patients on dialysis and patients not on dialysis	F. Hoffmann-La Roche Ltd	Approved in U.S., EU and Japan (Launched only in the EU and Japan)**
Peginesatide (synthetic peptide-based, erythropoiesis-stimulating agent)	Anemia associated with chronic kidney disease (CKD) in adult patients on dialysis	Affymax, Inc.	Filed for approval in U.S.
LEVADEX®	Migraine	MAP Pharmaceuticals	Filed for approval in U.S.
CIMZIA® (certoluzimab pegol)	Psoriasis/Ankylosing Spondylitis	UCB Pharma	Phase 3
Cipro Inhale	Cystic fibrosis lung infections	Bayer Schering Pharma AG	Completed Phase 2***
BAX-855 (pegylated rFVIII)	Hemophilia A	Baxter Healthcare	Phase 1
Longer-acting blood clotting proteins	Hemophilia	Baxter Healthcare	Research/Preclinical

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(1) Status definitions are:

*Approved* regulatory approval to market and sell product obtained in the U.S., EU and other countries.

*Filed* an application for approval and marketing has been filed with the applicable government health authority.

*Phase 3 or Pivotal* product in large-scale clinical trials conducted to obtain regulatory approval to market and sell the drug (these trials are typically initiated following encouraging Phase 2 trial results).

*Phase 2* a drug candidate in clinical trials to establish dosing and efficacy in patients.

*Phase 1* a drug candidate in clinical trials, typically in healthy subjects, to test safety.

*Research/Preclinical* a drug candidate is being studied in research by way of vitro studies and/or animal studies

\* In February 2012, we sold our rights to receive royalties on future worldwide net sales of CIMZIA® effective as of January 1, 2012 until the agreement with UCB is terminated or expires.

\*\* Amgen Inc. prevailed in a patent lawsuit against F. Hoffmann-La Roche Ltd and as a result of this legal ruling Roche is currently prevented from marketing MIRCERA® in the U.S until July 2014. In February 2012, we sold our rights to receive royalties on future worldwide net sales of MIRCERA® effective as of January 1, 2012 until the agreement with Roche is terminated or expires.

\*\*\* This drug candidate was developed using our proprietary pulmonary delivery technology that was transferred by us to Novartis in an asset sale transaction that closed on December 31, 2008. As part of the transaction, Novartis assumed our rights and obligations for our Cipro Inhale agreements with Bayer Schering Pharma AG; however, we maintained the rights to receive certain royalties on commercial sales of Cipro Inhale if the drug candidate is approved.

With respect to all of our collaboration and license agreements with third parties, please refer to Item 1A, Risk Factors, including without limitation, We are a party to numerous collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.

**Overview of Selected Nektar Proprietary Drug Development Programs and Significant Partnered Drug Development Programs**

***NKTR-118 and NKTR-119, License Agreement with AstraZeneca AB***

In September 2009, we entered into a global license agreement with AstraZeneca AB (AstraZeneca) pursuant to which we granted AstraZeneca a worldwide, exclusive, perpetual, royalty-bearing license under our patents and other intellectual property to develop, market and sell NKTR-118 and NKTR-119. Under the terms of this agreement, AstraZeneca made a license payment to us of \$125.0 million and AstraZeneca has responsibility for all activities and bears all costs associated with research, development and commercialization for NKTR-118 and NKTR-119. For NKTR-118, we are also entitled to up to \$235.0 million upon certain filings and commercial launch milestones for NKTR-118, and \$375.0 million in sales milestones if the product achieves certain annual commercial sales levels. With respect to the \$235.0 million in milestones due upon certain filings and commercial launch milestones for NKTR-118, when filing occurs in the US and in the EU or Japan, Nektar will be entitled to up to \$95.0 million of those milestones. The remaining milestone payments are due upon the commercial launches of NKTR-118 in those regions. For NKTR-119, we are also eligible to receive significant development milestones as well as significant sales milestones if the program achieves certain annual commercial sales levels. For both NKTR-118 and NKTR-119, we are also entitled to significant double-digit royalty payments, varying by country of sale and level of annual net sales. Our right to receive royalties (subject to certain adjustments) in any particular country will expire upon the later of (a) specified period of time after the first commercial sale of the product in that country or (b) the expiration of patent rights in that particular country.

NKTR-118 is an orally-available peripheral opioid antagonist that is in Phase 3 clinical studies being conducted by AstraZeneca which AstraZeneca calls the KODIAC study. The KODIAC study is evaluating the



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efficacy and safety of NKTR-118 for the treatment of opioid-induced constipation (OIC) in patients with non-cancer pain and cancer pain. The KODIAC study includes two 12-week, randomized, placebo-controlled efficacy studies (with approximately 630 randomized patients each) and an open-label, randomized, 52-week long-term safety study with a usual care comparator arm. The 12-week efficacy studies will compare response rate among placebo and two different doses of NKTR-118 with primary endpoint at 12 weeks. There is a three month safety extension following one of the two 12-week studies. AstraZeneca is planning global regulatory submissions for NKTR-118, with first regulatory filings for NKTR-118 in the US and EU planned for 2013 if the KODIAC studies are successful.

Data from a Phase 2 study conducted by us showed that NKTR-118 achieved the primary endpoint of change from baseline in spontaneous bowel movements in patients taking opioids with chronic OIC. The study also showed that there was no apparent reversal of opioid-mediated analgesia with any of the NKTR-118 dose groups, as measured by no change in Numeric Rating Scale pain scores, no evidence of opioid withdrawal, and no increase in mean daily opioid use. The most commonly reported side effects from the Phase 2 clinical study of NKTR-118 were dose dependent gastrointestinal-related effects, which were mild and transient.

According to the American Pain Society and IMS Health, over 200 million opioid prescriptions are filled in the U.S. annually with annual worldwide sales of opioids exceeding \$10 billion. Depending on the population studied and the definitions used, OIC occurs in up to 40-90% of patients taking opioids. Clinically, OIC is the most prevalent side effect of opioid therapy. Currently, there are no specific oral drugs approved or specifically indicated to treat OIC.

NKTR-119 is an early stage drug development program that is intended to combine NKTR-118 with selected opioids, with the goal of treating pain without the side effect of constipation traditionally associated with opioid therapy. AstraZeneca has agreed to use commercially reasonable efforts to develop one product based on NKTR-119 and has the right to develop multiple products which combine NKTR-118 with other opioids.

### ***NKTR-102 (next generation topoisomerase I inhibitor)***

We are developing NKTR-102, a next generation topoisomerase I (topo I) inhibitor, that was designed using our PEGylation technology. NKTR-102 is a novel macromolecular chemotherapeutic designed to enhance the anti-cancer effects of topo I inhibition while minimizing its toxicities. Unlike irinotecan, a first generation topo I inhibitor that exhibits a high initial peak concentration and short half-life, NKTR-102's unique pro-drug design results in a lowered initial peak concentration of active topo I inhibitor in the blood. The large NKTR-102 molecule is inactive when administered. Over time, the body's natural enzymatic processes slowly metabolize the linkers within the molecule, continuously freeing active drug that then can work to stop tumor cell division through topo I inhibition. In preclinical models, NKTR-102 achieved a 300-fold increase in tumor concentration as compared to irinotecan. Because NKTR-102 is a large molecule, based on preclinical studies we believe that it may penetrate the leaky vasculature within the tumor environment more readily than normal vasculature, concentrating and trapping NKTR-102 in tumor tissue. Clinical studies have shown that NKTR-102 has an extended pharmacokinetic profile and remains in circulation throughout the entire chemotherapy cycle, providing sustained exposure to topo I inhibition.

NKTR-102 is currently being evaluated as a single-agent therapy (145 mg/m<sup>2</sup> every 21 days) in a Phase 3 open-label, randomized, multicenter clinical study in patients with metastatic breast cancer. This Phase 3 clinical study, which we call BEACON (BrEAst Cancer Outcomes with NKTR-102), was initiated in December 2011. The BEACON study plans to include approximately 160 investigator sites worldwide including sites in North America, Eastern and Western Europe, and certain countries in Asia/Pacific. The BEACON study plans to enroll approximately 840 patients with metastatic breast cancer who have had prior treatment with anthracycline, taxane and capecitabine in either the adjuvant or metastatic setting. This study will randomize patients on a 1:1 basis to receive single-agent NKTR-102 or a single agent chosen from a defined set of physician's choice alternatives. The physician's choice single agents will include the following: ixabepilone, vinorelbine,



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gemcitabine, eribulin, or a taxane. Randomization will be stratified by geographic region, prior treatment with eribulin and whether or not the patient has triple negative breast cancer. The primary endpoint of the BEACON study will be overall survival, and secondary endpoints will include progression-free survival and objective tumor response rate. Secondary endpoints and objectives also include clinical benefit rate, duration of response, pharmacokinetic data, safety profiles, quality-of-life measurements, and pharmacoeconomic implications. Exploratory objectives of the study will include collecting specific biomarker data to correlate with objective tumor response rate, progression-free survival, overall survival and selected toxicities.

According to the American Cancer Society and World Health Organization, more than one million women worldwide are diagnosed with breast cancer globally every year. The chance of developing invasive breast cancer at some time in a woman's life is a little less than one in eight (12%). In 2011, there were an estimated 230,000 new cases of breast cancer in the United States and 460,000 new cases in Europe. Metastatic breast cancer refers to cancer that has spread from the breast to distant sites in the body. Anthracyclines and taxanes are the among the most active and widely used chemotherapeutic agents for breast cancer, but the increased use of these agents at an early stage of disease often renders tumors resistant to these drugs by the time the disease recurs, thereby reducing the number of treatment options for metastatic disease. There are currently no FDA-approved topoisomerase I inhibitors to treat breast cancer.

NKTR-102 is also being evaluated in a Phase 2 clinical study in patients with platinum-resistant ovarian cancer. This clinical study is an open label, randomized, study evaluating two treatment schedules of single-agent NKTR-102 (145 mg/m<sup>2</sup> every 14 days or every 21 days). Each schedule originally followed a two-stage Simon design and a total of 71 patients were initially included in the study that was completed in the first half of 2010. In the second half of 2010, we expanded this Phase 2 study to include approximately 50 additional women who had previously received Doxil<sup>®</sup> therapy to continue to evaluate the every 21-day dose schedule of single-agent NKTR-102 in this subset of women. On March 1, 2011, we announced that we intended to further expand this Phase 2 clinical study by approximately 60 additional patients. In November 2011, we announced that enrollment in this expanded study had significantly slowed due to a shortage of Doxil<sup>®</sup> resulting from serious manufacturing issues being experienced by the manufacturer and supplier of Doxil<sup>®</sup>. As of February 2012, approximately 94 patients of the 110 patients had been enrolled in the study. We are currently in the process of compiling and performing verification procedures on the preliminary interim results from the patients enrolled to date in this study. Results from this study and communication with government health authorities in both the U.S. and E.U. will guide our future development and regulatory strategy for NKTR-102 in ovarian cancer.

Ovarian cancer is also a significant health problem for women worldwide. According to the American Cancer Society, in 2012, there will be an estimated 22,280 new cases of ovarian cancer diagnosed and an estimated 15,500 deaths from ovarian cancer in the United States. Ovarian cancer is the ninth most common cancer among women, excluding non-melanoma skin cancers. It ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. Historically, less than 40% of women with ovarian cancer are cured. According to the World Health Organization, about 230,000 women globally are diagnosed each year with ovarian cancer.

A NKTR-102 Phase 2 clinical study was initiated in June 2008 to evaluate the efficacy and safety of NKTR-102 monotherapy versus irinotecan in second-line metastatic colorectal cancer patients with the KRAS mutant gene. The primary endpoint of the Phase 2 clinical study in metastatic colorectal cancer is progression-free survival as compared to standard irinotecan monotherapy. According to recent data presented at the American Society of Clinical Oncology in 2010, it is estimated that up to 43.5% of colorectal cancer cases have this mutation in the KRAS gene and do not respond to EGFR-inhibitors, such as cetuximab. The Phase 2 clinical study is designed to enroll 174 patients with metastatic colorectal cancer. The study is still enrolling and patient enrollment in this study has been challenging due to the fact that the comparator arm of this study, single-agent irinotecan, is not the common standard of care for second line metastatic colorectal therapy in the U.S. or EU. In June 2010, we started a Phase 1 dose-escalation clinical study designed to enroll up to approximately 40 patients to evaluate NKTR-102 in combination with 5-fluorouracil (5-FU)/leucovorin in refractory solid tumor cancers

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and the study is still ongoing. The chemotherapy agent 5-FU is currently used as a part of a combination treatment regimen for colorectal cancer in combination with irinotecan, which is also known as the FOLFIRI regimen.

Colorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer death in the U.S. According to the American Cancer Society, nearly 141,210 new cases of colon and rectal cancer were diagnosed in the U.S. in 2011, and about 49,000 people will die annually of the disease. Worldwide, over 1.2 million people are diagnosed annually with colorectal cancer. Most metastatic colorectal cancer patients have recurrence within two years and require retreatment with chemotherapy regimens. The majority of metastatic colorectal cancer patients receive irinotecan-based regimens, primarily in combination with 5-FU/leucovorin. Colorectal cancer is the third leading cause of cancer-related deaths in the United States when men and women are considered separately, and the second leading cause when both sexes are combined. It was expected to cause about 49,380 deaths (29,001 in men and 20,379 in women) during 2011 in the U.S. Worldwide, according to the World Health Organization, there are 690,000 deaths annually from colorectal cancers.

***BAY41-6551 (Amikacin Inhale, formerly NKTR-061), Agreement with Bayer Healthcare LLC***

In August 2007, we entered into a co-development, license and co-promotion agreement with Bayer Healthcare LLC (Bayer) to develop a specially-formulated Amikacin (BAY41-6551, Amikacin Inhale, formerly called NKTR-061). Under the terms of the agreement, Bayer is responsible for most future clinical development and commercialization costs, all activities to support worldwide regulatory filings, approvals and related activities, further development of formulated Amikacin and final product packaging for BAY41-6551. We are responsible for all future development of the nebulizer device through the completion of Phase 3 clinical studies and for clinical and commercial manufacturing and supply of the nebulizer device. We have engaged third party contract manufacturers to perform our device manufacturing obligations for this program. We are entitled to up to \$60.0 million in development milestone payments as well as sales milestone payments upon achievement of certain annual sales targets. We are also entitled to royalties based on annual worldwide net sales of BAY41-6551. Our right to receive these royalties in any particular country will expire upon the later of ten years after the first commercial sale of the product in that country or the expiration of certain patent rights in that particular country, subject to certain exceptions. The agreement expires in relation to a particular country upon the expiration of all royalty and payment obligations between the parties related to such country. Subject to termination fee payment obligations, Bayer also has the right to terminate the agreement for convenience. In addition, the agreement may also be terminated by either party for certain product safety concerns, the product's failure to meet certain minimum commercial profile requirements or uncured material breaches by the other party.

BAY41-6551 is in clinical development to treat Gram-negative pneumonias, including hospital-acquired (HAP), healthcare-associated, and ventilator-associated pneumonias. Gram-negative pneumonias are often the result of complications of other patient conditions or surgeries. Gram-negative pneumonias carry a mortality risk that can exceed 50% in mechanically-ventilated patients and accounts for a substantial proportion of the pneumonias in intensive care units today. BAY41-6551 is designed to be an adjunctive therapy to the current antibiotic therapies administered intravenously as standard of care. The targeted aerosol delivery platform in BAY41-6551 delivers the antimicrobial agent directly to the site of infection in the lungs. This drug candidate can be integrated with conventional mechanical ventilators or used as a hand-held off-vent device for patients no longer requiring breathing assistance. This drug candidate has completed Phase 2 clinical development. In 2011, Bayer received agreement with the U.S. Food and Drug Administration (FDA) on the design of the Phase 3 clinical studies of BAY41-6551 under the Special Protocol Assessment (SPA) process that is intended to support the submission of a New Drug Application (NDA) if the Phase 3 clinical study commences and is successful.

Bayer and Nektar have been working together to prepare for Phase 3 clinical studies of BAY41-6551 following the consummation of the collaboration in August 2007. The program is significantly behind schedule. The reason for this is that Bayer and Nektar decided to finalize the design of the device for commercial

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manufacturing prior to initiating Phase 3 clinical development with the objective of commencing Phase 3 clinical trials as soon as possible following completion of this work. Please refer to Item 1A, Risk Factors, "If we or our partners are not able to manufacture drugs or drug substances in quantities and at costs that are commercially feasible, we may fail to meet our contractual obligations or our proprietary and partnered product candidates may experience clinical delays or constrained commercial supply which could significantly harm our business."

***NKTR-181 (mu-opioid analgesic molecule for chronic pain)***

NKTR-181 is an orally-available mu-opioid drug candidate in development as a long-acting analgesic to treat chronic pain. NKTR-181 is designed with the objective to address the abuse liability and serious central nervous system (CNS) side effects associated with current opioid therapies. NKTR-181 is a novel mu-opioid analgesic molecule created using Nektar's proprietary polymer conjugate technology, which provides it with a long-acting profile and slows its entry into the CNS. Its potential differentiating properties are inherent to the design of the new molecule and as a new molecular structure, NKTR-181 does not rely on a formulation approach to prevent its conversion into a more abusable form of an opioid.

In 2011, we completed two separate Phase 1 clinical studies of NKTR-181. The first study, a single-ascending dose study of NKTR-181 evaluated the pharmacokinetics and pharmacodynamics of a 50-fold range of single oral doses of NKTR-181 in 84 healthy subjects at up to 500 mg dose levels. The second study, a multiple-ascending dose study of NKTR-181 evaluated the pharmacokinetics and pharmacodynamics of four separate dose cohorts of NKTR-181 (100 mg – 400 mg) administered orally twice-daily. The study enrolled a total of 60 healthy subjects over an eight-day treatment period, and included a placebo arm (n=3) for each dose cohort. Measurements in the study include plasma concentrations-time profiles, reductions in pupil diameter, and a cold pressor test, a model of pain used in healthy subjects to measure central analgesic activity. In this multiple dose Phase 1 clinical study, NKTR-181 exhibited a sustained analgesic response, which we believe supports its future development as a twice-daily oral tablet for the treatment of chronic pain conditions. Pupillometry data from the study demonstrated that NKTR-181's centrally-mediated opioid effects are dose-dependent and indicates that the molecule enters the brain slowly, which has the potential to reduce the euphoria and other CNS side effects that are associated with current opioids. NKTR-181 was also well-tolerated at all doses evaluated in both studies. The Phase 2 clinical program is planned to begin in mid-2012 and will include a randomized, double-blind, efficacy and safety study of NKTR-181 as compared to placebo in patients with chronic pain.

According to a 2011 report from the National Academy of Sciences, chronic pain conditions, such as osteoarthritis, back pain and cancer pain, affect at least 126 million adults in the U.S. annually and contribute to over \$100 billion a year in lost productivity. Opioids are considered to be the most effective therapeutic option for pain. However, opioids cause significant problems for physicians and patients because of their serious side effects such as respiratory depression and sedation, as well as the risks they pose for addiction, abuse, misuse, and diversion. The FDA has cited prescription opioid analgesics as being at the center of a major public health crisis of addiction, misuse, abuse, overdose and death. A 2010 report from the Center for Disease Control and Prevention (CDC) notes that emergency room visits tied to the abuse of prescription painkillers is at an all-time high, having increased 111 percent over a 5-year period.

***NKTR-192 (mu-opioid analgesic molecule for acute pain)***

NKTR-192 is an orally-available mu-opioid analgesic molecule in preclinical development that is intended to be a short-acting analgesic to treat acute pain. NKTR-192 is also designed to address the abuse liability and serious central nervous system (CNS) side effects associated with current opioid therapies. NKTR-192 is also designed to have slow entry into the CNS. Its differentiating properties are inherent to the design of the new molecule and as a new molecular structure, NKTR-192 does not rely on a formulation approach to prevent its conversion into a more abusable form of an opioid. NKTR-192 completed preclinical work in 2011 and we plan to begin a Phase 1 clinical study in 2012 following submission of an investigational new drug application (IND)

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and the expiration or completion of the FDA review period and our resolution of any issues raised by the FDA, if any, prior to the IND becoming effective.

**Overview of Select Technology Licensing Collaborations and Programs**

We have a number of product candidates in clinical development and approved products in collaboration with our partners that use our technology or involve rights over which we have patents or other proprietary intellectual property. In a typical collaboration involving our PEGylation technology, we license our proprietary intellectual property related to our PEGylation technology or proprietary conjugated drug molecules in consideration for upfront payments, development milestone payments and royalties from sales of the resulting commercial product as well as sales milestones. In certain cases, we also manufacture and supply our proprietary PEGylation materials to our partners.

***Peginesatide, Agreement with Affymax, Inc.***

In April 2004, we entered into a license, manufacturing and supply agreement with Affymax, Inc. (Affymax), under which we granted Affymax a worldwide, non-exclusive license to certain of our proprietary PEGylation technology to develop, manufacture and commercialize peginesatide. Peginesatide is a synthetic PEGylated peptidic compound that binds to and stimulates the erythropoietin receptor and thus acts as an erythropoietin stimulating agent (ESA). The compound was discovered by Affymax and is being co-developed by Affymax and Takeda Pharmaceutical Company Limited. In May 2011, Affymax filed a NDA with the FDA for peginesatide to treat anemia in patients with chronic kidney disease (CKD) on dialysis. If approved, peginesatide may be the first once-monthly ESA for anemia in CKD for dialysis patients available in the U.S. In December 2011, the FDA Oncologic Drugs Advisory Committee (ODAC) voted 15 to 1, with 1 abstention, that peginesatide demonstrated a favorable benefit/risk profile for use in the treatment of dialysis patients with anemia due to CKD. While the FDA is not bound by the recommendation of ODAC, its guidance will be considered by the FDA in its review of the NDA. The scheduled Prescription Drug User Fee Act (PDUFA) date for peginesatide is March 27, 2012. The FDA endeavors to complete its review of NDAs by the PDUFA date but does not always do so and the FDA's decision regarding a NDA can be delayed significantly beyond the original PDUFA date through various regulatory delays or regulatory actions.

We currently manufacture our proprietary PEGylation materials for Affymax on a fixed price basis subject to annual adjustments. Affymax has an option to convert this manufacturing pricing arrangement to cost plus at any time prior to the date the NDA for peginesatide is submitted to the FDA. In addition, Affymax is responsible for all clinical development, regulatory and commercialization expenses and we are entitled to development milestones and royalties on net sales of peginesatide. We will share a portion of our future royalty payments with Enzon Pharmaceuticals, Inc. Our right to receive royalties in any particular country will expire upon the later of ten years after the first commercial sale of the product in that country or the expiration of patent rights in that particular country. The agreement expires on a country-by-country basis upon the expiration of Affymax's royalty obligations. The agreement may also be terminated by either party for the other party's continued material breach after expiration of a cure period or by us in the event that Affymax challenges the validity or enforceability of any patent licensed to them under the agreement.

***LEVADEX<sup>®</sup>, Agreement with MAP Pharmaceuticals***

In June 2004, we entered into a license agreement with MAP Pharmaceuticals, Inc. (MAP) which includes a worldwide, exclusive license, to certain of our patents and other intellectual property rights to develop and commercialize a formulation of dihydroergotamine for administration to patients via the pulmonary or nasal delivery route. In 2006, we amended and restated this agreement. Under the terms of the agreement, we have the right to receive certain milestone payments based on development criteria that are solely the responsibility of MAP and royalties based on net sales of LEVADEX<sup>®</sup>. Our right to receive royalties in any particular country will expire upon the later of (i) 10 years after first commercial sale in that country, (ii) the date upon which the

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licensed know-how becomes known to the general public, and (iii) expiration of certain patent claims, each on a country-by-country basis. Either party may terminate the agreement upon a material, uncured default of the other party. On May 26, 2011, MAP submitted a NDA to the FDA for LEVADEX and the PDUFA date is March 26, 2012. The FDA endeavors to complete its review of NDAs by the PDUFA date but does not always do so and the FDA's decision regarding a NDA can be delayed significantly beyond the original PDUFA date through various regulatory delays or regulatory actions.

***BAX 855 and Long-Acting Therapies for Hemophilia A and Hemophilia B, Agreement with Subsidiaries of Baxter International***

In September 2005, we entered into an exclusive research, development, license, manufacturing and supply agreement with Baxter Healthcare SA and Baxter Healthcare Corporation (Baxter) to develop products with an extended half-life for the treatment and prophylaxis of Hemophilia A patients using our proprietary PEGylation technology. The first product in this collaboration, BAX 855, is a longer-acting (PEGylated) form of a full-length recombinant factor VIII (rFVIII) protein which entered Phase 1 clinical development in late 2011. BAX 855 uses Nektar's proprietary PEGylation technology and is also based on Baxter's ADVATE [Antihemophilic Factor (Recombinant) Plasma/Albumin-Free Method] full-length rFVIII molecule and plasma/albumin-free (PAF) manufacturing process. The Phase 1 trial is a prospective, open-label study that will assess the safety, tolerability and pharmacokinetics of BAX 855 in previously-treated patients aged 12 years or older with severe hemophilia A. When used for prophylaxis, Baxter's ADVATE requires patients to infuse every two to three days to reduce the occurrence of bleeding episodes. This Phase 1 clinical study is the first step in assessing whether BAX 855 can be infused less frequently. If the Phase 1 clinical study is successful, Baxter plans to initiate Phase 3 studies for the program.

In December 2007, we expanded our agreement with Baxter to include the license of our PEGylation technology and proprietary PEGylation methods with the potential to improve the half-life of any future drug products Baxter may develop for the treatment and prophylaxis of Hemophilia B patients. Under the terms of the agreement with Baxter, we are entitled to research and development funding, and we manufacture our proprietary PEGylation materials for Baxter on a cost plus basis. Baxter is responsible for all clinical development, regulatory, and commercialization expenses. In relation to Hemophilia A, we are entitled to up to \$84.0 million in total development and sales milestone payments of which \$8.5 million has been paid to date, as well as royalties on net sales varying by product and country of sale. Our right to receive these royalties in any particular country will expire upon the later of ten years after the first commercial sale of the product in that country or the expiration of patent rights in certain designated countries or in that particular country.

In relation to Hemophilia B and other blood-clotting factor diseases, we are entitled to up to \$44.0 million in development and sales milestone payments of which \$6.0 million has been paid to date, as well as royalties on net sales varying by product and country of sale. Our right to receive these royalties in any particular country will expire upon the later of twelve years after the first commercial sale of the product in that country or the expiration of patent rights in certain designated countries or in that particular country. The agreement expires in relation to a particular product and country upon the expiration of all of Baxter's royalty obligations related to such product and country. The agreement may also be terminated by either party for the other party's material breach or insolvency, provided that such other party has been given a chance to cure or remedy such breach or insolvency. Subject to certain limitations as to time, and possible termination fee payment obligations, Baxter also has the right to terminate the agreement for convenience. We have the right to terminate the agreement or convert Baxter's license from exclusive to non-exclusive in the event Baxter fails to comply with certain diligence obligations.

***Cipro Inhale, Agreement with Bayer Schering Pharma AG Assigned to Novartis as of December 31, 2008***

We were a party to a collaborative research, development and commercialization agreement with Bayer Schering Pharma AG related to the development of an inhaled powder formulation of Ciprofloxacin for the

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treatment of chronic lung infections caused by *Pseudomonas aeruginosa* in cystic fibrosis patients. Cipro Inhale has completed Phase 2 clinical development with Bayer for the treatment of chronic lung infections. As of December 31, 2008, we assigned the agreement to Novartis Pharma AG in connection with the closing of the pulmonary asset sale transaction. We maintain the right to receive certain potential royalties in the future based on net product sales if Cipro Inhale receives regulatory approval and is successfully commercialized.

**Overview of Select Licensing Partnerships for Approved Products**

***Neulasta®*, Agreement with Amgen, Inc.**

In July 1995, we entered into a non-exclusive supply and license agreement (1995 Agreement) with Amgen, Inc., pursuant to which we licensed our proprietary PEGylation technology to be used in the development and manufacture of Neulasta. Neulasta selectively stimulates the production of neutrophils that are depleted by cytotoxic chemotherapy, a condition called neutropenia that makes it more difficult for the body to fight infections. On October 29, 2010, we amended and restated the 1995 Agreement by entering into a supply, dedicated suite and manufacturing guarantee agreement (2010 Agreement) and an amended and restated license agreement with Amgen Inc. and Amgen Manufacturing, Limited (together referred to as Amgen). Under the terms of the 2010 Agreement, we guarantee the manufacture and supply of our proprietary PEGylation materials (Polymer Materials) to Amgen in an existing manufacturing suite to be used exclusively for the manufacture of Polymer Materials for Amgen in our manufacturing facility in Huntsville, Alabama. This supply arrangement is on a non-exclusive basis (other than the use of the manufacturing suite and certain equipment) whereby we are free to manufacture and supply the Polymer Materials to any other third party and Amgen is free to procure the Polymer Materials from any other third party. Under the terms of the 2010 Agreement, we received a \$50.0 million upfront payment in return for guaranteeing supply of certain quantities of Polymer Materials to Amgen and the Additional Rights described below, and Amgen will pay manufacturing fees calculated based on fixed and variable components applicable to the Polymer Materials ordered by Amgen and delivered by us. Amgen has no minimum purchase commitments. If quantities of the Polymer Materials ordered by Amgen exceed specified quantities (with each specified quantity representing a small portion of the quantity that we historically supplied to Amgen), significant additional payments become payable to us in return for guaranteeing supply of additional quantities of the Polymer Materials.

The term of the Agreement runs through October 29, 2020. In the event we become subject to a bankruptcy or insolvency proceeding, we cease to own or control the manufacturing facility in Huntsville, Alabama, we fail to manufacture and supply the Polymer Materials or certain other events occur, Amgen or its designated third party will have the right to elect, among certain other options, to take title to the dedicated equipment and access the manufacturing facility to operate the manufacturing suite solely for the purpose of manufacturing the Polymer Materials (Additional Rights). Amgen may terminate the 2010 Agreement for convenience or due to an uncured material default by us. Either party may terminate the 2010 Agreement in the event of insolvency or bankruptcy of the other party.

***PEGASYS®*, Agreement with F. Hoffmann-La Roche Ltd**

In February 1997, we entered into a license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche), under which we granted Roche a worldwide, exclusive license to use certain intellectual property related to our PEGylation materials to manufacture and commercialize a certain class of products, of which PEGASYS is the only product currently commercialized. PEGASYS is approved in the U.S., E.U. and other countries for the treatment of Hepatitis C and is designed to help the patient's immune system fight the Hepatitis C virus. As a result of Roche exercising a license extension option in December 2009, beginning in 2010 Roche has the right to manufacture all of its requirements for our proprietary PEGylation materials for PEGASYS and we supply raw materials or perform additional manufacturing, if any, only on a back-up basis. The agreement expires on the later of January 10, 2015 or the expiration of our last relevant patent containing a valid claim.

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***Somavert<sup>®</sup>, Agreement with Pfizer, Inc.***

In January 2000, we entered into a license, manufacturing and supply agreement with Sensus Drug Development Corporation (subsequently acquired by Pharmacia Corp. in 2001 and then acquired by Pfizer, Inc. in 2003), for the PEGylation of Somavert (pegvisomant), a human growth hormone receptor antagonist for the treatment of acromegaly. We currently manufacture our proprietary PEGylation reagent for Pfizer on a price per gram basis. The agreement expires on the later of ten years from the grant of first marketing authorization in the designated territory, which occurred in March 2003, or the expiration of our last relevant patent containing a valid claim. In addition, Pfizer may terminate the agreement if marketing authorization is withdrawn or marketing is no longer feasible due to certain circumstances, and either party may terminate for cause if certain conditions are met.

***PEG-Intron<sup>®</sup>, Agreement with Merck (through its acquisition of Schering-Plough Corporation)***

In February 2000, we entered into a manufacturing and supply agreement with Schering-Plough Corporation (Schering) for the manufacture and supply of our proprietary PEGylation materials to be used by Schering in production of a pegylated recombinant human interferon-alpha (PEG-Intron). PEG-Intron is a treatment for patients with Hepatitis C. Schering was acquired by and become a wholly-owned subsidiary of Merck & Co., Inc. We currently manufacture our proprietary PEGylation materials for Schering on a price per gram basis. In December 2010, the parties amended the manufacturing and supply agreement to provide for a transition plan to an alternative manufacturer and extension of the term through the successful manufacturing transition or December 31, 2018 at the latest. The amended agreement provided for a one-time payment and milestone payments as well as increased pricing for any future manufacturing performed by us.

***Macugen<sup>®</sup>, Agreement with Eyetech, Inc.***

In 2002, we entered into a license, manufacturing and supply agreement with Eyetech, Inc. (Eyetech), pursuant to which we license certain intellectual property related to our proprietary PEGylation technology for the development and commercialization of Macugen<sup>®</sup>, a PEGylated anti-vascular endothelial growth factor aptamer currently approved in the U.S. and E.U. for age-related macular degeneration. We currently manufacture our proprietary PEGylation materials for Eyetech on a price per gram basis. Under the terms of the agreement, we will receive royalties on net product sales in any particular country for the longer of ten years from the date of the first commercial sale of the product in that country or the duration of patent coverage. We share a portion of the payments received under this agreement with Enzon Pharmaceuticals, Inc. The agreement expires upon the expiration of our last relevant patent containing a valid claim. In addition, Eyetech may terminate the agreement if marketing authorization is withdrawn or marketing is no longer feasible due to certain circumstances, and either party may terminate for cause if certain conditions are met.

***CIMZIA<sup>®</sup>, Agreement with UCB Pharma***

In December 2000, we entered into a license, manufacturing and supply agreement for CIMZIA<sup>®</sup> (certolizumab pegol) with Celltech Chiroscience Ltd., which was acquired by UCB Pharma (UCB) in 2004. Under the terms of the agreement, UCB is responsible for all clinical development, regulatory, and commercialization expenses. We have the right to receive manufacturing revenue on the basis of a fixed price per gram. We were also entitled to receive royalties on net sales of the CIMZIA<sup>®</sup> product for the longer of ten years from the first commercial sale of the product anywhere in the world or the expiration of patent rights in a particular country. In February 2012, we sold our rights to receive royalties on future worldwide net sales of CIMZIA<sup>®</sup> effective as of January 1, 2012 until the agreement with UCB is terminated or expires. This sale is further discussed in Note 14 of Item 8, Financial Statements and Supplementary Data. We share a portion of the payments we receive from UCB with Enzon Pharmaceuticals, Inc. The agreement expires upon the expiration of all of UCB's royalty obligations, provided that the agreement can be extended for successive two year renewal.

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periods upon mutual agreement of the parties. In addition, UCB may terminate the agreement should it cease the development and marketing of CIMZIA<sup>®</sup> and either party may terminate for cause under certain conditions.

***MIRCERA<sup>®</sup> (C.E.R.A.) (Continuous Erythropoietin Receptor Activator), Agreement with F. Hoffmann-La Roche Ltd***

In December 2000, we entered into a license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche), which was amended and restated in its entirety in December 2005. Pursuant to the agreement, we license our intellectual property related to our proprietary PEGylation materials for the manufacture and commercialization of Roche's MIRCERA<sup>®</sup> product. As of the end of 2006, we were no longer required to manufacture and supply our proprietary PEGylation materials for MIRCERA<sup>®</sup>, however, in February 2012, we entered into a new supply arrangement with Roche under which we agreed to resume manufacture of our proprietary PEGylation materials for MIRCERA on a non-exclusive basis for a specified time period. MIRCERA<sup>®</sup> is a novel continuous erythropoietin receptor activator indicated for the treatment of anemia associated with chronic kidney disease in patients on dialysis and patients not on dialysis. We were entitled to receive royalties on net sales of the MIRCERA<sup>®</sup> product in any particular country for the longer of ten years from the first commercial sale of the product in that country or the expiration of patent rights in that particular country. In February 2012, we sold our rights to receive royalties on future worldwide net sales of MIRCERA<sup>®</sup> effective as of January 1, 2012 until the agreement with Roche is terminated or expires. This sale is further discussed in Note 14 of Item 8, Financial Statements and Supplementary Data. The agreement expires upon the expiration of all of Roche's royalty obligations, unless earlier terminated by Roche for convenience or by either party for cause under certain conditions.

**Significant Developments in our Business that Occurred in 2008**

***Exit from the Inhaled Insulin Programs***

In 1995, we entered into a collaborative development and licensing agreement with Pfizer to develop and market Exubera<sup>®</sup> and, in 2006 and 2007, we entered into a series of interim letter agreements with Pfizer to develop a next generation form of dry powder inhaled insulin and proprietary inhaler device, also known as NGI. In January 2006, Exubera received marketing approval in the U.S. and EU for the treatment of adults with Type 1 and Type 2 diabetes. Under the collaborative development and licensing agreement, Pfizer had sole responsibility for marketing and selling Exubera. We performed all of the manufacturing of the Exubera dry powder insulin, and we supplied Pfizer with the Exubera inhalers through third party contract manufacturers (Bespak Europe Ltd. and Tech Group North America, Inc.). We recorded no revenue from Pfizer related to these activities for the years ended December 31, 2011, 2010, 2009, and 2008.

On October 18, 2007, Pfizer announced that it was exiting the Exubera business and gave notice of termination under our collaborative development and licensing agreement. On November 9, 2007, we entered into a termination agreement and mutual release with Pfizer. Under this agreement we received a one-time payment of \$135.0 million in November 2007 from Pfizer in satisfaction of all outstanding contractual obligations under our then-existing agreements relating to Exubera and NGI. All agreements between Pfizer and us related to Exubera and NGI, other than the termination agreement and mutual release and a related interim Exubera manufacturing maintenance letter, terminated on November 9, 2007. In February 2008, we entered into a termination agreement with Bespak and Tech Group pursuant to which we paid an aggregate of \$40.2 million in satisfaction of outstanding accounts payable and termination costs and expenses that were due under the Exubera inhaler contract manufacturing agreement. We also entered into a maintenance agreement with both Pfizer and Tech Group to preserve key personnel and manufacturing capacity to support potential future Exubera inhaler manufacturing if we found a new partner for the inhaled insulin program.

On April 9, 2008, we announced that we had ceased all negotiations with potential partners for Exubera and NGI as a result of new data analysis from ongoing clinical trials conducted by Pfizer which indicated an increase in the number of new cases of lung cancer in Exubera patients who were former smokers as compared to patients



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in the control group who were not former smokers. In April 2008, we ceased all spending associated with maintaining Exubera manufacturing capacity and any further NGI development, including, but not limited to, terminating the Exubera manufacturing capacity maintenance arrangements with Pfizer and Tech Group.

### ***Asset Sale to Novartis***

On December 31, 2008, we completed the sale of certain assets related to our pulmonary business, associated technology and intellectual property to Novartis Pharma AG and Novartis Pharmaceuticals Corporation (together referred to as Novartis) for a purchase price of \$115.0 million in cash (Novartis Pulmonary Asset Sale). Under the terms of the transaction, we transferred to Novartis certain assets and obligations related to our pulmonary technology, development and manufacturing operations including:

dry powder and liquid pulmonary technology platform including but not limited to our pulmonary inhalation devices, formulation technology, manufacturing technology and related intellectual property;

capital equipment, information systems and facility lease obligations for our pulmonary development and manufacturing facility in San Carlos, California;

manufacturing and associated development services payments for the Cipro Inhale program;

manufacturing and royalty rights to the Tobramycin Inhalation Powder (TIP) program through the termination of our collaboration agreement with Novartis;

certain other interests that we had in two private companies; and

approximately 140 of our personnel primarily dedicated to our pulmonary technology, development programs, and manufacturing operations.

In addition, we retained all of our rights to BAY41-6551, partnered with Bayer Healthcare LLC, certain royalty rights for the Cipro Inhale development program partnered with Bayer Schering Pharma AG, and certain intellectual property rights specific to inhaled insulin.

In connection with the Novartis Pulmonary Asset Sale, we also entered into an Exclusive License Agreement with Novartis Pharma. Pursuant to the Exclusive License Agreement, Novartis Pharma granted back to us an exclusive, irrevocable, perpetual, non-transferable, royalty-free and worldwide license under certain specific patent rights and other related intellectual property rights acquired by Novartis Pharma from Nektar in the transaction, as well as certain improvements or modifications thereto that are made by Novartis Pharma after the closing. Certain of such patent rights and other related intellectual property rights relate to our development program for inhaled vancomycin or are necessary for us to satisfy certain of our continuing contractual obligations to third parties, including in connection with development, manufacture, sale, and commercialization activities related to BAY41-6551. We also entered into a service agreement pursuant to which we have subcontracted to Novartis certain services to be performed related to our partnered program for BAY41-6551 and a transition services agreement pursuant to which Novartis and we will provide each other with specified services for limited time periods following the closing of the Novartis Pulmonary Asset Sale to facilitate the transition of the acquired assets and business from us to Novartis.

### **Government Regulation**

The research and development, clinical testing, manufacture and marketing of products using our technologies are subject to regulation by the FDA and by comparable regulatory agencies in other countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing (in vitro, in animals, and in human clinical trials), manufacture, labeling, storage, recordkeeping, approval, marketing, advertising and promotion of our products.

## Edgar Filing: NEKTAR THERAPEUTICS - Form 10-K

The approval process required by the FDA before a product using any of our technologies may be marketed in the U.S. depends on whether the chemical composition of the product has previously been approved for use in

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other dosage forms. If the product is a new chemical entity that has not been previously approved, the process includes the following:

extensive preclinical laboratory and animal testing;

submission of an Investigational New Drug application (IND) prior to commencing clinical trials;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for the intended indication; and

submission to the FDA of an NDA for approval of a drug, a BLA for approval of a biological product or a Premarket Approval Application (PMA) or Premarket Notification 510(k) for a medical device product (a 510(k)).

If the active chemical ingredient has been previously approved by the FDA, the approval process is similar, except that certain preclinical tests relating to systemic toxicity normally required for the IND and NDA or BLA may not be necessary if the company has a right of reference to such data or is eligible for approval under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or the biosimilars provisions of the Public Health Services Act.

Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the safety and efficacy of the product and its chosen formulation. Preclinical safety tests must be conducted by laboratories that comply with FDA good laboratory practices (GLP) regulations. The results of the preclinical tests for drugs, biological products and combination products subject to the primary jurisdiction of the FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) are submitted to the FDA as part of the IND and are reviewed by the FDA before clinical trials can begin. Clinical trials may begin 30 days after receipt of the IND by the FDA, unless the FDA raises objections or requires clarification within that period.

Clinical trials involve the administration of the drug to healthy volunteers or patients under the supervision of a qualified, identified medical investigator according to a protocol submitted in the IND for FDA review. Drug products to be used in clinical trials must be manufactured according to current good manufacturing practices (cGMP). Clinical trials are conducted in accordance with protocols that detail the objectives of the study and the parameters to be used to monitor participant safety and product efficacy as well as other criteria to be evaluated in the study. Each protocol is submitted to the FDA in the IND.

Apart from the IND process described above, each clinical study must be reviewed by an independent Institutional Review Board (IRB) and the IRB must be kept current with respect to the status of the clinical study. The IRB considers, among other things, ethical factors, the potential risks to subjects participating in the trial and the possible liability to the institution where the trial is conducted. The IRB also reviews and approves the informed consent form to be signed by the trial participants and any significant changes in the clinical study.

Clinical trials are typically conducted in three sequential phases. Phase 1 involves the initial introduction of the drug into healthy human subjects (in most cases) and the product generally is tested for tolerability, pharmacokinetics, absorption, metabolism and excretion. Phase 2 involves studies in a limited patient population to:

determine the preliminary efficacy of the product for specific targeted indications;

determine dosage and regimen of administration; and

identify possible adverse effects and safety risks.

If Phase 2 trials demonstrate that a product appears to be effective and to have an acceptable safety profile, Phase 3 trials are undertaken to evaluate the further clinical efficacy and safety of the drug and formulation



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within an expanded patient population at geographically dispersed clinical study sites and in large enough trials to provide statistical proof of efficacy and tolerability. The FDA, the clinical trial sponsor, the investigators or the IRB may suspend clinical trials at any time if any one of them believes that study participants are being subjected to an unacceptable health risk. In some cases, the FDA and the drug sponsor may determine that Phase 2 trials are not needed prior to entering Phase 3 trials.

Following a series of formal meetings and communications between the drug sponsor and the regulatory agencies, the results of product development, preclinical studies and clinical studies are submitted to the FDA as an NDA or BLA for approval of the marketing and commercial shipment of the drug product. The FDA may deny approval if applicable regulatory criteria are not satisfied or may require additional clinical or pharmaceutical testing or requirements. Even if such data are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy all of the criteria for approval. Additionally, the approved labeling may narrowly limit the conditions of use of the product, including the intended uses, or impose warnings, precautions or contraindications which could significantly limit the potential market for the product. Further, as a condition of approval, the FDA may impose post-market surveillance, or Phase 4, studies or risk evaluation and mitigation strategies. Product approvals, once obtained, may be withdrawn if compliance with regulatory standards is not maintained or if safety concerns arise after the product reaches the market. The FDA may require additional post-marketing clinical testing and pharmacovigilance programs to monitor the effect of drug products that have been commercialized and has the power to prevent or limit future marketing of the product based on the results of such programs. After approval, there are ongoing reporting obligations concerning adverse reactions associated with the product, including expedited reports for serious and unexpected adverse events.

Each manufacturing establishment producing drug product for the U.S. market must be registered with the FDA and typically is inspected by the FDA prior to NDA or BLA approval of a drug product manufactured by such establishment. Establishments handling controlled substances must also be licensed by the U.S. Drug Enforcement Administration. Manufacturing establishments of U.S. marketed products are subject to inspections by the FDA for compliance with cGMP and other U.S. regulatory requirements. They are also subject to U.S. federal, state, and local regulations regarding workplace safety, environmental protection and hazardous and controlled substance controls, among others.

A number of the drugs we are developing are already approved for marketing by the FDA in another form or using another delivery system. We believe that, when working with drugs approved in other forms, the approval process for products using our alternative drug delivery or formulation technologies may involve less risk and require fewer tests than new chemical entities do. However, we expect that our formulations will often use excipients not currently approved for use. Use of these excipients will require additional toxicological testing that may increase the costs of, or length of time needed to, gain regulatory approval. In addition, as they relate to our products, regulatory procedures may change as regulators gain relevant experience, and any such changes may delay or increase the cost of regulatory approvals.

For product candidates currently under development utilizing pulmonary technology, the pulmonary inhaler devices are considered to be part of a drug and device combination for deep lung delivery of each specific molecule. The FDA will make a determination as to the most appropriate center and division within the agency that will assume primary responsibility for the review of the applicable applications, which would consist of an IND and an NDA or BLA where CDER or CBER are determined to have primary jurisdiction or an investigational device exemption application and PMA or 510(k) where the Center for Devices and Radiological Health (CDRH) is determined to have primary jurisdiction. In the case of our product candidates, CDER in consultation with CDRH could be involved in the review. The assessment of jurisdiction within the FDA is based upon the primary mode of action of the drug or the location of the specific expertise in one of the centers.

Where CDRH is determined to have primary jurisdiction over a product, 510(k) clearance or PMA approval is required. Medical devices are classified into one of three classes – Class I, Class II, or Class III – depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and

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effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a Premarket Notification requesting permission to commercially distribute the device. This process is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in Class III, requiring PMA approval.

To date, our partners have generally been responsible for clinical and regulatory approval procedures, but we may participate in this process by submitting to the FDA a drug master file developed and maintained by us which contains data concerning the manufacturing processes for the inhaler device or drug. For our proprietary products, we prepare and submit an IND and are responsible for additional clinical and regulatory procedures for product candidates being developed under an IND. The clinical and manufacturing, development and regulatory review and approval process generally takes a number of years and requires the expenditure of substantial resources. Our ability to manufacture and market products, whether developed by us or under collaboration agreements, ultimately depends upon the completion of satisfactory clinical trials and success in obtaining marketing approvals from the FDA and equivalent foreign health authorities.

Sales of our products outside the U.S. are subject to local regulatory requirements governing clinical trials and marketing approval for drugs. Such requirements vary widely from country to country.

In the U.S., 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 U.S. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. In addition, the Orphan Drug Act provides for protocol assistance, tax credits, research grants, and exclusions from user fees for sponsors of orphan products. Once a product receives orphan drug exclusivity, a second product that is considered to be the same drug for the same indication may be approved during the exclusivity period only if the second product is shown to be clinically superior to the original orphan drug in that it is more effective, safer or otherwise makes a major contribution to patient care or the holder of exclusive approval cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similar incentives also are available for orphan drugs in the E.U.

In the U.S., the FDA may grant Fast Track designation to a product candidate, which allows the FDA to expedite the review of new drugs that are intended for serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. An important feature of Fast Track designation is that it emphasizes the critical nature of close, early communication between the FDA and the sponsor company to improve the efficiency of product development.

## **Patents and Proprietary Rights**

We invest a significant portion of our resources in the creation and development of new drug compounds that serve unmet needs in the treatment of patients. In doing so, we create intellectual property. As part of our strategy to secure our intellectual property created by these efforts, we routinely apply for patents, rely on trade secret protection, and enter into contractual obligations with third parties. When appropriate, we will defend our intellectual property, taking any and all legal remedies available to us, including, for example, asserting patent infringement, trade secret misappropriation and breach of contract claims. As of January 1, 2012, we owned greater than 120 U.S. and 420 foreign patents. Currently, we have over approximately 110 patent applications pending in the U.S. and 550 pending in other countries.

A focus area of our current drug creation and development efforts centers on our innovations in and improvements to our PEGylation and advanced polymer conjugate technology platforms. In this area, our patent

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portfolio contains patents and patent applications that encompass our PEGylation and advanced polymer conjugate technology platforms, some of which we acquired in our acquisition of Shearwater Corporation in June 2001. More specifically, our patents and patent applications cover polymer architecture, drug conjugates, formulations, methods of making polymers and polymer conjugates, and methods of administering polymer conjugates. Our patent strategy is to file patent applications on innovations and improvements to cover a significant majority of the major pharmaceutical markets in the world. Generally, patents have a term of twenty years from the earliest priority date (assuming all maintenance fees are paid). In some instances, patent terms can be increased or decreased, depending on the laws and regulations of the country or jurisdiction that issued the patent.

In January 2002, we entered into a Cross-License and Option Agreement with Enzon Pharmaceuticals, Inc., pursuant to which we and Enzon provided certain licenses to selected portions of each party's PEGylation patent portfolio. In certain cases, we have the option to license certain of Enzon's PEGylation patents for use in our proprietary products or for sublicenses to third parties in each case in exchange for payments to Enzon based on manufacturing profits, revenue share or royalties on net sales if a designated product candidate is approved in one or more markets.

In connection with the Novartis Pulmonary Asset Sale, as of December 31, 2008, we entered into an exclusive license agreement with Novartis Pharma. Pursuant to the exclusive license agreement, Novartis Pharma grants back to us an exclusive, irrevocable, perpetual, royalty-free and worldwide license under certain specific patent rights and other related intellectual property rights acquired by Novartis from us in the Novartis Pulmonary Asset Sale, as well as certain improvements or modifications thereto that are made by Novartis. Certain of such patent rights and other related intellectual property rights relate to our development program for inhaled vancomycin or are necessary for us to satisfy certain continuing contractual obligations to third parties, including in connection with development, manufacture, sale, and commercialization activities related to BAY41-6551 partnered with Bayer Healthcare LLC.

The patent positions of pharmaceutical and biotechnology companies, including ours, involve complex legal and factual issues. There can be no assurance that the patents we apply for will be issued to us or that the patents that are issued to us will be held valid and enforceable in a court of law. Even for patents that are enforceable, we anticipate that any attempt to enforce our patents would be time consuming and costly. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, we do not know whether any of our pending patent applications will be granted with broad coverage or whether the claims that eventually issue, or those that have issued, will be circumvented. Since publication of discoveries in scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications or that we were the first to file patent applications for such inventions. Moreover, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office, which could result in substantial cost to us, even if the eventual outcome is favorable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. Please refer to Item 1A, Risk Factors, including but not limited to "We may not be able to obtain intellectual property licenses related to the development of our technology on a commercially reasonable basis, if at all," and "If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection."

U.S. and foreign patent rights and other proprietary rights exist that are owned by third parties and relate to pharmaceutical compositions and reagents, medical devices and equipment and methods for preparation, packaging and delivery of pharmaceutical compositions. We cannot predict with any certainty which, if any, of these rights will be considered relevant to our technology by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. We could incur substantial costs in defending ourselves and our partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could

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effectively block our ability to develop or commercialize some or all of our products in the U.S. and abroad and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from third parties. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternative technology. The failure to obtain licenses if needed may have a material adverse effect on our business, results of operations and financial condition.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that we can meaningfully protect our trade secrets. Others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to, or disclose, our trade secrets. Please refer to Item 1A, Risk Factors, including but not limited to We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.

In certain situations in which we work with drugs covered by one or more patents, our ability to develop and commercialize our technologies may be affected by limitations in our access to these proprietary drugs. Even if we believe we are free to work with a proprietary drug, we cannot guarantee that we will not be accused of, or determined to be, infringing a third party's rights and be prohibited from working with the drug or found liable for damages. Any such restriction on access or liability for damages would have a material adverse effect on our business, results of operations and financial condition.

It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

## **Customer Concentrations**

Our revenue is derived from our collaboration agreements with partners, under which we may receive contract research payments, milestone payments based on clinical progress, regulatory progress or net sales achievements, royalties or manufacturing revenue. UCB Pharma and Roche, represented 27% and 16% of our revenue, respectively, for the year ended December 31, 2011. No other collaboration partner accounted for more than 10% of our total revenue during the year ended December 31, 2011.

## **Backlog**

Pursuant to our collaboration agreements, we manufacture and supply our proprietary PEGylation materials, inventory is produced and sales are made pursuant to customer purchase orders for delivery. The volume of our proprietary PEGylation materials actually ordered by our customers, as well as shipment schedules, are subject to frequent revisions that reflect changes in both the customers' needs and our manufacturing capacity. In our partnered programs where we provide contract research services, those services are typically provided under a work plan that is subject to frequent revisions that change based on the development needs and status of the program. The backlog at a particular time is affected by a number of factors, including scheduled date of manufacture and delivery and development program status. In light of industry practice and our own experience, we do not believe that backlog as of any particular date is indicative of future results.

## **Competition**

Competition in the pharmaceutical and biotechnology industry is intense and characterized by aggressive research and development and rapidly-evolving science, technology, and standards of medical care throughout



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the world. We frequently compete with pharmaceutical companies and other institutions with greater financial, research and development, marketing and sales, manufacturing and managerial capabilities. We face competition from these companies not just in product development but also in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies.

### ***Science and Technology Competition***

We believe that our proprietary and partnered products will compete with others in the market on the basis of one or more of the following parameters: efficacy, safety, ease of use and cost. We face intense science and technology competition from a multitude of technologies seeking to enhance the efficacy, safety and ease of use of approved drugs and new drug molecule candidates. A number of the drug candidates in our pipeline have direct and indirect competition from large pharmaceutical companies and biopharmaceutical companies. With our PEGylation and advanced polymer conjugate technologies, we believe we have competitive advantages relating to factors such as efficacy, safety, ease of use and cost for certain applications and molecules. We constantly monitor scientific and medical developments in order to improve our current technologies, seek licensing opportunities where appropriate, and determine the best applications for our technology platforms.

In the fields of PEGylation and advanced polymer conjugate technologies, our competitors include Dr. Reddy's Laboratories, Enzon Pharmaceuticals, Inc., Mountain View Pharmaceuticals, Inc., SunBio Corporation, NOF Corporation, and Novo Nordisk A/S (formerly assets held by Neose Technologies, Inc.). Several other chemical, biotechnology and pharmaceutical companies may also be developing PEGylation technology, advanced polymer conjugate technology or technologies intended to deliver similar scientific and medical benefits. Some of these companies license intellectual property or pegylation materials to other companies, while others apply the technology to create their own drug candidates.

### ***Product and Program Specific Competition***

#### ***NKTR-118 (orally-available peripheral opioid antagonist)***

There are no oral drugs approved specifically for the treatment of opioid-induced constipation (OIC) or opioid bowel dysfunction (OBD). The only approved treatment for OIC is a subcutaneous treatment known as methylnaltrexone bromide marketed by Salix Pharmaceuticals, Ltd under a license from Progenics Pharmaceuticals, Inc. Methylnaltrexone bromide is indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. On December 20, 2011, Salix and Progenics announced positive results from a Phase 3 clinical study of oral methylnaltrexone in chronic, non-cancer pain patients with opioid-induced constipation. Other therapies used to treat OIC and OBD include over-the-counter laxatives and stool softeners, such as docusate sodium, senna, and milk of magnesia. These therapies do not address the underlying cause of constipation as a result of opioid use and are generally viewed as ineffective or only partially effective to treat the symptoms of OIC and OBD.

There are a number of companies developing potential products which are in various stages of clinical development and are being evaluated for the treatment of OIC and OBD in different patient populations. Potential competitors include Progenics Pharmaceuticals, Inc. in collaboration with Salix Pharmaceuticals, Ltd., Adolor Corporation, GlaxoSmithKline, Ironwood Pharmaceuticals, Inc. in collaboration with Forest Laboratories, Mundipharma Int. Limited, Theravance, Inc., Sucampo Pharmaceuticals, Alkermes, Inc. and Takeda Pharmaceutical Company Limited.

#### ***NKTR-102 (next-generation topoisomerase I inhibitor)***

There are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for breast and ovarian cancers including but not limited to: Avastin® (bevacizumab), Navalbine®

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(vinorelbine), Ixempra® (ixabepilone), Ellence® (epirubicin), Gemzar® (gemcitabine), Herceptin® (trastuzumab), Hycamtin® (topotecan), Halaven® (eribulin), Paraplatin® (carboplatin), and Taxol® (paclitaxel). These therapies are only partially effective in treating breast and ovarian cancer. Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for these cancers include Bristol-Meyers Squibb, Eisai, Inc., Roche Holding Group (including its Genentech subsidiary), GlaxoSmithKline plc, Pfizer, Inc., Eli Lilly & Co., and many others. There are currently no drugs in Phase 3 development to specifically treat metastatic breast cancer following anthracycline, taxane and capecitabine therapy in either the adjuvant or metastatic setting.

There are also a number of chemotherapies and cancer therapies approved today and in clinical development for the treatment of colorectal cancer. Approved therapies for the treatment of colorectal cancer include Eloxatin® (oxaliplatin), Camptosar® (irinotecan), Avastin® (bevacizumab), Erbitux® (cetuximab), Vectibi® (panitumumab), Xeloda® (capecitabine), Adrucil® (fluorouracil), and Wellcovorin® (leucovorin). These therapies are only partially effective in treating the disease. There are a number of drugs in various stages of preclinical and clinical development from companies exploring cancer therapies or improved chemotherapeutic agents to potentially treat colorectal cancer. If these drugs are approved, they could be competitive with NKTR-102 if it is approved by government health authorities. These include products in development from Bristol-Myers Squibb Company, Pfizer, Inc., GlaxoSmithKline plc, Antigenics, Inc., F. Hoffman-La Roche Ltd, Novartis AG, Cell Therapeutics, Inc., Neopharm Inc., Mediatech Research Ltd, Alchemia Limited, and many others.

***BAY41-6551 (Amikacin Inhale, formerly NKTR-061)***

There are currently no approved drugs on the market for adjunctive treatment or prevention of Gram-negative pneumonias in mechanically ventilated patients which are also administered via the pulmonary route. The current standard of care includes approved intravenous antibiotics which are partially effective for the treatment of either hospital-acquired pneumonia or ventilator-associated pneumonia in patients on mechanical ventilators. These drugs include drugs that fall into the categories of antipseudomonal cephalosporins, antipseudomonal carbapenems, beta-lactam/beta-lactamase inhibitors, antipseudomonal fluoroquinolones, such as ciprofloxacin or levofloxacin, and aminoglycosides, such as amikacin, gentamycin or tobramycin.

**Research and Development**

Our total research and development expenditures can be disaggregated into the following significant types of expenses (in millions):

	Years Ended December 31,		
	2011	2010	2009
Salaries and employee benefits	\$ 43.8	\$ 37.8	\$ 29.4
Stock compensation expense	7.9	7.2	3.4
Facility and equipment	12.9	13.0	9.9
Outside services, including Contract Research Organizations	43.0	33.4	38.9
Supplies, including clinical trial materials	14.9	13.1	10.4
Travel, lodging and meals	3.1	2.5	1.7
Other	1.0	1.1	1.4
Research and development expense	\$ 126.8	\$ 108.1	\$ 95.1

**Manufacturing and Supply**

We have a manufacturing facility located in Huntsville, Alabama that is capable of manufacturing PEGylated derivatives and starting materials for active pharmaceutical ingredients (APIs). The facility is also used to produce APIs to support the early phases of clinical development of our proprietary drug candidates. The facility and associated equipment are designed and operated to be consistent with the all applicable laws and regulations.

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As we do not maintain the capability to manufacture finished drug products, we utilize contract manufacturers to manufacture the finished drug product for us. We source drug starting materials for our manufacturing activities from one or more suppliers. For the drug starting materials necessary for our proprietary drug candidate development, we have agreements for the supply of such drug components with drug manufacturers or suppliers that we believe have sufficient capacity to meet our demands. However, from time to time, we source critical raw materials and services from one or a limited number of suppliers and there is a risk that if such supply or services were interrupted, it would materially harm our business. In addition, we typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

## **Environment**

As a manufacturer of PEG reagents for the U.S. market, we are subject to inspections by the FDA for compliance with cGMP and other U.S. regulatory requirements, including U.S. federal, state and local regulations regarding environmental protection and hazardous and controlled substance controls, among others. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We have incurred, and may continue to incur, significant expenditures to ensure we are in compliance with these laws and regulations. We would be subject to significant penalties for failure to comply with these laws and regulations.

## **Employees and Consultants**

As of December 31, 2011, we had 423 employees, of which 315 employees were engaged in research and development, commercial operations and quality activities and 108 employees were engaged in general administration and business development. Of the 423 employees, 342 were located in the United States and 81 were located in India. We have a number of employees who hold advanced degrees, such as Ph.D.s. None of our employees are covered by a collective bargaining agreement, and we have experienced no work stoppages. We believe that we maintain good relations with our employees.

To complement our own expert professional staff, we utilize specialists in regulatory affairs, process engineering, manufacturing, quality assurance, clinical development and business development. These individuals include certain of our scientific advisors as well as independent consultants.

## **Available Information**

Our website address is <http://www.nektar.com>. The information in, or that can be accessed through, our website is not part of this annual report on Form 10-K. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports are available, free of charge, on or through our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission (SEC). The public may read and copy any materials we file with the SEC 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 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding our filings at [www.sec.gov](http://www.sec.gov).

**Table of Contents****EXECUTIVE OFFICERS OF THE REGISTRANT**

The following table sets forth the names, ages and positions of our executive officers as of February 28, 2012:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Howard W. Robin	59	Director, President and Chief Executive Officer
John Nicholson	60	Senior Vice President and Chief Financial Officer
Stephen K. Doberstein, Ph.D.	53	Senior Vice President and Chief Scientific Officer
Gil M. Labrucherie, J.D.	40	Senior Vice President, General Counsel and Secretary
Jillian B. Thomsen	46	Senior Vice President, Finance and Chief Accounting Officer
Rinko Ghosh	48	Senior Vice President and Chief Business Officer

*Howard W. Robin* has served as our President and Chief Executive Officer since January 2007 and has served as a member of our Board of Directors since February 2007. Mr. Robin served as Chief Executive Officer, President and director of Sirna Therapeutics, Inc., a clinical-stage biotechnology company pioneering RNAi-based therapies for serious diseases and conditions, from July 2001 to November 2006 and served as their Chief Operating Officer, President and Director from January 2001 to June 2001. From 1991 to 2001, Mr. Robin was Corporate Vice President and General Manager at Berlex Laboratories, Inc., the U.S. pharmaceutical subsidiary of the German pharmaceutical firm Schering AG, and, from 1987 to 1991, he served as their Vice President of Finance and Business Development and Chief Financial Officer. From 1984 to 1987, Mr. Robin was Director of Business Planning and Development at Berlex and was a Senior Associate with Arthur Andersen LLP prior to joining Berlex. Since February 2006, Mr. Robin has served as a member of the Board of Directors of Acologix, Inc., a biopharmaceutical company focused on therapeutic compounds for the treatment of osteo-renal diseases. He received his B.S. in Accounting and Finance from Fairleigh Dickinson University in 1974.

*John Nicholson* has served as our Senior Vice President and Chief Financial Officer since December 2007. Mr. Nicholson joined the Company as Senior Vice President of Corporate Development and Business Operations in October 2007 and was appointed Senior Vice President and Chief Financial Officer in December 2007. Before joining Nektar, Mr. Nicholson spent 18 years in various executive roles at Schering Berlin, Inc., the U.S. management holding company of Bayer Schering Pharma AG, a pharmaceutical company. From 1997 to September 2007, Mr. Nicholson served as Schering Berlin Inc.'s Vice President of Corporate Development and Treasurer. From 2001 to September 2007, he concurrently served as President of Schering Berlin Insurance Co., and from February 2007 through September 2007, he also concurrently served as President of Bayer Pharma Chemicals and Schering Berlin Capital Corp. Mr. Nicholson holds a B.B.A. from the University of Toledo.

*Stephen K. Doberstein, Ph.D.* has served as our Senior Vice President and Chief Scientific Officer since January 2010. From October 2008 through December 2009, Dr. Doberstein served as Vice President, Research at Xoma (US) LLC, a publicly traded clinical stage biotechnology company. From July 2004 until August 2008, he served as Vice President, Research at privately held Five Prime Therapeutics, a clinical stage biotechnology company. From September 2001 until July 2004, Dr. Doberstein was Vice President, Research at privately held Xencor, Inc., a clinical stage biotechnology company. From 1997 to 2000, he held various pharmaceutical research positions at Exelixis, Inc., a publicly traded clinical stage biotechnology company. Prior to working at Exelixis, Dr. Doberstein was a Howard Hughes Postdoctoral Fellow and a Muscular Dystrophy Association Senior Postdoctoral Fellow at the University of California Berkeley. Dr. Doberstein received his Ph.D. Biochemistry, Cell and Molecular Biology from the Johns Hopkins University School of Medicine and received a B.S. in Chemical Engineering from the University of Delaware.

*Gil M. Labrucherie* has served as our Senior Vice President, General Counsel and Secretary since April 2007, responsible for all aspects of our legal affairs. Mr. Labrucherie served as our Vice President, Corporate

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Legal from October 2005 through April 2007. From October 2000 to September 2005, Mr. Labrucherie was Vice President of Corporate Development at E2open. While at E2open, Mr. Labrucherie was responsible for global corporate alliances and merger and acquisition activity. Prior to E2open, he was the Senior Director of Corporate Development at AltaVista Company, an Internet search company, where he was responsible for strategic partnerships and mergers and acquisitions. Mr. Labrucherie began his career as an associate in the corporate practice of the law firm of Wilson Sonsini Goodrich & Rosati and Graham & James (DLA Piper Rudnick). Mr. Labrucherie received his J.D. from the Berkeley Law School and a B.A. from the University of California Davis.

*Jillian B. Thomsen* has served as our Senior Vice President, Finance and Chief Accounting Officer since February 2010. From March 2006 through March 2008, Ms. Thomsen served as our Vice President Finance and Corporate Controller and from April 2008 through January 2010 she served as our Vice President Finance and Chief Accounting Officer. Before joining Nektar, Ms. Thomsen was Vice President Finance and Deputy Corporate Controller of Calpine Corporation from September 2002 to February 2006. Ms. Thomsen is a certified public accountant and previously was a senior manager at Arthur Andersen LLP, where she worked from 1990 to 2002, and specialized in audits of multinational consumer products, life sciences, manufacturing and energy companies. Ms. Thomsen holds a Masters of Accountancy from the University of Denver and a B.A. in Business Economics from Colorado College.

*Rinko Ghosh* has served as our Senior Vice President and Chief Business Officer since March 2010. He served as our Senior Vice President, Business Development and Alliance Management from March 2008 through February 2010, our Vice President, Business Development from August 2006 until February 2008, Senior Director, Business Development from July 2005 until July 2006, and prior to that he worked in a variety of corporate and business development roles for us from May 2001 to June 2005. From February 2001 to April 2001, he was engaged as a commercial development consultant at Aviron (now Medimmune/AstraZeneca) in Palo Alto. From 1999 to 2000, Mr. Ghosh was co-Chief Executive Officer of a private biotechnology company in Asia. From 1994 to 1999, he was engaged as a management consultant with A.T. Kearney, a global management consulting firm. From 1989 to 1992, he worked as an environmental consultant with Environ Corporation, a human health and environmental consulting firm. Mr. Ghosh earned his M.B.A. from the Wharton School, University of Pennsylvania, his M.S. in Environmental Engineering from Vanderbilt University, and his B.S. in Chemical Engineering from the Indian Institute of Technology, Bombay.

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### **Item 1A. Risk Factors**

We are providing the following cautionary discussion of risk factors, uncertainties and assumptions that we believe are relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results and our forward-looking statements. We note these factors for investors as permitted by Section 21E of the Exchange Act and Section 27A of the Securities Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this section to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations.

### **Risks Related to Our Business**

*Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.*

We have a number of proprietary drug candidates and partnered drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical studies are long, expensive and highly uncertain processes. It will take us, or our collaborative partners, several years to complete clinical studies. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or our own financial constraints.

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of clinical development. Typically, there is a high rate of attrition for drug candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure is increased for our drug candidates that are based on new technologies, such as the application of our advanced polymer conjugate technology to small molecules, including NKTR-118, NKTR-119, NKTR-102, NKTR-181, NKTR-192 and other drug candidates currently in discovery research or preclinical development. The failure of one or more of our drug candidates could have a material adverse effect on our business, financial condition and results of operations.

*Even with success in preclinical testing and previously completed clinical trials, the risk of clinical failure for any drug candidate remains high prior to regulatory approval.*

A number of companies have suffered significant unforeseen failures in late stage clinical studies due to factors such as inconclusive efficacy results and adverse medical events, even after achieving positive results in earlier clinical studies that were satisfactory both to them and to reviewing government health authorities. While the NKTR-118, NKTR-102, and Amikacin Inhale drug candidates have each demonstrated positive results from Phase 2 clinical studies, there is a substantial risk that Phase 3 clinical study outcomes from these drug candidates from larger patient populations will not demonstrate positive efficacy, safety or other clinical outcomes sufficient to support regulatory filings and achieve regulatory approval. Phase 3 clinical outcomes remain very unpredictable and it is possible that one or more of these Phase 3 clinical studies could fail at any time due to efficacy, safety or other important clinical findings or regulatory requirements. If one or more of these drug candidates fail in Phase 3 clinical studies, it would have a material adverse effect on our business, financial condition and results of operations.

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***If we or our partners do not obtain regulatory approval for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be negatively affected.***

We or our partners may not obtain regulatory approval for drug candidates on a timely basis, or at all, or the terms of any approval (which in some countries includes pricing approval) may impose significant restrictions or limitations on use. Drug candidates must undergo rigorous animal and human testing and an extensive FDA mandated or equivalent foreign government health authority review process for safety and efficacy. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and other U.S. and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

Even if we or our partners receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. Our partnered drugs that have obtained regulatory approval, and the manufacturing processes for these products, are subject to continued review and periodic inspections by the FDA and other regulatory authorities. Discovery from such review and inspection of previously unknown problems may result in restrictions on marketed products or on us, including withdrawal or recall of such products from the market, suspension of related manufacturing operations or a more restricted label. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

***We will need to raise substantial additional capital to repay the \$215.0 million in convertible notes due in September 2012 and fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions.***

On February 29, 2012, we received \$124.0 million in gross proceeds from the sale of our royalty interest in the CIMZIA® and MIRCERA® drug products. Additionally, we incurred approximately \$4.5 million in transaction costs. We plan to use the proceeds from this transaction towards the repayment of our \$215.0 million in convertible subordinated notes due in September 2012. We are actively pursuing other non-dilutive financing alternatives such as the sale of additional royalty interests held by us or term loan arrangements. We may seek to repurchase our convertible notes through cash purchases in open market transactions, privately negotiated transactions and/or a tender offer, if we can do so on attractive terms. If non-dilutive financing alternatives are not available to us on commercially reasonable terms or at all, in order to continue future operations as planned, we will be required to pursue dilutive equity-based financing alternatives such as the issuance of convertible debt or common stock to fund the remaining balance of the convertible notes and to provide sufficient capital to fund our future operations. The issuance of convertible notes, common stock, preferred stock or securities convertible into or exchangeable for our securities would dilute the percentage ownership of our current common stock security holders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders. If we issue convertible notes or enter into a term loan arrangement, the payment of principal and interest on such indebtedness may limit funds available for our business activities such as the continued advancement of our research and development pipeline, and such indebtedness could impose covenants that restrict our ability to operate our business. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments.

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*We have substantial future capital requirements and there is a risk we may not have access to sufficient capital to meet our current business plan. If we do not receive substantial milestone payments from our existing collaboration agreements, execute new high value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.*

As of December 31, 2011, we had cash, cash equivalents, and investments in marketable securities valued at approximately \$414.9 million and indebtedness of approximately \$239.9 million, including approximately \$215.0 million in convertible subordinated notes due September 2012, \$17.0 million in capital lease obligations, and \$7.9 million of other liabilities. While we believe that our cash position will be sufficient to meet our liquidity requirements through at least the next 12 months, our future capital requirements will depend upon numerous unpredictable factors, including:

if and when we receive potential milestone payments and royalties from our existing collaborations if the drug candidates subject to those collaborations achieve clinical, regulatory or commercial success, in particular, if the Phase 3 KODIAC studies being conducted by AstraZeneca for NKTR-118 are successful and AstraZeneca files an NDA with the FDA and a marketing application with the European Medicines Agency for NKTR-118, we will be entitled to \$95 million in milestone payments;

the progress, timing, cost and results of our clinical development programs in particular our Phase 3 BEACON study for NKTR-102 and our planned Phase 2 clinical study for NKTR-181;

the success, progress, timing and costs of our efforts to implement new collaborations, licenses and other transactions that increase our current net cash, such as the sale of additional royalty interests held by us, term loan or other debt arrangements, and the issuance of securities;

the cost, timing and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates that we have licensed to our collaboration partners (e.g., NKTR-118, Amikacin Inhale, BAX 855);

the outcome of the regulatory review process and commercial success of drug products for which we are entitled to receive royalties (e.g., Affymax's peginesatide and Map Pharmaceutical's Levadex);

the number of patients, enrollment criteria, primary and secondary endpoints, and the number of clinical studies required by the government health authorities in order to consider for approval our drug candidates and those of our collaboration partners;

our general and administrative expenses, capital expenditures and other uses of cash; and

disputes concerning patents, proprietary rights, or license and collaboration agreements that negatively impact our receipt of milestone payments or royalties or require us to make significant payments arising from licenses, settlements, adverse judgments or ongoing royalties.

A significant multi-year capital commitment is required to advance our drug candidates through the various stages of research and development in order to generate sufficient data to enable high value collaboration partnerships with significant up-front payments or to successfully achieve regulatory approval. If sufficient capital is not available to us or is not available on commercially reasonable terms, it could require us to delay or reduce one or more of our research and development programs. If we are unable to sufficiently advance our research and development programs, it could substantially impair the value of such programs and result in a material adverse effect on our business, financial condition and results of operations.





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***The results from the expanded Phase 2 clinical study for NKTR-102 in women with platinum-resistant/refractory ovarian cancer are unlikely to result in a review or an approval of a new drug application (NDA) by the United States Food and Drug Administration (FDA), and the future results from this trial are difficult to predict.***

We expanded the NKTR-102 Phase 2 study by 110 patients in women with platinum-resistant/refractory ovarian cancer that had received prior Doxil<sup>®</sup> therapy with the potential for us to consider an early NDA submission after we evaluate these expanded study results. As of February 2012, approximately 94 of the planned 110 patients had been enrolled in the study. Due to an ongoing supply shortage of Doxil<sup>®</sup>, we do not expect to complete full enrollment of this study. We are currently in the process of compiling and performing verification procedures on preliminary interim results from the patients. Acceptance and approval of an NDA by the FDA almost always requires the sponsor to conduct comparative Phase 3 clinical studies prior to acceptance for review or approval of an NDA. As a result, acceptance for review or approval of an accelerated NDA submitted to the FDA based on overall response rate from our single-arm Phase 2 study in platinum-resistant/refractory ovarian cancer would be unusual and is highly unlikely. Therefore we do not expect the FDA to accept or approve an accelerated NDA based on this Phase 2 clinical study. The FDA has significant discretion to determine what constitutes a high unmet medical need, what therapies should be considered available to patients regardless of which therapies are approved or typically prescribed in a particular setting, the relevance of certain efficacy end points (e.g. overall response rate, progression free survival, overall survival), and the number of patients required to be studied to demonstrate sufficient therapeutic benefit and safety profile. One or more of such judgments and determinations by the FDA could impair our ability to submit an accelerated NDA for platinum resistant/refractory ovarian cancer patients, and even if submitted, whether the FDA would accept it for review and/or approve the NDA.

Further, this expansion of our Phase 2 study in platinum resistant/refractory ovarian cancer will necessarily change the final efficacy (e.g., overall response rates, progression-free survival, overall survival) and safety (i.e., frequency and severity of serious adverse events) results, and, accordingly, the final results in this study remain subject to substantial change and could be materially and adversely different from previously announced results. If the clinical studies for NKTR-102 ovarian cancer are not successful, it could significantly harm our business, results of operations and financial condition.

***While we have conducted numerous experiments using laboratory and home-based chemistry techniques that have not been able to convert NKTR-181 into a rapid-acting and more abusable opioid, there is a risk that in the future a technique could be discovered to convert NKTR-181 into a rapid-acting and more abusable opioid which would significantly diminish the value of this drug candidate.***

An important objective of our NKTR-181 drug development program is to create a unique opioid molecule that does not rapidly enter a patient's central nervous system and therefore has the potential to be less susceptible to abuse than alternative opioid therapies. To date, we have conducted numerous experiments using laboratory and home-based chemistry techniques that have been unable to convert NKTR-181 into a rapidly-acting, more abusable form of opioid. In the future, an alternative chemistry technique, process or method of administration, or combination thereof, may be discovered to enable the conversion of NKTR-181 into a more abusable opioid which could significantly and negatively impact the potential of NKTR-181.

***If we are unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer.***

We intend to continue to seek partnerships with pharmaceutical and biotechnology partners to fund a portion of our research and development capital requirements. For example, in September 2009 we entered into a license agreement with AstraZeneca for NKTR-118 and NKTR-119 that included an upfront payment of \$125.0 million. The timing of new collaboration partnerships is difficult to predict due to availability of clinical data, the outcomes from our clinical studies, the number of potential partners that need to complete due diligence and

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approval processes, the definitive agreement negotiation process and numerous other unpredictable factors that can delay, impede or prevent significant transactions. If we are unable to find suitable partners or to negotiate collaboration arrangements with favorable commercial terms with respect to our existing and future drug candidates or the licensing of our intellectual property, or if any arrangements we negotiate, or have negotiated, are terminated, it could have a material adverse effect on our business, financial condition and results of operations.

***Preliminary and interim data from our clinical studies that we announce or publish from time to time is subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data becomes available.***

From time to time, we publish preliminary or interim data from our clinical studies. Preliminary data remains subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data is also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our business prospects.

***The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.***

It is very difficult to estimate the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payer reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the commercial terms of any collaboration partnership potential for such drug candidate or, if we have already entered into a collaboration for such drug candidate, the revenue potential from royalty and milestone payments could be significantly diminished and would negatively impact our business, financial condition and results of operations.

***We may not be able to obtain intellectual property licenses related to the development of our technology on a commercially reasonable basis, if at all.***

Numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties relate to pharmaceutical compositions, methods of preparation and manufacturing, and methods of use and administration. We cannot predict with any certainty which, if any, patent references will be considered relevant to our or our collaboration partners' technology or drug candidates by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. In certain cases, we have existing licenses or cross-licenses with third parties, however the scope and adequacy of these licenses is very uncertain and can change substantially during long development and commercialization cycles for biotechnology and pharmaceutical products. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If we are required to enter into a license with a third party, our potential economic benefit for the products subject to the license will be diminished. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and selling the drug.

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*We are a party to numerous collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.*

We currently derive, and expect to derive in the foreseeable future, all of our revenue from collaboration agreements with biotechnology and pharmaceutical companies. These collaboration agreements contain complex commercial terms, including:

clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of performance;

research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered drug candidate development programs;

clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;

intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;

royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and

indemnity obligations for intellectual property infringement, product liability and certain other claims.

On September 20, 2009, we entered into a worldwide exclusive license agreement with AstraZeneca for the further development and commercialization of NKTR-118 and NKTR-119. In addition, we have also entered into complex commercial agreements with Novartis in connection with the sale of certain assets related to our pulmonary business, associated technology and intellectual property to Novartis (the Novartis Pulmonary Asset Sale), which was completed on December 31, 2008. As part of the Novartis Pulmonary Asset Sale, we entered an exclusive license agreement with Novartis Pharma pursuant to which Novartis Pharma grants back to us an exclusive, irrevocable, perpetual, royalty-free and worldwide license under certain specific patent rights and other related intellectual property rights necessary for us to satisfy certain continuing contractual obligations to third parties, including in connection with development, manufacture, sale and commercialization activities related to our partnered program for Amikacin Inhale with Bayer. We also entered into a service agreement pursuant to which we have subcontracted to Novartis certain services to be performed related to our partner program for Amikacin Inhale. Our agreements with AstraZeneca and Novartis contain complex representations and warranties, covenants and indemnification obligations that could result in substantial future liability and harm our financial condition if we breach any of our agreements with AstraZeneca or Novartis or any third party agreements impacted by these complex transactions.

From time to time, we have informal dispute resolution discussions with third parties regarding the appropriate interpretation of the complex commercial terms contained in our agreements. One or more disputes may arise or escalate in the future regarding our collaboration agreements, transaction documents, or third-party license agreements that may ultimately result in costly litigation and unfavorable interpretation of contract terms, which would have a material adverse effect on our business, financial condition and results of operations.

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***We could be involved in legal proceedings and may incur substantial litigation costs and liabilities that will adversely affect our business, financial condition and results of operations.***

From time to time, third parties have asserted, and may in the future assert, that we or our partners infringe their proprietary rights, such as patents and trade secrets, or have otherwise breached our obligations to them. The third party often bases its assertions on a claim that its patents cover our technology platform or drug candidates or that we have misappropriated its confidential or proprietary information. Similar assertions of infringement could be based on future patents that may issue to third parties. In certain of our agreements with our partners, we are obligated to indemnify and hold harmless our collaboration partners from intellectual property infringement, product liability and certain other claims, which could cause us to incur substantial costs and liability if we are called upon to defend ourselves and our partners against any claims. If a third party obtains injunctive or other equitable relief against us or our partners, they could effectively prevent us, or our partners, from developing or commercializing, or deriving revenue from, certain drugs or drug candidates in the U.S. and abroad. For instance, F. Hoffmann-La Roche Ltd, to which we license our proprietary PEGylation reagent intellectual property for use in the MIRCERA<sup>®</sup> product, was a party to a significant patent infringement lawsuit brought by Amgen Inc. related to Roche's proposed marketing and sale of MIRCERA<sup>®</sup> to treat chemotherapy anemia in the U.S. In October 2008, a federal court ruled in favor of Amgen, issuing a permanent injunction preventing Roche from marketing or selling MIRCERA<sup>®</sup> in the U.S. Roche and Amgen subsequently entered into a settlement and limited license agreement which allows Roche to begin selling MIRCERA<sup>®</sup> in the U.S. in July 2014. Currently, the Research Foundation of the State University of New York (SUNY) seeks to recover amounts it alleges it is owed pursuant to a technology licensing contract between SUNY and us. SUNY has filed an action in the United States District Court for the Northern District of New York. We dispute SUNY's claims. However, we cannot predict with certainty the eventual outcome of any pending or future litigation. Costs associated with such litigation, substantial damage claims, indemnification claims or royalties paid for licenses from third parties could have a material adverse effect on our business, financial condition and results of operations.

Third-party claims involving proprietary rights or other matters could also result in substantial settlement payments or substantial damages to be paid by us. For instance, a settlement might require us to enter a license agreement under which we would pay substantial royalties or other compensation to a third party, diminishing our future economic returns from the related drug. In October 2011, we entered into a settlement related to a trade secret and breach of contract litigation where we agreed to make an upfront payment of \$2.7 million and a future contingent payment of \$3.0 million if a certain drug candidate receives FDA approval. In 2006, we entered into a litigation settlement related to an intellectual property dispute with the University of Alabama in Huntsville pursuant to which we paid \$11.0 million and agreed to pay an additional \$10.0 million in equal \$1.0 million installments over ten years ending with the last payment due on July 1, 2016.

***If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.***

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own greater than 120 U.S. and 420 foreign patents and a number of pending patent applications that cover various aspects of our technologies. We have filed patent applications, and plan to file additional patent applications, covering various aspects of our PEGylation and advanced polymer conjugate technologies and our proprietary product candidates. There can be no assurance that patents that have issued will be valid and enforceable or that patents for which we apply will issue with broad coverage, if at all. The coverage claimed in a patent application can be significantly reduced before the patent is issued and, as a consequence, our patent applications may result in patents with narrow coverage that may not prevent competition from similar drugs. The scope of our patent claim coverage can be critical to our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. As part of the patent application process, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in

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substantial cost to us, even if the eventual outcome is favorable. Further, an issued patent may undergo further proceedings to limit its scope so as not to provide meaningful protection and any claims that have issued, or that eventually issue, may be circumvented or otherwise invalidated. Any attempt to enforce our patents or patent application rights could be time consuming and costly. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following commercialization of related products.

There are many laws, regulations and judicial decisions that dictate and otherwise influence the manner in which patent applications are filed and prosecuted and in which patents are granted and enforced. Changes to these laws, regulations and judicial decisions are subject to influences outside of our control and may negatively affect our business, including our ability to obtain meaningful patent coverage or enforcement rights to any of our issued patents. New laws, regulations and judicial decisions may be retroactive in effect, potentially reducing or eliminating our ability to implement our patent-related strategies. Changes to laws, regulations and judicial decisions that affect our business are often difficult or impossible to foresee, which limits our ability to adequately adapt our patent strategies to these changes.

***Our manufacturing operations and those of our contract manufacturers are subject to governmental regulatory requirements, which, if not met, would have a material adverse effect on our business, results of operations and financial condition.***

We and our contract manufacturers are required in certain cases to maintain compliance with current good manufacturing practices (cGMP), including cGMP guidelines applicable to active pharmaceutical ingredients, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. We anticipate periodic regulatory inspections of our drug manufacturing facilities and the manufacturing facilities of our contract manufacturers for compliance with applicable regulatory requirements. Any failure to follow and document our or our contract manufacturers' adherence to such cGMP regulations or satisfy other manufacturing and product release regulatory requirements may disrupt our ability to meet our manufacturing obligations to our customers, lead to significant delays in the availability of products for commercial use or clinical study, result in the termination or hold on a clinical study or delay or prevent filing or approval of marketing applications for our products. Failure to comply with applicable regulations may also result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. The results of these inspections could result in costly manufacturing changes or facility or capital equipment upgrades to satisfy the FDA that our manufacturing and quality control procedures are in substantial compliance with cGMP. Manufacturing delays, for us or our contract manufacturers, pending resolution of regulatory deficiencies or suspensions would have a material adverse effect on our business, results of operations and financial condition.

***If we or our contract manufacturers are not able to manufacture drugs or drug substances in sufficient quantities that meet applicable quality standards, it could delay clinical studies, result in reduced sales or constitute a breach of our contractual obligations, any of which could significantly harm our business, financial condition and results of operations.***

If we or our contract manufacturers are not able to manufacture and supply sufficient drug quantities meeting applicable quality standards required to support large clinical studies or commercial manufacturing in a timely manner, we risk delaying our clinical studies or those of our collaboration partners, reducing drug sales by our collaboration partners or breaching contractual obligations. As a result, we could incur substantial costs and damages, and reduce or even eliminate product or royalty revenue. In some cases, we rely on contract manufacturing organizations to manufacture and supply drug product for our clinical studies and those of our

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collaboration partners. Pharmaceutical manufacturing involves significant risks and uncertainties related to the demonstration of adequate stability, sufficient purification of the drug substance and drug product, the identification and elimination of impurities, optimal formulations, process validation, and challenges in controlling for all of these variables. We have faced and may in the future face significant difficulties, delays and unexpected expenses as we validate third party contract manufacturers required for drug supply to support our clinical studies and the clinical studies and products of our collaboration partners. Failure by us or our contract manufacturers to supply drug product in sufficient quantities that meet all applicable quality requirements could result in supply shortages for our clinical studies or the clinical studies and commercial activities of our collaboration partners. Such failures could significantly and materially delay clinical trials and regulatory submissions or result in reduced sales, any of which could significantly harm our business prospects, results of operations and financial condition.

Failures in device manufacturing has similar effects. For instance, we entered a service agreement with Novartis pursuant to which we subcontract to Novartis certain important services to be performed in relation to our partnered program for Amikacin Inhale with Bayer Healthcare LLC. If our subcontractors do not dedicate adequate resources to our programs, we risk breach of our obligations to our partners. Building and validating large scale clinical or commercial-scale manufacturing facilities and processes, recruiting and training qualified personnel and obtaining necessary regulatory approvals is complex, expensive and time consuming. In the past we have encountered challenges in scaling up manufacturing to meet the requirements of large scale clinical trials without making modifications to the drug formulation, which may cause significant delays in clinical development. We have experienced repeated significant delays in starting the Phase 3 clinical development program for Amikacin Inhale as we seek to finalize and validate the device design with a demonstrated capability to be manufactured at commercial scale. This work is ongoing and there remains significant risk in finalizing, validating, and producing the device at sufficient quantities meeting applicable quality requirements until this work is completed. Drug/device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient/doctor use, maintenance of clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. There continues to be substantial and unpredictable risk and uncertainty related to manufacturing and supply until such time as the commercial supply chain is validated and proven.

***Our revenue is exclusively derived from our collaboration agreements, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue.***

Our revenue is derived from our collaboration agreements from which we receive contract research payments, milestone payments based on clinical progress, regulatory progress or net sales achievements, royalties and manufacturing revenue. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from significant milestone payments based on the execution of new collaboration agreements, the timing of clinical outcomes, regulatory approval, commercial launch and the achievement of certain annual sales thresholds. The amount of our revenue derived from collaboration agreements in any given period will depend on a number of unpredictable factors, including our ability to find and maintain suitable collaboration partners, the timing of the negotiation and conclusion of collaboration agreements with such partners, whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors.

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*If our partners, on which we depend to obtain regulatory approvals for and to commercialize our partnered drug candidates, are not successful, or if such collaborations fail, the development or commercialization of our partnered drug candidates may be delayed or unsuccessful.*

When we sign a collaborative development agreement or license agreement to develop a drug candidate with a pharmaceutical or biotechnology company, the pharmaceutical or biotechnology company is generally expected to:

design and conduct large scale clinical studies;

prepare and file documents necessary to obtain government approvals to sell a given drug candidate; and/or

market and sell the drugs when and if they are approved.

Our reliance on collaboration partners poses a number of risks to our business, including risks that:

we may be unable to control whether, and the extent to which, our partners devote sufficient resources to the development programs or commercial marketing and sales efforts;

disputes may arise or escalate in the future with respect to the ownership of rights to technology or intellectual property developed with partners;

disagreements with partners could lead to delays in, or termination of, the research, development or commercialization of product candidates or to litigation or arbitration proceedings;

contracts with our partners may fail to provide us with significant protection, or to be effectively enforced, in the event one of our partners fails to perform;

partners have considerable discretion in electing whether to pursue the development of any additional product candidates and may pursue alternative technologies or products either on their own or in collaboration with our competitors;

partners with marketing rights may choose to devote fewer resources to the marketing of our partnered products than they do to products of their own development or products in-licensed from other third parties;

the timing and level of resources that our partners dedicate to the development program will affect the timing and amount of revenue we receive;

we do not have the ability to unilaterally terminate agreements (or partners may have extension or renewal rights) that we believe are not on commercially reasonable terms or consistent with our current business strategy;



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partners may be unable to pay us as expected; and

partners may terminate their agreements with us unilaterally for any or no reason, in some cases with the payment of a termination fee penalty and in other cases with no termination fee penalty.

Given these risks, the success of our current and future partnerships is highly unpredictable and can have a substantial negative or positive impact on our business. We have entered into collaborations in the past that have been subsequently terminated, such as our collaboration with Pfizer for the development and commercialization of inhaled insulin that was terminated by Pfizer in November 2007. If other collaborations are suspended or terminated, our ability to commercialize certain other proposed product candidates could also be negatively impacted. If our collaborations fail, our product development or commercialization of product candidates could be delayed or cancelled, which would negatively impact our business, results of operations and financial condition.

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*If we are unable either to create sales, marketing and distribution capabilities or to enter into agreements with third parties to perform these functions, we will be unable to commercialize our products successfully.*

We currently have no sales, marketing or distribution capabilities. To commercialize any of our drugs that receive regulatory approval for commercialization, we must either develop internal sales, marketing and distribution capabilities, which would be expensive and time consuming, or enter into collaboration arrangements with third parties to perform these services. If we decide to market our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. Factors that may inhibit our efforts to commercialize our products directly or indirectly with our partners include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to use or prescribe our products;

the lack of complementary products or multiple product pricing arrangements may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

*If we, or our partners through our collaborations, are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our products, which would adversely affect our business, results of operations and financial condition.*

To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In the event that we market our products without a partner, we would be required to build a sales and marketing organization and infrastructure, which would require a significant investment and we may not be successful in building this organization and infrastructure in a timely or efficient manner.

*We purchase some of the starting material for drugs and drug candidates from a single source or a limited number of suppliers, and the partial or complete loss of one of these suppliers could cause production delays, clinical trial delays, substantial loss of revenue and contract liability to third parties.*

We often face very limited supply of a critical raw material that can only be obtained from a single, or a limited number of, suppliers, which could cause production delays, clinical trial delays, substantial lost revenue opportunity or contract liability to third parties. For example, there are only a limited number of qualified suppliers, and in some cases single source suppliers, for the raw materials included in our PEGylation and advanced polymer conjugate drug formulations, and any interruption in supply or failure to procure such raw materials on commercially feasible terms could harm our business by delaying our clinical trials, impeding commercialization of approved drugs or increasing our costs to the extent we cannot pass on increased costs to a manufacturing customer.

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***We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.***

We rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

***We expect to continue to incur substantial losses and negative cash flow from operations and may not achieve or sustain profitability in the future.***

For the year ended December 31, 2011, we reported a net loss of \$134.0 million. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestone payments and royalties received, the timing of revenue under our collaboration agreements, the amount of investments we make in our proprietary product candidates and the regulatory approval and market success of our product candidates. We may not be able to achieve and sustain profitability.

Other factors that will affect whether we achieve and sustain profitability include our ability, alone or together with our partners, to:

develop drugs utilizing our technologies, either independently or in collaboration with other pharmaceutical or biotech companies;

effectively estimate and manage clinical development costs, particularly the cost of the BEACON study and the Phase 2 clinical study for NKTR-181;

receive necessary regulatory and marketing approvals;

maintain or expand manufacturing at necessary levels;

achieve market acceptance of our partnered products;

receive royalties on products that have been approved, marketed or submitted for marketing approval with regulatory authorities; and

maintain sufficient funds to finance our activities.

***If government and private insurance programs do not provide payment or reimbursement for our partnered products or proprietary products, those products will not be widely accepted, which would have a negative impact on our business, results of operations and financial condition.***

In both domestic and foreign markets, sales of our partnered and proprietary products that have received regulatory approval will depend in part on market acceptance among physicians and patients, pricing approvals by government authorities and the availability of payment or reimbursement from third-party payers, such as government health administration authorities, managed care providers, private health insurers and other organizations. Such third-party payers are increasingly challenging the price and cost effectiveness of medical products and services. Therefore, significant uncertainty exists as to the pricing approvals for, and the payment or reimbursement status of, newly approved healthcare products. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our proposed products for marketing and could further limit pricing approvals for, and reimbursement of, our products from government authorities and third-party payers. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our products would limit market acceptance of such products.



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***We depend on third parties to conduct the clinical trials for our proprietary product candidates and any failure of those parties to fulfill their obligations could harm our development and commercialization plans.***

We depend on independent clinical investigators, contract research organizations and other third-party service providers to conduct clinical trials for our proprietary product candidates. We rely heavily on these parties for successful execution of our clinical trials. Though we are ultimately responsible for the results of their activities, many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, but the independent clinical investigators may prioritize other projects over ours or communicate issues regarding our products to us in an untimely manner. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials or our reliance on results of trials that we have not directly conducted or monitored could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

***Significant competition for our polymer conjugate chemistry technology platforms and our partnered and proprietary products and product candidates could make our technologies, products or product candidates obsolete or uncompetitive, which would negatively impact our business, results of operations and financial condition.***

Our PEGylation and advanced polymer conjugate chemistry platforms and our partnered and proprietary products and product candidates compete with various pharmaceutical and biotechnology companies. Competitors of our PEGylation and polymer conjugate chemistry technologies include Dr. Reddy's Laboratories Ltd., Enzon Pharmaceuticals, Inc., SunBio Corporation, Mountain View Pharmaceuticals, Inc., Novo Nordisk A/S (formerly assets held by Neose Technologies, Inc.), and NOF Corporation. Several other chemical, biotechnology and pharmaceutical companies may also be developing PEGylation technologies or technologies that have similar impact on target drug molecules. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use.

There are several competitors for our proprietary product candidates currently in development. For Amikacin Inhale, the current standard of care includes several approved intravenous antibiotics for the treatment of either hospital-acquired pneumonia or ventilator-associated pneumonia in patients on mechanical ventilators. For NKTR-118, there are currently several alternative therapies used to address opioid-induced constipation (OIC) and opioid-induced bowel dysfunction (OBD), including subcutaneous Relistor® (methylnaltrexone bromide) and oral and rectal over-the-counter laxatives and stool softeners such as docusate sodium, senna and milk of magnesia. In addition, there are a number of companies developing potential products which are in various stages of clinical development and are being evaluated for the treatment of OIC and OBD in different patient populations, including Adolor Corporation, Progenics Pharmaceuticals, Inc. in collaboration with Salix Pharmaceuticals, Ltd., Mundipharma Int. Limited, Sucampo Pharmaceuticals, Alkermes, Inc. and Takeda Pharmaceutical Company Limited. For NKTR-102, there are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for ovarian and breast cancers including but not limited to: Avastin® (bevacizumab), Camptosar® (irinotecan), Doxil® (doxorubicin HCl), Ellence® (epirubicin), Gemzar® (gemcitabine), Herceptin® (trastuzumab), Hycamtin® (topotecan), Iniparib, Paraplatin® (carboplatin), and Taxol® (paclitaxel). Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for these cancers include Bristol-Meyers Squibb, Eli Lilly & Co., Roche, GlaxoSmithKline plc, Johnson and Johnson, Pfizer, Inc., Sanofi Aventis, and many others. There are approved therapies for the treatment of colorectal cancer, including Eloxatin® (oxaliplatin), Camptosar® (irinotecan), Avastin® (bevacizumab), Erbitux® (cetuximab), Vectibix® (panitumumab), Xeloda® (capecitabine), Adrucil® (fluorouracil), and Wellcovorin® (leucovorin). In addition, there are a number of drugs in various stages of preclinical and clinical development from companies exploring cancer therapies or improved chemotherapeutic

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agents to potentially treat colorectal cancer, including, but not limited to, products in development from Bristol-Myers Squibb Company, Pfizer, Inc., GlaxoSmithKline plc, Antigenics, Inc., F. Hoffmann-La Roche Ltd, Novartis AG, Cell Therapeutics, Inc., Neopharm Inc., Mediatech Research Ltd, Alchemia Limited, Enzon Pharmaceuticals, Inc. and others.

There can be no assurance that we or our partners will successfully develop, obtain regulatory approvals for and commercialize next-generation or new products that will successfully compete with those of our competitors. Many of our competitors have greater financial, research and development, marketing and sales, manufacturing and managerial capabilities. We face competition from these companies not just in product development but also in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. As a result, our competitors may succeed in developing competing technologies, obtaining regulatory approval or gaining market acceptance for products before we do. These developments could make our products or technologies uncompetitive or obsolete.

### ***If product liability lawsuits are brought against us, we may incur substantial liabilities.***

The manufacture, clinical testing, marketing and sale of medical products involve inherent product liability risks. If product liability costs exceed our product liability insurance coverage, we may incur substantial liabilities that could have a severe negative impact on our financial position. Whether or not we are ultimately successful in any product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources and might result in adverse publicity, all of which would impair our business. Additionally, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

### ***Our future depends on the proper management of our current and future business operations and their associated expenses.***

Our business strategy requires us to manage our business to provide for the continued development and potential commercialization of our proprietary and partnered drug candidates. Our strategy also calls for us to undertake increased research and development activities and to manage an increasing number of relationships with partners and other third parties, while simultaneously managing the capital necessary to support this strategy. Our decision to bear a majority or all of the clinical development costs of NKTR-102 substantially increases our future capital requirements. If we are unable to manage effectively our current operations and any growth we may experience, our business, financial condition and results of operations may be adversely affected. If we are unable to effectively manage our expenses, we may find it necessary to reduce our personnel-related costs through reductions in our workforce, which could harm our operations, employee morale and impair our ability to retain and recruit talent. Furthermore, if adequate funds are not available, we may be required to obtain funds through arrangements with partners or other sources that may require us to relinquish rights to certain of our technologies, products or future economic rights that we would not otherwise relinquish or require us to enter into other financing arrangements on unfavorable terms.

### ***We are dependent on our management team and key technical personnel, and the loss of any key manager or employee may impair our ability to develop our products effectively and may harm our business, operating results and financial condition.***

Our success largely depends on the continued services of our executive officers and other key personnel. The loss of one or more members of our management team or other key employees could seriously harm our business, operating results and financial condition. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are also dependent on the continued services of our technical personnel because of the highly technical nature of our

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products and the regulatory approval process. Because our executive officers and key employees are not obligated to provide us with continued services, they could terminate their employment with us at any time without penalty. We do not have any post-employment noncompetition agreements with any of our employees and do not maintain key person life insurance policies on any of our executive officers or key employees.

***Because competition for highly qualified technical personnel is intense, we may not be able to attract and retain the personnel we need to support our operations and growth.***

We must attract and retain experts in the areas of clinical testing, manufacturing, regulatory, finance, marketing and distribution and develop additional expertise in our existing personnel. We face intense competition from other biopharmaceutical companies, research and academic institutions and other organizations for qualified personnel. Many of the organizations with which we compete for qualified personnel have greater resources than we have. Because competition for skilled personnel in our industry is intense, companies such as ours sometimes experience high attrition rates with regard to their skilled employees. Further, in making employment decisions, job candidates often consider the value of the stock options they are to receive in connection with their employment. Our equity incentive plan and employee benefit plans may not be effective in motivating or retaining our employees or attracting new employees, and significant volatility in the price of our stock may adversely affect our ability to attract or retain qualified personnel. If we fail to attract new personnel or to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

***If earthquakes and other catastrophic events strike, our business may be harmed.***

Our corporate headquarters, including a substantial portion of our research and development operations, are located in the San Francisco Bay Area, a region known for seismic activity and a potential terrorist target. In addition, we own facilities for the manufacture of products using our PEGylation and advanced polymer conjugate technologies in Huntsville, Alabama and own and lease offices in Hyderabad, India. There are no backup facilities for our manufacturing operations located in Huntsville, Alabama. In the event of an earthquake or other natural disaster, political instability, or terrorist event in any of these locations, our ability to manufacture and supply materials for drug candidates in development and our ability to meet our manufacturing obligations to our customers would be significantly disrupted and our business, results of operations and financial condition would be harmed. Our collaborative partners may also be subject to catastrophic events, such as hurricanes and tornadoes, any of which could harm our business, results of operations and financial condition. We have not undertaken a systematic analysis of the potential consequences to our business, results of operations and financial condition from a major earthquake or other catastrophic event, such as a fire, sustained loss of power, terrorist activity or other disaster, and do not have a recovery plan for such disasters. In addition, our insurance coverage may not be sufficient to compensate us for actual losses from any interruption of our business that may occur.

***We have implemented certain anti-takeover measures, which make it more difficult to acquire us, even though such acquisitions may be beneficial to our stockholders.***

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even though such acquisitions may be beneficial to our stockholders. These anti-takeover provisions include:

establishment of a classified board of directors such that not all members of the board may be elected at one time;

lack of a provision for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;

the ability of our board to authorize the issuance of blank check preferred stock to increase the number of outstanding shares and thwart a takeover attempt;

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prohibition on stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;

establishment of advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings; and

limitations on who may call a special meeting of stockholders.

Further, provisions of Delaware law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from acquiring us. These provisions may also discourage, delay or prevent a third party from acquiring a large portion of our securities or initiating a tender offer or proxy contest, even if our stockholders might receive a premium for their shares in the acquisition over the then current market prices. We also have a change of control severance benefit plan which provides for certain cash severance, stock award acceleration and other benefits in the event our employees are terminated (or, in some cases, resign for specified reasons) following an acquisition. This severance plan could discourage a third party from acquiring us.

***The price of our common stock is expected to remain volatile.***

Our stock price is volatile. During the year ended December 31, 2011, based on closing bid prices on The NASDAQ Global Select Market, our stock price ranged from \$12.53 to \$4.22 per share. We expect our stock price to remain volatile. In addition, as our convertible notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of our notes. Also, interest rate fluctuations can affect the price of our convertible notes. A variety of factors may have a significant effect on the market price of our common stock or notes, including:

announcements of data from, or material developments in, our clinical studies and those of our collaboration partners, including data regarding efficacy and safety, delays in clinical development, regulatory approval or commercial launch;

announcements by collaboration partners as to their plans or expectations related to drug candidates and approved drugs in which we have a substantial economic interest;

announcements regarding terminations or disputes under our collaboration agreements;

fluctuations in our results of operations;

developments in patent or other proprietary rights, including intellectual property litigation or entering into intellectual property license agreements and the costs associated with those arrangements;

announcements of technological innovations or new therapeutic products that may compete with our approved products or products under development;

announcements of changes in governmental regulation affecting us or our competitors;

hedging activities by purchasers of our convertible notes;



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litigation brought against us or third parties to whom we have indemnification obligations;

public concern as to the safety of drug formulations developed by us or others; and

general market conditions.

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**Item 1B. *Unresolved Staff Comments***

None.

**Item 2. *Properties***

**California**

We lease a 102,283 square foot facility in the Mission Bay Area of San Francisco, California (Mission Bay Facility), under an operating lease which expires in 2020. In November 2010, we moved into the Mission Bay Facility relocating all of our functions from the San Carlos, California facility (San Carlos Facility), including our corporate headquarters and research and development for our PEGylation and advanced polymer conjugate technology operations. In December 2011, we expanded our lease of the Mission Bay Facility to include an additional 24,002 square feet of space. However, we retain the right to terminate the lease expansion on May 31, 2013. If we do not exercise the early termination right, the lease for the expanded space will expire in 2020, on the same date as the original lease agreement for the Mission Bay Facility.

Our lease for approximately 100,000 square feet of the San Carlos Facility is under a capital lease which expires in 2016. We have subleased a portion of the San Carlos Facility and are currently seeking one or more subtenants for the remaining space.

**Alabama**

We currently own three facilities consisting of approximately 149,333 square feet in Huntsville, Alabama, which house laboratories as well as administrative, clinical and commercial manufacturing facilities for our PEGylation and advanced polymer conjugate technology operations.

**India**

We own a research and development facility consisting of approximately 88,000 square feet, near Hyderabad, India. In addition, we lease approximately 504 square feet of office space in Hyderabad, India, under a one-year operating lease that will expire in 2012.

**Item 3. *Legal Proceedings***

From time to time, we are subject to legal proceedings, including the proceedings described specifically below. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

On November 18, 2009, the Research Foundation of the State University of New York (SUNY) filed an action against Nektar in the United States District Court for the Northern District of New York. SUNY seeks to recover amounts it alleges it is owed pursuant to a technology licensing contract between Nektar and SUNY. We dispute SUNY's claims. Discovery in the matter is continuing and a trial ready date has been set for September 1, 2012. We believe that SUNY's claims are without merit. No reasonable estimate of the possible loss or range of loss can be made at this time and no liabilities have been recorded for this matter on our Consolidated Balance Sheets as of December 31, 2011 or 2010.

**Item 4. *[Removed and Reserved]***

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity and Related Stockholder Matters**

Our common stock trades on the NASDAQ Global Select Market under the symbol NKTR. The table below sets forth the high and low closing sales prices for our common stock as reported on the NASDAQ Global Select Market during the periods indicated.

	High	Low
<b>Year Ended December 31, 2010:</b>		
1st Quarter	\$ 15.52	\$ 9.39
2nd Quarter	15.58	11.25
3rd Quarter	15.21	11.60
4th Quarter	15.88	12.30
<b>Year Ended December 31, 2011:</b>		
1st Quarter	\$ 12.53	\$ 8.58
2nd Quarter	10.44	7.22
3rd Quarter	7.65	4.85
4th Quarter	5.62	4.22

**Holders of Record**

As of February 24, 2012, there were approximately 251 holders of record of our common stock.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We currently expect to retain any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

There were no sales of unregistered securities and there were no common stock repurchases made during the year ended December 31, 2011.

**Securities Authorized for Issuance Under Equity Compensation Plans**

Information regarding our equity compensation plans as of December 31, 2011 is disclosed in Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters of this Annual Report on Form 10-K and is incorporated herein by reference from our proxy statement for our 2011 annual meeting of stockholders to be filed with the SEC 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.

**Performance Measurement Comparison**

The material in this section is being furnished and shall not be deemed filed with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall the material in this section be deemed to be incorporated by reference in any registration statement or other document filed with the SEC under the Securities Act or the Exchange Act, except as otherwise expressly stated in such filing.

The following graph compares, for the five year period ended December 31, 2011, the cumulative total stockholder return (change in stock price plus reinvested dividends) of our common stock with (i) the NASDAQ Composite Index, (ii) the NASDAQ Pharmaceutical Index, (iii) the RGD SmallCap Pharmaceutical Index, (iv) the NASDAQ Biotechnology Index and (v) the RDG SmallCap Biotechnology Index. Measurement points are the last trading day of each of our fiscal years ended December 31, 2007, December 31, 2008, December 31,

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2009, December 31, 2010 and December 31, 2011. The graph assumes that \$100 was invested on December 31, 2006 in the common stock of the Company, the NASDAQ Composite Index, the Nasdaq Pharmaceutical Index, the RGD SmallCap Pharmaceutical Index, the NASDAQ Biotechnology Index and the RDG SmallCap Biotechnology Index and assumes reinvestment of any dividends. The stock price performance in the graph is not intended to forecast or indicate future stock price performance.

**Table of Contents****Item 6. Selected Financial Data****SELECTED CONSOLIDATED FINANCIAL INFORMATION****(In thousands, except per share information)**

The selected consolidated financial data set forth below should be read together with the consolidated financial statements and related notes, Management's Discussion and Analysis of Financial Condition and Results of Operations, and the other information contained herein.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
<b>Statements of Operations Data:</b>					
Revenue:					
Product sales(1)	\$ 24,864	\$ 27,412	\$ 30,116	\$ 37,799	\$ 177,026
Royalty revenues	10,327	7,255	5,172	3,456	3,729
License, collaboration and other revenue(2)	36,289	124,372	36,643	48,930	92,272
Total revenue	71,480	159,039	71,931	90,185	273,027
Total operating costs and expenses(3)	195,417	187,294	167,063	172,837	309,175
Loss from operations	(123,937)	(28,255)	(95,132)	(82,652)	(36,148)
Gain on debt extinguishment				50,149	
Interest and other income (expense), net	(9,023)	(8,802)	(7,640)	(2,639)	4,696
Provision (benefit) for income taxes	1,018	881	(253)	(806)	1,309
Net loss	\$ (133,978)	\$ (37,938)	\$ (102,519)	\$ (34,336)	\$ (32,761)
Basic and diluted net loss per share(4)	\$ (1.19)	\$ (0.40)	\$ (1.11)	\$ (0.37)	\$ (0.36)
Shares used in computing basic and diluted net loss per share(4)	112,942	94,079	92,772	92,407	91,876

	As of December 31,				
	2011	2010	2009	2008	2007
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 414,936	\$ 315,932	\$ 396,211	\$ 378,994	\$ 482,353
Working capital	\$ 1,174	\$ 289,871	\$ 260,650	\$ 337,846	\$ 425,191
Total assets	\$ 606,550	\$ 521,225	\$ 575,518	\$ 560,536	\$ 725,103
Deferred revenue	\$ 127,831	\$ 145,347	\$ 192,372	\$ 65,577	\$ 80,969
Convertible subordinated notes	\$ 214,955	\$ 214,955	\$ 214,955	\$ 214,955	\$ 315,000
Other long-term liabilities	\$ 21,741	\$ 22,585	\$ 23,344	\$ 25,585	\$ 27,543
Accumulated deficit	\$ (1,398,525)	\$ (1,264,547)	\$ (1,226,609)	\$ (1,124,090)	\$ (1,089,754)
Total stockholders' equity	\$ 197,811	\$ 90,662	\$ 102,367	\$ 190,154	\$ 214,439

(1) 2007 product sales include commercial manufacturing revenue from Exubera bulk dry powder insulin and Exubera inhalers.

(2) 2007 collaboration and other revenue included Exubera commercialization readiness revenue.

(3) Operating costs and expenses includes the Gain on sale of pulmonary assets of \$69.6 million in 2008 and the Gain on termination of collaborative agreements, net of \$79.2 million in 2007.

(4) Basic and diluted net loss per share is based upon the weighted average number of common shares outstanding.

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*The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this section as well as factors described in Part I, Item 1A Risk Factors.*

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**  
**Overview**

***Strategic Direction of Our Business***

We are a clinical-stage biopharmaceutical company developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms, which are designed to improve the benefits of drugs for patients. Our current proprietary pipeline is comprised of drug candidates across a number of therapeutic areas including oncology, pain, anti-infectives, anti-viral and immunology. Our research and development activities involve small molecule drugs, peptides and other potential biologic drug candidates. We create our innovative drug candidates by using our proprietary advanced polymer conjugate technologies and expertise to modify the chemical structure of drugs to create new molecular entities. Polymer chemistry is a science focused on the synthesis or bonding of polymer architectures with drug molecules to alter the properties of a molecule when it is bonded with polymers. Additionally, we may utilize established pharmacologic targets to engineer a new drug candidate relying on a combination of the known properties of these targets and our proprietary polymer chemistry technology and expertise. Our drug candidates are designed to improve the pharmacokinetics, pharmacodynamics, half-life, bioavailability, metabolism or distribution of drugs and improve the overall benefits and use of a drug for the patient. Our objective is to apply our advanced polymer conjugate technology platform to create new drug candidates in multiple therapeutic areas that address large potential markets.

Our most advanced proprietary product candidate, NKTR-118, is a peripheral opioid antagonist that is currently being evaluated for the treatment of opioid-induced constipation. We are a party to an exclusive worldwide license agreement with AstraZeneca for the global development and commercialization of NKTR-118 and NKTR-119. NKTR-119 is an early stage research and development program that is designed to combine various opioids with NKTR-118. On March 15, 2011, AstraZeneca announced enrollment of the first patient in Phase 3 clinical studies for NKTR-118 that AstraZeneca calls the KODIAC study. This Phase 3 clinical program is designed to investigate the safety and efficacy of NKTR-118 as a medicine to relieve opioid-induced constipation, a common side effect of prescription opioids when used for chronic pain management. The outcome of the KODIAC study will have a substantial impact on our financial condition as we are entitled to \$235.0 million in regulatory filing and commercial launch milestones. If the KODIAC study is successful and AstraZeneca files for regulatory approval with the FDA and the European Medicines Agency (EMA), Nektar will be entitled to \$95.0 million of these milestones. We will be entitled to the remaining \$140.0 million of these milestones if NKTR-118 is approved by the FDA and EMA and commercial launch is achieved in the U.S. and one major country in the European Union (EU). Following the commercial launch of NKTR-118, we are entitled to significant and escalating double-digit royalties varying by country of sale and based on the level of annual net sales. Therefore, the results from the KODIAC study, the timing and outcome of approval review of NKTR-118 by the FDA and EMA, the timing of the commercial launch of NKTR-118 (if approved), and the level of NKTR-118 sales, will have a significant impact on our financial condition and future business prospects.

Our second most advanced drug candidate, NKTR-102, is a next-generation topoisomerase I inhibitor, currently being evaluated as a single-agent therapy in a Phase 3 open-label, randomized, multicenter clinical study in patients with metastatic breast cancer. This Phase 3 clinical study, which we call the BEACON study (BrEAsT Cancer Outcomes with NKTR-102), was initiated by us in December 2011. The BEACON study is scheduled to enroll approximately 840 patients with metastatic breast cancer. The BEACON study will require a substantial investment over the next three years. In the first quarter of 2012, we are also completing an expanded Phase 2 clinical study for NKTR-102 in patients with platinum-resistant ovarian cancer. The original Phase 2

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clinical study was completed in mid-2010 and we further expanded this study to enroll up to 110 additional women with platinum-resistant ovarian cancer who had progressed after prior treatment with Doxil® (doxorubicin HCl liposome injection). In November 2011, we announced that enrollment in this expanded Phase 2 study was slower than anticipated because of a shortage of Doxil® related to serious manufacturing issues being experienced by the manufacturer and supplier of Doxil®. As of February 2012, approximately 94 of the planned 110 patients had been enrolled in the study. We are currently in the process of compiling and performing verification procedures on certain top-line results (i.e. objective tumor response rate) from the patients enrolled to date. Results from this study and communication with government health authorities in both the United States and EU, will guide our future development and regulatory strategy for NKTR-102 in ovarian cancer.

We also have a significant collaboration with Bayer Healthcare LLC (Bayer) for Amikacin Inhale, an inhaled solution of amikacin, an aminoglycoside antibiotic, that has completed Phase 2 development. Preparations for a Phase 3 clinical study, which we currently expect to start in the second half of 2012, are continuing. The program is significantly behind schedule due to our plan with Bayer to finalize the design of the nebulizer device for commercial manufacturing prior to initiating Phase 3 clinical development, with the objective of commencing Phase 3 clinical trials as soon as possible following completion of this work. We expect to continue to make significant investments over the next two years in establishing manufacturing capability for the nebulizer device necessary to support the Phase 3 clinical study of this drug candidate and, if such study is successful and the drug candidate is approved by government health authorities, the commercial supply of the nebulizer device.

While the late stage clinical development programs described above are key elements of the future success of our company, we believe it is critically important that we continue to make substantial investments in our earlier stage drug candidate pipeline. For example, we plan to advance NKTR-181 into Phase 2 clinical trials in 2012 and we also plan to file an investigational new drug application (IND) for NKTR-192 in 2012. While we believe that our substantial investment in research and development has the potential to create significant value if one or more of our drug candidates demonstrates positive clinical results and/or receives regulatory approval in one or more major markets, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval and the timing and outcome of clinical trial results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition, and market value.

Historically, we have entered into a number of license and supply contracts under which we manufactured and supplied our proprietary PEGylation reagents on a cost-plus or fixed price basis. Our current strategy is to manufacture and supply PEGylation reagents to support our proprietary drug candidates or our third party collaborators where we have a strategic development and commercialization relationship or where we derive substantial economic benefit. As a result, whenever possible, we are renegotiating or not seeking renewal of legacy manufacturing supply arrangements that do not include a strategic development or commercialization component. For example, in October 2010, we entered into a supply, dedicated suite and manufacturing guarantee agreement with Amgen, Inc. and Amgen Manufacturing, Limited, which has significantly amended economic and other terms in the non-exclusive supply and license agreement we previously entered into with Amgen in 1995. In addition, in December 2010, we entered into an amended manufacturing and supply agreement with Merck (through its acquisition of Schering-Plough Corporation) to provide for transfer to an alternative manufacturer and revised economics for an interim supply arrangement until that transition is completed.

**Table of Contents****Key Developments and Trends in Liquidity and Capital Resources**

At December 31, 2011, we had approximately \$414.9 million in cash, cash equivalents, and investments in marketable securities and \$239.9 million in indebtedness. We have \$215.0 million in outstanding convertible subordinated notes due September 2012. We have no material credit facility or other material committed sources of capital. We expect the clinical development of our proprietary drug candidates including NKTR-102, NKTR-061, NKTR-181, and NKTR-192 will continue to require significant investments in order to advance through the clinic with the objective of entering into a collaboration partnership or obtaining regulatory approval. Historically, we have financed our operations primarily through cash from licensing, collaboration and manufacturing agreements and public and private placements of debt and equity securities. While in the past we have received a number of significant payments from license and collaboration agreements and other significant transactions, we do not currently anticipate completing new transactions with substantial upfront payments in the near future. As discussed above, the success of the KODIAC study is critical to providing cash to fund our operations and there can be no assurance as to the outcome of this study.

On February 29, 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® in exchange for \$124.0 million. Additionally, we incurred approximately \$4.5 million in transaction costs. While the net proceeds from this transaction will fund more than 50% of the September 2012 repayment obligation for the outstanding convertible notes, we intend to pursue other financing alternatives before the convertible note maturity date which could include the sale of additional royalty interests from legacy agreements or term loan arrangements. Where we believe it is in the best interests of the company and our stockholders, we are pursuing financing alternatives that are not dilutive to the ownership of our common stock security holders. However, if non-dilutive financing alternatives are not available to us on commercially reasonable terms or at all, we could be required to pursue dilutive equity-based financing alternatives such as an offering of convertible debt or common stock. If we are not successful in raising additional funds through financing activities in 2012, we may be required to reduce our research and development spending in one or more programs, as well as general and administrative expenses, in order to conserve working capital until additional funding becomes available either from our existing collaborations, new collaboration partnerships or additional fundraising activities. Our substantial debt, the market price of our common stock, and the general economic and equity market climate, among other factors, could have material adverse effects on our financial condition and could affect our ability to obtain short-term and long-term financing alternatives.

**Results of Operations****Years Ended December 31, 2011, 2010, and 2009**

Revenue (in thousands, except percentages)

	Years Ended December 31,			Increase/ (Decrease)	Increase/ (Decrease)	Percentage Increase/ (Decrease) 2011 vs. 2010	Percentage Increase/ (Decrease) 2010 vs. 2009
	2011	2010	2009				
Product sales	\$ 24,864	\$ 27,412	\$ 30,116	\$ (2,548)	\$ (2,704)	(9)%	(9)%
Royalty revenues	10,327	7,255	5,172	3,072	2,083	42%	40%
License, collaboration and other	36,289	124,372	36,643	(88,083)	87,729	(71)%	>100%
Total revenue	\$ 71,480	\$ 159,039	\$ 71,931	\$ (87,559)	\$ 87,108	(55)%	>100%



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Our revenue is derived from our collaboration agreements, under which we may receive product sales revenue, royalties, license fees, milestone payments or contract research payments. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured. Upfront fees received for license and collaborative agreements are recognized ratably over our expected performance period under the arrangement. As a result, there may be significant variations in the timing of receipt of cash payments and our recognition of revenue. Management makes its best estimate of the period over which we expect to fulfill our performance obligations. Given the uncertainties in research and development collaborations, significant judgment is required by management to determine the performance periods.

***Product sales***

Product sales include cost-plus and fixed price manufacturing and supply agreements with our collaboration partners. Product sales decreased during the years ended December 31, 2011 and 2010 compared to the prior periods primarily as a result of decreased product demand from our collaboration partners due in part to the transfer of manufacturing activities to certain collaboration partners. The timing of shipments is based on the demand and requirements of our collaboration partners and is not ratable throughout the year. We expect product sales to increase in 2012 compared with 2011.

***Royalty revenues***

We receive royalty revenue from certain of our collaboration partners based on their net sales of commercial products. Royalty revenues increased during the years ended December 31, 2011 and 2010 compared to the prior periods primarily as a result of the increase in royalties received from Roche's MIRCERA<sup>®</sup> and UCB Pharma's CIMZIA<sup>®</sup> product sales.

During the years ended December 31, 2011, 2010, and 2009, we recognized \$8.3 million, \$5.4 million, and \$2.7 million, respectively, in aggregate royalties from net sales of MIRCERA<sup>®</sup> and CIMZIA<sup>®</sup>. As noted above, in February 2012, we sold all of our rights to receive future royalty payments on CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup>. However, although any future CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> royalties will go directly to the purchaser of these royalty interests, as this transaction will be recorded as a liability that amortizes over the life of the estimated royalty payment period, we will continue to recognize the royalties as revenue, which we expect to increase in 2012.

***License, collaboration and other revenue***

License, collaboration and other revenue includes amortization of upfront payments and milestone payments received in connection with our license and collaboration agreements and reimbursed research and development expenses. The level of license, collaboration and other revenue depends in part upon the estimated amortization period of the upfront payments, the achievement of milestones, the continuation of existing collaborations, the amount of reimbursed research and development work, and entering into new collaboration agreements, if any.

License, collaboration and other revenue for the year ended December 31, 2011 decreased compared to the year ended December 31, 2010 primarily due to the complete recognition as of December 31, 2010 of the \$125.0 million upfront payment received in the fourth quarter of 2009 from AstraZeneca in connection with the NKTR-118 and NKTR-119 global license agreement. This decrease was partially offset by the recognition of a \$5.0 million license fee, \$6.0 million in milestones earned under existing collaboration agreements, and increases in revenue recognized in 2011 from upfront payments received by us during 2010.

We expect license, collaboration and other revenue in 2012 to be consistent with 2011.

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For the year ended December 31, 2010, the increase in license, collaboration and other revenue compared to the year ended December 31, 2009 is primarily attributable to recognition of the upfront payment received from AstraZeneca for NKTR-118 and NKTR-119 in the fourth quarter of 2009, contract research and other revenue from AstraZeneca, and the recognition of the license extension option payment received from Roche in December 2009. Under the AstraZeneca license agreement and related technology transfer agreement, we recognized \$101.4 million and \$23.6 million of the \$125.0 million upfront payment and \$6.5 million and \$1.5 million of contract research and other revenue for the years ended December 31, 2010 and 2009, respectively. We recognized \$5.1 million and \$0.2 million, respectively, of the \$31.0 million license extension option payment from Roche for the years ended December 31, 2010 and 2009, respectively.

The timing and future success of our drug development programs and those of our collaboration partners are subject to a number of risks and uncertainties. See Part I, Item 1A Risk Factors for discussion of the risks associated with the complex nature of our collaboration agreements.

**Revenue by geography**

Revenue by geographic area is based on locations of our partners. The following table sets forth revenue by geographic area (in thousands):

	Years Ended December 31,		
	2011	2010	2009
United States	\$ 37,896	\$ 29,636	\$ 29,511
European countries	33,584	129,403	42,420
Total revenue	\$ 71,480	\$ 159,039	\$ 71,931

The decrease in revenue attributable to European countries for the year ended December 31, 2011 compared to the year ended December 31, 2010 and the increase in the year ended December 31, 2010 compared to the year ended December 31, 2009 is primarily attributable to the revenue we recognized from the AstraZeneca license agreement.

**Cost of goods sold (in thousands, except percentages)**

	Years Ended December 31,			Increase/ (Decrease) 2011 vs. 2010	Increase/ (Decrease) 2010 vs. 2009	Percentage Increase/ (Decrease) 2011 vs. 2010	Percentage Increase/ (Decrease) 2010 vs. 2009
	2011	2010	2009				
Cost of goods sold	\$ 21,891	\$ 25,667	\$ 30,948	\$ (3,776)	\$ (5,281)	(15)%	(17)%
Product gross profit	2,973	1,745	(832)	1,228	2,577	70%	>100%
Product gross margin	12%	6%	(3)%				

The decrease in cost of goods sold during the year ended December 31, 2011 compared to the year ended December 31, 2010 is primarily due to the \$2.5 million decrease in product sales in 2011 and an increase in overall commercial and proprietary manufacturing activity in 2011 compared to 2010 that resulted in decreased costs per unit. The increase in product gross margin during the year ended December 31, 2011 compared to the year ended December 31, 2010 is primarily due to the different mix of products sold and the decreased costs per unit in 2011 resulting from increased manufacturing activity.

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The decrease in cost of goods sold during the year ended December 31, 2010 compared to the year ended December 31, 2009 is primarily due to the \$2.7 million decrease in product sales and the inclusion in cost of goods sold in 2009 of a \$2.1 million success fee that became due to one of our former consulting firms in 2009. The increase to product gross margin during the year ended December 31, 2010 compared to the year ended December 31, 2009 is primarily attributable to the \$2.1 million success fee included in cost of goods sold in 2009.

As a result of the fixed cost base associated with our manufacturing activities, we expect product gross margin to fluctuate in future periods depending on the level of manufacturing orders from our customers. However, due to the fixed price nature of certain of our significant supply agreements, we expect that gross margin will decrease in 2012 compared to 2011.

**Research and development expense (in thousands, except percentages)**

	Years Ended December 31,			Increase/ (Decrease) 2011 vs. 2010	Increase/ (Decrease) 2010 vs. 2009	Percentage Increase/ (Decrease) 2011 vs. 2010	Percentage Increase/ (Decrease) 2010 vs. 2009
	2011	2010	2009				
Research and development expense	\$ 126,766	\$ 108,065	\$ 95,109	\$ 18,701	\$ 12,956	17%	14%

Research and development expense consists primarily of personnel costs, including salaries, benefits, and stock-based compensation, clinical study costs, direct costs of outside research, materials, supplies, licenses and fees. Research and development expense also includes certain overhead allocations consisting of various support and facilities related costs.

The increase in research and development expense for the year ended December 31, 2011 compared to the year ended December 31, 2010 is primarily attributable to a \$7.5 million increase in direct research and development program costs and related materials costs, a \$3.0 million increase in salaries and employee benefits resulting from increased headcount to support our expanded clinical efforts, and a \$6.3 million increase in support and facilities-related costs, which includes increased non-cash depreciation and non-cash rent expenses related to our new facility in the Mission Bay Area of San Francisco, California (Mission Bay Facility).

The increase in research and development expense for the year ended December 31, 2010 compared to the year ended December 31, 2009 is primarily attributable to an \$8.4 million increase in salaries and employee benefits due to increased headcount to support our expanded clinical development efforts and further investment in and development of proprietary drug candidates in our research and development pipeline. The increase also includes a \$3.8 million increase in non-cash stock-based compensation expense due to our higher stock price and increased headcount, a \$3.1 million increase to facilities and equipment costs primarily due to the completion of our India research facility and to the move to our Mission Bay Facility, and a \$2.7 million increase in supplies, including clinical trial materials. These expense increases were partially offset by a \$5.5 million decrease in outside services, including contract research organizations, due primarily to lower expenses for the NKTR-118 and NKTR-119 programs as a result of our successful completion of Phase 2 clinical studies and collaboration with AstraZeneca pursuant to the license agreement entered into in September 2009.

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We utilize our employee and infrastructure resources across multiple development projects as well as our research programs directed towards identifying drug candidates based on our technology platform. The following table shows expenses incurred for preclinical study support, contract manufacturing for clinical supplies, clinical and regulatory services provided by third parties and direct materials costs for each of our drug candidates. The table also presents other costs and overhead consisting of personnel, facilities and other indirect costs (in thousands):

	Clinical Study Status(1)	Years Ended December 31,		
		2011	2010	2009
NKTR-102 (topoisomerase I inhibitor-polymer conjugate)(2)	Phase 3	\$ 13,106	\$ 14,730	\$ 17,509
BAY41-6551 (Amikacin Inhale)(3)	Completed Phase 2	11,389	12,606	13,482
NKTR-181 (mu-opioid analgesic molecule for chronic pain)	Phase 1	9,747	4,389	
NKTR-192 (mu-opioid analgesic molecule for acute pain)	Pre-clinical	3,100		
NKTR-118 (orally available peripheral opioid antagonist)(4)	Phase 3	988	3,439	9,607
Other product candidates	Various	12,071	9,597	9,377
<b>Total third party and direct materials costs</b>		<b>50,401</b>	<b>44,761</b>	<b>49,975</b>
Personnel, overhead and other costs		59,433	48,736	36,672
Stock-based compensation and depreciation		16,932	14,568	8,462
Research and development expense		\$ 126,766	\$ 108,065	\$ 95,109

- (1) Clinical Study Status definitions are provided in the chart found in Part I, Item 1. Business.
- (2) In addition, during the year ended December 31, 2011, we made \$11.2 million of prepayments to certain vendors in our BEACON study
- (3) Partnered with Bayer Healthcare LLC in August 2007. As part of the Novartis Pulmonary Asset Sale, we retained an exclusive license to this technology for the development and commercialization of this drug candidate.
- (4) Partnered with AstraZeneca in 2009. In general, all development costs incurred by us after partnering with AstraZeneca are reimbursed by AstraZeneca.

We expect research and development expense to substantially increase over the next several years. We plan to continue to advance NKTR-102 in the BEACON study (metastatic breast cancer) and in Phase 2 clinical studies in ovarian and colorectal cancers. Our expanded Phase 2 clinical study in platinum resistant/refractory ovarian cancer patients is expected to continue throughout 2012. Based on our compilation and review of preliminary interim results in the expanded Phase 2 study in ovarian cancer and our communications with government health authorities, we will decide the future of our clinical development efforts in this indication. At the same time, we continue to advance the Phase 2 clinical study for NKTR-102 in colorectal cancer patients. We will be funding all of the clinical development costs for NKTR-102 without reimbursement from a collaboration partner for the foreseeable future. The clinical development costs for NKTR-102 will be significant. Although we are still in the early stages of the BEACON study, we estimate that the total third party and direct material costs over the life of the BEACON study will range from approximately \$110.0 million to \$120.0 million, of which \$14.0 million was paid as of December 31, 2011, and that it will be completed around the end of 2014. We are unable to estimate the dates or costs to complete the clinical development efforts for the ovarian and colorectal cancer indications in which we are studying NKTR-102.

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In addition to our NKTR-102 development activities, in 2012, we plan to initiate a Phase 2 clinical study for NKTR-181 that we expect to complete in 2013. We also plan to invest in an initial Phase 1 clinical study for NKTR-192 that we expect to complete in 2012. In addition, we plan to continue to make substantial investments to support the clinical and commercial manufacturing preparation and scale-up for the nebulizer devices to supply Bayer for the Amikacin Inhale program. Under our collaboration agreement with Bayer, we are responsible for all clinical and commercial supply of the nebulizer devices for Amikacin Inhale. We do not expect to have any significant future research and development costs associated with NKTR-118 and NKTR-119 as AstraZeneca is responsible for all further development and commercialization costs for these drug candidates.

In addition to our drug candidates that we plan to have in clinical development during 2012 and beyond, we believe it is vitally important to continue our substantial investment in a diverse pipeline of new drug candidates to continue to build on the value of our business. Our discovery research organization is identifying new drug candidates by applying our technology platform to a wide range of molecule classes, including small molecules and large proteins, peptides and antibodies, across multiple therapeutic areas. We plan to continue to advance our most promising early research drug candidates into preclinical development with the objective to advance these early stage research programs to human clinical studies over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. In order to advance our drug candidates through clinical development, the drug candidates are tested in numerous preclinical safety, toxicology and efficacy studies. We then conduct clinical studies for our drug candidates that take several years to complete. The cost and time required to complete clinical trials may vary significantly over the life of a clinical development program as a result of a variety of factors, including but not limited to:

the number of patients required to fully enroll a clinical study;

the length of time required to enroll clinical study participants;

the number and location of sites included in the clinical studies;

the clinical studies designs required by the health authorities (i.e. primary and secondary end points);

the potential for changing standards of care for the target patient population;

the competition for patient recruitment from competitive drug candidates being studied in the same clinical setting;

the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;

the safety and efficacy profile of the drug candidate;

the use of clinical research organizations to assist with the management of the trials; and

the costs and timing of, and the ability to secure, approvals from government health authorities.

Furthermore, our strategy includes entering into collaborations with third parties to participate in the development and commercialization of some of our drug candidates such as those collaborations that we have already completed for NKTR-118, NKTR-119 and Amikacin Inhale. In

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these situations, the clinical development program and process for a drug candidate and the estimated completion date will largely be under the control of that third party and not under our control. We cannot forecast with any degree of certainty which of our drug candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

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The risks and uncertainties associated with our research and development projects are discussed more fully in Item 1A Risk Factors. Other than for the BEACON study, due to the uncertainties discussed above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from a collaboration arrangement or the commercialization of a drug candidate.

**General and administrative expense (in thousands, except percentages)**

	Years Ended December 31,			Increase/ (Decrease)	Increase/ (Decrease)	Percentage Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010	2009	2011 vs. 2010	2010 vs. 2009	2011 vs. 2010	2010 vs. 2009
General and administrative expense	\$ 46,760	\$ 40,986	\$ 41,006	\$ 5,774	\$ (20)	14%	<1%

General and administrative expenses are associated with administrative staffing, business development, finance, marketing, and legal.

For the year ended December 31, 2011 compared to the year ended December 31, 2010, general and administrative expense increased by \$2.7 million due to a payment obligation related to the settlement of a commercial litigation matter. In addition, general and administrative expense increased due to personnel-related costs, support and facilities-related costs, and other administrative costs. In 2012, after excluding the impact of the 2011 commercial litigation settlement, we expect general and administrative expenses to increase modestly compared to 2011.

General and administrative expenses for the year ended December 31, 2010 remained at a consistent level compared to the year ended December 31, 2009.

**Impairment of long lived assets (in thousands except percentages)**

	Years Ended December 31,			Increase/ (Decrease)	Increase/ (Decrease)	Percentage Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010	2009	2011 vs. 2010	2010 vs. 2009	2011 vs. 2010	2010 vs. 2009
Impairment of long-lived assets	\$	\$ 12,576	\$	\$ (12,576)	\$ 12,576	(100%)	n/a

During the year ended December 31, 2010, we relocated all of our operations previously located in San Carlos, California, including our corporate headquarters, to our Mission Bay Facility in San Francisco, California. We determined that the carrying value of the San Carlos facility exceeded its fair value based on a discounted cash flow model and an impairment charge of \$12.6 million was recognized as a result.

**Table of Contents****Interest income (in thousands except percentages)**

	Years Ended December 31,			Increase/ (Decrease)	Increase/ (Decrease)	Percentage Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010	2009	2011 vs. 2010	2010 vs. 2009	2011 vs. 2010	2010 vs. 2009
Interest income	\$ 2,244	\$ 1,545	\$ 3,688	\$ 699	\$ (2,143)	45%	(58)%

The increase in interest income for the year ended December 31, 2011 compared to the year ended December 31, 2010 is a result of higher average cash and investment balances partially offset by the impact of lower interest rates earned on our cash, cash equivalents, and available-for-sale investments.

The decrease in interest income for the year ended December 31, 2010 compared to the year ended December 31, 2009 is primarily attributable to lower interest rates earned on our cash, cash equivalents, and available-for-sale investments.

**Interest expense (in thousands except percentages)**

	Years Ended December 31,			Increase/ (Decrease)	Increase/ (Decrease)	Percentage Increase/ (Decrease)	Percentage Increase/ (Decrease)
	2011	2010	2009	2011 vs. 2010	2010 vs. 2009	2011 vs. 2010	2010 vs. 2009
Interest expense	\$ 10,223	\$ 11,174	\$ 12,176	\$ (951)	\$ (1,002)	(9)%	(8)%

The decrease in interest expense for the year ended December 31, 2011 compared to the year ended December 31, 2010 is primarily attributable to the complete amortization of deferred financing costs during 2010 from our 3.25% convertible subordinated notes due September 2012.

As noted above, in February 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA®. Although we are required to make payments to the purchaser of these rights only in certain situations, this transaction will be recorded as a liability. While we do not anticipate making any cash payments representing interest, we will impute interest on the transaction and record interest expense at the effective interest rate of approximately 17%. As a result, we expect interest expense in 2012 to increase significantly from 2011.

The decrease in interest expense during the year ended December 31, 2010 compared to the year ended December 31, 2009 is primarily attributable to the complete amortization of deferred financing costs during 2010 from our 3.25% convertible subordinated notes due September 2012 and decreased interest expense from capital leases.

**Liquidity and Capital Resources**

We have financed our operations primarily through revenue from product sales, royalties and research and development contracts, as well as public and private placements of debt and equity. As of December 31, 2011, we had cash, cash equivalents and investments in marketable securities of \$414.9 million and indebtedness of \$239.9 million, including \$215.0 million of convertible subordinated notes, \$17.0 million in capital lease obligations and \$7.9 million in other liabilities. Additionally at December 31, 2011, we had letter of credit arrangements with certain financial institutions and vendors, including our landlord, totaling \$2.4 million. These letters of credit will expire during 2012 and are secured by investments of similar amounts. We have no material credit facility or other material committed sources of capital.



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On February 29, 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA® in exchange for \$124.0 million. Additionally, we incurred approximately \$4.5 million in transaction costs. While the net payments from this transaction will fund more than 50% of the September 2012 repayment obligation for the outstanding convertible notes, we intend to pursue other financing alternatives before the convertible note maturity date which could include the sale of additional royalty interests or term loan arrangements. We may also seek from time to time to purchase or retire our outstanding convertible notes through cash purchases and/or exchanges for other of our securities in open market transactions, privately negotiated transactions and/or a tender offer, if we can do so on attractive terms. We will evaluate financing alternatives, if any, in light of the then-existing market conditions. Where we believe it is in the best interests of the company and our stockholders, we are pursuing financing alternatives that are not dilutive to the ownership of our common stock security holders. However, if non-dilutive financing alternatives are not available to us on commercially reasonable terms or at all, we could be required to pursue dilutive equity-based financing alternatives such as an offering of convertible debt or common stock. In addition, we expect the Phase 3 clinical trials of NKTR-102 to require particularly significant resources because we anticipate bearing a majority or all of the development costs for that drug candidate. If we are not successful in raising additional funds through financing activities in 2012, we may be required to reduce our research and development spending in one or more programs, as well as general and administrative expenses, in order to conserve working capital until additional funding becomes available either from our existing collaborations or additional fundraising activities. Our substantial debt, the market price of our common stock, and the general economic and equity market climate, among other factors, could substantially weaken our financial condition and could reduce or eliminate our ability to obtain short-term and long-term financing alternatives. Please refer to Part I, Item 1A, Risk Factors, *We may need to raise substantial additional capital to repay the \$215.0 million in convertible notes due in September 2012 and fund our future operations, and we may be unable to secure such capital without dilutive financing transactions and We have substantial future capital requirements and there is a risk we may not have access to sufficient capital to meet our current business plan. If we do not receive substantial milestone payments from our existing collaboration agreements, execute new high value collaboration partnerships, or if we are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.*

Due to the potential for continued uncertainty in the credit markets in 2012, we may experience reduced liquidity with respect to some of our investments in marketable securities. These investments are generally held to maturity, which is less than two years. However, if the need arose to liquidate such securities before maturity, we may experience losses on liquidation. At December 31, 2011, the average time to maturity of the investments held in our portfolio was approximately ten months and the maturity of any single investment did not exceed twenty-four months. To date we have not experienced any liquidity issues with respect to these securities, but should such issues arise, we may be required to hold some, or all, of these securities until maturity. We believe that, even allowing for potential liquidity issues with respect to these securities, our remaining cash, cash equivalents, and investments will be sufficient to meet our anticipated cash needs for at least the next twelve months.

***Cash flows from operating activities***

Cash flows used in operating activities for the year ended December 31, 2011 totaled \$113.7 million, which includes \$7.0 million for semi-annual interest payments on our convertible subordinated notes, \$11.2 million of prepayments to certain vendors in our BEACON study, and \$125.0 million of other net operating cash uses, partially offset by the receipt of \$29.5 million from collaboration agreements, of which \$16.5 million was included in accounts receivable at December 31, 2010 resulting from an upfront payment obligation arising from an amendment to one of our manufacturing and supply agreements. We expect that cash flows used in operating activities, excluding upfront payments received, if any, will increase in 2012 as a result of increased spending on our proprietary research and development programs and, in particular, our BEACON study.

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During the year ended December 31, 2010, net cash used in operating activities totaled \$55.9 million, which primarily consisted of spending on operating costs and expenses and includes \$7.0 million for interest payments on our convertible subordinated notes, and was partially offset by a \$50.0 million upfront payment received from Amgen under the supply, dedicated suite and manufacturing guarantee agreement that we entered into with Amgen in October 2010.

During the year ended December 31, 2009, net cash provided by operating activities totaled \$39.7 million, which included the \$125.0 million upfront payment received from AstraZeneca under the license agreement we entered into for NKTR-118 and NKTR-119 and a \$31.0 million license extension payment received from Roche in December 2009.

**Cash flows from investing activities**

We purchased \$9.7 million, \$31.5 million, and \$16.4 million of property and equipment in the years ended December 31, 2011, 2010, and 2009, respectively. Additionally, we made advanced payments on property and equipment purchases of \$4.3 million in the year ended December 31, 2009. Our capital expenditures increased in 2010, as we constructed the leasehold improvements for the Mission Bay Facility and completed our research and development facility in Hyderabad, India. We expect our capital expenditures in 2012 to be consistent with 2011.

On December 31, 2008, we completed the sale of certain pulmonary assets to Novartis for a purchase price of \$115.0 million. We paid \$0.2 million in transaction costs related to the sale during the year ended December 31, 2008 and \$4.4 million in transaction costs during the year ended December 31, 2009.

**Cash flows used in financing activities**

On January 24, 2011, we completed a public offering of our common stock with gross proceeds of approximately \$220.4 million. As part of the public offering, we incurred approximately \$0.6 million in legal and accounting fees, filing fees, and other offering expenses.

We received proceeds from issuance of common stock related to our employee option and stock purchase plans of \$4.5 million, \$8.9 million, and \$4.8 million in the years ended December 31, 2011, 2010, and 2009, respectively.

**Contractual Obligations (in thousands)**

	Total	Payments Due by Period			
		<=1 Yr 2012	2-3 Yrs 2013-2014	4-5 Yrs 2015-2016	2017+
<b>Obligations(1)</b>					
Convertible subordinated notes, including interest	\$ 221,941	\$ 221,941	\$	\$	\$
Capital leases, including interest(2)	24,662	5,028	10,320	9,314	
Operating leases(3)	22,000	480	1,709	7,444	12,367
Purchase commitments(4)	10,073	10,073			
Litigation settlement, including interest	5,000	1,000	2,000	2,000	
	\$ 283,676	\$ 238,522	\$ 14,029	\$ 18,758	\$ 12,367

(1) The above table does not include certain commitments and contingencies which are discussed in Note 7 of Item 8. Financial Statements and Supplementary Data.

(2) These amounts primarily result from capital lease obligations arising from our office space lease at 201 Industrial Road in San Carlos, California. As of November 29, 2010, we have ceased use of this space as a

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result of the relocation of all of our California functions, including our corporate headquarters and an R&D center, to our Mission Bay Facility. We have subleased a portion of the San Carlos Facility and are currently seeking one or more subtenants for the remaining space. This is further discussed in Note 6 of Item 8. Financial Statements and Supplementary Data.

- (3) In November 2010, we moved into our Mission Bay Facility, which includes our corporate headquarters and an R&D center. Under the terms of the sublease we entered into with Pfizer Inc. on September 30, 2009 for the Mission Bay Facility, we will begin making non-cancelable lease payments in 2014. On December 28 2011, we amended the sublease of the Mission Bay Facility to include an additional 24,002 square feet of space. Under the terms of the amendment, beginning January 1, 2012, we will begin making lease payments for this additional space of \$40,000 per month until May 31, 2013. The sublease is discussed in Note 6 of Item 8. Financial Statements and Supplementary Data.
- (4) Substantially all of this amount was subject to open purchase orders as of December 31, 2011 that were issued under existing contracts. This amount does not represent any minimum contract termination liabilities for our existing contracts.

Given our current cash requirements, we forecast that we will have sufficient cash to meet our net operating expense requirements and contractual obligations at least through December 31, 2012. We plan to continue to invest in the advancement of our research and development drug candidate pipeline and our future cash requirements will depend upon the timing and results of these investments. Our capital needs will depend on many factors, including continued progress in our research and development programs, progress with preclinical and clinical trials of our proprietary and partnered drug candidates, our ability to successfully enter into additional collaboration agreements for one or more of our proprietary drug candidates or intellectual property that we control, the time and costs involved in obtaining regulatory approvals, the costs of developing and scaling our clinical and commercial manufacturing operations, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technologies and the status of competitive products.

Our substantial debt, the market price of our securities, and the general economic climate, among other factors, could have material consequences for our financial condition and could affect our sources of short-term and long-term funding. Our ability to meet our ongoing operating expenses and repay our outstanding indebtedness is dependent upon our and our partners' ability to successfully complete clinical development of, obtain regulatory approvals for and successfully commercialize new drugs. Even if we or our partners are successful, we may require additional capital to continue to fund our operations and repay our debt obligations as they become due. There can be no assurance that additional funds, if and when required, will be available to us on favorable terms, if at all.

***Off Balance Sheet Arrangements***

We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing.

**Critical Accounting Policies**

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

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 our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources, and evaluate our estimates on an ongoing basis. Actual results may differ from those estimates under different assumptions or conditions. We have determined that for the periods reported in this report, the following accounting policies and estimates are critical in understanding our financial condition and results of our operations.

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***Revenue Recognition***

License, collaboration and other research revenue is recognized based on the facts and circumstances of each contractual agreement and includes amortization of upfront fees. We defer income under contractual agreements when we have further obligations that indicate that a separate earnings process has not been completed. Upfront fees are recognized ratably over the expected performance period under each arrangement. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, clinical development activities, or manufacturing activities through the completion of clinical development or the termination or expiration of the collaboration agreement. Given the complexities and uncertainties of collaboration arrangements, significant judgment is required by management to determine the duration of the performance period.

As of December 31, 2011, we had \$41.1 million of deferred upfront fees related to five collaboration agreements that are being amortized over 6 to 20 years, or an average of 12 years. For our collaboration agreements, our performance obligations may span the life of the agreement. For these, the shortest reasonable period is the end of the development period (estimated to be 4 to 6 years) and the longest period is the contractual life of the agreement, which is generally 10-12 years from the first commercial sale. Given the statistical probability of drug development success in the bio-pharmaceutical industry, drug development programs have only a 5% to 10% probability of reaching commercial success. If we had determined a longer or shorter amortization period was appropriate, our annual upfront fee amortization for these agreements could be as low as \$4.0 million or as high as \$17.0 million as compared to the \$5.4 million recognized in the year ended December 31, 2011.

As of December 31, 2011, we also had \$83.9 million of deferred upfront fees related to five license, manufacturing and supply agreements that are being amortized over periods from 2 and 10 years. Our performance obligations for these agreements may include technology transfer assistance and/or back-up manufacturing and supply services for a specified period of time; therefore, the time estimated to complete the performance obligations related to licenses is either specified or is much shorter than the collaboration agreements. We may experience delays in the execution of technology transfer plans, which may result in a longer amortization period for applicable agreements.

Our original estimates are periodically evaluated to determine if circumstances have caused the estimates to change and if so, amortization of revenue is adjusted prospectively.

***Stock-Based Compensation***

We use the Black-Scholes option valuation model for the respective equity grant to determine the estimated fair value of our stock-based compensation arrangements on the date of grant (grant date fair value) and expense this value, as adjusted for the estimated historical forfeiture rate, ratably over the service period of the option or performance period of the restricted stock unit award (RSU). The Black-Scholes option pricing model requires the input of highly subjective assumptions. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect fair value estimates, in management's opinion, the existing models may not provide a reliable single measure of the fair value of our employee stock options or common stock purchased under our employee stock purchase plan. In addition, management continually assesses the assumptions and methodologies used to calculate the estimated fair value of stock-based compensation. Circumstances may change and additional data may become available over time, which could result in changes to the assumptions and methodologies, and which could materially impact our fair value determination, as well as our stock-based compensation expense.

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### ***Clinical Trial Accruals***

We record accruals for the estimated costs of our clinical trial activities performed by third parties. We generally accrue costs associated with the start-up and reporting phases of the clinical trials ratably over the estimated duration of the start-up and reporting phases. If the actual timing of these phases varies from the estimate, we will adjust the accrual prospectively. We accrue costs associated with the treatment phase of clinical trials based on the total estimated cost of the treatment phase on a per patient basis and we expense the per patient cost ratably based on patient enrollment in the trials. Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and recognized as expense as the related goods are delivered or the related services are performed.

### **Recent Accounting Pronouncements**

#### ***FASB Accounting Standards Update 2011-08, Intangibles – Goodwill and Other (Topic 350), Testing Goodwill for Impairment***

In September 2011, the Financial Accounting Standards Board (FASB) issued new accounting guidance intended to simplify goodwill impairment testing. Entities will be allowed to perform a qualitative assessment on goodwill impairment to determine whether a quantitative assessment is necessary. This guidance is effective for our interim and annual periods beginning January 1, 2012. We do not believe the adoption of this guidance will have a material impact on our consolidated financial statements.

### **Item 7A. *Quantitative and Qualitative Disclosures About Market Risk* Interest Rate and Market Risk**

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in liquid, high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in securities with maturities of two years or less and maintain a weighted average maturity of one year or less.

A hypothetical 50 basis point increase in interest rates would result in an approximate \$1.7 million decrease, less than 1%, in the fair value of our available-for-sale securities at December 31, 2011. This potential change is based on sensitivity analyses performed on our investment securities at December 31, 2011. Actual results may differ materially. The same hypothetical 50 basis point increase in interest rates would have resulted in an approximate \$0.6 million decrease, less than 1%, in the fair value of our available-for-sale securities at December 31, 2010.

Due to the potential for continued uncertainty in the credit markets in 2012, we may experience reduced liquidity with respect to some of our investments in marketable securities. These investments are generally held to maturity, which is less than two years. However, if the need arose to liquidate such securities before maturity, we may experience losses on liquidation. As of December 31, 2011, we held \$399.6 million of available-for-sale investments, excluding money market funds, with an average time to maturity of ten months. To date we have not experienced any liquidity issues with respect to these securities, but should such issues arise, we may be required to hold some, or all, of these securities until maturity. We believe that, even allowing for potential liquidity issues with respect to these securities, our remaining cash, cash equivalents, and investments will be sufficient to meet our anticipated cash needs for at least the next twelve months. Based on our available cash and our expected operating cash requirements, we currently do not intend to sell these securities prior to maturity and it is more likely than not that we will not be required to sell these securities before we recover the amortized cost basis. Accordingly, we believe there are no other-than-temporary impairments on these securities and have not recorded any provisions for impairment.

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**Foreign Currency Risk**

The majority of our revenue, expense, and capital purchasing activities are transacted in U.S. dollars. However, since a portion of our operations consists of research and development activities outside the United States, we have entered into transactions in other currencies, primarily the Indian Rupee, and we therefore are subject to foreign exchange risk.

Our international operations are subject to risks typical of international operations, including, but not limited to, differing economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. We do not utilize derivative financial instruments to manage our exchange rate risks.

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**Item 8. *Financial Statements and Supplementary Data***

**NEKTAR THERAPEUTICS**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Nektar Therapeutics

We have audited the accompanying consolidated balance sheets of Nektar Therapeutics as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Nektar Therapeutics at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Nektar Therapeutics' internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2012 expressed an unqualified opinion thereon.

As discussed in Note 1 to the consolidated financial statements, Nektar Therapeutics changed its method of accounting for revenue recognition effective January 1, 2011.

/s/ ERNST & YOUNG LLP

Redwood City, California

February 29, 2012



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Nektar Therapeutics

We have audited Nektar Therapeutics' internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Nektar Therapeutics' 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 Annual 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 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 its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Nektar Therapeutics maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Nektar Therapeutics as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2011 of Nektar Therapeutics and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California

February 29, 2012

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**NEKTAR THERAPEUTICS**  
**CONSOLIDATED BALANCE SHEETS**

	2011	December 31, 2010
	(In thousands, except par value information)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,312	\$ 17,755
Short-term investments	225,856	298,177
Accounts receivable, net of allowance of nil at December 31, 2011 and 2010	4,938	25,102
Inventory	12,656	7,266
Other current assets	17,944	5,679
<b>Total current assets</b>	<b>276,706</b>	<b>353,979</b>
Long-term investments	173,768	
Property and equipment, net	78,576	89,773
Goodwill	76,501	76,501
Other assets	999	972
<b>Total assets</b>	<b>\$ 606,550</b>	<b>\$ 521,225</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,019	\$ 7,194
Accrued compensation	12,807	9,252
Accrued expenses	6,669	8,540
Accrued clinical trial expenses	11,953	12,144
Deferred revenue, current portion	19,643	20,584
Convertible subordinated notes, current portion	214,955	
Other current liabilities	6,486	6,394
<b>Total current liabilities</b>	<b>275,532</b>	<b>64,108</b>
Convertible subordinated notes		214,955
Capital lease obligations, less current portion	14,582	17,014
Deferred revenue, less current portion	108,188	124,763
Deferred gain	3,278	4,152
Other long-term liabilities	7,159	5,571
<b>Total liabilities</b>	<b>408,739</b>	<b>430,563</b>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 10,000 shares authorized Series A, \$0.0001 par value; 3,100 shares designated; no shares issued or outstanding at either December 31, 2011 or 2010		
Common stock, \$0.0001 par value; 300,000 authorized; 114,485 shares and 94,517 shares issued and outstanding at December 31, 2011 and 2010, respectively	11	9
Capital in excess of par value	1,597,428	1,354,232
Accumulated other comprehensive (loss) income	(1,103)	968
Accumulated deficit	(1,398,525)	(1,264,547)
<b>Total stockholders' equity</b>	<b>197,811</b>	<b>90,662</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 606,550</b>	<b>\$ 521,225</b>

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The accompanying notes are an integral part of these consolidated financial statements.

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**NEKTAR THERAPEUTICS**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2011	2010	2009
	(In thousands, except per share information)		
<b>Revenue:</b>			
Product sales	\$ 24,864	\$ 27,412	\$ 30,116
Royalty revenues	10,327	7,255	5,172
License, collaboration and other revenue	36,289	124,372	36,643
<b>Total revenue</b>	<b>71,480</b>	<b>159,039</b>	<b>71,931</b>
<b>Operating costs and expenses:</b>			
Cost of goods sold	21,891	25,667	30,948
Research and development	126,766	108,065	95,109
General and administrative	46,760	40,986	41,006
Impairment of long-lived assets		12,576	
<b>Total operating costs and expenses</b>	<b>195,417</b>	<b>187,294</b>	<b>167,063</b>
<b>Loss from operations</b>	<b>(123,937)</b>	<b>(28,255)</b>	<b>(95,132)</b>
<b>Non-operating income (expense):</b>			
Interest income	2,244	1,545	3,688
Interest expense	(10,223)	(11,174)	(12,176)
Other income (expense), net	(1,044)	827	848
<b>Total non-operating expense, net</b>	<b>(9,023)</b>	<b>(8,802)</b>	<b>(7,640)</b>
<b>Loss before provision (benefit) for income taxes</b>	<b>(132,960)</b>	<b>(37,057)</b>	<b>(102,772)</b>
<b>Provision (benefit) for income taxes</b>	<b>1,018</b>	<b>881</b>	<b>(253)</b>
<b>Net loss</b>	<b>\$ (133,978)</b>	<b>\$ (37,938)</b>	<b>\$ (102,519)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (1.19)</b>	<b>\$ (0.40)</b>	<b>\$ (1.11)</b>
<b>Weighted average shares outstanding used in computing basic and diluted net loss per share</b>	<b>112,942</b>	<b>94,079</b>	<b>92,772</b>

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****NEKTAR THERAPEUTICS****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

	Common Shares	Par Value	Capital in Excess of Par Value	Accumulated Other Comprehensive Income/(Loss) (In thousands)	Accumulated Deficit	Total Stockholders Equity
Balance at December 31, 2008	92,503	\$ 9	\$ 1,312,796	\$ 1,439	\$ (1,124,090)	\$ 190,154
Stock option exercises and RSU release	742		4,696			4,696
Stock-based compensation			10,326			10,326
Shares issued for Employee Stock Purchase Plan	36		124			124
Other comprehensive loss				(414)		(414)
Net loss					(102,519)	(102,519)
Comprehensive loss						(102,933)
Balance at December 31, 2009	93,281	9	1,327,942	1,025	(1,226,609)	102,367
Stock option exercises and RSU release	1,176		8,340			8,340
Stock-based compensation			17,399			17,399
Shares issued for Employee Stock Purchase Plan	60		551			551
Other comprehensive loss				(57)		(57)
Net loss					(37,938)	(37,938)
Comprehensive loss						(37,995)
Balance at December 31, 2010	94,517	9	1,354,232	968	(1,264,547)	90,662
Sale of common stock, net of issuance costs of \$617	19,000	2	219,781			219,783
Stock option exercises and RSU release	866		3,916			3,916
Stock-based compensation			18,885			18,885
Shares issued for Employee Stock Purchase Plan	102		614			614
Other comprehensive loss				(2,071)		(2,071)
Net loss					(133,978)	(133,978)
Comprehensive loss						(136,049)
Balance at December 31, 2011	114,485	\$ 11	\$ 1,597,428	\$ (1,103)	\$ (1,398,525)	\$ 197,811

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****NEKTAR THERAPEUTICS****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
<b>Cash flows from operating activities:</b>			
Net loss	\$ (133,978)	\$ (37,938)	\$ (102,519)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	14,951	16,551	14,881
Stock-based compensation	18,885	17,399	10,326
Impairment of long-lived assets		12,576	
Other non-cash transactions	1,359	198	(657)
Changes in assets and liabilities:			
Accounts receivable	20,164	(20,301)	6,034
Inventory	(5,390)	(795)	2,848
Other assets	(12,267)	577	(200)
Accounts payable	(3,384)	4,274	(8,046)
Accrued compensation	3,555	(800)	(1,518)
Accrued expenses	1,013	1,683	(4,191)
Accrued clinical trial expenses	(191)	(2,023)	(3,455)
Deferred revenue	(17,516)	(47,025)	126,795
Other liabilities	(943)	(247)	(559)
Net cash (used in) provided by operating activities	(113,742)	(55,871)	39,739
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(9,722)	(31,457)	(16,390)
Advance payments for property and equipment			(4,312)
Maturities of investments	383,052	475,813	310,707
Sales of investments	210,089	15,479	17,318
Purchases of investments	(695,371)	(443,122)	(451,918)
Transaction costs for sale of pulmonary assets			(4,440)
Net cash (used in) provided by investing activities	(111,952)	16,713	(149,035)
<b>Cash flows from financing activities:</b>			
Issuance of common stock, net of issuance costs	224,313	8,891	4,820
Payments of loan and capital lease obligations	(1,978)	(1,356)	(1,285)
Net cash provided by financing activities	222,335	7,535	3,535
Effect of exchange rates on cash and cash equivalents	916	(219)	(226)
Net decrease in cash and cash equivalents	(2,443)	(31,842)	(105,987)
Cash and cash equivalents at beginning of year	17,755	49,597	155,584
Cash and cash equivalents at end of year	\$ 15,312	\$ 17,755	\$ 49,597
<b>Supplemental disclosure of cash flows information:</b>			
Cash paid for interest	\$ 10,277	\$ 10,599	\$ 11,225

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Cash paid for income taxes	\$	957	\$	407	\$	743
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**Supplemental schedule of non-cash investing and financing activities:**

Property and equipment acquired through capital leases	\$		\$	195	\$	
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The accompanying notes are an integral part of these consolidated financial statements.

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**NEKTAR THERAPEUTICS**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2011**

**Note 1 Organization and Summary of Significant Accounting Policies**

***Organization***

We are a clinical-stage biopharmaceutical company headquartered in San Francisco, California and incorporated in Delaware. We are developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms designed to improve the therapeutic benefits of drugs.

Our development activities have required significant resources to date and are expected to continue to require significant resources. As a result, we expect to continue to incur substantial losses and negative cash flows from operations in the future. Historically, we have financed our operations primarily through cash from licensing, collaboration and manufacturing agreements and public and private placements of debt and equity securities. At December 31, 2011, we had approximately \$414.9 million in cash, cash equivalents, and investments in marketable securities and \$239.9 million in indebtedness, including \$215.0 million in outstanding convertible subordinated notes due September 2012. On February 24, 2012, we entered into an agreement whereby we received an aggregate cash payment of \$124.0 million in exchange for the right to receive all royalty payments arising from future worldwide net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> from and after January 1, 2012 under our license, manufacturing and supply agreements with UCB Pharma (UCB) and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche), respectively. Additionally, we incurred approximately \$4.5 million in transaction costs. We plan to use the net payments from this agreement to in part repay the convertible subordinated notes due September 28, 2012 (see Note 14).

***Basis of Presentation, Principles of Consolidation and Use of Estimates***

Our consolidated financial statements include the financial position, results of operations and cash flows of our wholly-owned subsidiaries: Nektar Therapeutics AL, Corporation (Nektar AL), Nektar Therapeutics (India) Private Limited, Nektar Therapeutics UK, Ltd. (Nektar UK) and Aerogen, Inc. All intercompany accounts and transactions have been eliminated in consolidation. The merger of Nektar AL, an Alabama corporation, with and into its parent corporation, Nektar Therapeutics, was made effective July 31, 2009. As of the effective date, the separate existence of Nektar AL ceased, and all rights, privileges, powers and franchises of Nektar AL are vested in Nektar Therapeutics, the surviving corporation. On December 2, 2010, we completed the dissolution of Aerogen, Inc. and all remaining assets were transferred to Nektar Therapeutics.

Our consolidated financial statements are denominated in U.S. dollars. Accordingly, changes in exchange rates between the applicable foreign currency and the U.S. dollar will affect the translation of each foreign subsidiary's financial results into U.S. dollars for purposes of reporting our consolidated financial results. Translation gains and losses are included in accumulated other comprehensive loss in the stockholders' equity section of the balance sheet. To date, such cumulative translation adjustments have not been material to our consolidated financial position. Aggregate gross foreign currency transaction gains (losses) recorded in operations for the years ended December 31, 2011, 2010, and 2009 were not material.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates, including those related to deferred revenue recognition periods, inventories, the impairment of investments, the impairment of goodwill and long-lived



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assets, restructuring and contingencies, stock-based compensation, and litigation, amongst others. We base our estimates on historical experience and on other assumptions that management believes are reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

### ***Reclassifications***

Certain items previously reported in specific financial statement captions have been reclassified to conform to the current period presentation. Such reclassifications do not impact previously reported total revenue, operating loss or net loss or total assets, liabilities or stockholders' equity.

### ***Cash, Cash Equivalents, and Investments, and Fair Value of Financial Instruments***

We consider all investments in marketable securities with an original maturity of three months or less to be cash equivalents. Investments are designated as available-for-sale and are carried at fair value, with unrealized gains and losses reported in stockholders' equity as accumulated other comprehensive income (loss). The disclosed fair value related to our investments is based primarily on the reported fair values in our period-end brokerage statements. We independently validate these fair values using available market quotes and other information. Investments in securities with maturities of less than one year, or where management's intent is to use the investments to fund current operations or to make them available for current operations, are classified as short-term investments.

Interest and dividends on securities classified as available-for-sale, as well as amortization of premiums and accretion of discounts to maturity, are included in interest income. Realized gains and losses and declines in value of available-for-sale securities judged to be other-than-temporary, if any, are included in other income (expense). The cost of securities sold is based on the specific identification method.

The carrying value of cash, cash equivalents, and investments approximates fair value and is based on quoted market prices.

### ***Accounts Receivable and Significant Customer Concentrations***

Our customers are primarily pharmaceutical and biotechnology companies that are located in the U.S. and Europe. Our accounts receivable balance contains billed and unbilled trade receivables from product sales and royalties, as well as time and materials based billings from collaborative research and development agreements. We provide for an allowance for doubtful accounts by reserving for specifically identified doubtful accounts. We generally do not require collateral from our customers. We perform a regular review of our customers' payment histories and associated credit risk. We have not experienced significant credit losses from our accounts receivable. At December 31, 2011, four different customers represented 26%, 20%, 19% and 17%, respectively, of our accounts receivable. At December 31, 2010, two different customers represented 66% and 21%, respectively, of our accounts receivable.

### ***Inventory and Significant Supplier Concentrations***

Inventory is generally manufactured upon receipt of firm purchase orders from our licensing partners. Inventory includes direct materials, direct labor, and manufacturing overhead and is determined on a first-in, first-out basis. Inventory is stated at the lower of cost or market and is net of reserves determined using specific identification plus an estimated reserve for potential defective or excess inventory based on historical experience or projected usage. Supplies inventory related to research and development activities are expensed when purchased.

We are dependent on our suppliers and contract manufacturers to provide raw materials, drugs and devices of appropriate quality and reliability and to meet applicable regulatory requirements. In certain cases, we rely on

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single sources of supply. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop and produce our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

### ***Property and Equipment***

Property and equipment are stated at cost. Major improvements are capitalized, while maintenance and repairs are expensed when incurred. Manufacturing, laboratory and other equipment are depreciated using the straight-line method generally over estimated useful lives of three to seven years. Leasehold improvements and buildings are depreciated using the straight-line method over the shorter of the estimated useful life or the remaining term of the lease.

We periodically review our property and equipment for recoverability whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Generally, an impairment loss would be recognized if the carrying amount of an asset exceeds the sum of the discounted cash flows expected to result from the use and eventual disposal of the asset (see Note 10).

### ***Goodwill***

Goodwill represents the excess of the price paid for another entity over the fair value of the assets acquired and liabilities assumed in a business combination. We test for impairment in the fourth quarter of each year using an October 1 measurement date, as well as at other times when impairment indicators exist or when events occur or circumstances change that would indicate the carrying amount may not be fully recoverable.

We are organized in one reporting unit and have evaluated the goodwill for the Company as a whole. Goodwill is tested for impairment using a two-step approach. The first step is to compare the fair value of our net assets, including assigned goodwill, to the book value of our net assets, including assigned goodwill. If the fair value is greater than our net book value, the assigned goodwill is not considered impaired. If the fair value is less than our net book value, we perform a second step to measure the amount of the impairment, if any. The second step would be to compare the book value of our assigned goodwill to the implied fair value of our goodwill. We did not recognize any goodwill-related impairment charges during 2011, 2010, or 2009.

### ***Revenue Recognition***

We enter into arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may contain one or more of the following elements: upfront fees, contract research and development, milestone payments, manufacturing and supply, royalties, and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. Revenue is recognized separately for each element.

On January 1, 2011, we adopted on a prospective basis Accounting Standards Update (ASU) 2009-13, which amends the criteria to identify separate units of accounting within Subtopic 605-25, Revenue Recognition-Multiple-Element Arrangements. The adoption of the standard did not impact our financial position or results of operations as of and for the year ended December 31, 2011 as we did not enter into or materially modify any multiple-element arrangements during that period. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are materially different from those recognized for our existing multiple-element arrangements.

### ***Product sales***

Product sales are primarily derived from cost-plus and fixed price manufacturing and supply agreements with our collaboration partners and revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured. We have not experienced any significant returns from our customers.

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### *Royalty revenues*

Generally, we are entitled to royalties from our partners based on their net sales of approved drugs. We recognize royalty revenue when the cash is received or when the royalty amount to be received is estimable and collection is reasonably assured.

### *License, collaboration and other*

Upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 are recognized ratably over our expected performance period under each respective arrangement. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaborative arrangements, significant judgment is required to determine the duration of the performance period.

On January 1, 2011, we elected to prospectively adopt ASU 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our various license and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

Our license and collaboration agreements with our partners provide for payments to us upon the achievement of development milestones, such as the completion of clinical trials or regulatory submissions and approvals for drug candidates. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty whether any such milestones would be achieved at the time these licensing and collaboration agreements were entered into. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as each milestone is achieved. This policy election may result in revenue recognition patterns for future milestones that are materially different from those recognized for milestones received in the periods prior to adoption during which milestones were deferred and recognized ratably over the period of time from the achievement of the milestone to the estimated date when the next milestone will be achieved. During the year ended December 31, 2011, we achieved two development milestones totaling \$4.5 million from two of our collaboration agreements. Under the milestone method of revenue recognition, these substantive milestones were recognized in their entirety upon achievement in the year ended December 31, 2011, whereas under our previous milestone revenue recognition policy, we would have recognized approximately \$1.5 million related to such amounts during this period. As a result, in the year ended December 31, 2011, this change in accounting policy resulted in increased revenues and a corresponding decrease to net loss of approximately \$3.0 million, or \$0.03 per share.

Our license and collaboration agreements with certain partners also provide for contingent payments to us based solely upon the performance of the respective partner. For such contingent amounts we expect to recognize the payments as revenue when earned under the applicable contract, provided that collection is reasonably assured.

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Our license and collaboration agreements with our partners also provide for payments to us upon the achievement of specified sales volumes of approved drugs. We consider these payments to be similar to royalty payments and we will recognize such sales-based payments upon achievement of such sales volumes, provided that collection is reasonably assured.

### ***Shipping and Handling Costs***

We record costs related to shipping and handling of product to customers in cost of goods sold.

### ***Stock-Based Compensation***

Stock-based compensation arrangements include stock option grants and restricted stock unit (RSU) awards under our equity incentive plans, as well as shares issued under our Employee Stock Purchase Plan (ESPP), in which employees may purchase our common stock at a discount to the market price.

We use the Black-Scholes option valuation model for the respective grant to determine the estimated fair value of the option or RSU award on the date of grant (grant date fair value) and the estimated fair value of common stock purchased under the ESPP. The Black-Scholes option pricing model requires the input of highly subjective assumptions. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models may not provide a reliable single measure of the fair value of our employee stock options or common stock purchased under the ESPP. Management will continue to assess the assumptions and methodologies used to calculate the estimated fair value of stock-based compensation. Circumstances may change and additional data may become available over time, which could result in changes to these assumptions and methodologies, and which could materially impact our fair value determination.

We expense the value of the portion of the option or award that is ultimately expected to vest on a straight line basis over the requisite service periods in our Consolidated Statements of Operations. Stock-based compensation expense for purchases under the ESPP are recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount. Expense amounts are allocated among inventory, cost of goods sold, research and development expense, and general and administrative expense based on the function of the applicable employee. Stock-based compensation charges are non-cash charges and as such have no impact on our reported cash flows.

### ***Research and Development Expense***

Research and development costs are expensed as incurred and include salaries, benefits and other operating costs such as outside services, supplies and allocated overhead costs. We perform research and development for our proprietary drug candidates and technology development and for certain third parties under collaboration agreements. For our proprietary drug candidates and our internal technology development programs, we invest our own funds without reimbursement from a third party.

We record accruals for the estimated costs of our clinical trial activities performed by third parties. We generally accrue costs associated with the start-up and reporting phases of the clinical trials ratably over the estimated duration of the start-up and reporting phases. We accrue costs associated with the treatment phase of clinical trials based on the total estimated cost of the treatment phase on a per patient basis and we expense the per patient cost ratably based on patient enrollment in the trials. Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and recognized as expense as the related goods are delivered or the related services are performed.

**Table of Contents****Net Loss Per Share**

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding during the periods presented. For all periods presented in the Consolidated Statements of Operations, the net loss available to common stockholders is equal to the reported net loss. Basic and diluted net loss per share are the same due to our historical net losses and the requirement to exclude potentially dilutive securities which would have an anti-dilutive effect on net loss per share. The weighted average of these potentially dilutive securities has been excluded from the diluted net loss per share calculation and is as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Convertible subordinated notes	9,989	9,989	9,989
Stock options	11,338	9,338	10,653
<b>Total</b>	<b>21,327</b>	<b>19,327</b>	<b>20,642</b>

**Income Taxes**

We account for income taxes under the liability method; under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. We record a valuation allowance against deferred tax assets to reduce their carrying value to an amount that is more likely than not to be realized. When we establish or reduce the valuation allowance related to the deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period such determination is made.

We utilize a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

**Comprehensive loss**

Comprehensive loss is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. Our other comprehensive loss is comprised of net loss, gains and losses from the foreign currency translation of the assets and liabilities of our India subsidiary, and unrealized gains and losses on investments.

**Recent Accounting Pronouncements**

In September 2011, the Financial Accounting Standards Board issued new accounting guidance intended to simplify goodwill impairment testing. Entities will be allowed to perform a qualitative assessment of goodwill impairment to determine whether a quantitative assessment is necessary. This guidance is effective for our interim and annual periods beginning January 1, 2012. We do not believe the adoption of this guidance will have a material impact on our consolidated financial statements.

**Table of Contents****Note 2 Cash, Cash Equivalents, and Available-For-Sale Investments**

Cash, cash equivalents, and available-for-sale investments are as follows (in thousands):

	Estimated Fair Value at	
	December 31, 2011	December 31, 2010
Cash and cash equivalents	\$ 15,312	\$ 17,755
Short-term investments	225,856	298,177
Long-term investments	173,768	
 Total cash, cash equivalents, and available-for-sale investments	 \$ 414,936	 \$ 315,932

Our portfolio of cash, cash equivalents, and available-for-sale investments includes (in thousands):

	Estimated Fair Value at	
	December 31, 2011	December 31, 2010
Corporate notes and bonds	\$ 344,427	\$ 190,527
U.S. corporate commercial paper	9,464	82,361
Obligations of U.S. government agencies	44,230	25,289
Obligations of U.S. states and municipalities	1,503	
Cash and money market funds	15,312	17,755
 Total cash, cash equivalents, and available-for-sale investments	 \$ 414,936	 \$ 315,932

The following table summarizes our portfolio of available-for-sale investments reported as short-term and long-term investments by contractual maturity (in thousands):

	Estimated Fair Value at	
	December 31, 2011	December 31, 2010
Less than one year	\$ 213,386	\$ 298,177
Greater than one year but less than two years	186,238	
 Total available-for-sale investments	 \$ 399,624	 \$ 298,177

We invest in liquid, high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in securities with maturities of two years or less and maintain a weighted average maturity of one year or less. Investments in securities with remaining maturities of less than one year, or where management's intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

Gross unrealized gains and losses were not significant at December 31, 2011 and 2010. The gross unrealized losses were primarily due to changes in interest rates on fixed income securities. Based on our available cash and our expected operating cash requirements we currently do not intend to sell these securities and it is more likely than not that we will not be required to sell these securities before we recover the amortized cost basis. Accordingly, we believe there are no other-than-temporary impairments on these securities and have not recorded a provision for impairment.

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During the years ended December 31, 2011, 2010, and 2009, we sold available-for-sale securities totaling \$210.1 million, \$15.5 million and \$17.3 million, respectively, and realized gains and losses were not significant in any of those periods. The proceeds from these sales were re-invested in new securities.

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At December 31, 2011 and 2010, we had letter of credit arrangements in favor of a landlord and certain vendors totaling \$2.4 million. These letters of credit are secured by investments of similar amounts.

The following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of December 31, 2011 and 2010 (in thousands):

<b>As of December 31, 2011:</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money market funds	\$ 13,950	\$	\$	\$ 13,950
U.S. corporate commercial paper		9,464		9,464
Corporate notes and bonds		344,427		344,427
Obligations of U.S. government agencies		44,230		44,230
Obligations of U.S. states and municipalities		1,503		1,503