AFFYMAX INC
Form 10-K
March 14, 2012

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Item 8. Financial Statements and Supplementary Data.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2011

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-33213

AFFYMAX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0579396**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

4001 Miranda Avenue
Palo Alto, CA 94304
(650) 812-8700
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common stock, par value $0.001 per share	The NASDAQ Stock Market LLC (NASDAQ Global 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 o No ý

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

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 ý No o

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

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

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

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

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

The aggregate market value of the registrant's common stock, $0.001 par value, held by non-affiliates of the registrant as of June 30, 2011 was $182,507,870 (based upon the closing sales price of such stock as reported on the Nasdaq Global Market on such date). Excludes an aggregate of 8,872,357 shares of the registrant's common stock held by officers, directors and affiliated stockholders. For purposes of determining whether a stockholder was an affiliate of the registrant at June 30, 2011, the registrant has assumed that a stockholder was an affiliate of the registrant at June 30, 2011 if such stockholder (i) beneficially owned 10% or more of the registrant's common stock and/or (ii) was affiliated with an executive officer or director of the registrant at June 30, 2011. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 29, 2012, the registrant had outstanding 35,772,805 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Proxy Statement for the 2012 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2011, are incorporated by reference into Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference into this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "intend," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the timing, design and results of our clinical trials and drug development program, the continuation and success of our collaboration with Takeda Pharmaceutical Company Limited, and the timing, likelihood and success of the commercialization of peginesatide. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, timing or achievements to be materially different from any future results, performance, timing or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K under Item 1A "Risk Factors," including risks relating to the timing of, and requirements for, regulatory approvals, including the United States Food and Drug Administration's interpretation and evaluation of the data from the Phase 3 trials, in particular with respect to the secondary analyses in non-dialysis patients, and risk evaluation and mitigation strategies, postmarketing studies and label restrictions, risks relating to data quality and integrity particularly in non-inferiority designed trials, risks relating to the continued safety and efficacy of peginesatide in clinical development, the potential for once-monthly dosing and room temperature stability, the timing of patient accrual in ongoing and planned clinical trials, research and development efforts, the factors affecting the potential commercialization of peginesatide, industry and competitive environment, controversy surrounding the class of erythropoiesis stimulating agents, reimbursement coverage, intellectual property rights and potential disputes, financing requirements and ability to access capital, and other matters. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I.

Item 1. Business.

Overview

We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. Our product candidate, peginesatide, is for the treatment of anemia in chronic kidney disease patients on dialysis. The New Drug Application, or NDA, for peginesatide is currently under review by the United States, or U.S., Food and Drug Administration, or FDA. We have a worldwide collaboration to develop and commercialize peginesatide with Takeda Pharmaceutical Company Limited, or Takeda, the largest pharmaceutical company in Japan, and plan to co-commercialize peginesatide in the U.S., if approved by the FDA.

Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic kidney disease, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may lead to chronic fatigue or increase the risk of other diseases or death. Currently, recombinant erythropoietin, or rEPO, is used to

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treat anemia due to chronic kidney disease in patients on dialysis and not on dialysis, and to treat chemotherapy-induced anemia in cancer patients. We estimate that rEPO generated approximately $2.0 billion of net revenues in the U.S. for 2011 attributable to use in dialysis patients with chronic kidney disease. Peginesatide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Peginesatide is designed to be longer acting than currently marketed ESAs in the U.S. for dialysis patients, and therefore has the potential to offer reduced cost and complexity for healthcare providers.

In late June 2010, we announced preliminary top-line results from our peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Two of these trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a specified range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were based primarily on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. In addition, peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 trials. However, some differences were observed when secondary analyses were conducted, including a difference in a subgroup analysis conducted in the PEARL trials where the frequency of CSE events was higher in the peginesatide group relative to the comparator in non-dialysis patients, as previously described in our Current Report on Form 8-K dated June 21, 2010.

In October 2010, we met with the FDA to discuss the regulatory path for peginesatide based on the initial analysis of the Phase 3 results. Based on these discussions with the FDA, we submitted a NDA for peginesatide to the FDA for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. In July 2011, the FDA accepted our submission and filed the NDA for review, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. In December 2011, the FDA Oncologic Drugs Advisory Committee, or 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 chronic kidney disease. While the FDA is not bound by the recommendation of the advisory committee, its guidance will be considered by the FDA in its review of the NDA that was submitted for peginesatide.

Despite meeting the primary efficacy endpoints and the CSE for peginesatide, the differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for peginesatide, particularly in view of the heightened concerns surrounding the safety of ESAs. Any negative perception of peginesatide's safety relative to other ESAs would significantly reduce the likelihood of obtaining regulatory approval for peginesatide. The Phase 3 results have caused significant delay and may negatively impact the likelihood of regulatory approval, and may significantly increase the likelihood of FDA requirements, restrictions and conditions if regulatory approval is obtained. For example, the ODAC discussed various measures, including a risk evaluation and mitigation strategy, a postmarketing study and label restrictions, to assure safe use of peginesatide, including minimizing the risk of administration to non-dialysis patients. Any or all of these factors may significantly reduce the ultimate commercial potential of peginesatide.

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Anemia Background

Anemia, a condition in which the blood is deficient in red blood cells and hemoglobin, is a frequent and serious complication associated with a number of common chronic diseases. Anemia is associated with chronic fatigue and, if left untreated, may increase the risk of other diseases or even death. Red blood cells are normally formed in the circulating blood from precursor cells which are initially present primarily in the bone marrow. These cells are stimulated to divide and differentiate and are mobilized into circulation by erythropoietin, or EPO, a hormonal factor produced by the kidney. EPO acts by binding to and activating the EPO receptor on precursor cells. The activation of the EPO receptor stimulates the proliferation and maturation of the precursor cells to form red blood cells that contain hemoglobin. Hemoglobin is an iron-containing protein in red blood cells that functions primarily in the transport of oxygen to, and carbon dioxide from, the tissues of the body. Anemia can be caused by conditions such as chronic kidney disease, or treatments such as chemotherapy, that result in underproduction of EPO or a muted response to EPO.

Anemia generally exists in men when the hemoglobin level in blood, which is a measure of red blood cells, is less than 12 g/dL, or the hematocrit, which is a ratio of the volume packed red blood cells to the volume of whole blood, is less than 36%, and in women when hemoglobin is less than 11 g/dL or hematocrit is less than 33%. The FDA, the medical community and others have raised significant safety concerns relating to currently marketed ESAs as a result of reports of increased mortality and side effects from a number of clinical trials. Some of these safety concerns relate to targeting and maintaining high hemoglobin levels. The FDA recently required that revised warnings, including boxed warnings, be added to labels of currently marketed ESAs advising physicians to monitor hemoglobin levels and to use the lowest dose of ESA to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions. Boxed warnings for currently marketed ESAs also note increased risk of death and serious cardiovascular events when administered to target higher hemoglobin levels.

Anemia associated with Chronic Kidney Disease. One of the most common forms of chronic anemia occurs in patients with chronic kidney failure. According to the American Journal of Kidney Disease, chronic kidney failure affects as many as 26 million Americans. As kidney function deteriorates due to the underlying disease, the ability of the kidney to produce adequate EPO is impaired, resulting in decreased production of new red blood cells and anemia.

Over time, chronic kidney disease usually progresses to irreversible end-stage renal disease, the most severe stage of the disease. End-stage renal disease patients require either lifetime dependence on renal dialysis, a medical procedure in which blood is cleansed of impurities, or a kidney transplant. Patients with end-stage renal disease are nearly always moderately to severely anemic unless treated with an ESA like rEPO. According to the Centers for Medicare and Medicaid Services, or CMS, there are approximately 380,000 end-stage renal disease patients on dialysis in the U.S. served by approximately 5,000 dialysis facilities. Funding and reimbursement for this care are predominately through the Medicare End Stage Renal Disease Program. Prior to 2011, CMS generally reimbursed ESAs at a rate of 106% of the average ESA sales price. This allowed the dialysis facilities to realize a profit on the purchase and administration of ESAs, which constitutes an important component of their economic viability. However, under the 2008 Medicare Legislation, a new bundled payment system commenced in January 2011 for facilities that furnish renal dialysis services and home dialysis to Medicare beneficiaries with end-stage renal disease. Under the new system, CMS will make a single bundled payment to the dialysis facility for each dialysis treatment that will cover all renal dialysis services, including ESAs. The bundled payment system may create incentives for significantly lower utilization or dosing of ESAs, including peginesatide, and reduce the commercial potential for peginesatide. We cannot guarantee that future decisions by CMS will support current ESA utilization levels or provider adoption of peginesatide. CMS held Medicare Evidence Development & Coverage Advisory Committee, or MedCAC, meetings in March 2010 and January 2011 to review current ESA

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coverage policy based on the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease, and the role of ESAs in successful kidney transplantation, respectively. In November 2011, pursuant to the FDA label changes, CMS, through rulemaking, modified its performance incentive program for dialysis providers by removing a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients, which may create incentives for lower overall ESA utilization. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage or create disincentives which could have a materially negative impact on the size of the ESA market in the U.S. and reduce the overall size of the market peginesatide is expected to compete in at the time of launch.

Anemia associated with Other Conditions. We are developing peginesatide for treatment of anemia in chronic kidney disease patients on dialysis only. We are not currently investigating peginesatide's use in treating anemia due to other conditions, such as for non-dialysis patients or chemotherapy-induced anemia or anemia arising from the cancer itself.

Current Therapy and Limitations

We estimate that rEPO generated approximately $2.0 billion of net revenues in the U.S. for 2011 attributable to use in dialysis patients with chronic kidney disease. However, a decline of this market is forecasted with the implementation of the bundled payment system for reimbursement in 2011. Forms of rEPO variants have been used successfully to manage the anemia of dialysis, non-dialysis and cancer patients. rEPOs are similar, but not necessarily identical, to a patient's naturally occurring EPO. Differences exist among rEPOs with regard to composition and structure. As a result, differences also exist among rEPOs with regard to frequency of dosing, duration of effect and rate of rise in hemoglobin. There are several parameters that correlate with ESA dosing frequency. These parameters include how long it takes for the drug to disappear from circulation, as measured by half-life, and duration of action, as measured by how long the drug continues to have an effect.

Since its initial U.S. market introduction in 1989, rEPO has revolutionized the treatment of patients with anemia resulting from chronic diseases. Two current ESAs, epoetin alfa and epoetin beta, are biologically engineered hormones produced in mammalian cells by recombinant DNA technology. Both are relatively short-acting forms of rEPO that typically require frequent dosing to obtain a sustained correction of anemia. Darbepoetin alfa, which is marketed by Amgen, Inc., or Amgen, under the trade name Aranesp, is a biologically engineered hormone product closely related to and functionally similar to epoetin alfa. However, darbepoetin alfa has a terminal half-life approximately three times longer than epoetin alfa, as a result of the addition of higher level of glycosylation to stabilize the protein. The currently available rEPOs are marketed under a variety of trade names in different territories.

Frequency of Dosing. In the U.S., currently marketed ESAs are dosed between 1 to 3 times per week or up to every two weeks in chronic kidney disease patients on dialysis. One of our objectives is to provide a product with a duration of effect that results in a well-controlled hemoglobin response while still allowing once-monthly dosing.

Pure Red Cell Aplasia. Treatment of patients with rEPO has been shown in rare cases to cause the production of antibodies to both rEPO and naturally-occurring EPO. Typically these antibodies can bind to and neutralize both the rEPO drug and any naturally-occurring EPO in a patient's system. As a result, such patients become increasingly less responsive to rEPO therapy and can develop a form of anemia called Pure Red Cell Aplasia, or PRCA. This hematological disorder is characterized by severe, transfusion-dependent anemia, a scarcity of reticulocytes and an almost complete absence of red blood cell precursors in otherwise normal bone marrow. The FDA has required marketers of rEPO in the U.S. to include in their product prescribing information warnings of potential for rEPO-induced PRCA and a description of this adverse reaction. We believe that an ESA that does not cause PRCA and that

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can potentially be used to treat PRCA may have advantages in the marketplace over rEPOs that can cause PRCA.

Our Product Candidate: Peginesatide

Peginesatide is a synthetic peptide-based ESA designed for less frequent dosing compared to currently marketed ESAs in the U.S. for dialysis patients. It is currently an investigational agent, and we submitted a NDA for peginesatide to the FDA for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. In July 2011, the FDA accepted our submission and filed the NDA for review, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. In December 2011, the 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 chronic kidney disease. While the FDA is not bound by the recommendation of the advisory committee, its guidance will be considered by the FDA in its review of the NDA that was submitted for peginesatide. Peginesatide is designed to be dosed once every four weeks, compared to recombinant products sold in the U.S. that are predominately dosed either 1 to 3 times per week or up to every two weeks in the dialysis setting.

Potential Peginesatide Profile

Peginesatide is a relatively small synthetic peptide-based ESA that we are developing for the treatment of anemia due to chronic kidney disease in patients on dialysis. Peptides are composed of amino acids, commonly known as the building blocks of proteins. Typically, a peptide is composed of fewer than 50 amino acids, while a protein contains from 50 to well over 5,000 amino acids. Peptide-based therapeutics may display certain advantages compared to recombinant proteins, including simplicity and low cost of manufacture. In the past, development of peptide-based drug candidates was often slowed by low potency. A second problem historically associated with peptide-based drugs has been a requirement of frequent dosing in vivo. More recently, however, it has been possible to develop peptide-based drugs with potencies nearly equivalent to recombinant proteins and with less frequent dosing requirements. Through the use of our technology, peginesatide has the potential to require less frequent dosing than currently marketed ESAs in the U.S. for dialysis patients.

Our clinical trials to date have shown similar positive effects on red blood cell formation when peginesatide is given at comparable doses either intravenously or subcutaneously. These results suggest that peginesatide may be similarly effective in humans when administered by either route. We believe it may be easier to use peginesatide than some forms of rEPO, which often have different clinical effects when given subcutaneously versus intravenously.

In addition, based on stability data to date, we believe that peginesatide could be stored at room temperature in the hands of the health care providers for limited durations after refrigerated distribution. Currently marketed ESAs in the U.S. require cold storage conditions throughout the distribution and storage process until administration to patients.

Although peginesatide has the erythropoietic activity characteristic of naturally occurring EPO, its amino acid sequence is unrelated to that of EPO. Because peginesatide does not appear to display immunologic cross-reactivity with rEPO, we believe that peginesatide will not cause PRCA. We have conducted pre-clinical studies which have demonstrated that peginesatide can stimulate reticulocytes and elevate hemoglobin levels in an animal model of anti-EPO antibody mediated PRCA. An ongoing Phase 2 clinical trial of peginesatide in a small number of patients with PRCA has generally shown supportive results to date. These results suggest that peginesatide is not neutralized by antibodies to rEPO and thus may be effective in treating anemia in patients that have developed PRCA.

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Based on clinical trials completed to date in chronic kidney disease patients, the risk of developing antibodies to peginesatide was low (1.2%), and we have observed that peginesatide-induced antibodies do not appear to cross-react with rEPO. In approximately half of the patients who developed antibodies to peginesatide, the presence of antibodies was observed to be possibly associated with evidence of reduced efficacy of peginesatide. During the clinical trials, no new cases of PRCA were reported in any patients receiving peginesatide. However, results in future trials or those observed in practice may differ from the results obtained during in vivo studies or clinical trials to date.

Peginesatide Development Program

In the U.S., we are currently pursuing development of peginesatide to treat dialysis patients with anemia associated with chronic kidney disease and are not planning to pursue any other indications in the foreseeable future. We have suspended our development efforts to treat anemia in non-dialysis patients and chemotherapy-induced anemia.

Over 2,600 patients have received peginesatide in clinical trials completed to date. We believe the pharmacokinetics and pharmacodynamics of peginesatide have been shown from these trials to be appropriate for once-monthly dosing; however, no conclusions can be drawn as only the FDA can make determinations of safety and efficacy. We anticipate that peginesatide, if approved, would typically be dosed once every four weeks in chronic kidney disease patients on dialysis.

Pre-clinical and Toxicology Studies. Pre-clinical studies have shown that peginesatide, like EPO, acts through activation of the EPO receptor. Furthermore, pre-clinical in vivo studies have shown that the effects on erythropoiesis are very similar whether peginesatide is given intravenously or subcutaneously. We have conducted repeat-dose pre-clinical toxicology studies lasting as long as nine months, and have incorporated single-dose and repeat-dose studies exploring administration by either intravenous or subcutaneous injection in a variety of models using doses up to several hundred times the estimated monthly clinical dose. The primary toxicology observed to date has been associated with the exaggerated red blood cell production seen at high and/or frequent doses, a result similar to that observed with the rEPO class of drugs. However, the results from pre-clinical testing to date may not be predictive of results of future clinical trials or if approved by the FDA, usage by dialysis patients outside of clinical trials.

Chronic Kidney Disease

Phase 1 and Phase 2 Clinical Trials

We and Takeda have completed multiple Phase 1 and Phase 2 clinical trials of peginesatide at sites in the U.S. and the European Union, or E.U., in normal healthy volunteers, dialysis patients, non-dialysis patients, and peritoneal dialysis patients. These Phase 1 clinical trials were designed primarily to demonstrate bioavailability or bioequivalence of product concentrations and formulations while these Phase 2 trials were designed to determine the safety, pharmacodynamics and pharmacokinetics of peginesatide when administered to patients suffering from anemia. Two of these Phase 2 clinical trials were conducted to evaluate the use of peginesatide to treat anemic patients in additional segments of the chronic kidney disease patient population. One of the studies focused on evaluating peginesatide in patients undergoing peritoneal dialysis, a special form of dialysis that allows the process to be performed in the patient's home. Another trial was designed to evaluate the conversion of Aranesp-treated chronic kidney disease patients (on dialysis and not on dialysis) to once-monthly peginesatide.

We continue to conduct an ongoing Phase 2 clinical trial of peginesatide in a small number of patients with PRCA in the E.U.

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Phase 3 Clinical Trials

In late June 2010, we announced preliminary top-line results from the peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Two of these trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were primarily based on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. In addition, peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 studies. However, some differences were observed when secondary analyses were conducted, including a difference in a subgroup analysis conducted in the PEARL trials where the frequency of CSE events was higher in the peginesatide group relative to the comparator in non-dialysis patients, as previously described in our Current Report on Form 8-K dated June 21, 2010. Despite meeting the primary efficacy endpoints and the CSE for peginesatide, the differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding safety of ESAs.

In October 2010, we met with the FDA to discuss the regulatory path for peginesatide based on the initial analysis of the Phase 3 results. Based on these discussions with the FDA, we submitted a NDA for peginesatide to the FDA for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. In July 2011, the FDA accepted our submission and filed the NDA for review, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. In December 2011, the 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 chronic kidney disease. While the FDA is not bound by the recommendation of the advisory committee, its guidance will be considered by the FDA in its review of the NDA that was submitted for peginesatide.

Although the NDA for peginesatide has been filed and accepted for review, any negative perception of peginesatide's safety relative to other ESAs would significantly limit the likelihood of obtaining regulatory approval for peginesatide. The Phase 3 results have caused significant delay and may negatively impact the likelihood of regulatory approval, and may significantly increase the likelihood of FDA requirements, restrictions and conditions if regulatory approval is obtained. For example, the ODAC discussed various measures, including a risk evaluation and mitigation strategy, a postmarketing study and label restrictions, to assure safe use of peginesatide, including minimizing the risk of administration to non-dialysis patients. Any or all of these factors may significantly reduce the ultimate commercial potential of peginesatide.

Manufacturing and Supply

Peginesatide is chemically synthesized and peptide-based. Final peginesatide drug product is currently manufactured as a buffered aqueous solution for intravenous or subcutaneous administration. All of our current good manufacturing practices, or GMP, manufacturing is outsourced to third parties with oversight by our internal managers. We have limited non-GMP manufacturing capacity in-house. We intend to continue to rely on third party manufacturers to produce sufficient quantities of drug substance and product for any future clinical trials, postmarketing commitments and commercialization

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of peginesatide, and for any other potential products for which we retain significant development and commercialization rights.

We have established long term commercial supply agreements with two contract manufacturers, or CMOs, for peginesatide active pharmaceutical product, or API. Under our worldwide collaboration with Takeda, we will be responsible, through our CMOs, for the manufacture and supply of all quantities of peginesatide API to be used in development and commercialization worldwide, and Takeda will be responsible for final drug product manufacture and control.

Intellectual Property

We protect our technology through the use of patents, trade secrets and proprietary know-how. We have more than 20 issued U.S. patents, including claims covering compositions of compounds comprising peptides of a broad genus of ESA peptide sequences, methods of treating EPO disorders using these compounds and methods of synthesizing these types of ESA peptide compounds. We own several pending U.S. patent applications, all of which relate to our core peptide technologies or to particular peptide compounds. Our issued U.S. patent(s) covering peginesatide and any U.S. patent(s) that may issue based on pending patent applications containing claims covering peginesatide including issued claims relating to composition of matter begin expiring no earlier than 2024. We own foreign equivalent patents and patent applications based on our U.S. patents and patent applications. We also retain technical information related to manufacture and analysis of peginesatide as trade secrets.

We own and have rights to several proprietary peptide screening technologies, including the patented technologies of peptide phage display and peptides-on-plasmids. This technology enables us to identify initial novel peptide sequences and provides information that our scientists can use to design a variety of peptide compounds to optimize bioactivity and produce pharmaceutical candidate compounds having desired properties.

The table below sets forth our ESA-related U.S. patents and their current anticipated expiry and a related description of related foreign patents as provided below:

ESA-Related U.S. Patents Assigned or Exclusively Licensed

Pat No.	Title	Expiry
5,773,569	Compounds and Peptides that Bind to the Erythropoietin Receptor	6/30/2015
5,830,851	Methods of Administering Peptides that Bind to the Erythropoietin Receptor	11/3/2015
5,986,047	Peptides that Bind to the Erythropoietin Receptor	11/19/2013
6,703,480	Peptide Dimers as Agonists of the Erythropoietin (EPO) Receptor and Associated Methods of Synthesis and Use	11/24/2019
7,084,245	Peptides that Bind to the Erythopoietin Receptor	5/12/2024
7,414,105	Peptides that Bind to the Erythopoietin Receptor	5/12/2024
7,459,522	Peptide Dimers as Agonists of the Erythropoietin (EPO) Receptor and Associated Methods of Synthesis and Use	11/24/2019
7,528,104	Peptides that Bind to the Erythopoietin Receptor	5/12/2024
7,550,433	Erythropoietin Receptor Peptide Formulations and Uses	6/2/2026
7,855,175	Peptides that Bind to the Erythopoietin Receptor	5/12/2024
7,906,485	Erythropoietin Receptor Peptide Formulations and Uses	6/2/2026
7,919,118	Spacer Moiety for Poly(ethylene glycol)-Modified Peptide-Based Compounds	5/12/2024
7,919,461	Erythropoietin Receptor Peptide Formulations and Uses	6/2/2026

In addition to the U.S. patents listed above, we own or have exclusive licenses to corresponding foreign patents in various countries outside the U.S.; these foreign counterpart patents are substantially

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similar to their counterpart U.S. patents. The foreign counterparts to the listed U.S. patents are scheduled to expire in various countries during the period 2012 to 2026.

Finally, in November 2011, we entered into a settlement and license agreement, or the Settlement and License Agreement, with Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies, or, collectively, Janssen, under which we obtained a non-exclusive license to the intellectual property in dispute. See "Our Strategic Alliance," "Legal Proceedings" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Annual Report on Form 10-K.

Third Party Intellectual Property

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. If one of these patents was found to cover our product candidates, proprietary technologies or their uses, we or our collaborators could be required to pay damages and could be restricted from commercializing our product candidates or using our proprietary technologies unless we or they obtain a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable right, which could prohibit us from making, using or selling our products, technologies or methods.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- a court prohibiting us from selling or licensing the product or using the proprietary technology unless the third party licenses its technology to us, which it is not required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross licenses to our technology; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

While we have conducted a search of patents issued to third parties, no assurance can be given that such patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, technology or methods. Because of the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a significant risk that third parties may allege they have patent rights encompassing our products, technology or methods.

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Research and Development Expenses

We have made substantial investments in research and development. Research and development costs consist of salaries, stock-based compensation, employee benefits, license fees, laboratory supplies, costs associated with clinical trials, including amounts paid to clinical research organizations, other professional services and facility costs. Research and development expenses were $76.3 million, $93.6 million, and $157.1 million, for the years ended December 31, 2011, 2010, and 2009, respectively.

Our Strategic Alliance

In February and June 2006, we entered into two agreements forming a collaboration to develop and commercialize peginesatide with Takeda. We and Takeda will co-develop and co-commercialize peginesatide in the U.S., and Takeda received an exclusive license to develop and commercialize peginesatide outside of the U.S. Takeda has primary responsibility and bears all costs for peginesatide's clinical development in support of regulatory approval for all territories outside the U.S. The February 2006 agreement and the June 2006 agreement are collectively referred to herein as the Arrangement.

Under the February 2006 agreement, we granted an exclusive license to Takeda for development and commercialization of peginesatide in Japan. In December 2011, however, Takeda announced that it has decided not to commercialize peginesatide in Japan. Takeda is conducting a Phase 3 clinical program in Japan for the treatment of patients with anemia associated with chronic kidney disease, which Takeda expects to complete notwithstanding its decision not to commercialize peginesatide in Japan. In Japan, the majority of Phase 2 and Phase 3 clinical trials are completed, and the findings to date suggest that peginesatide can become a promising treatment option for Japanese renal anemia patients. We and Takeda are actively exploring other options for the commercialization rights for peginesatide in the Japanese market, including potentially licensing it to a third party.

Further, under the February 2006 agreement, Takeda has paid us approximately $42 million to date, consisting of $17 million in upfront licensing fees, approximately $10 million for the purchase of equity, a $10 million cash milestone payment for the completion of the first Phase 1 trial of peginesatide in Japan, and in March 2010, a $5 million cash milestone payment for the initiation of Phase 3 trial of peginesatide in Japan. Upon Takeda's successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $33 million relating to the renal program. Takeda is responsible for all development and commercialization costs in Japan and will purchase the API for peginesatide from us. Assuming peginesatide is approved and launched in Japan, we will receive a royalty from Takeda on peginesatide sales in Japan.

Under the June 2006 agreement, we expanded our collaboration to develop and commercialize peginesatide worldwide, which includes the co-development and co-commercialization of peginesatide in the U.S. Takeda received an exclusive license to develop and commercialize peginesatide outside of the U.S. During the development period of the collaboration, beginning January 1, 2007, Takeda was responsible for the first $50 million of third party expenses related to development in pursuit of U.S. regulatory approval of peginesatide, which was fully utilized through the first quarter of 2008. Thereafter, Takeda has borne 70% of the third party U.S. development expenses while we have been responsible for 30% of third party expenses. During the development period, we retained responsibility for 100% of our internal development expenses, most notably employee-related expenses.

Further, under the June 2006 agreement, Takeda paid us an upfront license fee of $105 million, and we have received milestone payments upon completion of database lock of the Phase 3 clinical trials of $30 million for dialysis and non-dialysis. In addition, we earned a $10 million milestone in July 2011, as a result of the FDA acceptance for review of our NDA, which we recorded as collaboration revenue during the quarter ended September 30, 2011. Upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $75 million relating to the renal program, including $50 million of milestone payments upon

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approval by the FDA in dialysis indications. In February 2012, the Marketing Authorization Application, or MAA, filed by Takeda in early 2012 was accepted by the European Medicines Agency, or EMA, which triggered a $5 million milestone payment from Takeda. We received this milestone payment in the first quarter of 2012, and we expect to recognize it as revenue in the same period. We and Takeda will share equally in the net profits and losses of peginesatide in the U.S., which include certain expenses related to the marketing and launch of peginesatide.

Either party may terminate the February 2006 agreement or the June 2006 agreement for material breach by the other party. Takeda will have the right to terminate (a) for certain specified clinical development events or failures, or (b) for convenience upon six months written notice to us. In the event of any termination, Takeda will transfer and assign to us all rights to peginesatide in the affected territories. In addition, if Takeda terminates for convenience prior to the first commercial sale in the U.S. for reasons other than specified clinical development events or failures, then Takeda will pay us a termination fee.

During the commercialization period under the Arrangement, which commenced in June 2011 upon the submission of our NDA to the FDA, Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of peginesatide in the U.S. Certain employee-related expenses supporting preparation for commercialization of peginesatide in the U.S. are also shared equally. Such employee-related costs will include the cost of certain employees that would be required to commercialize the product such as field sales representatives, sales operations, medical science liaisons, nurse educators, conversion specialists, national accounts managers and reimbursement specialists. In addition, costs of certain employees in clinical, regulatory and other development functions supporting any post-marketing development activity required by the FDA or separately agreed to by the parties in the U.S. are shared equally.

Operating expenses incurred by us which have been subject to reimbursement by Takeda under the Arrangement, which excludes API manufacturing costs were as follows (in thousands):

	Year ended December 31,		
	2011	**2010**	**2009**
Research & Development	$ 19,849	$ 35,305	$ 112,079
Selling, General & Administrative	11,034	8,241	5,949
Total	$ 30,883	$ 43,546	$ 118,028

We are also entitled to a launch allowance to help fund the initial costs associated with preparing to launch the product in the U.S., whereby Takeda will fund the first $20 million of U.S. commercial expenses. This launch allowance is non-refundable; however, in the event the product is approved for sale in the U.S., Takeda is entitled to deduct up to 8% of net sales from the profit share amounts which would have otherwise been due to us each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in profit sharing post-launch stemming from the launch allowance, we have reflected amounts we receive under the terms of the launch allowance as a liability on our balance sheet. As of December 31, 2011, we have received $6.1 million of the launch allowance, which is reflected in the caption "Advance from Takeda" on our balance sheet.

The Arrangement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of peginesatide. We share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of peginesatide. Specifically, we have primary responsibility for peginesatide's clinical development plan and clinical trials in the dialysis indication, and the non-dialysis indication to the extent of any further development, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the

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extent any such indication is developed. We and Takeda have agreed to suspend the development of peginesatide to treat chemotherapy-induced anemia and to focus all development efforts for peginesatide on the treatment of chronic kidney disease anemia. We are responsible for U.S. regulatory filings in the dialysis, non-dialysis, chemotherapy induced anemia and anemia of cancer indications, including holding the NDAs for those indications. Takeda is responsible for regulatory filings outside the U.S. and the creation of a global safety database.

Takeda will have primary responsibility, directly or indirectly through sublicensees, and bears all costs for peginesatide clinical development in support of regulatory approval for all territories outside the U.S. and will pay us a variable royalty based on annual net sales of peginesatide outside the U.S.

Under the February 2006 agreement, Takeda also obtained a right of first negotiation to any backup products for peginesatide developed by us or our third party partners. Specifically, during the first ten years of the agreement, if we or third party partners develop a product that advances to Phase 2 clinical trials and competes with peginesatide in the renal or oncology indications, we are obligated to offer to Takeda the right to develop and commercialize such product in Japan before offering the product opportunity in Japan to any other third party.

In November 2011, as contemplated under the Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as they relate to the manufacture of peginesatide API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of the product. We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of peginesatide worldwide. Takeda remains responsible for the fill and finish steps in the manufacture of peginesatide worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda has agreed to pay an aggregate of $10.8 million in deposits for commercial API shipments of existing materials already manufactured by us. Through December 31, 2011, we have received $7.2 million and shipped $5.2 million of API. The value of API shipped to Takeda has been recorded as deferred revenue. The remainder of the amount paid by Takeda has been recorded as a liability on our balance sheet.

In November 2011, concurrent with the execution of the Settlement and License Agreement with Janssen, we and Takeda entered into an amendment to the Arrangement. Under the terms of this amendment, Takeda has agreed to pay up to $6.5 million in additional milestones to us in consideration of the upfront and milestone payments we are required to make to Janssen under the Settlement and License Agreement. $5.25 million of these milestones are earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million is tied to regulatory events in the E.U. As of December 31, 2011, none of these milestones have yet been achieved and as such, we have not received any related payments from Takeda. We are solely responsible for the royalty payments to Janssen.

In February 2012, as contemplated under the Arrangement, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for peginesatide including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs field force but share marketing, account management and payer reimbursement related activities with Takeda. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of full time equivalent, or FTE, expenses used to calculate eligible commercial expenses incurred by us and Takeda thereunder. Consistent with the terms of the Arrangement, Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

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License, Manufacturing and Supply Agreement with Nektar

In April 2004, we entered into a License, Manufacturing and Supply Agreement with Nektar Therapeutics AL Corporation, or Nektar, under which we obtained from Nektar a worldwide, non-exclusive license, with limited rights to grant sublicenses, under certain intellectual property covering pegylation technology to manufacture, develop and commercialize peginesatide. The license we obtained consists of a license under intellectual property owned by Nektar and a sublicense under intellectual property owned by Enzon Pharmaceuticals, Inc., or Enzon, licensed to Nektar pursuant to a cross-license agreement between Nektar, Inhale Therapeutic Systems, Inc. and Enzon.

In consideration of the license grant, we agreed to pay royalties on the sales of peginesatide. We also agreed to pay milestone payments totaling up to an additional $7 million, plus possible additional milestones in connection with our partnering activities relating to peginesatide or merger and acquisition activities.

In July 2006, we paid Nektar a $17.6 million milestone payment triggered by our receipt of a $105 million upfront payment from Takeda. In August 2011, we paid Nektar a $2.0 million milestone payment triggered by the acceptance from the FDA of our NDA submission for review.

Under the agreement, we also engaged Nektar for the manufacture and supply of our requirements of bulk poly(ethylene) glycol reagent for the manufacture of peginesatide. This relationship is managed by a managing committee formed by representatives from both us and Nektar. Nektar is obligated to engage a third party manufacturer in the event of Nektar's failure (as defined in the agreement) to supply reagent, but currently Nektar remains our sole-source of these reagents.

This agreement expires, on a country by country basis, upon the expiration of our royalty payment obligations. The agreement may be terminated by either party for the other party's material breach provided that such other party has been given a chance to cure such breach, or by Nektar for our challenge of the validity or enforceability of any patents licensed thereunder.

Marketing and Sales

While we do not currently have any marketed products, we are currently in the early stages of building out our commercial infrastructure to support sales and marketing of peginesatide if approved by the FDA. Our business model is to become a fully integrated biopharmaceutical company and it is to that end that we are developing commercial capabilities in the renal market in order to co-commercialize peginesatide under our Arrangement with Takeda. Costs associated with the sales and marketing infrastructure we are building are included in selling, general and administrative costs in our accompanying financial statements.

Competition

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. These companies also have significantly greater research capabilities than us. Many universities and private and public research institutes are active in chronic kidney disease research, some in direct competition with us. We also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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We estimate that rEPO generated approximately $2.0 billion of net revenues in the U.S. for 2011 attributable to use in dialysis patients with chronic kidney disease. If approved in the U.S. for treatment of anemia associated with chronic kidney disease in dialysis patients, we anticipate that peginesatide would compete with EPOGEN and potentially Aranesp, which are both marketed by Amgen. Aranesp, introduced in 2001, has significant market share in the U.S, particularly in the oncology and the non-dialysis markets, although it is approved for treatment in dialysis patients as well. In Europe, Roche has obtained regulatory approval to market, and has launched, a PEGylated ESA called Mircera. Mircera reportedly has greater plasma stability than any of the currently marketed products. PEG is a polymer that increases the time rEPO remains in the circulation and consequently can be dosed less frequently. Mircera has also obtained regulatory approval in the U.S., but as a result of Roche and Amgen's patent infringement litigation, Mircera has been found to infringe several U.S. patents owned by Amgen and has been enjoined from being sold in the U.S. until mid-2014 under the terms of a limited license.

If Mircera enters the U.S. markets before peginesatide or upon its entry, we believe that Mircera will be in direct competition with peginesatide because of its ability to be longer acting than currently marketed ESAs in the U.S. for dialysis patients; therefore, it could potentially limit the market for peginesatide. In addition to currently marketed ESAs, there are several ESA product candidates in various stages of active development, including small molecules, by potential competitors, including FibroGen, Inc., that may promote the production of naturally-occurring EPO in patients.

In addition, the introduction of biosimilars into the rEPO market in the U.S. would constitute additional competition for peginesatide, if approved. A biosimilar product is a subsequent version of an existing, branded biologic product. Several biosimilar versions of rEPO are available for sale in Europe, and in January 2012, Hospira, Inc. announced the beginning of its U.S. Phase 3 clinical program for its biosimilar version of rEPO with results anticipated in 2013. The patent for the existing, branded product must expire in a given market before biosimilars may enter that market. The patents for epoetin alfa, a version of rEPO, expired in 2004 in the E.U., and the remaining patents expire from 2012 through 2015 in the U.S. Upon entry into the U.S. market, biosimilars are expected to compete with peginesatide, if approved, and may drive down its price and sales volume, which would adversely affect our revenues.

Finally, we face competition to enter into supply agreements with the major operators of dialysis clinics in the U.S. In particular, we may not be able to reach an agreement with either of the largest operators of dialysis clinics in the U.S., DaVita Inc. and Fresenius Medical Care, or DaVita and Fresenius, because DaVita entered into a supply agreement with Amgen to begin in January 2012, and Fresenius entered into a supply agreement with Amgen also to begin in January 2012. Amgen's supply agreements with DaVita and Fresenius may limit the market opportunity for peginesatide and adversely impact our ability to generate product sales.

Government Regulation and Product Approvals

The clinical development, manufacturing and potential marketing of peginesatide is subject to regulation by various authorities in the U.S., the E.U. and other countries, including, in the U.S., the FDA, and, in the E.U., the EMA. In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The FDA has very broad enforcement authority and failure to abide by applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, disgorgement of profits,

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recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approval, refusal to approve pending applications, and criminal prosecution.

Product development and approval within these regulatory frameworks takes a number of years, and involves the expenditure of substantial resources. Regulatory approval is required in all major markets in which products will be tested in development. At a minimum, such approval requires evaluation of data relating to quality, safety and efficacy of a product for its proposed use. The specific types of data required and the regulations relating to these data differ depending on the territory, the drug involved, the proposed indication and the stage of development.

In the U.S., specific pre-clinical data, chemical data and a proposed clinical study protocol must be submitted to the FDA as part of an Investigational New Drug application, or IND, which, unless the FDA objects, will become effective 30 days following receipt by the FDA. Phase 1 trials may commence only after the IND application becomes effective. Prior regulatory approval for human healthy volunteer studies is also required in member states of the E.U. Currently, in each member state of the E.U., following successful completion of Phase 1 trials, data are submitted in summarized format to the applicable regulatory authority in the member state in respect of applications for the conduct of later Phase 2 trials. In the U.S., following successful completion of Phase 1 trials, further submissions to regulatory authorities are necessary in relation to Phase 2 and 3 trials to update the existing IND. Authorities may require additional data before allowing the trials to commence and could demand discontinuation of studies at any time if there are significant safety issues. In addition to regulatory review, a clinical trial involving human subjects has to be approved by an independent body. The exact composition and responsibilities of this body differ from country to country.

Information generated in the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent regulatory approval at any stage of the approval process. Failure to demonstrate adequately the quality, safety and efficacy of a therapeutic drug under development would delay or prevent regulatory approval of the product and even if clinical trials were successfully completed, there could be no assurance that applications for required authorizations to manufacture or market potential products would be submitted, or that any such application would be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all. In order to gain marketing approval, a dossier must be submitted to the relevant authority for review, which is known in the U.S. as a NDA and in the E.U. as a MAA. The format is usually specified by each authority, although in general it will include information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product and non-clinical and clinical data. In May 2011, we submitted a NDA for peginesatide to the FDA for treatment of anemia in chronic kidney disease patients on dialysis, which the FDA accepted and filed for review in July 2011. In February 2012, Takeda submitted a MAA that was accepted by the EMA. However, there can be no assurance that such applications will be reviewed or approved by the FDA or EMA, respectively, in a timely manner, or at all.

Further, the potential commercial success of peginesatide is subject to the recent and future actions of CMS. Prior to 2011, CMS generally reimbursed ESAs at average selling price plus 6%. In January 2011, however, a new bundled payment system commenced whereby CMS will make a single bundled payment to dialysis facilities for each dialysis treatment that will cover all renal dialysis services, including ESAs. In November 2011, pursuant to FDA label changes, CMS, through rulemaking, modified its performance incentive program for dialysis providers by removing a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients. These recent events by CMS, and further action by the agency, may create incentives for lower overall utilization of ESAs and reduce the commercial potential for peginesatide.

Finally, pharmaceutical companies are subject to various federal and state healthcare laws. These healthcare laws include: federal "sunshine laws" that require transparency regarding financial arrangements with healthcare providers; the federal Anti-Kickback Law that prohibits, among other

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things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration in exchange for referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting false claims for payment from Medicare, Medicaid or other third-party payors; and state law equivalents of each of these federal laws. Because of the far-reaching nature of these laws, there can be no assurance that we will be able to strictly comply with these laws.

U.S. Approval Process

In the U.S., if approved, peginesatide will be regulated by the FDA as a drug, but not as a biologic. No manufacturer may market a new drug until it has submitted a NDA to the FDA, and the FDA has approved it. The steps required before the FDA may approve an NDA generally include:

- preclinical laboratory tests and animal tests conducted in compliance with FDA's good laboratory practice requirements;
- development, manufacture and testing of active pharmaceutical product and dosage forms suitable for human use in compliance with current GMP;
- the submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its specific intended use(s);
- the submission to the FDA of a NDA; and
- FDA review and approval of the NDA.

FDA approval of the NDA is required before marketing of the product may begin in the U.S. The FDA has agreed to certain performance goals in the review of NDAs. Although applications for non-priority drug products are intended to be reviewed within 10 months, the review process may be substantially extended by FDA requests for additional information, preclinical or clinical studies, clarification regarding information already provided in the submission, submission of a risk evaluation and mitigation strategy or proposed labeling. The FDA may refer an application to an advisory committee for review, which was convened for review of peginesatide. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations when making decisions. Even though the advisory committee made a favorable recommendation, the FDA may still reject an application for approval. Before approving a NDA, the FDA will typically inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless GMP compliance is satisfactory. FDA also typically inspects facilities responsible for performing animal testing, as well as clinical investigators who participate in clinical trials and the sponsor. The FDA may refuse to approve a NDA if applicable regulatory criteria are not satisfied. In addition, the FDA may require additional testing or information, may limit the indications for use and may require post-marketing testing and surveillance to monitor the safety or efficacy of a product. For example, the advisory committee discussed various measures, including a risk evaluation and mitigation strategy, a postmarketing study and label restrictions, to assure safe use of peginesatide. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Because the testing and approval process requires substantial time, effort and financial resources, our product candidates may not be approved on a timely basis, if at all.

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E.U. Approval Process

In the E.U., there is, for many products, a choice of two different authorization routes: centralized and decentralized. Under the centralized route, one marketing authorization is granted for the entire E.U., while under the decentralized route a series of national marketing authorizations are granted. In the centralized system, applications are reviewed by members of the Committee for Medicinal Products for Human Use, on behalf of the EMA. The EMA will, based upon the review of the Committee for Medicinal Products for Human Use, provide an opinion to the European Commission on the safety, quality and efficacy of the product. The decision to grant or refuse an authorization is made by the European Commission. In circumstances where use of the centralized route is not mandatory, we can choose to use the decentralized route, in which case the application will be reviewed by each member state's regulatory agency. If the regulatory agency grants the authorization, other member states' regulatory authorities are asked to "mutually recognize" the authorization granted by the first member state's regulatory agency. Approval can take several months to several years or be denied. The approval process can be affected by a number of factors. Additional studies or clinical trials may be requested during the review and may delay marketing approval and involve unbudgeted costs. Regulatory authorities may conduct inspections of relevant facilities and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further, inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing surveillance to monitor adverse effects, or other additional studies as deemed appropriate. After approval for the initial indication, further clinical trials are usually necessary to gain approval for additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect product marketability. In February 2012, Takeda submitted a MAA that was accepted by the EMA under the centralized authorization route.

Employees

As of December 31, 2011, we had 130 employees. We had 78 employees engaged in research and development, and the remainder of our employees were engaged in other selling, general and administrative functions or medical affairs. None of our employees are subject to a collective bargaining agreement. We believe that we have good relations with our employees.

About Affymax

We were incorporated in Delaware in July 2001 under the name Affymax, Inc. The address of our principal executive office is 4001 Miranda Avenue, Palo Alto, California 94304, and our telephone number is (650) 812-8700. Our website address is *www.affymax.com*. We do not incorporate the information on our website into this Annual Report on Form 10-K, and you should not consider it part of this Annual Report on Form 10-K.

We have a registration for the trademarks "Affymax" and "Affymax and logo" in the U.S.

Available Information

We file electronically with the U.S. Securities and Exchange Commission our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934. We make available on our website at www.affymax.com, free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Further, copies of these reports are located at the Securities and

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Exchange Commission's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at *www.sec.gov*. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

Our business faces significant risks, some of which are set forth below to enable readers to assess, and be appropriately apprised of, many of the risks and uncertainties applicable to the forward-looking statements made in this Annual Report on Form 10-K. You should carefully consider these risk factors as each of these risks could adversely affect our business, operating results and financial condition. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently believe to be immaterial, may also adversely affect our business.

Risks Related to Our Business

We are dependent on the success of peginesatide. Peginesatide is a new chemical entity and currently our only product candidate. We cannot give any assurance the development program for peginesatide will be successful or completed in a timely or effective manner. Our previously announced Phase 3 results present challenges to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding safety of erythropoiesis stimulating agents, or ESAs. Our failure to demonstrate the safety and effectiveness of peginesatide to the satisfaction of the United States, or U.S., Food and Drug Administration, or FDA, will prevent us from receiving regulatory approval and would have a material and adverse impact on our business. Even if the FDA approves our New Drug Application, or NDA, the length of the review process may be longer than anticipated or the FDA may impose requirements, conditions and restrictions that could significantly increase costs or delay and limit our ability to successfully commercialize peginesatide or otherwise severely harm our business.

Peginesatide, an ESA, is a new chemical entity and currently our only product candidate. In order to commercialize peginesatide, we will be required to establish that peginesatide is sufficiently safe and effective to obtain regulatory approvals, which we may fail to do.

In late June 2010, we announced preliminary top-line results from the peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Two of these trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were based primarily on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. In addition, peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure,

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unstable angina and arrhythmia from a pooled safety database across the four Phase 3 trials. However, some differences were observed when secondary analyses were conducted, including a difference in a subgroup analysis conducted in the PEARL trials where the frequency of CSE events was higher in the peginesatide group relative to the comparator in non-dialysis patients, as previously described in our Current Report on Form 8-K dated June 21, 2010 and in Part I, Item 1. *Business* of our Annual Report on Form 10-K for the year ended December 31, 2010.

The differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding the safety of ESAs. Based on our discussions with the FDA regarding the regulatory path for peginesatide in light of the Phase 3 results, we submitted a NDA for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. Although the NDA has been filed and accepted for review, any negative perception of peginesatide's safety relative to other ESAs would significantly limit the likelihood of obtaining regulatory approval for peginesatide. The issues arising from the Phase 3 results have caused significant delay and may negatively impact the likelihood of regulatory approval, and may significantly increase the likelihood of FDA requirements, restrictions and conditions if regulatory approval is obtained. Any or all of these factors may significantly reduce the ultimate commercial potential of peginesatide. Regardless of whether peginesatide met the statistical criteria for non-inferiority to the comparator drugs, peginesatide could still fail to establish that it is sufficiently safe for regulatory approval for any indication. In addition to data from clinical trials, extensive data from pre-clinical studies, including carcinogenicity studies, has been submitted as part of the NDA. As peginesatide is the first ESA to undergo carcinogenicity studies, the regulatory requirements and standards for review remain uncertain and may increase the risk for regulatory approval. The results from earlier pre-clinical testing and prior clinical trials may not be predictive of results obtained in other pre-clinical models, later clinical trials or in a practice setting. In addition, the approval of our NDA may be delayed or fail for many reasons, including:

- safety issues, including serious adverse events associated with peginesatide, and concerns surrounding use of ESAs generally;

- difficulties arising from administration, data gathering and analysis of our large and complex Phase 3 clinical program for peginesatide, which involved numerous third parties, approximately 2,600 patients and over 300 sites in the U.S. and Europe, compliance with a variety of government regulations, and a number of significant new initiatives and processes for which we did not have any prior experience implementing, including the adjudication of cardiovascular events by an independent review committee;

- risks associated with non-inferiority trials, which are studies devised and statistically powered to show that the test drug is not inferior to the comparator drug;

- risks associated with data integrity and difficulty in obtaining complete and accurate data on a timely basis which may result from our large and complex Phase 3 trial design for a variety of other reasons, including shortage of resources, delays in data entry, inaccurate or inconsistent data entry, failure to follow the clinical trial protocols, inadequate monitoring or training of sites, inadequate oversight of third party clinical research organizations, or CROs, delays or failures to establish adequate procedures, remediations or corrective actions that regulatory agencies may not find sufficient, problems maintaining contact with patients after treatment or as a consequence of the open-label, non-inferiority design of the Phase 3 trials;

- suspension or termination of clinical trials for various reasons, including exposure of the participating patients to unacceptable health risks or noncompliance with regulatory requirements;

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manufacturing issues or failure to manufacture or obtain from third parties materials of sufficient quality;

inadequate effectiveness or safety concerns arising from clinical trials or pre-clinical studies, including the carcinogenicity studies;

the failure of patients to complete clinical trials due to death or the length of our clinical program, side effects, dissatisfaction with peginesatide or other reasons including adverse medical effects unrelated to treatment with peginesatide;

our lack of experience as an organization in obtaining regulatory approvals;

governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and

varying interpretation of data by FDA and similar foreign regulatory agencies.

Further analysis, regulatory review or inspections or additional data may reveal further issues associated with the Phase 3 results. For example, negative imbalances in safety events, which could give rise to safety concerns whether or not they are statistically significant, or potential issues surrounding data quality, which may be of greater concern for non-inferiority designed trials, may negatively impact the ultimate acceptability of the data for regulatory approval. As noted in the FDA's March 2010 draft Guidance for Industry Non-inferiority Clinical Trials, there is a critical need for particular attention to study quality and conduct when planning and executing a non-inferiority study, as poor quality can sometimes lead to an apparent finding of non-inferiority that is incorrect. The FDA appears to be increasing its focus on clinical data quality which may delay or increase the risk of failure to obtain regulatory approval. For example, in late 2009, Basilea Pharmaceutica AG failed to obtain approval for ceftobiprole from the FDA as the agency cited unreliable or unverifiable data and inadequate monitoring on the part of sponsor Johnson & Johnson as the basis for the agency's decision. As the sponsor of the peginesatide clinical trials, the FDA holds us accountable for oversight of our clinical trials, including monitoring performed by our CROs. To the extent the FDA determines that we failed to properly oversee our clinical trials and the CROs, the FDA may find our Phase 3 results or other clinical data unreliable. Our failure to adequately demonstrate the safety and effectiveness of peginesatide or the integrity of the data will prevent us from receiving regulatory approval and will have a material adverse impact on our business.

Obtaining approval of a NDA by the FDA is highly uncertain and like many product candidates, we may fail to obtain approval even though our NDA for peginesatide has been filed and accepted for review. The NDA review process is extensive, lengthy, expensive and uncertain, and the FDA may delay action on the NDA significantly beyond the March 27, 2012 date assigned under the Prescription Drug User Fee Act, limit or deny approval of peginesatide for many reasons, including:

we may not be able to demonstrate to the satisfaction of the FDA that peginesatide is safe and effective for any indication;

the data arising from the clinical trials, including the Phase 3 results, the development program or the NDA for peginesatide may not be satisfactory to the FDA;

the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials or conclude that the data fails to meet statistical or clinical significance;

the FDA may have difficulties approving a dosing regimen for peginesatide in view of the FDA's safety concerns surrounding hemoglobin variability, rates of rise and excursions with ESAs as a class;

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- the FDA may not find the data from preclinical studies, including our carcinogenicity studies, and clinical studies sufficient to demonstrate that peginesatide's clinical and other benefits outweighs its safety risks;

- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;

- the FDA may not accept data generated at our clinical trial sites and monitored by third party CROs;

- the FDA may determine that we did not properly oversee third party CROs and our clinical trials;

- the FDA may have difficulties approving a risk evaluation and mitigation strategy, or REMS, or labeling for peginesatide;

- the FDA may identify deficiencies in our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers or Takeda Pharmaceutical Company Limited, or Takeda, our collaboration partner; and

- the FDA may still deny approval as it is not bound by the recommendations of its Oncologic Drug Advisory Committee, or ODAC, which voted 15 to 1, with 1 abstention, in December 2011 that peginesatide demonstrated a favorable benefit/risk profile for use in the treatment of dialysis patients with anemia due to chronic kidney disease.

A delay in the FDA review of our NDA, or denial of approval, would delay or foreclose commercialization of peginesatide.

Even if the FDA ultimately approves our NDA, the FDA may impose requirements, conditions and restrictions that could significantly increase costs or delay and limit our ability to successfully commercialize peginesatide. For example, as a result of our Phase 3 clinical results with respect to non-dialysis patients, the ODAC discussed various measures, including a REMS, a postmarketing study and label restrictions, to assure safe use of peginesatide, including minimizing the risk of administration to non-dialysis patients.

The FDA may require a REMS plan for peginesatide, which could include:

- a medication guide to explain the risks and benefits of peginesatide;

- a communication plan to disseminate information regarding the risks of peginesatide, the applicable safety protocols and the REMS plan e.g., a "Dear Healthcare Provider" letter;

- limited or targeted distribution including elements to assure safe use, which could require healthcare providers who administer peginesatide to have specialized training, experience or certifications, require dialysis centers to be specially certified, require patients to sign an informed consent acknowledging the risks of peginesatide prior to treatment, require monitoring of each patient who uses peginesatide and require them to be enrolled in a registry; and

- an implementation system to monitor, evaluate, and improve the implementation of the REMS plan.

The FDA may also require postmarketing studies or trials to further evaluate the safety of peginesatide and may require postmarketing commitments to monitor adverse events. Finally, the FDA may impose label restrictions to address safety concerns. Such label restrictions could include limited indications and usage, expanded contraindications and expanded warnings and precautions. Any REMS plan, postmarketing studies, trials or commitments or label restrictions could significantly delay, limit, or prevent, successful commercialization of peginesatide or otherwise severely harm our business and financial condition.

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Results from the Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or TREAT, heightens concerns surrounding safety of ESAs and increases the regulatory risk for peginesatide as the class faces greater regulatory scrutiny. These concerns may limit our ability to develop and obtain regulatory approval for peginesatide, or to do so on a timely basis. The FDA recently announced label changes including additional boxed warnings and more conservative dosing guidelines for ESAs in the treatment of anemia in chronic kidney disease. We cannot predict what future actions the FDA may take that could affect the potential of peginesatide given the uncertain regulatory environment.

In late 2009, Amgen Inc., or Amgen, announced the results of TREAT, its large, randomized, double-blind, placebo-controlled Phase 3 study of patients with chronic kidney disease (not requiring dialysis), anemia and type-2 diabetes. In this study, treatment of anemia with Aranesp to a target hemoglobin of 13 g/dL, which was higher than the 10 g/dL - 12 g/dL range previously approved by the FDA in the label. Study results reportedly failed to show benefit compared to the control group with regard to composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or chronic renal replacement. In addition, higher rates of stroke were reported amongst patients treated with Aranesp compared to the control group. Further, among a subgroup of patients with a history of cancer at baseline, a statistically significant increase in deaths from cancer was observed in the Aranesp treated patients compared to placebo treated patients. However, Aranesp treatment reportedly was associated with a statistically significant reduction in blood transfusions and a modest improvement in patient reported fatigue.

In January 2010, FDA officials published an editorial in the New England Journal of Medicine entitled "Erythropoiesis-Stimulating Agents Time for a Reevaluation" and plans to convene a public advisory committee meeting to evaluate the use of ESAs in the treatment of anemia due to chronic kidney disease. The editorial noted that a number of randomized trials, including TREAT, have attempted to show that using ESAs to raise hemoglobin concentrations to higher targets improves clinical outcomes but rather have suggested the opposite. Accordingly, the article indicates that more conservative hemoglobin targets (well below 12 g/dL), more frequent hemoglobin monitoring, and more cautious dosing, should be evaluated.

In February 2010, the FDA announced that ESAs must be prescribed and used under a REMS to ensure the safe use of these drugs. As part of the REMS, a medication guide explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs for all indications. In addition, in the case of oncology use, the FDA required ESA manufacturers to implement training for hospitals and healthcare professionals and the signing of a patient informed consent acknowledging the risks of ESA use prior to treatment. As part of any REMS, the manufacturer has reporting and monitoring obligations to ensure compliance.

In October 2010, the FDA convened a cardio-renal advisory committee to review TREAT and to re-evaluate the use of ESAs in the treatment of anemia in chronic kidney disease. Although the advisory panel voted against withdrawal of the indication for Aranesp's use in non-dialysis patients even those with a history of stroke, and voted against the adoption of the TREAT control group dosing regimen (treatment once hemoglobin is below 9 g/dL), the advisory committee discussion included potential areas of concerns regarding the use of ESAs, including hemoglobin variability and rates of excursions associated with current dosing regimens, use by certain subgroups including diabetics and hyporesponders, among others, for further consideration in clinical trials.

In June 2011, the FDA cited increased risks of cardiovascular events as a basis for more conservative dosing guidelines for use of ESAs in chronic kidney disease and announced related changes to ESA labeling. The FDA removed the prior target range of 10-12 g/dL and while separately issuing guidance for non-dialysis patients, the FDA recommended that dialysis patients initiate treatment when the hemoglobin is less than 10 g/dL and to reduce or interrupt dosing if hemoglobin

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level approaches or exceeds 11 g/dL. The FDA also required Amgen to conduct additional clinical trials to explore dosing strategies, including in dialysis patients to minimize hemoglobin variability, rates of change and excursions while exploring benefit. The FDA may continue to impose further restrictions or requirements on ESAs, including on peginesatide.

The TREAT results and the FDA's recent and potential future actions represent additional challenges to ESAs as a class and increase the uncertainty associated with peginesatide's regulatory approval. Even prior to these recent events, for the last several years, the FDA, the medical community, and others have recently raised significant safety concerns relating to commercially available ESAs as a result of reports of increased mortality and side effects from a number of clinical trials. These concerns have resulted in a number of negative actions affecting the market for ESAs, including the following:

As a result of concerns associated with administering ESAs to target higher hemoglobin levels, the FDA required revised warnings, including boxed warnings, be added to labels of currently marketed ESAs advising physicians to monitor hemoglobin levels and to use the lowest dose of ESA to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions.

The FDA also issued a public health advisory statement re-evaluating the safe use of the ESA class and convened the ODAC, in May 2007 to consider recent information on risks associated with ESAs for use in the treatment of anemia in cancer patients. The ODAC recommended that the FDA institute restrictions on the usage of currently marketed ESAs, including limitations on the treatment of certain types of cancer and the duration of treatment.

The FDA also convened a joint meeting in September 2007 of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to review the risks and benefits of ESAs.

The FDA approved revised boxed warnings and other safety-related product labeling changes for commercially available ESAs during 2007 and thereafter.

In addition, the FDA convened another ODAC meeting in March 2008 to review data from more recent clinical trials with breast cancer patients and cervical cancer patients using currently marketed ESAs, and to consider additional action. The ODAC recommended the use of informed consents and further restrictions on the use of currently marketed ESAs for the treatment of chemotherapy-induced anemia, including the exclusion of patients with metastatic breast or head and neck cancer as well as those cancer patients potentially receiving curative treatment.

In July 2008, the FDA announced additional safety-related label restrictions for the use of commercially available ESAs including revisions to the boxed warnings to provide that ESAs are not indicated for patients undergoing chemotherapy expected to cure their cancer. In addition, the FDA required new prescribing information to assure that ESA therapy is not initiated until the hemoglobin level drops below 10 g/dL.

In 2008, these factors and the uncertain regulatory climate resulted in our and Takeda's decision to suspend the development of peginesatide to treat chemotherapy-induced anemia. Further, in 2010, based on our discussion with the FDA, we and Takeda decided to submit an NDA for treatment of anemia in chronic kidney disease patients for dialysis patients only. These events may have a material adverse effect on our business and future financial results.

We cannot predict what further action, if any, the FDA may take, which may include, among others, additional label restrictions, the use of informed consents, further lowering or removal of target hemoglobin levels, or even the removal of indications from the label altogether. Further, regardless of

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whether the FDA takes additional action or not, the Centers for Medicare and Medicaid Services, or CMS, and private payors may still decide separately to lower or discontinue reimbursement as CMS has recently adopted changes and continues to evaluate reimbursement policy for ESAs.

The controversy surrounding ESAs and FDA concerns has, and may further negatively affect peginesatide, including the completion of our development program. These safety concerns may increase the risk of not achieving regulatory approval or negatively affect the timing or costs associated with obtaining regulatory approval, including potential risk mitigation activities we may be required to complete either prior to or after product approval. We cannot predict the scope of the REMS we may ultimately be required to implement by the FDA and the impact on the use of peginesatide. Even a small imbalance in safety events or unfavorable signal or trend against peginesatide may increase the risk of or the conditions or limitations associated with approval by the FDA, as regulators are increasingly uncomfortable with the safety of the comparator ESAs. Any of these factors could significantly delay or negatively impact the commercialization of peginesatide.

Our development program for peginesatide may not lead to a commercial drug either because we fail to adequately demonstrate that it is safe and effective in clinical trials and or pre-clinical studies and we therefore fail to obtain necessary approvals from the FDA and similar foreign regulatory agencies, or because we have inadequate financial or other resources to advance peginesatide through development and commercialization. The Phase 3 results remain subject to a final determination as to the safety and efficacy of peginesatide by the FDA. Any significant delay or failure to obtain approval of peginesatide would have a material and adverse impact on our business as we would have to incur substantial expense and it would take a significant amount of time and resources to bring any future product candidate to market, if ever.

We have relied and continue to rely on numerous third parties, particularly CROs, to conduct and complete our development program for peginesatide. If we cannot obtain the necessary third-party assistance on acceptable terms, then we may not be able to obtain regulatory approval for peginesatide.

Due to the size and limited experience of our organization, we have relied heavily on CROs, contractors and other third parties to assist us in managing, monitoring and otherwise conducting clinical trials. Our Phase 3 clinical program for peginesatide was large and complex and conducted at over 300 sites in the U.S. and Europe. Even though we have completed our Phase 3 clinical program and our NDA was accepted for review, we continue to require the assistance of these third parties through the FDA review process and in the future. We have had significant difficulties obtaining the necessary and quality resources. We continue to compete with larger and other companies for the attention and assistance of these third parties. If we are unsuccessful in obtaining the needed assistance on acceptable terms, we will have difficulty maintaining our timelines and obtaining approval for peginesatide.

Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements, and regulatory authorities may find remediation efforts by us or our CROs insufficient. Recently, the FDA appears to be increasing its focus on clinical data quality, which may delay or reduce the likelihood of regulatory approval.

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Even if peginesatide is approved by the FDA, we may not be able to commercialize it successfully.

If peginesatide is approved by the FDA, our success will depend on our ability to commercialize the product successfully, including the ability to:

- achieve acceptance and generate product sales through Takeda's execution of agreements with one or more major operators of dialysis clinics on commercially reasonable terms; obtain a Medicare reimbursement code for peginesatide, and receive adequate levels of reimbursement;
- hire, train, deploy and support a qualified commercial and medical affairs organization and field force;
- support the process of dialysis clinics to safely and efficiently convert dialysis patients to peginesatide;
- create market demand for peginesatide through our education, marketing and sales activities, as well as through our co-promotion agreement with Takeda, including our ability to establish or demonstrate the safety and efficacy of peginesatide;
- comply with requirements established by the FDA, including REMS, postmarketing studies, trials or commitments or label restrictions;
- comply with other healthcare regulatory requirements;
- manufacture the Active Pharmaceutical Ingredient, or API, for peginesatide in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and at an acceptable quality and pricing level in order to meet commercial demand; and
- ensure that the entire supply chain for peginesatide from API to finished product efficiently and consistently delivers peginesatide to our customers.

If we are unable to successfully commercialize peginesatide, then we will not be able to generate product sales, which will have a material adverse impact on our business and our prospects.

If we are unable either to build commercial, medical affairs and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize peginesatide successfully.

We currently have limited commercial and medical affairs capabilities, and we have no experience commercializing a pharmaceutical product. To commercialize peginesatide, we must either further develop internal sales, marketing, contracting, reimbursement, and distribution capabilities, or make arrangements with third parties to perform these services. As we currently plan to market peginesatide directly with Takeda, we must commit significant time and financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize peginesatide directly or indirectly with Takeda include:

- our inability to recruit and retain adequate numbers of effective commercial and medical affairs personnel;
- the inability of sales personnel to obtain access to adequate numbers of physicians to prescribe peginesatide;

our inability to train sales personnel, who will have no prior experience with our company or peginesatide, to deliver a consistent and appropriate message regarding peginesatide and be credible and persuasive in convincing physicians to prescribe the product;

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our inability to equip sales personnel with effective materials, including medical and sales literature to help them inform and educate physicians and other healthcare providers regarding peginesatide and its proper administration;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

our inability to manage a potential substantial increase in our number of full-time employees in a matter of months; and

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

If we, or Takeda through our collaboration, are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing peginesatide, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market peginesatide, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms. 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 that event, our product revenues would likely be lower than if we marketed and sold our products directly.

Our commercial success depends upon attaining significant market acceptance of peginesatide among physicians, patients and health care payors. Further, our commercial success depends upon attaining significant market acceptance of peginesatide among the major operators of dialysis clinics as well as reaching an agreement with one or more of such major operators of dialysis clinics. We may not be able to reach agreement with either of the largest operators of dialysis clinics in the U.S., DaVita Inc. and Fresenius Medical Care, or DaVita and Fresenius, respectively, because DaVita entered into a seven-year supply agreement with Amgen commencing in January 2012 and Fresenius entered into a "multi-year" supply agreement with Amgen also commencing in January 2012.

Peginesatide has not been approved or commercialized for any indication and we are planning to pursue approval from the FDA for treatment of anemia associated with chronic kidney disease in dialysis patients. Even if approved for sale by the appropriate regulatory authorities, reimbursement on a bundled basis adopted by CMS may create incentives for significantly lower utilization or dosing of ESAs, including peginesatide, and physicians may not prescribe peginesatide, in which case our ability to sell product and become profitable would be adversely impacted.

The therapeutic indication targeted by peginesatide has been served by our competitor's products for many years. These products may now be said to be the standard of care, and it may be difficult to encourage healthcare providers to switch from products with which they and their patients have become comfortable. This dialysis market, which peginesatide will attempt to penetrate, is highly established and concentrated, with two ESA products serving a significant majority of all dialysis patients on Medicare. In addition, dialysis clinics using ESAs could incur substantial expense in administration and training if they were to switch from current ESAs to peginesatide. The concentration of customers for ESAs within the dialysis market may pose a risk to our ability to obtain revenues or favorable margins on peginesatide, if approved.

Finally, if we cannot reach an agreement with one or more of the major companies operating dialysis clinics in the U.S., or even if we can but we cannot do so on favorable terms or on a timely basis, the revenue opportunity for peginesatide could be significantly reduced. In particular, we may not be able to reach an agreement with either of the largest operators of dialysis clinics in the U.S., DaVita and Fresenius, because DaVita entered into an ESA-supply agreement with Amgen to begin in January

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2012, and Fresenius entered into an ESA-supply agreement with Amgen also to begin in January 2012. Amgen markets the ESAs EPOGEN and Aranesp.

In November 2011, DaVita and Amgen announced the execution of a seven-year agreement whereby Amgen would supply EPOGEN to meet at least 90% of DaVita's requirements for ESAs used in providing dialysis services in the U.S. commencing in January 2012. In addition, Fresenius announced the execution of a "multi-year" agreement with Amgen whereby Amgen would supply EPOGEN on a "non-exclusive" basis to Fresenius commencing in January 2012. Amgen has not disclosed this agreement with Fresenius in any of its public filings to date.

The specific terms of the Amgen-DaVita agreement and the Amgen-Fresenius agreement have not been publicly disclosed, and we cannot predict how these agreements may impact the commercial opportunity for peginesatide if and when it is launched. But these agreements may limit the market opportunity for peginesatide and adversely impact our ability to generate product sales.

Our commercial success depends on the market opportunity for peginesatide, which may be significantly reduced as a result of the increasing controversy surrounding ESAs, the TREAT results and recent and future actions by the FDA and CMS.

Safety concerns have significantly reduced the market for ESAs in recent years. As the perception of the risks of ESA usage continues to increase with the controversy surrounding the TREAT results, the concerns are likely to further negatively impact the use of ESAs and the commercial potential of peginesatide. The FDA's recent actions, including the removal of target hemoglobin ranges, may limit the use of ESAs in chronic kidney disease in dialysis patients. In addition, we cannot guarantee that future decisions by CMS will support current ESA utilization levels or provider adoption of peginesatide. CMS held Medicare Evidence Development & Coverage Advisory Committee, or MedCAC, meetings in March 2010 and January 2011 to review current ESA coverage policy based on the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease, and the role of ESAs in successful kidney transplantation, respectively. In November 2011, pursuant to the FDA label changes, CMS, through rulemaking, modified its performance incentive program for dialysis providers by removing a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients, which may create incentives for lower overall ESA utilization. These recent events and further action by FDA to continue to restrict ESA use or decrease reimbursement coverage by CMS could have a materially negative impact on the size of the ESA market in the U.S. and reduce the overall size of the market peginesatide is expected to compete in at the time of launch. Not only may a small imbalance in safety events or unfavorable signal or trend against peginesatide increase FDA approval risk or the risk of peginesatide obtaining reimbursement, but any negative perception of peginesatide's safety relative to other ESAs could keep us from successfully commercializing peginesatide.

Peginesatide is our only product candidate and we may not develop any other product candidates for the foreseeable future.

Peginesatide is the main focus of our business, which we expect to be the case for the foreseeable future. Accordingly, until we are able to obtain additional financing and resources to commercialize peginesatide, we are unlikely to be able to successfully discover or develop any other product candidates. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs even some activities related to the support of peginesatide. We have limited ability and resources to pursue internal research and programs and strategic collaborations for the development of new products. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in

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identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including, but not limited to, the following:

- the financial and internal resources may be insufficient and are needed for peginesatide;
- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory requirements for approval;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a product candidate may not be accepted by patients, the medical community or third party payors.

The U.S. market opportunity for peginesatide may deteriorate significantly after the entry of biosimilars in the U.S.

In March 2010, federal legislation gave the FDA authority to create an abbreviated approval path for biological products that are demonstrated to be "biosimilar" to, or "interchangeable" with, an FDA-approved biological product. In February 2012, the FDA released three draft guidance documents regarding this abbreviated approval path for biosimilar products, and the FDA is accepting public comments on these documents. A biosimilar product would be a subsequent version of an existing, branded FDA-approved biologic product. The patent for the existing branded product must expire in a given market before biosimilars may enter that market.

The patents for epoetin alfa, a version of recombinant human erythropoietin, or rEPO, expired in 2004 in the European Union, or E.U., and the remaining patents expire from 2012 through 2015 in the U.S. Biosimilars of rEPO are currently being developed or sold in the E.U., and in various other markets outside the U.S. And in January 2012, Hospira Inc. announced the beginning of its U.S. Phase 3 clinical program for its biosimilar of rEPO with results anticipated in 2013.

We expect that biosimilars, including rEPO, will be sold at a discount to existing branded products when they are launched in the U.S. as in the E.U. The introduction of biosimilars into the rEPO market in the U.S. could prove to be a significant threat to peginesatide if they are able to demonstrate biosimilarity to existing rEPO. Biosimilars will constitute additional competition for peginesatide, if approved, and are expected to drive its price and sales volume down, which would adversely affect our revenues.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future, which will require us to obtain substantial additional financing. If we incur significant delays or expenses and are unable to obtain additional financing, we will be unable to complete the development and commercialization of peginesatide and may need to cease operations. Even if we obtain additional financing, when needed, we may never achieve or sustain profitability.

We have experienced significant operating losses since our inception in 2001. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. At December 31, 2011, we had an accumulated deficit of $450.3 million. Due to the recognition of revenues from milestone payments from our collaboration with Takeda, we were profitable for the three and nine months ended June 30, 2010 and may have profitable quarters from time to time if we are successful in obtaining FDA approval for peginesatide. We continue to expect to incur substantial losses in order to complete the development and commercialization of peginesatide.

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Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to:

- prepare to launch and commercialize peginesatide, including building our own commercial organization, sales force and infrastructure to address renal markets;
- prepare for the manufacturing process for peginesatide at our contract manufacturers for commercial launch;
- pursue approval of the NDA for peginesatide through the FDA review process, which is a lengthy and uncertain process; and
- complete clinical development of peginesatide, and any postmarketing requirements.

We believe that our existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. However, further challenges or delays to approval and commercialization of peginesatide may require us to raise additional funding to complete the development and commercialization of peginesatide. Since the announcement of our Phase 3 data in late June 2010 and the arbitration decision in October 2010, we have experienced a severe decline in our stock price, which has impaired our ability to access capital on potentially favorable terms. In contrast, our funding needs have only increased with the delays in the peginesatide development program, the potential loss of milestone payments from Takeda associated with the non-dialysis indication. Our failure to raise capital when needed may harm our business and operating results.

The current capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Securing funding has been particularly difficult for companies of our size with limited capital resources. Continuation of this market and the issues arising from our Phase 3 results significantly limit our ability to raise funds such that that there can be no assurance we can raise the additional funds, when needed, to support our continuing operations and maintain current development and commercialization timelines for peginesatide.

To date, our sources of cash have been limited primarily to the proceeds from the sale of our securities to private and public investors and payments by Takeda under our collaboration agreements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, if available, our stockholders may experience significant dilution particularly given the stock price decline we experienced subsequent to the announcement of our Phase 3 results. Further, our equity line of credit with Azimuth Opportunity Ltd., or Azimuth, is subject to a number of conditions that limits our ability to draw against such facility. Any debt financing, if available, may involve security interests on our assets or restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to raise additional funds when required or on acceptable terms, we may have to:

- assume greater risks and significantly delay, scale back, or discontinue the development and/or commercialization of peginesatide;
- relinquish our existing rights to peginesatide;
- eliminate or defer formulation research and development or other manufacturing efforts that may be required to successfully develop or commercially launch peginesatide; or
- pursue merger and acquisition alternatives.

We expect to continue to incur substantial operating losses as we pursue regulatory review and approval of the NDA, add infrastructure and operations to support commercialization of peginesatide,

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and potentially begin new research and development programs. Our ability to generate product sales depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our product candidate, peginesatide. If due to lengthy and complicated development, clinical and regulatory requirements or any other reason, we are unable to commercialize peginesatide, we may never be able to commercialize any future product candidates.

Even if we receive regulatory approval of peginesatide, we must successfully commercialize peginesatide before we can become profitable. We expect to incur substantial expenses associated with our commercialization efforts, as well as share in those of Takeda's, prior to obtaining approval of peginesatide in preparation for launch into a highly competitive market as well as thereafter. Accordingly, we may never generate significant revenues and, even if we do generate product sales, we may never achieve or sustain profitability.

Peginesatide may require extensive additional clinical evaluation and will require regulatory approval, significant marketing efforts and substantial investment before it can provide us or our partners with any revenue. If we or our partners are unable to develop and commercialize peginesatide or even if we receive marketing approval for peginesatide, sales revenue therefrom may be insufficient, and we may not achieve or sustain profitability, and we may be unable to continue our operations.

Competition in the pharmaceutical industry is intense. If our competitors are able to develop and market products that are more effective, safer or less costly than peginesatide, our commercial opportunity will be reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, in particular companies that have an approved ESA on the market. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects or are less expensive than peginesatide or any other future products that we may develop and commercialize. Significant delays in the approval or commercialization of peginesatide could allow our competitors to bring new products to market before we do and impair our ability to commercialize peginesatide. Competitors may also reduce the price of their ESAs in order to gain market share. These price reductions could force us to lower the price of peginesatide in order to compete effectively, resulting in lower revenues and reduced margins on the sales of peginesatide.

We anticipate that, if approved, for treatment of anemia associated with chronic kidney disease in dialysis patients, peginesatide would compete with EPOGEN and potentially Aranesp, which are both marketed by Amgen, NeoRecormon and Mircera, which are currently marketed outside the U.S. by Roche. Mircera reportedly has greater plasma stability and is longer acting than any rEPO product that is currently on the market. As a result of the patent litigation between Roche and Amgen, Mircera has been found to infringe several U.S. patents owned by Amgen and has been enjoined from being sold in the U.S. until the expiration of these patents in mid-2014 under a limited license. If Mircera enters the U.S. market before peginesatide or upon its entry, we believe that Mircera will be in direct competition with peginesatide, and therefore could potentially limit the market for peginesatide, because of its ability to be longer acting. Other potential competitors, including FibroGen, Inc., are developing small molecules designed to promote the production of greater levels of naturally-occurring EPO in patients. The introduction of biosimilars into the ESA market, or new market entrants, could also prove to be a significant threat to us as it could not only limit the market for peginesatide, but could also drive down the price of ESAs.

Most of these competitors have substantially greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Current marketers of ESAs also have the ability to bundle sales of existing ESA products with their other products, potentially disadvantaging peginesatide, which we plan to sell on a stand-alone basis. Established pharmaceutical and large biotechnology companies may invest heavily to discover and develop novel compounds or drug delivery

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technology that could make peginesatide obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through strategic partnerships with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Our competitors may succeed in obtaining patent or other intellectual property protection, receiving FDA approval, or discovering, developing and commercializing products before we do.

The success of peginesatide is dependent upon the strength and performance of our collaboration with Takeda in the U.S. If we fail to maintain our existing collaboration with Takeda, such termination would likely have a material adverse effect on our ability to continue to develop peginesatide and our business.

The maintenance and successful performance of our strategic collaboration with Takeda for development of peginesatide is an important part of our business model. Our collaboration with Takeda is extremely complex, particularly in the context of our planned U.S. commercial launch with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties in decision making. Accordingly, significant aspects of the development and commercialization of peginesatide require Takeda's agreement or approval prior to implementation, which could cause significant delays that may materially impact the potential success of peginesatide in the U.S. Further, if we are not able to reach agreement with Takeda or maintain our existing collaboration with Takeda on plans and efforts to develop and commercialize peginesatide, our business could be severely and adversely affected. Takeda has the ability to terminate each of the collaboration agreements upon an uncured material breach by us or even in the absence of a material breach with six months notice. Currently, Takeda could terminate either or both of our collaboration agreements, which would likely have a material adverse effect on the advancement of our peginesatide program and our business. Events such as the suspension of the peginesatide oncology program, the impact of the Phase 3 results on the renal program particularly on the non-dialysis indication, and the decreased market opportunity for ESAs may increase the possibility that Takeda may elect to terminate the collaboration or limit the resources Takeda is willing to commit to peginesatide on a worldwide basis, particularly in advance of obtaining regulatory approvals for peginesatide. In December 2011, Takeda notified us of its decision not to commercialize peginesatide in Japan, which may negatively impact Takeda's overall commitment in the U.S. or elsewhere. Through the collaboration, Takeda currently provides development and commercialization funding and performs important functions, including conduct of certain clinical trials and manufacturing activities, and is expected to pay us milestone payments upon the completion of certain events, all of which would be unavailable to us in the case of an early termination of the collaboration. Even in the absence of a termination, the significant resources and commitment that may be required to successfully commercialize peginesatide in the U.S. may be limited, and Takeda's failure to provide funding or perform its obligations on a timely basis in anticipation of commercial launch may have a material adverse effect on our business and the success of peginesatide, in particular in the U.S. If we fail to maintain the Takeda collaboration or establish and maintain additional strategic collaborations for any other potential product candidates that we may pursue:

- the development of peginesatide or future product candidates may be terminated or delayed;
- our cash expenditures related to development of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of each of our current and future product candidates; and
- we may be unable to meet demand for any future products that we may develop.

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Any of these events could have a material adverse effect on our business.

The commercial success of peginesatide in the U.S. depends in significant part on the development and commercialization efforts of Takeda, over which we have limited control in the U.S. The corporate governance structure and division of roles and responsibilities with Takeda under our co-promotion agreement is complex and requires substantial coordination and focus on the part of Takeda to successfully execute our plans. Outside of the U.S. in the Takeda territory, we are solely dependent on the efforts and commitments of Takeda, either directly or through third parties, to further develop and commercialize peginesatide. If our collaborations are unsuccessful, our ability to develop and commercialize products through our collaborations, and to generate future product sales, would be significantly reduced.

Our dependence on Takeda for our global collaboration with peginesatide subjects us to a number of risks, including our ability to successfully develop and commercialize peginesatide in the U.S. and sole reliance on Takeda, either directly or through third parties, to further develop, obtain and maintain regulatory approvals and achieve market acceptance of peginesatide in the Takeda territory.

Under our collaboration with Takeda in the U.S., we co-develop and co-commercialize peginesatide in the U.S. Because we share responsibility with Takeda for clinical development and commercialization activities in the U.S., which involves a complex corporate governance structure and division of roles and responsibilities, the conduct and success of the peginesatide program is substantially dependent on the efforts of Takeda over which we have limited or no control. Further, as Takeda has significant rights, responsibilities and decision-making authority over commercialization of peginesatide in the U.S. including final decision making authority with respect to pricing, contracting and distribution activities, any failure of Takeda to act in a timely manner or make adequate investments of funds or resources may delay further development or commercialization of peginesatide that may result in a negative impact on our planned timelines, require us to contribute more resources to successfully commercialize peginesatide and decrease the likelihood of commercial success for peginesatide in the U.S.

Outside of the U.S., Takeda holds an exclusive license to develop and commercialize peginesatide and has primary responsibility for filing regulatory submissions and obtaining product approvals in those territories, including in Europe and Japan. As a consequence, any progress and commercial success in those territories is dependent solely on Takeda's efforts and commitment to the program. Takeda's recent decision not to commercialize peginesatide in Japan and the delay or failure to secure a third party to commercialize the product in a timely manner may significantly reduce the commercial opportunity in that territory. In addition, Takeda may delay, reduce or terminate development efforts relating to peginesatide elsewhere, independently develop products that compete with peginesatide, or fail to commit sufficient resources to the marketing and distribution of peginesatide. Competing products or programs, either developed by Takeda or to which our collaboration partners have rights or acquire in the future, may result in our partners' withdrawal of support for peginesatide.

In the event that Takeda fails to diligently develop or commercialize peginesatide, our collaboration and co-promotion agreements provide us the right to allege breach and if successfully asserted, terminate our partner's rights in certain instances. However, our ability to enforce the diligence provisions and establish breach of Takeda's diligence or other obligations so as to obtain meaningful recourse within a reasonable timeframe is uncertain. Further, any decision to pursue available remedies including termination would impact the potential success of peginesatide and we may choose not to as we may not be able to find another partner and any new collaboration will likely not provide comparable financial terms to those in our Takeda Arrangement. In the event of our termination, this may require us to commercialize peginesatide on our own, which is likely to result in significant additional expense and delay. Significant changes in Takeda's business strategy, resource commitment and the willingness or ability of Takeda to complete its obligations under the Arrangement, particularly in advance of obtaining regulatory approvals in the U.S. and abroad, could materially affect the potential success of peginesatide.

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We have limited ability to control and influence Takeda in its strategic decisions. This is particularly important as we are currently planning for commercialization of peginesatide in the U.S. If Takeda were to breach or terminate either of our collaboration agreements or otherwise inadequately perform or fail to perform its obligations thereunder in a timely manner, the development and commercialization of peginesatide would be delayed, terminated or negatively impacted. Moreover, if Takeda fails to successfully develop and commercialize peginesatide outside of the U.S., our potential to generate future revenue in the Takeda territory would be significantly reduced.

Reimbursement may not be available for peginesatide, which would materially diminish our sales and our ability to sell our products profitably.

Market acceptance and sales of peginesatide will depend on reimbursement policies and may be affected by future health care reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for peginesatide. Also, we cannot be sure that reimbursement amounts or policies will not reduce the demand for, or the price of, peginesatide. We have not commenced efforts to have peginesatide reimbursed by government or third party payors. If reimbursement is not available, is available only to limited levels or is not available in a timely manner, then we may not be able to commercialize peginesatide.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell peginesatide profitably.

In response to the FDA's recent boxed warning and public health advisories, CMS has significantly restricted coverage of ESAs. In July 2007, CMS issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Neoplastic Conditions, or the National Coverage Decision, that determined that ESA treatment was not reasonable or necessary for certain medical conditions, including any anemia of cancer not related to cancer treatment, among others. The National Coverage Decision also established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia and contains a coverage restriction for hemoglobin levels greater than 10g/dL, which has had a material adverse effect on the use of ESAs. In July 2007, CMS also issued revisions to its reimbursement policies for the use of ESAs for end stage renal disease in cases where hemoglobin levels exceed 13 g/dL and also decreased the monthly dosing limits. In July 2008, CMS announced that ESAs are a potential topic for another National Coverage Decision citing adverse effects in cancer and chronic kidney disease patients, including dialysis patients, while noting the large costs but uncertain benefits. In March 2010, CMS convened a MedCAC meeting to review the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease and in January 2011 to review the role of ESAs in successful kidney transplantation. In November 2011, pursuant to the FDA label changes, CMS, through rulemaking, modified its performance incentive program for dialysis providers by removing a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients, which may create incentives for lower overall ESA utilization. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage or create disincentives which could have a materially negative impact on the size of the ESA market in the U.S. and reduce the overall size of the market peginesatide is expected to compete in at the time of launch.

As a result of these reimbursement and other legislative proposals and the trend towards managed health care in the U.S., third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of approved products for medical indications other than those for which the FDA has granted market approvals. In addition, major third party payors have begun to follow CMS's restrictive

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reimbursement policies, which has further decreased the market for ESAs. As a result, significant uncertainty exists as to whether and how much third party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

CMS policies are constantly changing and we cannot guarantee that they will not decrease, limit or deny reimbursement of peginesatide in the future.

CMS, the agency within the Department of Health and Human Services that manages Medicare and will be responsible for reimbursement of the cost of peginesatide administered to Medicare beneficiaries, has asserted the authority of Medicare not to cover particular drugs if it determines that they are not "reasonable and necessary" for Medicare beneficiaries, or to cover them at a lesser rate, compared to drugs that CMS considers to be therapeutically comparable. We cannot be certain that CMS will not decrease, limit or deny reimbursement of peginesatide for any therapeutic indication we may pursue. Even if CMS ultimately authorizes reimbursement for peginesatide, it may be not do so in a timely manner. As the costs of the Medicare program continue to grow, CMS may be compelled to make difficult decisions regarding the trade-offs of supporting the reimbursement of certain public health expenditures over others. Depending on methods CMS uses to calculate the cost-benefit of treatments competing for share of the Medicare budget, ESAs (including peginesatide) may not be considered to offer sufficient overall health benefit to justify reimbursement at levels that will allow us to achieve and sustain profitability. In addition, as a result of the recent safety concerns relating to ESAs, CMS recently announced policies significantly restricting the coverage of ESAs and has proposed another National Coverage Decision on the topic that may further negatively affect reimbursement of ESAs. CMS has instituted dramatic Medicare reimbursement changes in the past that adversely impacted the businesses of companies in other segments of the healthcare industry, and we cannot determine that CMS will not do the same in the markets in which we operate.

Medicare reimbursement policies under a new bundled payment system could create disincentives for use of ESAs.

Prior to this year, CMS generally reimbursed healthcare providers for use of ESAs at average selling price, or ASP, plus 6%. However, under the 2008 Medicare Legislation a new bundled payment system commenced in January 2011 for facilities that furnish renal dialysis services and home dialysis to Medicare beneficiaries with end-stage renal disease. Under the new bundled payment system, providers are expected to be reimbursed a fixed amount per patient. We cannot guarantee that peginesatide will be reimbursed by CMS or in a manner that will support physician adoption and depending upon the implementation of the bundled payment, may not be favorable to the entry of new ESAs such as peginesatide. In fact, a capitated reimbursement payment methodology may create incentives for significantly lower utilization or dosing of ESAs, including peginesatide, and reduce the commercial potential for peginesatide.

Significant challenges remain with us and Takeda to manufacture peginesatide on a commercial scale. Our dependence upon third parties for manufacture and supply may cause delays in, or prevent us from, successfully developing and commercializing peginesatide. In accordance with the terms of our collaboration, Takeda has responsibility for manufacture of finished product and as a consequence, we have limited ability to control risks associated with that portion of the manufacturing process.

The peginesatide manufacturing process is a complicated, time-consuming process. Manufacture of peginesatide API involves long lead times. We do not currently have the infrastructure or capability internally to manufacture the peginesatide needed to conduct our clinical trials or to commercialize

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peginesatide. We are and will continue to rely upon contract manufacturers to produce our clinical trial materials and in the future commercial supplies of peginesatide. For the foreseeable future, we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of peginesatide for all our uses, including commercialization. If our contract manufacturers or other third parties fail to deliver materials for the manufacture of peginesatide or peginesatide itself on a timely basis, with sufficient quality and at commercially reasonable prices, and if we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise delay or discontinue development, commercialization or production.

Peginesatide is a new chemical entity and the manufacturing process for commercial scale production in accordance with applicable regulatory guidelines remains challenging and as such, there are risks associated with the commercial scale manufacture of the API. Similar challenges exist for the manufacture of finished product that must meet a variety of regulatory requirements that vary from country to country and continue to change. Any of these risks and others may prevent or delay us from successfully developing peginesatide, including the following:

- stability or formulation issues including the potential failure of product registration studies to establish sufficient stability to obtain adequate shelf life at refrigerated or room temperature;
- cost overruns, process scale-up, process reproducibility;
- difficulties in maintaining or upgrading equipment and manufacturing facilities on a timely basis; and
- regulatory issues or changes that may cause significant modifications in the manufacturing process or facilities or otherwise impact our ability to offer competitive product presentations or formulations.

We have transferred responsibility of manufacture of peginesatide finished product to Takeda and we therefore have limited control and ability to address risks associated with that portion of the manufacturing process. Further, some of suppliers and manufacturing arrangements, including the provision of bulk poly(ethylene) glycol reagent for the manufacture of peginesatide from Nektar Therapeutics AL, Corporation, or Nektar, are currently single-sourced, leaving us at greater risk of supply interruptions, potential delays and failure to obtain regulatory approvals and commercialize. Unless we are able to successfully negotiate with Nektar, which we may not be able to do on acceptable terms, we may have difficulties under our existing arrangement with Nektar from obtaining proprietary information and additional services from Nektar which may be useful or necessary to obtain regulatory approvals or for commercial manufacture of peginesatide.

We, Takeda, and our third party manufacturers are required to comply with applicable FDA manufacturing practice regulations. If there is any failure by us, Takeda or one of our third party manufacturers or suppliers to maintain compliance with these regulations, the production of peginesatide could be interrupted, resulting in delays and additional costs. Additionally, our third party manufacturers must pass a pre-approval inspection before we can obtain regulatory approval for peginesatide. If for any reason these third parties are unable or unwilling to perform under our agreements or enter into new agreements with us, we may not be able to locate alternative manufacturers or enter into favorable agreements with them in an expeditious manner. We could also experience manufacturing delays if our third party manufacturers, Takeda or suppliers give greater priority to the production of other products over peginesatide. Any inability to acquire sufficient quantities of peginesatide or components thereof in a timely manner from third parties could delay clinical trials or result in product shortages and prevent us from developing and commercializing peginesatide in a cost-effective manner or on a timely basis. Further, our lack of experience providing

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reliable supply of product may deter health care providers and dialysis centers from selecting or otherwise switching to peginesatide from our competitors' products.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of peginesatide and any other product candidates we may pursue, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect peginesatide from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

We have licensed from third parties rights to numerous issued patents and patent applications. The rights that we acquire from licensors or collaborators are protected by patents and proprietary rights owned by them, and we rely on the patent protection and rights established or acquired by them. The remaining patent terms may not provide meaningful protection. Moreover, third parties may challenge the patents, patent applications and other proprietary rights held by our licensors or collaborators. We generally do not unilaterally control the prosecution of patent applications licensed from third parties. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we may exercise over internally developed intellectual property.

Even if we are able to obtain issued patents, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily protect us from competition or from claims of a third party that our products infringe their issued patents. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents, in our patents or in third party patents or applications therefor.

The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make similar compounds but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;
- we or our licensors or collaborators might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not result in issued patents;
- our issued patents and the issued patents of our licensors or collaborators may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

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We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our technology and other confidential information, then our ability to receive patent protection or protect our proprietary information may be jeopardized.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

Our ability, and that of our commercial partners, to commercialize any approved product will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and foreign counterparts related to peginesatide and other programs as well as underlying platform technologies and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted, that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

The failure to obtain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the further development and marketing of any product. There can also be no assurance that patents owned by us will not be challenged by others. We could incur substantial costs in proceedings, including interference proceedings before the U.S. Patent and Trademark Office and comparable proceedings before similar agencies in other countries in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our inventions and products, as well as about the enforceability, validity or scope of protection afforded by our patents.

Patent applications in the U.S. and elsewhere are published only after 18 months from the priority date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to peginesatide and any future products may have already been filed by others without our knowledge. In the event an infringement claim is brought against us, we may be required to pay substantial legal and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing related product development and commercialization and may be subject to damage awards.

Any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or

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proceedings may expose us or our collaborators to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms or at all. In addition, we may be restricted or prevented from manufacturing, developing or commercializing peginesatide or from developing, manufacturing and selling any future products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses. If it is determined that we have infringed an issued patent, we could be compelled to pay significant damages, including punitive damages.

Virtually all of our competitors are able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations, in-license technology that we need, out-license our existing technologies or enter into collaborations that would assist in commercially exploiting any technology.

If we fail to attract and keep senior management and key commercial, medical affairs, clinical and scientific personnel, we may be unable to successfully develop, conduct our clinical trials and commercialize peginesatide or any other future product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, commercial, medical affairs, clinical and scientific personnel, and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management, commercial, medical affairs, clinical and scientific staff, particularly John Orwin, our Chief Executive Officer, Jeffrey Knapp, our Chief Commercial Officer and Dr. Anne-Marie Duliege, our Chief Medical Officer. The loss of services of Mr. Orwin, Mr. Knapp or Dr. Duliege, or one or more of our other members of senior management could delay or prevent the successful completion of our development or the commercialization of peginesatide.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms. Our ability to retain or attract qualified personnel has been negatively impacted by the Phase 3 results and the severe decline in our stock price. Each of our officers and key employees may terminate his/her employment at any time without notice and without cause or good reason.

As we evolve from a company primarily involved in research and development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

As we advance peginesatide through the development stage towards commercialization, we will need to expand our organization, including marketing and sales and medical affairs capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize peginesatide and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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Risks Related to Our Industry

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of peginesatide.

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and regulations may differ from country to country. Neither we nor Takeda is permitted to market peginesatide in the U.S. until we receive approval of our NDA from the FDA which we may never obtain. We have not received marketing approval for peginesatide or for any product approval. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the drug approval process. We initiated our Phase 3 clinical trials for peginesatide following extensive discussion with the FDA on the design of the program. Based on the nature of these discussions and guidance from the FDA in light of the current regulatory environment, we did not enter into a special protocol assessment, or SPA, with the FDA for our Phase 3 clinical trials for peginesatide. Nonetheless, in some instances a SPA could provide more assurance that the design, clinical endpoints, and statistical end analyses resulting from these trials would be acceptable to the FDA to support regulatory approval. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

a drug candidate may not be deemed safe or effective;

FDA officials may not find the data from pre-clinical studies and clinical trials sufficient;

the FDA might not approve our or our third party manufacturer's processes or facilities; or

the FDA may change its approval policies or adopt new regulations.

Even if peginesatide is approved by the FDA, we will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize peginesatide.

Any regulatory approvals that we or Takeda receive for peginesatide may also be subject to limitations on the indicated uses for which the product may be marketed, or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves peginesatide, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. Our Phase 3 results may increase the risk of significant additional requirements to maintain any regulatory approval that we might receive. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of peginesatide. We cannot predict the likelihood, nature or extent

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of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and we may not achieve or sustain profitability.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and healthcare privacy and security laws, we could face substantial penalties that could adversely affect our business, financial condition and results of operations.

We are subject to federal and state healthcare laws, including fraud and abuse and healthcare privacy and security laws. The healthcare laws that may affect our ability to operate include:

- federal "sunshine" laws that require transparency regarding financial arrangements with healthcare providers, such as the reporting and disclosure requirements imposed on drug manufacturers by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, regarding any "transfer of value" made or distributed to prescribers and other health care providers;

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, California, and other states such as Massachusetts and Vermont, mandate implementation of comprehensive compliance programs to ensure compliance with these laws.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations.. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid, and the curtailment or restructuring of operations. We believe that our operations are in material compliance with such laws, and we have enacted a compliance program to ensure such compliance. However, because of the far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws, or that the occurrence of one or more violations of these laws would not result in a material adverse effect on our financial condition and results of operations.

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Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad through our Takeda collaboration.

We intend to co-market peginesatide in the U.S., and have exclusively licensed Takeda to develop peginesatide in international markets. In order to market peginesatide in the E.U. and many other foreign jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. Foreign regulatory approvals may not be obtained on a timely basis, if at all. We or Takeda, as part of our peginesatide collaboration, may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Foreign governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market peginesatide in the U.S. and, through our Takeda collaboration, in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some foreign countries, particularly in the E.U., prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of peginesatide to other available therapies or a clinical trial that studies pharmacoeconomic benefits. If reimbursement of peginesatide is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We use hazardous chemicals and radioactive and biological materials in our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials. Although we believe our safety procedures for handling and disposing of these materials and waste products comply with these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages. We are uninsured for third party contamination injury.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of peginesatide.

We face an inherent risk of product liability as a result of conducting clinical trials and will face an even greater risk if we commercialize peginesatide. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of peginesatide. Even successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

decreased demand for peginesatide;

injury to our reputation;

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withdrawal of clinical trial participants;

costs of related litigation;

diversion of management's attention and resources;

substantial monetary awards to patients;

product recalls;

loss of revenue; and

the inability to commercialize peginesatide.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $11 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer. In addition, insurance coverage is becoming increasingly expensive, and in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Risks Related to the Ownership of Our Common Stock

The market price of our common stock has been highly volatile and is likely to remain highly volatile, and you may not be able to resell your shares at or above your purchase price.

The trading price of our common stock has been highly volatile. For the 52 weeks ended December 31, 2011, the closing price of our common stock ranged between a high of $7.99 per share and a low of $4.04 per share. Our stock is expected to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

actual or anticipated results from, and any delays in, our development program, regulatory review and commercialization of peginesatide;

actual or anticipated regulatory approvals including limitations, scope or conditions with respect thereto of peginesatide or competing products;

actual or anticipated contractual arrangements of peginesatide or competing products;

actual or anticipated changes in our funding requirements, capital resources and our ability to obtain financing and the terms thereof;

actual or anticipated actions taken by regulatory agencies including CMS with respect to ESAs generally or specifically as to peginesatide;

new products or services introduced or announced by us or our collaboration partners, or our competitors, including Roche's Mircera or biosimilars, and the timing of these introductions or announcements;

actions taken by regulatory agencies with respect to clinical trials, manufacturing process or sales and marketing activities;

changes in laws or regulations applicable to peginesatide, including but not limited to clinical trial requirements for approvals;

the success of our development efforts and clinical trials;

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the success of our efforts to discover, acquire or in-license additional products or product candidates;

developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

actual or anticipated variations in our quarterly operating results;

announcements of technological innovations by us, our collaborators or our competitors;

actual or anticipated changes in earnings estimates or recommendations by securities analysts;

conditions or trends in the biotechnology and biopharmaceutical industries;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;

changes in the market valuations of similar companies;

sales of common stock or other securities by us or our stockholders in the future;

additions or departures of key scientific or management personnel;

developments relating to proprietary rights held by us or our competitors;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; and

trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation or regulatory investigations have often been instituted against companies. Such litigation or investigations, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We currently have not had any material weaknesses for the years ended December 31, 2011, 2010 or 2009. We did identify a material weakness in the operation of our internal controls over financial reporting that occurred during the second quarter of 2008 which has been fully remediated. We cannot assure you that material weaknesses will not be identified in future periods. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting in future periods. If we do experience a material weakness in future periods, then investor confidence, our stock price and our ability to obtain additional financing on favorable terms could be adversely affected.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if

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any, within an organization have been detected. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market that were previously restricted from sale, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. In the event that we do raise capital through the sale of additional equity securities, the dilution represented by the additional shares of our equity securities in the public market could cause our stock price to fall, in which case investors may not be able to sell their shares of our equity securities at a price equal to or above the price they paid to acquire them.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income or future tax will be limited and may be further limited in the future due to ownership changes that have occurred or may occur in the future.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). An ownership change could limit our ability to utilize our NOL and tax credit carryforwards for taxable years including or following such "ownership change". The issuance of shares of our common stock in our March 2011 public offering resulted in an ownership change and further ownership changes may occur in the future, including as a result of transactions outside of our control, such as sales by existing stockholders, and as a consequence, our ability to utilize our NOL and tax credit carryforwards will be limited. Limitations imposed on the ability to use NOLs and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would otherwise be required if such limitations were not in effect and could cause such NOLs and tax credits to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credits. Similar rules and limitations may apply for state income tax purposes.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because of the significant decrease in our stock price as a result of the announcement of our Phase 3 data and the decision from the arbitration panel relating to the dispute with Johnson & Johnson. Further, our stock price may continue to experience extreme price volatility as has been experienced by biotechnology and biopharmaceutical companies in recent years. If we were to face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders.

Provisions in 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 if doing so would benefit our stockholders.

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These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- our board of directors is classified, consisting of three classes of directors with staggered three-year terms, with each class consisting as nearly as possible of one third of the total number of directors.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We currently lease approximately 113,000 square feet of laboratory and office space in Palo Alto, California under lease agreements that terminate in September 2014. We believe that our facilities adequately meet our present needs.

Item 3. Legal Proceedings.

In October 2010, the arbitration panel in our binding arbitration with certain subsidiaries of Johnson & Johnson, decided the ownership of a number of U.S. and international patents and patent applications related to certain EPO-R agonists, or the "intellectual property in dispute." The decision maintained Johnson & Johnson's sole inventorship and sole ownership of U.S. Patent No. 5,767,078, or the "078 Patent," and certain related foreign patents and patent applications, including European Patent application EP96/918,317. The arbitrators determined that we and Johnson & Johnson jointly own the remainder of the intellectual property in dispute, *i.e.*, U.S. Patent Nos. 5,773,569, 5,830,851, and 5,986,047 together with their foreign counterpart patents and patent applications.

The intellectual property in dispute relates primarily to a three-year Research and Development Agreement, or the R&D Agreement, entered into in 1992 between a division of Ortho Pharmaceutical Corporation, a subsidiary of Johnson & Johnson, and Affymax N.V. (a different company from us), for compounds directed at the EPO receptor. The R&D Agreement provided for any invention made by either party to be the property of the party making the invention and that joint inventions would be jointly owned.

In 1995, Affymax N.V., Affymax Technologies, N.V. and Affymax Research Institute were acquired by Glaxo Wellcome plc. Thereafter, in 2001, we acquired specified assets from Glaxo Wellcome plc and related entities, including the rights to the R&D Agreement (which had been finally terminated in 2000) and the rights to specified patents and patent applications that had previously been held by

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Affymax N.V. and Affymax Technologies, N.V. and comprised much of the intellectual property in dispute. Our claims of ownership of the intellectual property in dispute was based on the inventions of Affymax N.V. scientists.

After our company was founded in 2001, we pursued efforts to create a synthetic compound that activated the EPO receptor and had the biological and physical properties needed to be a commercially viable pharmaceutical product. Our efforts culminated in the first chemical synthesis of peginesatide in 2003.

In November 2010, we filed in the U.S. District Court for the Northern District of Illinois, or the District Court, a motion to vacate the arbitration award with respect to the ownership of the '078 Patent and related foreign cases. In December 2010, Johnson & Johnson filed its response and requested that the District Court confirm the arbitration award.

In March 2011, the District Court issued its decision to vacate in part the arbitrators' award relating to sole ownership by Johnson & Johnson of the European Patent EP96/918,317 and other foreign counterpart patents and patent applications to the '078 Patent. As a consequence, the District Court remanded the issues of inventorship and ownership of such foreign patents and patent applications to the arbitration panel. The District Court denied our motion to vacate in part and maintained the arbitration award with respect to the sole ownership by Johnson & Johnson of the '078 Patent in the U.S. In May 2011, we filed a notice of appeal relating to the District Court's decision as to the '078 Patent in the U.S. which remains pending with the Court of Appeals for the Federal Circuit. Concurrently, Johnson & Johnson filed an appeal with the Seventh Circuit Court of Appeals, and in October 2011, the Seventh Circuit Court reversed the District Court with the result that it remanded with instruction to confirm the arbitration award in full and set forth its view that the Court of Appeals for the Federal Circuit lacked jurisdiction.

In November 2011, we entered into a settlement and license agreement, or the Settlement and License Agreement, with Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies, or, collectively, Janssen, under which we obtained a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings.

The Settlement and License Agreement provides for fixed payments by us to Janssen of $6 million, which was paid in December 2011, and $2 million by June 30, 2012. The Settlement and License Agreement also provides for a $2.5 million milestone payment to Janssen upon FDA regulatory approval of peginesatide, and a $2.5 million milestone payment to Janssen upon regulatory approval of peginesatide in the first major European country. In addition, Janssen will also be entitled to low, single-digit royalties on sales of peginesatide in Europe, Japan and certain other countries outside of the U.S. until mid-2016.

From time to time, we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market For Our Common Stock

Our common stock has been traded on the NASDAQ Global Market under the symbol "AFFY" since December 15, 2006. As of February 29, 2012, there were approximately 85 holders of record of our common stock. The following table sets forth, for the periods indicated, the range of high and low sales prices of our common stock as quoted on the NASDAQ Global Market.

	High	Low
2011		
4th Quarter	$ 8.45	$ 4.14
3rd Quarter	$ 8.00	$ 3.93
2nd Quarter	$ 7.50	$ 5.82
1st Quarter	$ 8.50	$ 5.79

	High	Low
2010		
4th Quarter	$ 7.75	$ 4.90
3rd Quarter	$ 8.58	$ 5.12
2nd Quarter	$ 26.20	$ 5.89
1st Quarter	$ 25.45	$ 17.98

The closing price for our common stock as reported by the NASDAQ Global Market on February 29, 2012 was $10.21 per share.

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.

Recent Sales of Unregistered Securities

We did not make any unregistered sales of shares of our common stock during the fourth quarter ended December 31, 2011.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2011.

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Performance Graph(1)

The following graph shows the total stockholder return of an investment of $100 in cash on December 31,2006, through December 31, 2011 for (i) our common stock, (ii) the Nasdaq Composite Index (U.S.) and (iii) the Nasdaq Biotechnology Index as of December 31, 2011. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Affymax Inc., the NASDAQ Composite Index, and the NASDAQ Biotechnology Index

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*

$100 invested on 12/31/06 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

Item 6. Selected Financial Data.

The following selected financial data should be read together with our audited financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information included in this Annual Report on Form 10-K. The selected financial data in this section is not intended to replace our audited financial

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(1)

This Section is not "soliciting material," is not deemed "filed" with the Commission and is not to be incorporated by reference into any filing of Affymax, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

	Years Ended December 31,				
	2011	2010	2009	2008	2007
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenue:					
Collaboration revenue	$ 47,703	$ 112,503	$ 114,883	$ 82,162	$ 44,303
License and royalty revenue	17	18	16	689	33
Total revenue	47,720	112,521	114,899	82,851	44,336
Operating expenses:					
Research and development	76,308	93,638	157,125	137,492	69,398
Selling, general and administrative	32,818	33,331	36,716	34,090	24,075
Total operating expenses	109,126	126,969	193,841	171,582	93,473
Loss from operations	(61,406)	(14,448)	(78,942)	(88,731)	(49,137)
Interest income	169	275	934	4,545	11,393
Interest expense	(144)	(140)	(105)	(609)	(14)
Other income (expense), net	15	239	171	(1,433)	46
Net loss before provision (benefit) for income taxes	(61,366)	(14,074)	(77,942)	(86,228)	(37,712)
Provision (benefit) for income taxes	1	1	(1,411)	282	5,357
Net loss	$ (61,367)	$ (14,075)	$ (76,531)	$ (86,510)	$ (43,069)
Net loss per common share:					
Basic and diluted(1)	$ (1.84)	$ (0.57)	$ (4.06)	$ (5.68)	$ (2.88)
Weighted-average number of common shares used in computing basic and diluted net loss per loss common share	33,288	24,488	18,865	15,220	14,941

	December 31,				
	2011	2010	2009	2008	2007
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 98,504	$ 97,081	$ 160,588	$ 94,719	$ 168,337
Receivable from Takeda	6,937		18,561	21,688	15,331
Long-term investments		19,876	7,978	22,945	15,655
Total assets	118,995	131,387	211,510	167,720	225,792
Payable to Takeda		5,958			
Deposit from Takeda	1,998				
Advance from Takeda	6,121				
Accumulated deficit	(450,301)	(388,934)	(374,859)	(298,328)	(211,818)
Total stockholders' equity	75,997	72,547	66,905	8,984	84,185

(1) Please see Note 2 to the notes to our audited financial statements for an explanation of the method used to calculate the net loss per common share and the number of shares used in the computation of the per share amounts.

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

Overview

We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. Our product candidate, peginesatide, is for the treatment of anemia in chronic kidney disease patients on dialysis. The New Drug Application, or NDA, for peginesatide is currently under review by the U.S. Food and Drug Administration, or FDA. We have a worldwide collaboration to develop and commercialize peginesatide with Takeda Pharmaceutical Company Limited, or Takeda, the largest pharmaceutical company in Japan, and plan to co-commercialize peginesatide in the U.S., if approved by the FDA.

Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic kidney disease, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may lead to chronic fatigue or increase the risk of other diseases or death. Currently, recombinant EPO, or rEPO, is used to treat anemia due to chronic kidney disease in patients on dialysis and not on dialysis, and to treat chemotherapy-induced anemia in cancer patients. We estimate that rEPO generated approximately $2.0 billion of net revenues in the United States, or U.S., for 2011 attributable to use in dialysis patients with chronic kidney disease. Peginesatide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Peginesatide is designed to be longer acting than currently marketed ESAs in the U.S. for dialysis patients, and therefore has the potential to offer reduced cost and complexity for healthcare providers.

In late June 2010, we announced preliminary top-line results from our peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Of these trials, two trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were based on primarily assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. In addition, peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 studies. However, some differences were observed when secondary analyses were conducted, including a difference in a subgroup analysis conducted in the PEARL trials where the frequency of CSE events was higher in the peginesatide group relative to the comparator in non-dialysis patients, as previously described in our Current Report on Form 8-K dated June 21, 2010.

In October 2010, we met with the FDA to discuss the regulatory path for peginesatide based on the initial analysis of the Phase 3 results. Based on these discussions with the FDA, we submitted a NDA for peginesatide to the FDA for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. In July 2011, the FDA accepted our submission and filed the NDA for review, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. In December 2011, the FDA Oncologic Drugs Advisory Committee, or 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 chronic kidney disease. While the FDA is not bound by the recommendations of its

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advisory committees, their guidance will be considered by the FDA in its review of the NDA that was submitted for peginesatide

Despite meeting the primary efficacy endpoints and the CSE for peginesatide, the differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding safety of ESAs. Any negative perception of peginesatide's safety relative to other ESAs would significantly reduce the likelihood of obtaining regulatory approval for peginesatide. The Phase 3 results have caused significant delay and may negatively impact the likelihood of regulatory approval, and may significantly increase the likelihood of FDA requirements, restrictions and conditions if regulatory approval is obtained. For example, the ODAC discussed various measures, including a risk evaluation and mitigation strategy, a postmarketing study and label restrictions, to assure safe use of peginesatide, including minimizing the risk of administration to non-dialysis patients. Any or all of these factors may significantly reduce the ultimate commercial potential of peginesatide.

Effective January 31, 2011, our former Chief Executive Officer, Arlene M. Morris, resigned from her position as well as from our board of directors. As part of her separation agreement, Ms. Morris was obligated to provide consulting services through September 30, 2011. Under the terms of her severance arrangement, she received severance benefits in the form of cash, reimbursement of COBRA premiums, continued vesting of existing stock-based awards until September 30, 2011, and additional time to exercise vested stock-based awards after September 30, 2011. We recorded $935,000 of expense in the quarter ended March 31, 2011 related to the severance and consulting arrangement with Ms. Morris. Given the nature of the consulting arrangement, all costs were accrued and expensed in the quarter ended March 31, 2011.

In March 2011, we sold an aggregate of 9,745,762 shares of our common stock to the public at $5.90 per share. We received net proceeds of approximately $53.6 million, after deducting underwriting discounts and commissions and offering expenses.

In November 2011, we entered into a settlement and license agreement, or the Settlement and License Agreement, with Janssen Biotech, Inc. a subsidiary of Johnson & Johnson Pharmaceutical Research & Development, L.L.C., or Johnson & Johnson, and certain of its affiliated companies, or, collectively, Janssen, under which we obtained from Janssen a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings.

The Settlement and License Agreement provides for fixed payments by us to Janssen of $6 million within 30 days of execution thereof, which was paid in December 2011, and $2.0 million by June 30, 2012. The Settlement and License Agreement also provides for a $2.5 million milestone payment to Janssen upon FDA regulatory approval of peginesatide, and a $2.5 million milestone payment to Janssen upon regulatory approval of peginesatide in the first major European country. In addition, Janssen will also be entitled to low, single-digit royalties on sales of peginesatide in Europe, Japan and certain other countries outside of the United States until mid-2016. Upon execution of the Settlement and License Agreement in the fourth quarter of 2011, we recorded $8.0 million of research and development, or R&D, expense relating to the fixed payments. The milestone payments due upon regulatory approval will be capitalized when and if they become due and payable, and the resulting asset will be amortized over the period of expected benefit from the license granted in the Settlement and License Agreement.

Concurrent with the execution of the Settlement and License Agreement, we and Takeda entered into an amendment to our collaboration in connection with the above settlement payments to Janssen. Under the terms of this amendment, Takeda has agreed to pay us up to $6.5 million in additional milestones in consideration of the upfront and milestone payments we are required to make to Janssen

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under the Settlement and License Agreement. $5.25 million of these milestones are earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million is tied to regulatory events in the European Union or E.U. As of December 31, 2011, none of these milestones have yet been achieved and as such, we have not received any related payments from Takeda.

In November 2011, as contemplated under our Arrangement, we and Takeda executed a Commercial Active Pharmaceutical Ingredient, or API, Supply Agreement which formalizes our respective responsibilities as they relate to the manufacture of peginesatide API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of the product. We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of peginesatide worldwide. Takeda remains responsible for the fill and finish steps in the manufacture of peginesatide worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda has agreed to pay an aggregate of $10.8 million in deposits for commercial API shipments of existing materials already manufactured by us. Through December 31, 2011, we have received $7.2 million and shipped $5.2 million of API. The value of the API shipped to Takeda has been recorded as deferred revenue. The remainder of the amount paid by Takeda has been recorded as a liability on our balance sheet.

In February 2012, as contemplated under our collaboration, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for peginesatide including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs field force but share marketing, account management and payer reimbursement related activities with Takeda. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of full time equivalent, or FTE, expenses used to calculate eligible commercial expenses incurred thereunder. Consistent with the terms of the collaboration, Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

In February 2012, the Marketing Authorization Application, or MAA filed by Takeda in early 2012 was accepted, by the European Medicines Agency, or EMA which triggered a $5.0 million milestone payment from Takeda. We received this milestone payment in the first quarter of 2012, and we expect to recognize it as revenue in the same period.

To date, we have not generated any product revenue. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and API production, license fees and milestone payments from collaborative partners, operating and capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. As of December 31, 2011, we had an accumulated deficit of $450.3 million. Due to the recognition of revenues from milestone payments from Takeda under the Arrangement, we were profitable in the three and six months ended June 30, 2010 and may have profitable quarters from time to time if we are successful in obtaining FDA approval for peginesatide. We continue to expect to incur substantial losses in order to complete the development and commercialization of peginesatide.

We believe that our existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. However, further challenges or delays to approval and commercialization of peginesatide or significant commercialization costs may require us to raise additional funding to complete the development and commercialization of peginesatide. Since the announcement of our Phase 3 data in late June 2010 and the arbitration decision in October 2010, we have experienced a severe decline in our stock price, which has reduced our ability to access capital on potentially favorable terms. In contrast, our funding needs have only increased as the peginesatide development program has suffered delays, the potential loss of milestone payments from Takeda associated with the non-dialysis indication. There can be no

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assurance we can raise the additional funds to support our continuing operations, maintain current regulatory timelines and successfully commercialize peginesatide if approved, and funding may not be available to us on acceptable terms, or at all. Our failure to raise capital if and when needed may harm our business and operating results.

Our current view of the worldwide capital markets is that they are extremely volatile with limited accessibility, and many biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital, in the form of equity or otherwise, depending upon market conditions relative to our need for funds at such time. Continuation of this market and the issues arising from our Phase 3 results could significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Further, in prior periods, we have reduced our research capabilities and efforts, including the elimination of certain research programs, and even some activities related to the support of peginesatide. If we are unable to raise additional funds when needed, we could be required to further delay, scale back or eliminate some or all of our development programs and other operations, which could negatively impact our ability to complete development or commercialize peginesatide. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing would be difficult to obtain, if accessible at all, and our current stockholders may be significantly diluted. Any debt financing, if available, may involve restrictive covenants or security interests in our assets. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

Research and Development Expenses

R&D expenses consist of: (i) expenses incurred under agreements with contract research organizations and investigative sites, which conduct a substantial portion of our pre-clinical studies and all of our clinical trials; (ii) payments to contract manufacturing organizations, which produce our API; (iii) payments to consultants; (iv) license fees paid to third parties for use of their intellectual property; (v) employee-related expenses, which include salaries and related costs; and (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies. All R&D expenses are expensed as incurred.

For our R&D expenses, we have historically commenced tracking the costs for a project when we are working with another company or when the product candidate merits substantial increase in the level of effort. In recent years, our R&D efforts have been almost exclusively focused on the development of peginesatide, specifically on the Phase 3 trials commenced in 2008.

During the commercialization period, which commenced in June 2011 after the submission of our NDA to the FDA, Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of peginesatide in the U.S. Certain employee-related expenses supporting preparation for commercialization of peginesatide in the U.S. are also shared equally. Such employee-related costs will include the cost of certain employees that would be required to commercialize the product such as field sales representatives, sales operations, medical science liaisons, nurse educators, conversion specialists, national accounts managers and reimbursement specialists. In addition, costs of employees in clinical, regulatory and other development functions supporting any post-marketing development activity required by the FDA or separately agreed to by the parties in the U.S. are shared equally.

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The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. While we are currently focused on developing peginesatide, in the future we may develop additional product candidates internally and in-license product candidates, which would increase our R&D expenses in later periods.

During the year ended December 31, 2010, we finalized amendments for certain clinical trial activities completed in 2009. In the fourth quarter of 2010, we obtained final monitored site visit data and investigator contracts from our third party contract research organizations, or CROs, that allowed us to complete our reconciliation of the significant majority of the labor and investigator costs incurred throughout the course of our clinical trials to our previously recorded estimates. This data and contractual information was not available to us during the course of the trials. After extensive analysis to cost out and analyze the information provided, we determined that the costs incurred were lower than our previously recorded estimates. We believe these changes were only identifiable based on the information received in the fourth quarter of 2010. The change in estimate decreased expense by $12.1 million for the year ended December 31, 2010.

During the year ended December 31, 2011 we continued to work with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. During the year, we received notification from both of our major CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trials which resulted in a $1.8 million reversal of our clinical trial accrual in the year ended December 31, 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate change in estimate during the period decreased expense by $2.5 million for the year ended December 31, 2011.

Additional changes in estimate or adjustments could result in the future as we have ongoing clinical trial activity on our Phase 3b trial, and a Phase 2 study in Pure Red Cell Aplasia, or PRCA patients and such adjustments could impact R&D expense and collaboration revenue and amounts due to or from Takeda in subsequent periods.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist principally of salaries and related costs for personnel in commercial, medical affairs, executive, finance, accounting, business and commercial development, information technology, legal and human resources functions. Other SG&A expenses include costs to prepare for marketing, commercial and medical affairs support of peginesatide if approved by the FDA, as well as facility costs not otherwise included in R&D expense, patent filing, prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

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Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles or GAAP. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition and clinical development costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

Revenue Recognition

Collaboration Revenue

We recognize revenue in accordance with the Securities and Exchange Commission, or SEC, Staff Bulletin No. 101, *Revenue Recognition in Financial Statement*s, as amended by Staff Accounting Bulletin, or SAB No. 104, *Revision of Topic 13* and Accounting Standards Codification, or ASC, 605-25, *Multiple Element Arrangements*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

On January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*. This update amends the guidance on accounting for arrangements with multiple deliverables to require that each deliverable be evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. This update also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. We may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and the estimated selling price of identified units of accounting for new agreements. The adoption of ASU No. 2009-13 did not impact our financial position or results of operations as of and for the year ended December 31, 2011. The potential future impact of the adoption of this update will depend on the nature of any new arrangements or material modifications of existing arrangements that we enter into in the future.

During the development period under the Arrangement, which ended in May 2011 upon the submission of our NDA to the FDA, we recognized collaboration revenue using the Contingency Adjusted Performance Model, or CAPM. Under CAPM, revenue is eligible for recognition in the period the payment is earned under the Arrangement including amounts that are either received or due from Takeda. Revenue initially recognized is based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment is earned in relation to the total projected development period. The remaining portion of the payment is then recognized on a

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straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period included amounts due for upfront license fees, milestone payments earned, purchases of API and reimbursement of development expenses. In exchange for these payments, we continued to actively develop our compound for the treatment of anemia for chronic kidney disease through the end of the development period which occurred upon our submission of our NDA,

Beginning in June 2011, we have moved into the commercialization period as defined under our Arrangement with Takeda. According to the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to pre-commercialization services such as pre-marketing, launch, promotions, marketing, sale and distribution of peginesatide as well as development work that has taken place after our NDA has been filed with the FDA but before peginesatide receives FDA approval. Prior to approval of the product and commencement of profit sharing payments, our primary source of revenue during the commercialization period will likely consist of Takeda's reimbursement of our pre-commercialization and development efforts including cost of internal and external activities. For example, this includes work to prepare materials and other costs to present to the FDA ODAC and costs to implement and maintain a drug safety database.

In addition to the reimbursement of the services described above, the Arrangement provides us the potential to earn at risk milestone payments upon achievement of contractual criteria. During the commercialization period, our obligations include ongoing regulatory work to obtain FDA approval and commercial efforts related to our product launch. Any post-development activities incurred during the commercialization period is related to activities to obtain FDA approval after our NDA was filed and activities for commercial readiness in anticipation of FDA approval and product launch.

During the commercialization phase, we have re-evaluated the deliverables to be performed under the Arrangement to determine if the deliverables can be treated as separate units of accounting. We continue to follow the guidance of ASC 605-25 to determine whether the components of the Arrangement represent separate units of accounting. To determine if a delivered item can be treated as a separate unit of accounting, we evaluate (1) if the delivered item has value to Takeda on a standalone basis; (2) there is objective and reliable evidence of fair value of the undelivered item(s) and (3) if a general right of return exists for the delivered item (eg. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the company.

For each source of collaboration revenue, we apply the following revenue recognition model:

Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercial expenses (shared equally 50/50 according to the Arrangement) are recognized as revenue, in the period the related costs are incurred. Revenues related to reimbursement of costs of FTEs engaged in development related activities such as post-marketing studies, are recognized as revenue in the period the related costs are incurred. Such reimbursement is based on contractually negotiated reimbursement rates for each FTE as specified in the Arrangement.

Payments received from the shipment of commercial API prior to the launch of the product are recorded as deferred revenue as the earning process is not complete until either (1) the finished goods produced from each batch of API are sold and utilized for commercial purposes post-approval and charged back to us through the profit sharing each period or (2) the Arrangement has been terminated by Takeda or us.

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We account for milestones under ASU No. 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 the collaboration. 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 collaboration.

License and Royalty Revenue

Royalties are recognized as earned in accordance with contract terms, when third party results are reported and collectability is reasonably assured. Royalties received under agreements that were acquired by us in the 2001 spin out from GlaxoSmithKline or Glaxo are recorded net of the 50% that we are required to remit to Glaxo.

Clinical Trial Expense and Accruals

We record expense for external costs incurred on our clinical studies based on our estimates of the costs incurred each period. These clinical trial costs, which represent a significant component of R&D expenses, were $1.7 million, $14.9 million, and $90.0 million for the years ended December 31, 2011, 2010, and 2009, respectively. Our clinical trials are administered by CROs for our Phase 3 and Phase 2 clinical studies, who typically perform most of the total start-up activities for the trials, including document preparation, site identification pre-study visits, training as well as on-going program management.

There is a significant degree of estimation involved in quantifying the clinical study expenses due to the complexity and magnitude of the clinical trial activities. These estimates have been subject to frequent adjustments, especially for our Phase 3 trials, in part due to our negotiations with third-parties with respect to timing of reporting, patient progression and payments as well as our continuing negotiations with CROs on timely delivery and access to information necessary to validate our accruals.

During the year ended December 31, 2010, we finalized amendments for certain clinical trial activities completed in 2009 which decreased expense by $12.1 million for the year ended December 31, 2010 due to a change in estimate, as more fully described above in the *Research and Development Expenses* section.

During the year ended December 31, 2011, we have continued to work with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. During the year, we received notification from both of our major CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trials which resulted in a $1.8 million reversal of our clinical trial accrual in the year ended December 31, 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate change in estimate during the period decreased expense by $2.5 million for the year ended December 31, 2011.

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Additional changes in estimate or adjustments could result in the future as we have ongoing clinical trial activity on our Phase 3b trial, and a Phase 2 study in PRCA patients and such adjustments could impact R&D expense in subsequent periods.

Stock-Based Compensation

We currently use the Black-Scholes model to estimate the fair value of employee stock options and our employee stock purchase plan. Calculating the fair value of stock-based payment awards requires considerable judgment, including estimating stock price volatility, the amount of stock-based awards that are expected to be forfeited and the expected life of the stock-based payment awards. While fair value may be readily determinable for awards of stock or restricted stock units, or RSUs, market quotes are not available for long-term, non-transferable stock options because these instruments are not traded. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. We base our estimated expected option term and volatility on the realized volatilities of our peer companies. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. We review our valuation assumptions at each grant date, and, as a result, we are likely to change our valuation assumptions used to value stock-based awards granted in future periods. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under the authoritative guidance for share-based payments. Our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements.

The authoritative guidance for share-based payments requires that employee stock-based compensation costs be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. In determining whether an award is expected to vest, we use an estimated forward-looking forfeiture rate. We consider many factors when estimating expected forfeitures, including types of awards and historical experience. These estimates are revised in subsequent periods based upon changes in facts or circumstances that would affect our forfeiture rate. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different than what was recorded in the current period. For awards with a longer vesting period, the actual forfeiture rate and related expense may not be known for a longer period of time, which can result in more significant accounting adjustments once the awards are either vested or forfeited. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period.

Income Taxes

We account for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

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We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The guidance prescribes a minimum recognition threshold and measurement process for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We do not believe any such uncertain tax positions currently pending will have a material adverse effect on our financial statements, although an adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period. We had $70.6 million, $13.1 million, and $12.4 million of unrecognized tax benefits as of December 31, 2011, 2010, and 2009, respectively.

We experienced ownership changes, as defined by Sections 382 and 383 of the Internal Revenue Code which establishes an annual limit on the deductibility of pre-ownership change net operating loss and credit carryforwards. As a result of the ownership change and underlying annual limitation, some of our pre-ownership change net operating loss and all of our pre-ownership change credit carryforwards will expire unutilized. Accordingly, we have reduced our gross deferred tax asset related to the expiring carryforwards by $59.6 million as of December 31, 2011.

At December 31, 2011, we had federal and state net operating loss carryforwards of $345 million and $360 million, respectively, after taking into consideration the annual Section 382 limitation. The federal net operating loss carryforwards begin to expire in 2029 and state net operating loss carryforwards begin to expire in 2019, if not utilized.

At December 31, 2011 and 2010, our liability for uncertain income tax positions was $10.4 million and $10.2 million, respectively, and is reflected as long-term income tax liabilities on our balance sheet. Our policy is to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. For the years ended December 31, 2011, 2010, and 2009, we recognized $144,000, $140,000, and $105,000, respectively, of interest expense related to our liability for uncertain income tax positions. For the years ended December 31, 2011, 2010 and 2009, there were no penalties related to uncertain income tax positions. At December 31, 2011 and 2010, $986,000 and $842,000 was accrued for interest and penalties related to uncertain income tax positions. We do not anticipate that any of the unrecognized tax benefits will increase or decrease significantly over the next twelve months.

Restructuring Charges

As a result of the May 2010 amendment to our operating lease, we took possession of approximately 16,000 square feet of additional office space adjacent to our corporate headquarters in Palo Alto, California in May 2011. During the year ended December 31, 2011, management concluded that we would not occupy this additional office space, and we are actively seeking to sublease this space. Given these plans and the fact that this space is adequately separable from our existing facilities, in the second and fourth quarter of 2011, we recorded total restructuring charges of $869,000, which represents the present value of the estimated future facility costs for which we will obtain no future economic benefit over the term of our lease, net of estimated future sublease income. The $869,000 charge, as well as $72,000 of accretion was recorded during the year ended December 31, 2011 in selling, general and administrative or SG&A expenses in the statement of operations.

The estimates underlying the fair value of the lease-related restructuring liability involve significant assumptions regarding the time required to contract with a subtenant, the amount of space we may be able to sublease, the range of potential future sublease rates and the level of leasehold improvements expenditures that we may incur to sublease the property. We have evaluated a number of potential sublease scenarios with differing assumptions and have probability weighted these scenarios and calculated the present value of cash flows based on management's judgment. We will continue to

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monitor and update the liability balance when future events impact our cash flow estimates related to this excess space, which could result in additional restructuring charges in the future.

In August 2011, we initiated a restructuring plan to lower annual operating expenses that included a planned reduction in force of 22 positions. As a result, we recorded a restructuring charge in the year ended December 31, 2011 of $975,000 related to severance and benefits, of which $932,000 was reflected as R&D expense and $43,000 as SG&A expense in the statement of operations.

The following table summarizes the accrual balance and utilization by type for the restructuring (in thousands):

	Facilities Related	Employee Related	Total
Balance as of January 1, 2011	$	$	$
Restructuring charges accrued	869	975	1,844
Cash payments	(431)	(710)	(1,141)
Accretion	72		72
Balance at December 31, 2011	510	265	775
Less Current Portion	391	265	656
Long-term portion as of December 31, 2011	$ 119	$	$ 119

Results of Operations

Revenue

Revenue and percentage changes as compared to prior years are as follows (in thousands):

	Year ended December 31,			Percent Change	
	2011	2010	2009	2011/2010	2010/2009
Collaboration revenue	$ 47,703	$ 112,503	$ 114,883	(58)%	(2)%
License and royalty revenue	17	18	16	(6)%	13%
Total revenue	$ 47,720	$ 112,521	$ 114,899	(58)%	(2)%

We recognized $47.7 million, $112.5 million, and $114.9 million of collaboration revenue for the years ended December 31, 2011, 2010, and 2009, respectively. Collaboration revenue includes reimbursement payments from Takeda that are calculated as our expenses eligible for reimbursement from Takeda, net of Takeda's own eligible expenses. The decrease in collaboration revenue for the year ended December 31, 2011 compared to the year ended December 31, 2010 and for the year ended December 31, 2010 compared to the year ended December 31, 2009 was due to a reduction in overall research and development costs eligible for reimbursement under our collaboration with Takeda as we completed our Phase 3 clinical trials in early 2010. Collaboration revenue for the year ended December 31, 2010 was also impacted by our change in estimate adjustment recorded in the fourth quarter of 2010 related to our clinical trial expense which reduced revenue by $7.8 million. These decreases were partially offset by milestone payments received from Takeda in 2011 and 2010. During the year ended December 31, 2011, we received a $10 million cash milestone payment from Takeda for acceptance for review of our NDA by the FDA in the third quarter of 2011. For the year ended December 31, 2010, we received a $5 million milestone payment from Takeda for the initiation of Japan's Phase 3 renal indication in March 2010 and $30 million in milestone payments for the database lock of our non-dialysis and dialysis Phase 3 trials in the second quarter of 2010. We expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods.

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Collaboration revenue consists of net reimbursement of development and commercial expenses, milestone payments and purchases of API. During the development period under the Arrangement with Takeda, which ended upon the submission of our NDA to the FDA for review, collaboration revenue was recognized using CAPM. As a result, any payments from Takeda under the Arrangement were recorded as deferred revenue and recognized ratably over the estimated development period. Beginning June 2011, we have moved into the commercialization period where we now generally recognize revenue in the period earned as outlined in our revenue recognition policy in "Critical Accounting Policies Significant Judgments and Estimates." Below is a summary of the components of our collaboration revenue for the years ended December 31, 2011, 2010 and 2009 (in thousands):

	Year ended December 31,		
	2011	**2010**	**2009**
Revenue recognized under CAPM	$ 26,606	$ 121,503	$ 114,883
Expense reimbursement after CAPM	11,097		
Milestone payments	10,000		
Total collaboration revenue	$ 47,703	$ 112,503	$ 114,883

Research and Development Expenses

R&D expenses and percentage changes as compared to prior years are as follows (in thousands):

	Year ended December 31,			Percent Change	
	2011	**2010**	**2009**	**2011/2010**	**2010/2009**
Research and development expenses	$ 76,308	$ 93,638	$ 157,125	(19)%	(40)%

The decrease in research and development expenses for the year ended December 31, 2011 compared to the year ended December 31, 2010 was primarily due to a reduced CRO and investigative site costs as a result of the completion of the treatment and follow up of our Phase 3 clinical trials in early 2010 as well as due to a $2.5 million reversal of R&D expense due to a change in estimate in our clinical trial accrual related to final close-out activities with both of our major CROs on the Phase 3 studies. During the year ended December 31, 2011 we continued to work with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. We recently received notification from both of our major CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trials which resulted in a $1.8 million reversal of our clinical trial accrual in the year ended December 31, 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate change in estimate during the period decreased expense by $2.5 million for the year ended December 31, 2011. This decrease was partially offset by $8.0 million of fixed payments related to the Settlement and License Agreement, costs related to our Phase 3b study commenced in the third quarter and $932,000 in employee-related restructuring costs related to a reduction in force incurred in 2011. The decrease in R&D expenses for the year ended December 31, 2010 compared to the year ended December 31, 2009 was primarily due to the completion of the treatment and follow up of our Phase 3 clinical trials at the start of 2010 and a $12.1 million reversal of R&D expense due to a change in estimate in our clinical trial accrual related to our final reconciliation of investigator grants for our Phase 3 trials.

We expect R&D expenses to continue to decrease in 2012 due to the completion of the treatment and follow up of our Phase 3 clinical trials in 2010 which decrease could be partially offset by any additional research and clinical trials conducted to obtain additional data for peginesatide.

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Selling,General and Administrative Expenses

SG&A expenses and percentage changes as compared to prior years are as follows (in thousands):

	Year ended December 31,			Percent Change	
	2011	2010	2009	2011/2010	2010/2009
Selling, general and administrative expenses	$ 32,818	$ 33,331	$ 36,716	(2)%	(9)%

The decrease in SG&A expenses in 2011 as compared to 2010 was primarily due to lower legal costs related to protecting and defending our proprietary rights, such as patents. This decrease was partially offset by higher commercial expenses related to expansion of our commercial capabilities as we prepare for potential FDA approval of peginesatide, a facilities-related restructuring charge of $869,000 related to idle and excess office space, and increased employee compensation costs. The employee compensation costs were primarily a result of costs of $935,000 associated with the severance arrangement of our former Chief Executive Officer who departed during the first quarter of 2011. The decrease in SG&A expenses in 2010 as compared to 2009 was primarily due to lower legal costs related to protecting and defending our proprietary rights, such as patents. We expect to incur increasing SG&A expenses in future periods to support further development of our commercial capabilities to support our product after the potential approval of our NDA for peginesatide by the FDA.

Interest Income (Expense), Net

Interest income (expense), net and percentage changes as compared to prior years are as follows (in thousands):

	Year ended December 31,			Percent Change	
	2011	2010	2009	2011/2010	2010/2009
Interest income (expense), net	$ 25	$ 135	$ 829	(81)%	(84)%

The decrease in interest income (expense), net in 2011 as compared to 2010, as well as in 2010 as compared to 2009, was due primarily to lower levels of cash, cash equivalents and investments earning interest, as well as due to generally lower interest rates during the year.

Other Income (Expense), Net.

Other income (expense), net and percentage changes as compared to prior years are as follows (in thousands):

	Year ended December 31,			Percent Change	
	2011	2010	2009	2011/2010	2010/2009
Other income (expense), net	$ 15	$ 239	$ 171	(94)%	40%

Other income (expense), net, for the year ended December 31, 2010 consists primarily of $244,000 from a qualified therapeutic discovery grant received from the U.S. government. Other income (expense), net, for the year ended December 31, 2009 includes adjustments to the fair value of our UBS AG of Series C-2 ARS Rights, or ARS Rights, at sale of the related Auction Rate Securities.

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Provision (Benefit) for Income Taxes

Provision (benefit) for income taxes and percentage changes as compared to prior years are as follows (in thousands):

	Year ended December 31,			Percent Change	
	2011	2010	2009	2011/2010	2010/2009
Provision (benefit) for income taxes	$ 1	$ 1	$ (1,411)	*	*

*

Calculation not meaningful

We are subject to federal and California state income tax. For the years ended December 31, 2011 and 2010, we recorded provisions for minimum statutory state tax and provided no federal tax as a result of our net operating loss.

For the year ended December 31, 2009, we recorded a benefit for income taxes of $1.4 million. The tax benefit was for federal tax purposes, primarily the result of the Worker, Homeownership and Business Assistance Act of 2009 enacted in November 2009, which allowed us to carryback our 2008 net operating loss to 2007 and recover $1.3 million in alternative minimum taxes previously paid for the year ended December 31, 2007. We also recorded a $100,000 federal benefit related to refundable R&D credits available to us pursuant to a provision within the Housing Assistance Tax Act of 2008, which was effective for tax years ended after March 31, 2008 and December 31, 2009.

As of December 31, 2011 and 2010, we have a net deferred tax asset balance of $7.2 million each, in consideration of the uncertainty in income taxes liability recorded for the same amount. We considered the following positive and negative factors in determining that it was more likely than not that the net deferred tax asset as of December 31, 2011 and 2010 would be realized:

Net deductible temporary differences that were expected to reverse in 2011 and 2012;

There were no relevant tax strategies available that we would consider feasible; and

Uncertainties, such as regulatory approval of peginesatide would adversely affect our future operations.

We have incurred significant operating losses since inception and anticipate that we may incur continued losses in the future.

Liquidity and Capital Resources

Our cash, cash equivalents, and investments at December 31, 2011 and 2010 were as follows (in thousands):

	Year Ended December 31,	
	2011	2010
Cash and cash equivalents	$ 54,339	$ 63,499
Short-term investments	44,165	$ 33,582
Long-term investments		$ 19,876

Since our inception, we have financed our operations through sale of capital stock, license fees, milestone payments and reimbursement for development and commercial expenses and manufacturing costs from collaborative partners, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through December 31, 2011, we have received net proceeds of $445.4 million from the issuance of equity

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securities, including $53.6 million in net proceeds from the sale of 9,745,762 shares of our common stock in a secondary public offering in March 2011. We also received $122 million of upfront license fees, $55 million in milestone payments and $251.0 million for the reimbursement of development and commercial expenses and purchase of API from our Arrangement with Takeda. Takeda was responsible for the first $50 million of third party expenses related to the development in pursuit of U.S. regulatory approval of peginesatide, which was fully utilized by both parties through the first quarter of 2008. Thereafter, Takeda has borne 70% of the third party U.S. development expenses, while we have been responsible for 30% of third party expenses. During the development period, we retained responsibility for 100% of our internal development expenses, most notably employee-related expenses.

During the commercialization period, which commenced in June 2011 after the submission of our NDA to the FDA, Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of third party expenses related to the commercialization of peginesatide in the U.S. Certain employee-related expenses supporting preparation for commercialization of peginesatide in the U.S. are also shared equally. Such employee-related costs will include the cost of certain employees that would be required to commercialize the product such as field sales representatives, sales operations, medical science liaisons, nurse educators, conversion specialists, national accounts managers and reimbursement specialists. In addition, costs of employees in clinical, regulatory and other development functions supporting any post-marketing development activity required by the FDA or separately agreed to by the parties in the U.S. are shared equally.

We are also entitled to a launch allowance to help fund the initial costs associated with preparing to launch the product in the U.S., whereby Takeda will fund the first $20 million of U.S. commercial expenses. The launch allowance is non-refundable; however, in the event the product is approved for sale in the U.S., Takeda is entitled to deduct up to 8% of net sales from the profit share amounts which would have otherwise been due to us in each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in profit sharing post-launch stemming from the launch allowance, we have reflected amounts we receive under the terms of the launch allowance as a liability on our balance sheet. As of December 31, 2011, we have received $6.1 million of the launch allowance, which is reflected in the caption "Advance from Takeda" on the balance sheet.

In November 2011, as contemplated under our Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as they relate to the manufacture of peginesatide API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of the product. We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of peginesatide worldwide. Takeda remains responsible for the fill and finish steps in the manufacture of peginesatide worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda has agreed to pay an aggregate of $10.8 million in deposits for commercial API shipments of existing materials already manufactured by us. Through December 31, 2011, we have received $7.2 million and shipped $5.2 million of API. The value of the API shipped to Takeda has been recorded as deferred revenue. The remainder of the amount paid by Takeda has been recorded as a liability on our balance sheet.

In November 2011, we entered into the Settlement and License Agreement with Janssen, which requires us to make two fixed payments to Janssen of $6.0 million, which was paid in December 2011, and $2.0 million by June 30, 2012. The Settlement and License Agreement also requires us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of peginesatide, and a $2.5 million milestone payment to Janssen upon regulatory approval of peginesatide in the first major European country. In addition, Janssen will be entitled to royalties on sales of peginesatide in Europe, Japan and certain other countries outside of the United States until mid-2016. Upon execution of the Settlement and License Agreement in the fourth quarter of 2011, we recorded $8.0 million of R&D, expense relating to the fixed payments. The milestone payments due upon regulatory approval will be

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capitalized when and if they become due and payable, and the resulting asset will be amortized over the period of expected benefit from the license granted in the Settlement and License Agreement.

Concurrent with the execution of the Settlement and License Agreement, we and Takeda entered into an amendment to the Arrangement in connection with the above settlement payments to Janssen. Under the terms of this amendment, Takeda has agreed to pay us up to $6.5 million in additional milestones in consideration of the upfront and milestone payments to Janssen under the Settlement and License Agreement. $5.25 million of these milestones are earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million is tied to regulatory events in the E.U. We are solely responsible for the royalty payment to Janssen. As of December 31, 2011, none of these milestones have yet been achieved and as such, we have not received any related payments from Takeda.

In 2012, as contemplated under our Arrangement, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for peginesatide including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs field force but share marketing, account management and payer reimbursement related activities with Takeda In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of FTE expenses used to calculate eligible commercial expenses incurred by the Parties thereunder. Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

In February 2012, the Marketing Authorization Application, or MAA filed by Takeda in early 2012 was accepted, by the EMA which triggered a $5.0 million milestone payment from Takeda. We received this milestone payment in the first quarter of 2012, and we expect to recognize it as revenue in the same period

Net cash used in operating activities for the years ended December 31, 2011, 2010, and 2009, was $72.0 million, $49.2 million, and $80.8 million, respectively. Net cash used in operations for all periods reflects the benefit of reimbursement received from Takeda for development and commercial expense and purchase of API by Takeda. The $22.7 million increase in cash used in operating activities in 2011 as compared to 2010 was primarily due to a higher net loss in 2011 compared to 2010. The $31.6 million decrease in cash used in operating activities in 2010 as compared to 2009 was primarily the result of a lower net loss in 2010 as compared to 2009.

Net cash provided by investing activities for the year ended December 31, 2011 and 2009 of $8.0 million and $49.1 million, respectively, was primarily a result of proceeds from maturities of investments offset by purchases of investments. Net cash used in investing activities for the year ended December 31 2010 of $11.5 million was primarily a result of purchases of investments partially offset by proceeds from maturities and sales of investments.

Net cash provided by financing activities for the year ended December 31, 2011 was primarily attributable to net proceeds of $53.6 million received from our March 2011 public offering and proceeds received from the issuance of common stock upon exercise of stock options. Net cash used in financing activities for the year ended December 31, 2010 was primarily attributable to the $9.2 million repayment of a loan from UBS Financial Services or UBS related to investments for which there was no market during the year, partially offset by $4.9 million in net proceeds from a financing executed under our equity line of credit with Azimuth during the years. Net cash provided by financing activities for the year ended December 31, 2009 reflects the net proceeds from two financings during the year, specifically $41.6 million from the private placement in March 2009 and $80.6 million of net proceeds from a public offering in November 2009, as well as $9.2 million in proceeds from the UBS loan in

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December 2009. The private placement also included warrants to purchase 423,971 shares of common stock at $16.78 that are exercisable and expire in March 2014.

In September 2009 we obtained an equity line of credit arrangement, with Azimuth, that provides that, upon the terms and subject to the conditions set forth in the Purchase Agreement, Azimuth is committed to purchase up to $60.0 million worth of shares of our common stock over the 24-month term of the Purchase Agreement. In September 2010, we entered into an amendment, or the Amendment, to the Purchase Agreement with Azimuth which extends the term of the equity facility to September 2012 and reduces the minimum threshold price we may establish at which, upon presentation to Azimuth of a draw down notice, Azimuth is required to purchase shares of our common stock. The Amendment further provides that in no event may we sell under the Purchase Agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares of common stock on the effective date of the Amendment.

Our equity facility is subject to a number of conditions that limit our ability to draw against such facility. For example, Azimuth is not required to purchase our common stock when the price of our common stock is below $4.00 per share. In addition, Azimuth is not obligated to purchase shares of our common stock which, when aggregated with all other shares of our common stock then owned beneficially by Azimuth, would result in the beneficial ownership by Azimuth of more than 9.9% of the then issued and outstanding shares of our common stock. At December 31, 2011, this represents 3,537,585 shares. After deducting the shares purchased in October 2010, assuming that all remaining 2,538,524 shares were sold at the $6.61 closing price of our common stock at December 31, 2011 at the largest possible discount and assuming that Azimuth still owns these shares, the maximum aggregate net proceeds we could receive under the agreement with Azimuth would be approximately $15.6 million.

As of December 31, 2011, we had $99.6 million in cash, cash equivalents, restricted cash and investments. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, certificates of deposit, and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a focus on liquidity and capital preservation.

We believe that the existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. However, we may need to raise additional funding to complete the development and commercialization of peginesatide. Since the announcement of our Phase 3 data, we have experienced a severe decline in our stock price, which has reduced our ability to access capital on potentially favorable terms. In contrast, our need to raise funding has only increased due to the peginesatide development program delays and the reduction of potential milestone payments from Takeda associated with the non-dialysis indication. As we continue to develop and ultimately commercialize peginesatide, if approved, we may experience further challenges or delays to approval of peginesatide if issues arise or additional requirements are imposed based on our discussions with the FDA and other regulatory authorities. Our current view of the worldwide capital markets is that they are extremely volatile with limited accessibility, and many biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital, in the form of equity or otherwise, depending upon market conditions relative to our need for funds at such time. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Further, in prior periods, we have reduced our research capabilities and efforts, including the elimination of certain research programs, and even some activities related to the support of peginesatide. If we are unable to raise additional funds when needed, we could be required to further delay, scale back or eliminate some or all of our development programs

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and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

Our future capital requirements will depend on many forward looking factors, and we expect to continue to spend substantial amounts in order to:

- prepare to launch and commercialize peginesatide, including building our own commercial organization, sales force and infrastructure to address renal markets;
- prepare for the manufacturing process for peginesatide at our contract manufacturers for commercial launch;
- pursue approval of the NDA for peginesatide through the FDA review process, which is a lengthy and uncertain process; and
- complete clinical development of peginesatide, and any postmarketing requirements.

Contractual Obligations and Significant Commitments

Our future contractual obligations, including financing costs, at December 31, 2011 were as follows (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**Less Than 1 Year**	**1 - 3 Years**	**3 - 5 Years**	**More than 5 Years**
Operating lease obligations(1)	$ 11,645	$ 4,172	$ 7,473	$	$
Long-term income tax liability(2)	10,411				
Total fixed contractual obligations	$ 22,056	$ 4,172	$ 7,473	$	$

(1) Relates primarily to minimum lease payments for lease of our facilities, consisting of approximately 113,000 square feet which expire in September 2014.

(2) With respect to our long-term income tax liability as of December 31, 2011, we are unable to make a reasonably reliable estimate of the period of cash settlement, if any, with the respective taxing authorities.

In April 2004, we entered into a License, Manufacturing and Supply Agreement with Nektar Therapeutics AL, Corporation, or Nektar, under which we obtained from Nektar a worldwide, non-exclusive license, with limited rights to grant sublicenses, to certain intellectual property covering pegylation technology to manufacture, develop and commercialize peginesatide. In consideration of the license grant, we agreed to pay royalties on the sales of peginesatide. We also agreed to pay milestone payments totaling up to $7 million, plus possible additional milestones in connection with our partnering activities relating to peginesatide or merger and acquisition activities. In July 2006, we paid Nektar a $17.6 million milestone payment triggered by the Arrangement with Takeda. In August 2011, we paid Nektar a $2.0 million milestone payment triggered by our acceptance by the FDA of our NDA submission for review.

Under the agreement, we also engaged Nektar for the manufacture and supply of our requirements of bulk poly(ethylene) glycol reagent for the manufacture of peginesatide. This relationship is managed by a managing committee formed by representatives from both us and Nektar. Nektar is obligated to engage a third party manufacturer in the event of Nektar's failure (as defined in

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the agreement) to supply reagent. This agreement expires, on a country by country basis, upon the expiration of our royalty payment obligations. The agreement may be terminated by either party for the other party's material breach provided that such other party has been given a chance to cure such breach, or by Nektar for our challenge of the validity or enforceability of any patents licensed thereunder.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued ASU No. 2011-05, which is an update to Topic 220, *Presentation of Comprehensive Income*. This update amends current comprehensive income guidance and eliminates the option of presenting the components of other comprehensive income as part of the statement of stockholders' equity. This update presents an entity with the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The new guidance was originally proposed to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and applied retrospectively. In October 2011, the FASB proposed to defer the effective date of certain provisions in the guidance related to the presentation of reclassification adjustments. No effective date has been announced. As ASU No. 2011-05 relates only to the presentation of comprehensive income, we do not expect that the adoption of this update will have a material effect on our financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is an update to Topic 820, *Fair Value Measurement*. This update establishes common requirements for measuring fair value and related disclosures in accordance with GAAP and international financial reporting standards. This amendment did not require additional fair value measurements. ASU No. 2011-04 is effective for all interim and annual reporting periods beginning after December 15, 2011. We do not believe there will be a significant impact on our financial statements from the adoption of ASU No. 2011-04.

Off-Balance Sheet Arrangements

There were no significant off-balance sheet arrangements at December 31, 2011.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

Interest Rate Risk

Our exposure to market risk is confined to our cash, cash equivalents and investments. We do not use derivative financial instruments in our investment portfolio. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are subject to minimal interest rate risk. We currently do not hedge interest rate exposure. We do not believe that a decrease in interest rates would have a material negative impact on the value of our investment portfolio.

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The table below presents the weighted-average interest rates and related carrying amounts (in thousands) of our investment portfolio as of December 31, 2011 and 2010:

	2011		2010	
	Weighted-average Interest Rate	Carrying Amount	Weighted-average Interest Rate	Carrying Amount
Cash equivalents	0.01%	$ 45.244	0.01%	$ 61,096
Short-term investments	0.14%	$ 44,165	0.61%	$ 33,582
Long-term investments	N/A	N/A	0.38%	$ 19,876

Foreign Exchange Risk

We have no investments denominated in foreign currencies, and therefore our investments are not subject to foreign currency exchange risk. At each quarter end, we may have liabilities for costs incurred by overseas suppliers of goods or services and clinical trial programs that are denominated in foreign currencies that are not hedged because of their relatively small size, uncertainty of payment date, and/or short time until settlement. An increase or decrease in exchange rates on these unhedged exposures may affect our operating results.

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Item 8. Financial Statements and Supplementary Data.

Our financial statements and notes thereto appear on pages 72 to 106 of this Annual Report on Form 10-K.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Affymax, Inc.

We have audited the accompanying balance sheets of Affymax, Inc. as of December 31, 2011 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Affymax, Inc. at December 31, 2011 and 2010, and the 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Affymax, Inc.'s 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 March 14, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, CA
March 14, 2012

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AFFYMAX, INC.

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2011	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	$ 54,339	$ 63,499
Restricted cash		11
Short-term investments	44,165	33,582
Receivable from Takeda	6,937	
Deferred tax assets	351	438
Prepaid expenses and other current assets	1,828	2,012
Total current assets	107,620	99,542
Property and equipment, net	3,013	3,982
Restricted cash	1,135	1,135
Long-term investments		19,876
Deferred tax assets, net of current	6,888	6,802
Other assets	339	50
Total assets	$ 118,995	$ 131,387
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 941	$ 321
Accrued liabilities	13,462	11,594
Accrued clinical trial expenses	3,365	11,247
Payable to Takeda		5,958
Deferred revenue		18,497
Deposit from Takeda	1,998	
Total current liabilities	19,766	47,617
Long-term income tax liability	10,411	10,249
Advance from Takeda	6,121	
Deferred revenue, net of current	5,174	
Other long-term liabilities	1,526	974
Total liabilities	42,998	58,840
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock: $0.001 par value, 100,000,000 shares authorized; 35,733,181 and 25,451,338 shares issued and outstanding at December 31, 2011 and 2010, respectively	36	25
Additional paid-in capital	526,244	461,425
Accumulated deficit	(450,301)	(388,934)
Accumulated other comprehensive income	18	31
Total stockholders' equity	75,997	72,547
Total liabilities and stockholders' equity	$ 118,995	$ 131,387

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

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AFFYMAX, INC.

STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2011	**2010**	**2009**
Revenue:			
Collaboration revenue	$ 47,703	$ 112,503	$ 114,883
License and royalty revenue	17	18	16
Total revenue	47,720	112,521	114,899
Operating expenses:			
Research and development	76,308	93,638	157,125
Selling, general and administrative	32,818	33,331	36,716
Total operating expenses	109,126	126,969	193,841
Loss from operations	(61,406)	(14,448)	(78,942)
Interest income	169	275	934
Interest expense	(144)	(140)	(105)
Other income (expense), net	15	239	171
Net loss before provision (benefit) for income taxes	(61,366)	(14,074)	(77,942)
Provision (benefit) for income taxes	1	1	(1,411)
Net loss	$ (61,367)	$ (14,075)	$ (76,531)
Net loss per common share:			
Basic and diluted	$ (1.84)	$ (0.57)	$ (4.06)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	33,288	24,488	18,865

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

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AFFYMAX, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2008	15,304,419	$ 15	$ 306,828	$ (4)	$ (298,328)	$ 473	$ 8,984
Issuance of common stock upon exercise of stock options	212,424		720				720
Issuance of common stock upon vesting of restricted stock units	56,395						
Proceeds from common stock issued upon private placement, net of issuance costs	3,496,970	4	41,569				41,573
Proceeds from common stock issued upon public offering, net of issuance costs	4,726,027	5	80,585				80,590
Issuance of common stock related to the employee stock purchase plan	73,069		925				925
Deferred stock-based compensation			443	(443)			
Amortization of deferred stock-based compensation				447			447
Employee stock-based compensation			9,850				9,850
Nonemployee stock-based compensation			876				876
Repurchase of common stock	(209)		(1)				(1)
Components of other comprehensive loss:							
Net loss					(76,531)		(76,531)
Change in unrealized gain (loss) on marketable securities						(528)	(528)
Total comprehensive loss							(77,059)
Balance at December 31, 2009	23,869,095	$ 24	$ 441,795	$	$ (374,859)	$ (55)	$ 66,905
Issuance of common stock upon exercise of stock options	399,323		2,243				2,243
Issuance of common stock upon vesting of restricted stock units	53,544						
Proceeds from common stock issued upon private placement, net of issuance costs	999,061	1	4,882				4,883
Issuance of common stock related to the employee stock purchase plan	130,315		982				982
Deferred stock-based compensation			(379)	379			
Amortization of deferred stock-based compensation				(379)			(379)
Employee stock-based compensation			12,193				12,193
Nonemployee stock-based compensation			(291)				(291)
Components of other comprehensive loss:							
Net loss					(14,075)		(14,075)
Change in unrealized gain (loss) on marketable securities						86	86
Total comprehensive loss							(13,989)
Balance at December 31, 2010	25,451,338	$ 25	$ 461,425	$	$ (388,934)	$ 31	$ 72,547
Issuance of common stock upon exercise of stock options	95,917		371				371
Issuance of common stock upon vesting of restricted stock units	255,782						
Proceeds from common stock issued upon public offering, net of issuance costs	9,745,762	10	53,615				53,625
	184,382	1	807				808

Issuance of common stock related to the employee stock purchase plan							
Deferred stock-based compensation			(5)	5			
Amortization of deferred stock-based compensation				(5)			(5)
Employee stock-based compensation			9,773				9,773
Nonemployee stock-based compensation related to consultants			(10)				(10)
Nonemployee stock-based compensation related to former CEO			268				268
Components of other comprehensive loss:							
Net loss					(61,367)		(61,367)
Change in unrealized gain (loss) on marketable securities						(13)	(13)
Total comprehensive loss							(61,380)
Balance at December 31, 2011	35,733,181	$ 36	$ 526,244	$	$ (450,301)	$ 18	$ 75,997

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

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AFFYMAX, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2011	**2010**	**2009**
Cash flows from operating activities			
Net loss	$ (61,367)	$ (14,075)	$ (76,531)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,182	2,212	2,116
Amortization of discount/premium on investments	55	650	49
Stock-based compensation expense	10,025	11,523	11,172
Gain (loss) on disposal of fixed assets	11	2	65
Changes in operating assets and liabilities:			
Receivable from Takeda	(6,937)	18,561	3,127
Income taxes receivable		1,443	1,222
Prepaid expenses and other current assets	195	6,681	(2,046)
Other assets	(289)	342	3,326
Accounts payable	620	(143)	(150)
Accrued liabilities	1,868	(1,000)	2,772
Accrued clinical trial expenses	(7,882)	(28,252)	11,693
Payable to Takeda	(5,958)	5,958	
Income taxes payable			(163)
Deferred revenue	(13,322)	(53,475)	(37,873)
Deposit from Takeda	1,998		
Long-term income tax liability	162	140	113
Advance from Takeda	6,121		
Other long-term liabilities	552	199	301
Net cash used in operating activities	(71,966)	(49,234)	(80,807)
Cash flows from investing activities			
Purchases of property and equipment	(1,265)	(730)	(716)
Purchases of investments	(35,799)	(128,650)	(29,345)
Proceeds from sales of investments		16,042	1,948
Proceeds from maturities of investments	45,024	101,857	77,168
Proceeds from sale of property and equipment	41	2	18
Net cash provided by (used in) investing activities	8,001	(11,479)	49,073
Cash flows from financing activities			
Repurchases of common stock			(1)
Proceeds from issuance of common stock upon exercise of stock options	371	2,243	714
Proceeds from issuance of common stock related to employee stock purchase plan	809	982	925
Proceeds from common stock issued upon private placement, net of issuance costs		4,883	41,569
Proceeds from common stock issued upon public offering, net of issuance costs	53,625		80,585
Proceeds from UBS loan			9,192
Repayment of UBS loan		(9,192)	
Net cash provided by (used in) financing activities	54,805	(1,084)	132,984
Net increase (decrease) in cash and cash equivalents	(9,160)	(61,797)	101,250
Cash and cash equivalents at beginning of the year	63,499	125,296	24,046

Cash and cash equivalents at end of the year	$ 54,339	$ 63,499	$ 125,296
Supplemental disclosures of cash flow information:			
Income taxes paid	$ 1	$ 1	$ 181
Interest paid			1
Noncash investing and financing activities:			
Change in unrealized loss on investments	(13)	86	(528)
Deferred stock-based compensation, net of cancellations	(5)	(379)	(443)

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

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS

1. The Company

Affymax, Inc., a Delaware corporation, was incorporated on July 20, 2001. We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. We completed Phase 3 clinical trials of our product candidate, peginesatide, to treat anemia associated with chronic kidney disease in early 2010. In May 2011, we submitted our New Drug Application, or NDA, to the United States, or U.S., Food and Drug Administration, or FDA, seeking approval for peginesatide to treat adult dialysis patients with anemia associated with chronic kidney disease. Our NDA is currently under review with the FDA, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. In December 2011, the FDA Oncologic Drugs Advisory Committee, or 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 chronic kidney disease. While the FDA is not bound by the recommendations of its advisory committees, their guidance will be considered by the FDA in its review of NDA that was submitted for peginesatide. Peginesatide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or 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 revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are stated at cost, which approximates market value. We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Restricted Cash

Restricted cash represents cash for certificates of deposit provided as credit guarantees and security for an irrevocable letter of credit related to the lease of office space.

Comprehensive Loss

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on investments. At each balance sheet date presented, our accumulated other comprehensive loss consists

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

solely of unrealized gains and losses on investments. Comprehensive loss for the years ended December 31, 2011, 2010, and 2009 are as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Net loss	$ (61,367)	$ (14,075)	$ (76,531)
Decrease (increase) in unrealized gains (losses) on investments	(13)	183	(408)
Reclassification adjustment for (gains) losses on investments recognized in earnings		(97)	(120)
Comprehensive loss	$ (61,380)	$ (13,989)	$ (77,059)

Changes in Estimates

During the year ended December 31, 2010, we finalized amendments for certain clinical trial activities completed in 2009. In the fourth quarter of 2010, we obtained final monitored site visit data and investigator contracts from our third party contract research organizations, or CROs, that allowed us to complete our reconciliation of the significant majority of the labor and investigator costs incurred throughout the course of our clinical trials to our previously recorded estimates. This data and contractual information was not available to us during the course of the trials. After extensive analysis to cost out and analyze the information provided, we determined that the costs incurred were lower than our previously recorded estimates. The change in estimate decreased expense by $12.1 million for the year ended December 31, 2010. As this change in estimate was comprised of development costs charged to Takeda Pharmaceutical Company Limited, or Takeda, related to our two separate collaboration agreements, or the Arrangement, at a 70% reimbursement rate, this amount was a payable due back to Takeda.

During the year ended December 31, 2011, we continued to work with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. We recently received notification from both of our major CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trialsresulting in a $1.8 million reversal of our clinical trial accrual in the year ended December 31, 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate change in estimate decreased expense by $2.5 million or $0.08 per share for the year ended December 31, 2011.

Clinical Trial Expense and Accruals

We record expense for estimated clinical study external costs, which are a significant component of research and development or R&D expenses. These clinical trial costs were $1.7 million, $14.9 million and $90.0 million for the years ended December 31, 2011, 2010, and 2009, respectively. Clinical trials are administered by CROs for our Phase 3 and Phase 2 studies. CROs typically perform most of the total start-up activities for the trials, including document preparation, site identification pre-study visits, training as well as on-going program management.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

There is a significant degree of estimation involved in quantifying the clinical trial expenses. The complexity and magnitude of the activities and expenses can be significant and subject to frequent change during the studies, especially for our Phase 3 trials. The activities in our trials are performed globally, in many sites and countries, involving numerous CROs and third parties. If we do not receive complete and accurate information from the CRO or third parties on a timely basis or correctly estimate activity levels, we may have to record adjustments, which could potentially result in significant increases or decreases in R&D expenses, in subsequent periods.

Additional changes in estimate or adjustments could result in the future as we have ongoing clinical trial activity on our Phase 3b trial, and a Phase 2 study in Pure Red Cell Aplasia patients and such adjustments could impact R&D expense and collaboration revenue and amounts due to or from Takeda in subsequent periods.

Concentration of Risk and Uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents and investments. We deposit excess cash in accounts with three major financial institutions in the U.S. Deposits in these banks may exceed the amount of insurance provided on such deposits. We have not experienced any realized losses on our deposits of cash and cash equivalents.

We have experienced significant operating losses since inception. At December 31, 2011, we had an accumulated deficit of $450.3 million. We have generated no revenue from product sales to date. We have funded our operations to date principally from the sale of equity securities, upfront license fees, milestone payments and reimbursement for development and commercial expenses and manufacturing costs under our collaboration with Takeda, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. We expect to incur substantial additional operating losses for the next several years and will need to obtain additional financing in order to complete the development and commercialization of peginesatide. There can be no assurance that such financing will be available or will be at terms acceptable to us.

Our accounts receivable balance with Takeda of $6.9 million and $0 at December 31, 2011 and 2010, respectively. The receivable was comprised of the amounts due from Takeda for the reimbursement of development and commercial expenses we incurred during the fourth quarter of 2011 partially offset by amounts due to Takeda for reimbursement of development and commercial expenses they incurred during the same quarter. We have not experienced any credit losses from our Arrangement with Takeda and none are expected. We do not require collateral on our receivable.

We are currently developing our first product offering, peginesatide, and have no products that have received regulatory approval. Peginesatide will require approval from the FDA and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that peginesatide will receive the necessary approvals. If we are denied such approvals or such approvals are delayed, it would have a material adverse effect on us. To achieve profitable operations, we must successfully develop, test, manufacture and commercialize peginesatide. There can be no assurance that peginesatide can be developed successfully or manufactured at an acceptable cost and with appropriate performance characteristics, or that peginesatide will be successfully commercialized. These factors could have a material adverse effect on our future financial results.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

Further, some of our suppliers and manufacturing arrangements, including the provision of bulk poly(ethylene) glycol reagent for the manufacture of peginesatide from Nektar Therapeutics AL, Corporation, or Nektar, are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

Revenue Recognition

Collaboration Revenue

We recognize revenue in accordance with the Securities and Exchange Commission, or SEC, Staff Bulletin No. 101, *Revenue Recognition in Financial Statement*s, as amended by Staff Accounting Bulletin or SAB, No. 104, *Revision of Topic 13* and Accounting Standards Codification, or ASC, 605-25, *Multiple Element Arrangements*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

On January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*. This update amends the guidance on accounting for arrangements with multiple deliverables to require that each deliverable be evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. This update also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. We may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and the estimated selling price of identified units of accounting for new agreements. The adoption of ASU No. 2009-13 did not impact our financial position or results of operations as of and for year ended December 31, 2011. The potential future impact of the adoption of this update will depend on the nature of any new arrangements or material modifications of existing arrangements that we enter into in the future.

During the development period under the Arrangement, which ended in May 2011, upon the submission of our NDA to the FDA, we recognized collaboration revenue using the Contingency Adjusted Performance Model or CAPM. Under CAPM, revenue was eligible for recognition in the period the payment was earned under the Arrangement including amounts that were either received or due from Takeda. Revenue initially recognized was based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment was earned in relation to the total projected development period. The remaining portion of the payment was then recognized on a straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period included amounts due for upfront license fees, milestone payments earned, purchases of active pharmaceutical ingredient or API and reimbursement of development expenses. Our obligations under the Arrangement consisted primarily of actively developing our product candidate, peginesatide, for the treatment of anemia for chronic kidney disease through the end of the development period which occurred upon our submission of our NDA.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

Beginning in June 2011, we have moved into the commercialization period as defined under our Arrangement with Takeda. According to the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to pre-commercialization services such as pre-marketing, launch, promotions, marketing, sale and distribution of peginesatide as well as development work that has taken place after our NDA has been filed with the FDA but before peginesatide receives FDA approval. Prior to approval of the product and commencement of profit sharing payments, our primary source of revenue in the commercialization period will likely consist of Takeda's reimbursement of pre-commercialization and development efforts including costs of internal and external activities. For example, this includes work to prepare materials and other costs to present to the FDA ODAC and costs to implement and maintain a drug safety database.

In addition to the reimbursement of the services described above, the Arrangement provides us the potential to earn at risk milestone payments upon achievement of contractual criteria and profit sharing payments subsequent to product launch if approved. During the commercialization period, our obligations include ongoing regulatory work to obtain FDA approval and commercial efforts related to our product launch. Any post-development activities incurred during the commercialization period is related to activities to obtain FDA approval after our NDA was filed and activities related to commercial readiness in anticipation of FDA approval and product launch.

During the commercialization phase, we have re-evaluated the deliverables to be performed under the Arrangement to determine if the deliverables can be treated as separate units of accounting. We continue to follow the guidance of ASC 605-25 to determine whether the components of the Arrangement represent separate units of accounting. To determine if a delivered item can be treated as a separate unit of accounting, we evaluate (1) if the delivered item has value to Takeda on a standalone basis; (2) there is objective and reliable evidence of fair value of the undelivered item(s) and (3) if a general right of return exists for the delivered item (eg. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the company.

For each source of collaboration revenue, we apply the following revenue recognition model:

Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercial expenses (shared equally 50/50 according to the Arrangement) are recognized as revenue, in the period the related costs are incurred. Revenues related to reimbursement of costs of full time equivalent or FTEs engaged in development related activities such as post-marketing studies, are recognized as revenue in the period the related costs are incurred. Such reimbursement is based on contractually negotiated reimbursement rates for each FTE as specified in the Arrangement.

Payments received from the shipment of commercial API prior to the launch of the product are recorded as deferred revenue as the earning process is not complete until either (1) the finished goods produced from each batch of API are sold and utilized for commercial purposes post-approval and charged back to us through the profit sharing each period or (2) the Arrangement has been terminated by Takeda or us.

We account for milestones under ASU No. 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 the

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

collaboration. 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 collaboration.

Collaboration revenue consists of net reimbursement of development and commercial expenses, milestone payments and purchases of API during the development period under CAPM. During the development period under the Arrangement with Takeda, which ended in May 2011, collaboration revenue was recognized using CAPM. As a result, payments from Takeda under the Arrangement were recorded as deferred revenue and recognized ratably over the estimated development period. Below is a summary of the components of our collaboration revenue for the years ended December 31, 2011, 2010 and 2009 (in thousands):

	Year ended December 31,		
	2011	2010	2009
Revenue recognized under CAPM	$ 26,606	$ 112,503	$ 114,883
Expense reimbursement after CAPM	11,097		
Milestone payments	10,000		
Total collaboration revenue	$ 47,703	$ 112,503	$ 114,883

License and Royalty Revenue

Royalties are recognized as earned in accordance with contract terms, when third party results are reported and collectability is reasonably assured. Royalties received under agreements that were acquired by us in the 2001 spin out from GlaxoSmithKline or Glaxo are recorded net of the 50% that we are required to remit to Glaxo.

Fair Value of Financial Instruments

For financial instruments consisting of cash and cash equivalents, receivable from and payable to Takeda, advance from Takeda, accounts payable, deposit from Takeda and accrued liabilities included in our financial statements, the carrying amounts are reasonable estimates of fair value due to their short maturities. Estimated fair values for short-term and long-term investments are based on quoted market prices for the same or similar instruments. Based on borrowing rates currently available to us for loans with similar terms, the carrying value of lease obligations approximates fair value.

Investments

Investments are classified as available-for-sale and are carried at their fair market value based upon quoted market prices for these or similar instruments at the balance sheet date. Unrealized gains and losses are reported as a separate component of stockholders' equity until realized. The amortized

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

cost of these securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization as well as realized gains and losses are included in interest income. We assess our investments for potential other-than-temporary impairment based on factors including the length of time and extent to which the fair market value has been below our cost basis, the current financial condition of the investee and our intent and ability to hold the investment for a sufficient period of time to allow for any anticipated recovery in market value. If we conclude that an other-than-temporary impairment exists, we recognize an impairment charge to reduce the investment to fair value and record the related charge as a reduction of interest to other income (expense), net. We have elected to use settlement date accounting for purposes of recording transactions.

Research and Development

Research and development costs are expensed as incurred.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Assets under capital lease and leasehold improvements are amortized over the lesser of their estimated useful lives or the term of the related lease. Maintenance and repairs are charged to operations as incurred.

Segment Information

We operate in one business segment, which encompasses all the geographical regions. Collaboration revenue recognized was from Japan related to the Arrangement. License and royalty revenue was primarily from the U.S. All of our assets reside in the U.S. Management uses one measurement of profitability and does not segregate our business for internal reporting.

Income Taxes

We account for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The guidance prescribes a minimum recognition threshold and measurement process for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Net Loss per Common Share

Basic and diluted net loss per common share is computed using the weighted-average number of shares of common stock outstanding during the year. Stock options, common stock subject to repurchase, warrants, restricted stock units and common stock issuable pursuant to the 2006 Employee

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

Stock Purchase Plan were not included in the diluted net loss per common share calculation for all years presented because the inclusion of such shares would have had an antidilutive effect.

The computation of basic and diluted net loss per common share is as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2011	**2010**	**2009**
Numerator:			
Net loss	$ (61,637)	$ (14,075)	$ (76,531)
Denominator:			
Weighted-average common shares outstanding	33,288	24,488	18,866
Less: Weighted-average unvested common shares subject to repurchase			(1)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	33,288	24,488	18,865
Basic and diluted net loss per common share	$ (1.84)	$ (0.57)	$ (4.06)

The following number of shares were excluded from the denominator in the computation of diluted net loss per common share for the years presented because including them would have an antidilutive effect (in thousands):

	Year Ended December 31,		
	2011	**2010**	**2009**
Options to purchase common stock	4,262	3,890	2,430
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	41	29	16
Restricted stock units	362	503	107
Warrant to purchase common stock	426	426	426

Stock-Based Compensation

We account for equity instruments issued to employees and directors under the authoritative guidance for share-based payments.

The equity instruments we most typically grant are stock options and restricted stock units. Stock options are valued using the Black-Scholes valuation model while the fair value of restricted stock units is equivalent to the value of the equivalent number of shares of common stock on the date of grant. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest or do not vest as a result of employee terminations prior to vest.

We have issued stock options to nonemployees. We account for equity instruments issued to nonemployees in accordance with the authoritative guidance for equity-based payments to nonemployees, using a fair value approach.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board or FASB, issued ASU No. 2011-05, which is an update to Topic 220, *Presentation Of Comprehensive Income*. This update amends current comprehensive income guidance and eliminates the option of presenting the components of other comprehensive income as part of the statement of stockholders' equity. This update presents an entity with the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The new guidance was originally proposed to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and applied retrospectively. In October 2011, the FASB proposed to defer the effective date of certain provisions in the guidance related to the presentation of reclassification adjustments. No effective date has been announced. As ASU No. 2011-05 relates only to the presentation of comprehensive income, we do not expect that the adoption of this update will have a material effect on our financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is an update to Topic 820, *Fair Value Measurement*. This update establishes common requirements for measuring fair value and related disclosures in accordance with GAAP and international financial reporting standards. This amendment did not require additional fair value measurements. ASU No. 2011-04 is effective for all interim and annual reporting periods beginning after December 15, 2011. We do not believe there will be a significant impact on our financial statements from the adoption of ASU No. 2011-04.

3. Development and Commercialization Agreements with Takeda

We entered into two separate collaboration agreements with Takeda, which have been combined for accounting purposes due to their proximity of negotiation. Consideration from these collaboration agreements includes nonrefundable upfront license fees, reimbursement for sales of API, clinical and regulatory milestone payments, reimbursement of third party U.S. clinical development expenses, product profit share revenues (as co-promotion revenues) and royalties. The February 2006 agreement and the June 2006 agreements are collectively referred to herein as the Arrangement.

Under the February 2006 agreement, we granted an exclusive license to Takeda for development and commercialization of peginesatide in Japan. In December 2011, however, Takeda announced that it has decided not to commercialize peginesatide in Japan. Takeda is conducting a Phase 3 clinical program in Japan for the treatment of patients with anemia associated with chronic kidney disease, which Takeda expects to complete notwithstanding its decision not to commercialize peginesatide in Japan. In Japan, the majority of Phase 2 and Phase 3 clinical trials are completed. We and Takeda are actively exploring other options for the commercialization rights for peginesatide in the Japanese market, including potentially licensing it to a third party.

Further, under the February 2006 agreement, Takeda has paid us approximately $42 million to date, consisting of $17 million in upfront licensing fees, approximately $10 million for the purchase of equity, a $10 million cash milestone payment for the completion of the first Phase 1 trial of

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Development and Commercialization Agreements with Takeda (Continued)

peginesatide in Japan, and in March 2010, a $5 million cash milestone payment for the initiation of Phase 3 trial of peginesatide in Japan. Upon Takeda's successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $33 million relating to the renal program. Takeda is responsible for all development and commercialization costs in Japan and will purchase the API for peginesatide from us. Assuming peginesatide is approved and launched in Japan, we will receive a royalty from Takeda on peginesatide sales in Japan.

Under the June 2006 agreement, we expanded our collaboration to develop and commercialize peginesatide worldwide, which includes the co-development and co-commercialization of peginesatide in the U.S. Takeda received an exclusive license to develop and commercialize peginesatide outside of the U.S. During the development period of the collaboration, beginning January 1, 2007, Takeda was responsible for the first $50 million of third party expenses related to development in pursuit of U.S. regulatory approval of peginesatide, which was fully utilized through the first quarter of 2008. Thereafter, Takeda has borne 70% of the third party U.S. development expenses while we have been responsible for 30% of third party expenses. During the development period, we retained responsibility for 100% of our internal development expenses, most notably employee-related expenses.

Further, under the June 2006 agreement, Takeda paid us an upfront license fee of $105 million, and we have received milestone payments upon completion of database lock of the Phase 3 clinical trials of $30 million for dialysis and non-dialysis. In addition, we earned a $10 million milestone in July 2011, as a result of the FDA acceptance for review of our NDA, which was deemed to be at risk and recognized immediately upon achievement of the milestone. Upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $75 million relating to the renal program, including $50 million of milestone payments upon approval by the FDA in dialysis indications. In February 2012, the Marketing Authorization Application, or MAA filed by Takeda in early 2012 was accepted, by the European Medicines Agency, or EMA which triggered a $5.0 million milestone payment from Takeda. We received this milestone payment in the first quarter of 2012, and we expect to recognize it as revenue in the same period. We and Takeda will share equally in the net profits and losses of peginesatide in the U.S., which include certain expenses related to the marketing and launch of peginesatide.

During the commercialization period under the Arrangement, which commenced in June 2011 upon the submission of our NDA to the FDA, Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of peginesatide in the U.S. Certain employee-related expenses supporting preparation for commercialization of peginesatide in the U.S. are also shared equally. Such employee-related costs will include the cost of certain employees that would be required to commercialize the product such as field sales representatives, sales operations, medical science liaisons, nurse educators, conversion specialists, national accounts managers and reimbursement specialists. In addition, costs of certain employees in clinical, regulatory and other development functions supporting any post-marketing development activity required by the FDA or separately agreed to by the parties in the U.S. are shared equally.

We are also entitled to a launch allowance to help fund the initial costs associated with preparing to launch the product in the U.S., whereby Takeda will fund the first $20 million of U.S. commercial expenses. This launch allowance is non-refundable; however, in the event the product is approved for sale in the U.S., Takeda is entitled to deduct up to 8% of net sales from the profit share amounts

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Development and Commercialization Agreements with Takeda (Continued)

which would have otherwise been due to us each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in profit sharing post-launch stemming from the launch allowance, we have reflected amounts we receive under the terms of the launch allowance as a liability on our balance sheet. As of December 31, 2011, we have received $6.1 million of the launch allowance, which is reflected in the caption "Advance from Takeda" on our balance sheet.

Payments due under the launch allowance for which the earnings process is not yet complete are recognized as revenue when earned in accordance with SAB 104. Under the launch, those amounts paid by Takeda may ultimately be recaptured by Takeda via reductions in peginesatide revenues included in the profit sharing payment in the event peginesatide is approved for commercial sale in the U.S. by the FDA. As a result, we are deferring recognition of those payments until that contingency is resolved. If peginesatide is approved by the FDA, we would recognize previously deferred amounts paid under the launch allowance as revenue each period in an amount equal to the reduction in our revenues being incurred as a result of Takeda's reductions in peginesatide revenues included in the profit sharing. In the event the Arrangement with Takeda is terminated prior to approval of peginesatide in the U.S. we would recognize all previously deferred amounts paid under the launch allowance immediately as Takeda would not longer have any recourse to recoup those amounts paid.

The Arrangement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of peginesatide. We share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of peginesatide. Specifically, we have primary responsibility for peginesatide's clinical development plan and clinical trials in the dialysis indication, and the non-dialysis indication to the extent of any further development, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the extent any such indication is developed. We and Takeda have agreed to suspend the development of peginesatide to treat chemotherapy-induced anemia and to focus all development efforts for peginesatide on the treatment of chronic kidney disease anemia. We are responsible for U.S. regulatory filings in the dialysis, non-dialysis, chemotherapy induced anemia and anemia of cancer indications, including holding the NDAs for those indications. Takeda is responsible for regulatory filings outside the U.S. and the creation of a global safety database.

Takeda will have primary responsibility, directly or indirectly through sublicensees, and bears all costs for peginesatide clinical development in support of regulatory approval for all territories outside the U.S. and will pay us a variable royalty based on annual net sales of peginesatide outside the U.S.

Under the February 2006 agreement, Takeda also obtained a right of first negotiation to any backup products for peginesatide developed by us or our third party partners. Specifically, during the first ten years of the agreement, if we or third party partners develop a product that advances to Phase 2 clinical trials and competes with peginesatide in the renal or oncology indications, we are obligated to offer to Takeda the right to develop and commercialize such product in Japan before offering the product opportunity in Japan to any other third party.

We recognized $47.7 million, $112.5 million, and $114.9 million of collaboration revenue during the years ended December 31, 2011, 2010, and 2009, respectively. During the year ended December 31, 2010 we recorded a $12.1 million change in estimate to our clinical trial accruals as a result of our analysis of the final monitored site visit data for our Phase 3 clinical trials. As this change in estimate was comprised of development costs charged to Takeda at a 70% reimbursement rate, this amount was a payable due back to Takeda. The reimbursement received from Takeda in prior periods was recorded

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Development and Commercialization Agreements with Takeda (Continued)

as deferred revenue and collaboration revenue under our CAPM revenue recognition model. This change in estimate resulted in a reduction of $8.4 million of deferred revenue and a reversal of $7.8 million of collaboration revenue. The net impact to our statement of operations for this change in estimate was a $4.3 million decrease to our net loss or $0.18 per share for the year ended December 31, 2010.

The corresponding $8.4 million gross payable to Takeda as of December 31, 2010 was partially offset by the $2.5 million receivable due from Takeda for reimbursement of development and commercial expenses in the fourth quarter of 2010. The resulting net payable of $6.0 million is reflected on the accompanying balance sheet under the caption Payable to Takeda.

The amount due from Takeda as of December 31, 2011 was $6.9 million.

Going forward, we expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods. We do not expect to recognize any revenue related to commercial product sales under our Arrangement with Takeda, and do not expect to recognize any product profit sharing until after the product is approved by the FDA.

In November 2011, as contemplated under the Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as they relate to the manufacture of peginesatide API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of the product. We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of peginesatide worldwide. Takeda remains responsible for the fill and finish steps in the manufacture of peginesatide worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda has agreed to pay an aggregate of $10.8 million in deposits for commercial API shipments of existing materials already manufactured by us. Through December 31, 2011, we have received $7.2 million and shipped $5.2 million of API. The value of API shipped to Takeda has been recorded as deferred revenue. The remainder of the amount paid by Takeda has been recorded as a liability on our balance sheet.

In November 2011, we entered into a settlement and license agreement, or the Settlement and License Agreement, with Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies, or, collectively, Janssen, under which we obtained from Janssen a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings.

In November 2011, concurrent with the execution of the Settlement and License Agreement, we and Takeda entered into an amendment to the Arrangement. Under the terms of this amendment, Takeda has agreed to pay up to $6.5 million in additional milestones to us in consideration of the upfront and milestone payments we are required to make to Janssen under the Settlement and License Agreement. $5.25 million of these milestones are earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million is tied to regulatory events in the European Union or E.U. As of December 31, 2011, none of these milestones have yet been achieved and as such, we have not received any related payments from Takeda. We are solely responsible for the royalty payment to Janssen.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Development and Commercialization Agreements with Takeda (Continued)

In February 2012, as contemplated under the Arrangement, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for peginesatide including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs field force but share marketing, account management and payer reimbursement related activities with Takeda. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of FTE expenses used to calculate eligible commercial expenses incurred by us and Takeda thereunder. Consistent with the terms of the Arrangement, Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	December 31,	
	2011	**2010**
Leasehold improvements	$ 2,303	$ 2,115
Equipment	8,748	8,567
Software	2,428	2,431
Construction in progress	630	176
	14,109	13,289
Less: Accumulated depreciation and amortization	(11,097)	(9,307)
	$ 3,012	$ 3,982

Depreciation and amortization expense for the years ended December 31, 2011, 2010, and 2009, was $2.2 million, $2.2 million, and $2.1 million, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2011	**2010**
Compensation-related expenses	$ 7,971	$ 7,671
Research and development related costs	1,659	2,476
Janssen Biotech installment payment accrual	2,000	
Other	1,831	1,447
	$ 13,461	$ 11,594

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

5. Investments

The following is a summary of our available-for-sale marketable securities (in thousands):

	As of December 31, 2011				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 2,241	$	$	$	$ 2,241
Government securities	41,905	23	(4)		41,924
Total short-term investments	$ 44,146	$ 23	(4)	$	$ 44,165

	As of December 31, 2010				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 1,448	$	$	$	$ 1,448
Government securities	32,080	58	(4)		32,134
Total short-term investments	$ 33,528	$ 58	$ (4)	$	$ 33,582
Long-term investments:					
Government securities	$ 19,899	$ 5	$ (28)	$	$ 19,876
Total long-term investments	$ 19,899	$ 5	$ (28)	$	$ 19,876

The investments mature between January 2012 and August 2012.

6. Fair Value Measurements

We measure certain financial assets at fair value on a recurring basis, including cash equivalents and available for sale securities. The fair value of these assets was determined based on a three-tier hierarchy under the authoritative guidance for fair value measurements and disclosures that prioritizes the inputs used in measuring fair value as follows:

Level 1 observable inputs such as quoted prices in active markets.

Level 2 inputs other than quoted prices in active markets that are observable either directly or indirectly through corroboration with observable market data.

Level 3 unobservable inputs in which there is little or no market data, which would require us to develop its own assumptions.

Our cash equivalents and investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The valuation technique we used to measure fair value of our Level 1 money market securities is a market approach, using prices and other relevant information generated by market transactions involving identical securities. The types of investments that are generally classified within

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

6. Fair Value Measurements (Continued)

Level 2 of the fair value hierarchy include corporate securities, certificates of deposits and U.S. government securities. The valuation technique we used to measure fair value of our Level 2 investments is a market approach, which we review trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical investments was not available, we used market pricing and other observable market inputs for similar investments obtained from various third party data providers. These inputs represent quoted prices for similar investments in active markets or these inputs have been derived from observable market data.

The following table presents our investments measured at fair value on a recurring basis classified by the fair value measurements and disclosures valuation hierarchy (in thousands):

	As of December 31, 2011			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 45,244	$ 44,248	$ 996	$
Short-term investments:				
Certificates of deposit	$ 2,241	$	$ 2,241	$
Government securities	41,924		41,924	
Total short-term investments	$ 44,165	$	$ 44,165	$

	As of December 31, 2010			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 61,096	$ 59,353	$ 1,743	$
Short-term investments:				
Certificates of deposit	$ 1,448	$	$ 1,448	$
Government securities	32,134		32,134	
Total short-term investments	$ 33,582	$	$ 33,582	$
Long-term investments:				
Government securities	$ 19,876	$	$ 19,876	$
Total long-term investments	$ 19,876	$	$ 19,876	$

We held investments in auction rate securities or ARS and UBS AG of Series C-2 ARS Rights, or ARS Rights during the quarter ended June 30, 2010, which were classified within Level 3 of the fair value hierarchy because of the lack of observable inputs. The valuation technique we used to measure fair value of our Level 3 ARS and ARS Rights was an income approach and we used a discounted cash flow analysis. As of December 31, 2011 and December 31, 2010, we no longer hold ARS or ARS Rights as these investments were fully redeemed or sold in 2010.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

6. Fair Value Measurements (Continued)

The following table presents changes in Level 3 assets measured at fair value on a recurring basis for the years ended December 31, 2011 and 2010 (in thousands):

	Year Ended December 31,	
	2011	**2010**
Balance at beginning of the period	$	$ 17,883
Total realized gains related to ARS included in net loss		695
Total realized loss related to ARS included in net loss		(158)
Total realized losses related to ARS Rights included in net loss		(604)
Settlements		(17,816)
Balance at end of the period	$	$

Upon the sale and redemptions of our ARS during 2010, we recognized a realized loss of $158,000 for the year ended December 31, 2010. The fair value of our ARS Rights was decreased by $604,000 for the year ended December 31, 2010 and this reduction was recorded as a charge to other income (expense), net. We also reversed other-than-temporary impairment charges of $695,000 during that period.

7. Commitments and Contingencies

We rent our office facilities and certain equipment under noncancelable operating leases, which expire at various dates through September 2014. Under the terms of the leases, we are responsible for certain taxes, insurance and maintenance expenses.

Rent expense for the years ended December 31, 2011, 2010, and 2009 was $3.2 million, $2.8 million and $2.1 million, respectively. We recognize rent expense on a straight-line basis over the lease period.

Future minimum payments under noncancelable lease obligations as of December 31, 2011 are as follows (in thousands):

	Operating Leases
2012	4,172
2013	4,266
2014	3,207
2015	
2016	
Thereafter	
Total minimum lease payments	$ 11,645

Legal Proceedings

In October 2010, the arbitration panel in our binding arbitration with certain subsidiaries of Johnson & Johnson decided the ownership of a number of U.S. and international patents and patent

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

7. Commitments and Contingencies (Continued)

applications related to certain EPO-R agonists, or the "intellectual property in dispute." The decision maintained Johnson & Johnson's sole inventorship and sole ownership of U.S. Patent No. 5,767,078, or the "078 Patent," and certain related foreign patents and patent applications, including European Patent application EP96/918,317. The arbitrators determined that we and Johnson & Johnson jointly own the remainder of the intellectual property in dispute.

In November 2010, we filed in the U.S. District Court for the Northern District of Illinois, or the District Court, a motion to vacate the arbitration award with respect to the ownership of the '078 Patent and related foreign cases. In December 2010, Johnson & Johnson filed its response and requested that the District Court confirm the arbitration award.

In March 2011, the District Court issued its decision to vacate in part the arbitrators' award relating to sole ownership by Janssen of the European Patent EP96/918,317 and other foreign counterpart patents and patent applications to the '078 Patent. As a consequence, the District Court remanded the issues of inventorship and ownership of such foreign patents and patent applications to the arbitration panel. The District Court denied our motion to vacate in part and maintained the arbitration award with respect to the sole ownership by Johnson & Johnson of the '078 Patent in the U.S. In May 2011, we filed a notice of appeal relating to the District Court's decision as to the '078 Patent in the U.S. which remains pending with the Court of Appeals for the Federal Circuit. Concurrently, Johnson & Johnson filed an appeal with the Seventh Circuit Court of Appeals, and in October 2011, the Seventh Circuit Court reversed the District Court with the result that it remanded with instruction to confirm the arbitration award in full and set forth its view that the Court of Appeals for the Federal Circuit lacked jurisdiction.

In November 2011, we entered into the Settlement and License Agreement with Janssen under which we obtained a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings.

The Settlement and License Agreement requires us to make two fixed payments to Janssen, $6 million within 30 days of execution thereof, which was paid in December 2011, and $2 million by June 30, 2012 The Settlement and License Agreement also requires us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of peginesatide, and a $2.5 million milestone payment to Janssen upon regulatory approval of peginesatide in the first major European country. In addition, Janssen will be entitled to low, single-digit royalties on sales of peginesatide in Europe, Japan and certain other countries outside of the United States until mid-2016. Upon execution of the Settlement and License Agreement in the fourth quarter of 2011, we recorded $8.0 million of R&D expense relating to the fixed payments. The milestone payments due upon regulatory approval will be capitalized when and if they become due and payable, and the resulting asset will be amortized over the period of expected benefit from the license granted in the Settlement and License Agreement.

8. Stockholder's Equity

Preferred Stock

Our Certificate of Incorporation, as amended and restated in December 2006, designates and authorizes 10,000,000 shares of $0.001 par value preferred stock, of which no shares are issued and outstanding as of December 31, 2011 and 2010. The rights, preferences and privileges of any preferred

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

8. Stockholder's Equity (Continued)

stock to be issued pursuant to our current Certificate of Incorporation, as amended and restated, have yet to be established.

No dividends on preferred stock have been declared since inception through December 31, 2011.

Common Stock

Our Certificate of Incorporation authorizes us to issue 100,000,000 shares of $0.001 par value common stock.

Warrants

As of December 31, 2011, a warrant to purchase 1,987 shares of our common stock, at an exercise price of $15.09 per share, and warrants to purchase an aggregate of 423,971 shares of common stock, at an exercise price of $16.78 per share, were issued and outstanding, the latter which was related to a private placement. The warrants contain provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations. The first warrant expired in January 2012 and the latter warrants expire in March 2014.

Significant Equity Transactions

In September 2010, we entered into an amendment, or the Amendment, to the Common Stock Purchase Agreement with Azimuth Opportunity Ltd., or Azimuth, dated as of September 25, 2009. The original agreement provided that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase up to $60.0 million worth of shares of our common stock over the 24-month term of the purchase agreement, which was available to be drawn upon beginning January 2010. The Amendment extends the term of the equity facility to September 2012 and reduces the minimum threshold price we may establish at which, upon presentation to Azimuth of a draw down notice, Azimuth is required to purchase shares of our common stock. Our equity facility is subject to a number of conditions that limit our ability to draw against such facility.

In October 2010, we sold 999,061 shares of common stock to Azimuth under the Common Stock Purchase Agreement for an aggregate purchase price of $5.0 million. Our net proceeds from the sale of these shares was $4.9 million after deducting our offering expenses.

In March 2011, we completed a public offering of 9,745,762 shares of our common stock, at $5.90 per share. We received net proceeds of approximately $53.6 million, after deducting underwriting discounts and commissions and offering expenses.

Equity Incentive Plans

2001 Stock Option/Stock Issuance Plan

In September 2001, we adopted the 2001 Stock Option/Stock Issuance Plan or the 2001 Plan. The 2001 Plan provides for both the granting of stock options and issuing shares of stock to our employees and consultants. Stock options granted under the 2001 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options or ISOs, may be granted only to our employees. Nonqualified stock options or NSOs, may be granted to our employees, directors and consultants. Stock

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

8. Stockholder's Equity (Continued)

issued under the 2001 Plan may be issued to employees, directors and consultants. Stock options under the 2001 Plan may be granted for periods of up to 10 years and at prices no less than the fair market value for ISOs and 85% of the fair market value for NSOs, as determined by the Board of Directors. The exercise price of an ISO or NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. To date, stock options granted generally become exercisable over four years. We issue new shares of common stock upon exercise of stock options.

2006 Equity Incentive Plan

Upon the effectiveness of our initial public offering in December 2006, we adopted the 2006 Equity Incentive Plan, or the 2006 Plan. Shares of common stock issuable pursuant to all then outstanding stock awards granted under the 2001 Plan remained subject to the terms of the 2001 Plan and no additional stock awards were granted pursuant to the terms of the 2001 Plan upon the effective date of the 2006 Plan.

The 2006 Plan provides for both the granting of stock awards, including stock options and restricted stock units, to our employees, directors and consultants. Stock options granted under the 2006 Plan may be either ISOs or NSOs. ISOs may be granted only to our employees. NSOs may be granted to our employees, directors and consultants. Stock options under the 2006 Plan may be granted for periods of up to 10 years and at prices no less than the fair market value of our common stock on the date of grant. The exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the fair market value of our common stock on the date of grant. To date, stock options granted generally become exercisable over four years and do not allow for the early exercise of options prior to vesting. The terms of the restricted stock units granted by us to date provide for vesting and delivery of shares of common stock over three years or are subject to performance based vesting upon milestones. As of December 31, 2011 we reserved 5,508,443 shares of common stock for issuance under the 2006 Plan.

Under the 2006 Plan, we issue new shares of common stock upon exercise of stock options. The number of shares of common stock reserved for issuance automatically increases on January 1st of each year, from January 1, 2007 through January 1, 2016, by the lesser of (a) 4.5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (b) 1,400,000 shares. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2006 Plan is equal to the total share reserve, as increased from time to time pursuant to annual increases and shares subject to options granted pursuant to the 2001 Plan that have expired without being exercised in full.

There were 794,788, 230,956, and 1,465,659 total shares available for grant, combined, under the 2001 and 2006 Plans as of December 31, 2011, 2010, and 2009, respectively.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

8. Stockholder's Equity (Continued)

2006 Employee Stock Purchase Plan

Upon the effectiveness of the our initial public offering in December 2006, we adopted the 2006 Employee Stock Purchase Plan or the Purchase Plan. As of December 31, 2011 and 2010, we reserved a total of 573,158 and 445,902 shares of common stock, respectively, for issuance under the Purchase Plan. The share reserve automatically increases on January 1st of each year, from January 1, 2007 through January 1, 2016, by an amount equal to the lesser of (i) 0.5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or (ii) 175,000 shares. We issue new shares of common stock in connection with purchases of common stock under the Purchase Plan. The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. For the year ended December 31, 2011 and 2010, 184,382 and 130,315 shares of common stock, respectively, were purchased under the Purchase Plan.

9. Stock-Based Compensation

We measure and recognize stock-based compensation expense related to employees and directors under the authoritative guidance for share-based payments.

Stock-based compensation was recorded in the Statements of Operations as follows (in thousands):

	Year Ended December 31,		
	2011	**2010**	**2009**
Research and development	$ 4,632	$ 4,521	$ 5,026
Selling, general and administrative	5,393	7,002	6,146
	$ 10,025	$ 11,523	$ 11,172

Included in the amounts in the table above for the year ended December 31, 2011 are compensation costs related to the January 31, 2011 resignation of our former Chief Executive Officer, Arlene M. Morris. Under the terms of Ms. Morris' separation agreement, consistent with her 2008 employment agreement, she had a post-termination exercise period for vested stock options ending on the earlier of one year following the date of termination or the expiration of the option. As part of the separation agreement, Ms. Morris was obligated to provide consulting services through September 30, 2011. Effective upon her resignation, Ms. Morris' status changed from an employee to a consultant and her options and awards continued to vest until the end of her consulting arrangement in September 2011. In accordance with Accounting Standards Codification 718, *Shared Based Payments*, we recorded $268,000 of stock-based compensation expense related to her separation and consulting arrangement during the quarter ended March 31, 2011. Given the nature of the consulting agreement, all costs were accrued and expensed in the quarter ended March 31, 2011.

In March 2011, our board of directors approved an amendment to our 2006 Equity Incentive Plan to extend the post-termination exercise period from 90 days to two years for non-employee board members' options vested as of such director's termination date. No other terms of the awards were modified. This amendment applies to all existing and future option grants to non-employee board members.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Stock-Based Compensation (Continued)

We granted the following stock options and restricted stock units to employees and directors as follows:

	Year Ended December 31,					
	2011		2010		2009	
	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Stock options	1,110,924	$ 4.41	1,999,999	$ 9.64	659,175	$ 8.83
Restricted stock units	220,856	$ 6.96	460,158	$ 6.03		

As of December 31, 2011, there was unrecognized compensation cost of $14.2 million related to these stock options and restricted stock units. The unrecognized compensation cost as of December 31, 2011 is expected to be recognized over a weighted-average amortization period of 2.6 years.

Valuation assumptions and expense recognition

We estimate the fair value of employee and director stock options using the Black-Scholes valuation model. The fair value of employee and director stock options is amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee and director stock options was estimated using the following weighted-average assumptions for the years ended December 31, 2011, 2010, and 2009:

	Year Ended December 31,		
	2011	2010	2009
Expected volatility	80%	81%	88%
Risk-free interest rate	1.86%	2.10%	1.51%
Dividend yield	0.00%	0.00%	0.00%
Expected term (in years)	5.6	5.5	5.9

The expected term of stock options represents the average period the stock options are expected to remain outstanding and is based on the expected terms for industry peers as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. The expected stock price volatility for our stock options for the years ended December 31, 2011, 2010, and 2009 was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers as we did not have any significant trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. Although use of our own historical data became available at the end of 2011 as we had five full years of history, we have continued to use an average of our industry peers for consistency. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of our stock options. The expected dividend assumption is based on our history and expectation of dividend payouts.

We measured the fair value of restricted stock units using the closing price of our stock on the grant date. The fair value of restricted stock units is being amortized on a straight-line basis over the requisite service period of the awards.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Stock-Based Compensation (Continued)

We estimated the fair value of employee stock purchase rights granted under the Purchase Plan using the Black-Scholes valuation model. The weighted-average fair value of each stock purchase right for the years ended December 31, 2011, 2010, and 2009 was $2.63, $3.64, and $8.29 per share, respectively. The fair value of employee stock purchase rights is being amortized on a straight-line basis over the requisite service period of the purchase rights. The fair value of employee stock purchase rights were estimated using the following assumptions for the years ended December 31, 2011, 2010, and 2009:

	Year Ended December 31,		
	2011	**2010**	**2009**
Expected volatility	50% - 157%	85% - 193%	63% - 193%
Risk-free interest rate	0.04% - 1.00%	0.16% - 1.44%	0.17% - 4.67%
Dividend yield	0.00%	0.00%	0.00%
Expected term (in months)	6 - 24	6 - 24	6 - 24

There were no tax benefits related to employee stock-based compensation for the years ended December 31, 2011, 2010, and 2009.

Stock Option and Restricted Stock Unit Activity

The following table summarizes information about stock option and restricted stock unit activity for the three years ended December 31, 2011:

	Number of Shares	**Weighted-Average Price (Per Share)(1)**	**Weighted-Average Remaining Contractual Term (in years)**	**Aggregate Intrinsic Value (in thousands)(2)**
Stock Options:				
Balances at December 31, 2008	**2,130,116**	**$ 17.59**		
Granted	665,175	$ 12.11		
Exercised(3)	(212,424)	$ 3.36		
Forfeited	(137,252)	$ 19.63		
Cancelled	(15,208)	$ 29.34		
Balances at December 31, 2009	**2,430,407**	**$ 17.14**		
Granted	2,008,999	$ 14.14		
Exercised(3)	(399,323)	$ 5.62		
Forfeited	(90,043)	$ 17.33		
Cancelled	(60,020)	$ 25.37		
Balances at December 31, 2010	**3,890,020**	**$ 16.65**		
Granted	1,119,924	$ 6.53		
Exercised(3)	(95,917)	$ 3.87		
Forfeited	(428,353)	$ 16.57		
Cancelled	(224,165)	$ 19.69		
Balances at December 31, 2011	**4,261,509**	**$ 14.12**	**7.27**	**$ 1,160**
Options exercisable at December 31, 2011	**2,269,924**	**$ 17.78**	**5.94**	**$ 542**

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Stock-Based Compensation (Continued)

	Number of Shares	Weighted-Average Price (Per Share)(1)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)(2)
Restricted Stock Units:				
Balances at December 31, 2008	**188,950**	**$ 14.94**		
Granted (time-based)				
Vested	(56,395)	$ 15.49		
Forfeited	(25,486)	$ 14.49		
Balances at December 31, 2009	**107,069**	**$ 14.76**		
Granted (time-based)	235,158	$ 6.23		
Granted (performance-based)(4)	225,000	$ 5.83		
Vested	(53,544)	$ 24.24		
Forfeited	(10,282)	$ 7.97		
Balances at December 31, 2010	**503,401**	**$ 5.91**		
Granted (time-based)	220,856	$ 6.96		
Vested	(255,782)	$ 5.84		
Forfeited	(106,784)	$ 5.41		
Balances at December 31, 2011	**361,691**	**$ 6.75**	**1.59**	**$ 84**

(1) The weighted average price per share is determined using exercise price per share for stock options and fair value per share on transaction date for restricted stock units.

(2) The aggregate intrinsic value is calculated as

For options: the difference between the exercise price of the option and the fair value of our common stock for in-the-money options at December 31, 2011.

For restricted stock units: the difference between the grant date fair value of the unit and the fair value of our common stock for in-the-money units at December 31, 2011.

(3) The total intrinsic value of stock options exercised was $0.3 million, $6.9 million, and $4.2 million during the years ended December 31, 2011, 2010, and 2009, respectively, and was determined at the date of each exercise.

(4)

During 2010, the Board of Directors approved the grant of 225,000 performance-based restricted stock units to certain executive officers. These units vest 50% upon FDA acceptance of our NDA submission for review for peginesatide and 50% upon product launch of peginesatide. During 2011, 50% of these units vested when the FDA accepted our submission and filed the NDA for review.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Stock-Based Compensation (Continued)

The stock options outstanding and exercisable by exercise price at December 31, 2011 are as follows:

	Stock Options Outstanding			Stock Options Exercisable	
Range of Exercise Prices	Number of Shares	Weighted-Average Remaining Contractual Life in Years	Weighted-Average Exercise Price Per Share	Number of Shares	Weighted-Average Exercise Price Per Share
$0.80 - 10.06	2,054,529	8.60	$ 6.17	567,562	$ 5.76
$10.06 - 19.7	774,952	5.84	$ 14.50	658,936	$ 14.95
$19.70 - 30.27	1,163,533	6.80	$ 23.39	774,926	$ 23.43
$30.27 - 36.43	268,500	3.33	$ 33.82	268,500	$ 33.82
	4,261,514			2,269,924	

Deferred Stock-Based Compensation

In September 2003, we approved the repricing of existing employee stock options from $4.00 to $0.80 per share, which was deemed to be the fair market value. As a result of the repricing, stock options are subject to variable accounting. At December 31, 2011, the fair value of the common stock was $6.61 per share and approximately 7,000 repriced stock options remained outstanding. During the years ended December 31, 2011, 2010, and 2009, we have recorded deferred stock-based compensation (benefit) related to these stock options of $(5,000), $(379,000), and $443,000 respectively, and recorded stock-based compensation (income) expense of $(5,000), $(379,000), and $443,000, respectively.

Nonemployee Stock-Based Compensation

Stock-based compensation expense related to stock options granted and common stock issued to nonemployees is recognized as the stock options are earned. We believe that the estimated fair value of the stock options is more readily measurable than the fair value of the services received. The fair value of stock options granted to nonemployees is calculated at each grant date and remeasured at each reporting date. The stock-based compensation expense related to a grant will fluctuate as the fair value of our common stock fluctuates over the period from the grant date to the vesting date. We recorded nonemployee stock-based compensation (benefit) expense of $(10,000), $(291,000), and $876,000, respectively, for the years ended December 31, 2011, 2010, and 2009.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

10. Restructuring Charge

As a result of the May 2010 amendment to our operating lease, we took possession of approximately 16,000 square feet of additional office space adjacent to our corporate headquarters in Palo Alto, California in May 2011. During the year ended December 31, 2011, management concluded that we would not occupy this additional office space, and we are actively seeking to sublease this space. Given these plans and the fact that this space is adequately separable from our existing facilities, in the second and fourth quarter of 2011, we recorded total restructuring charges of $869,000, which represents the present value of the estimated future facility costs for which we will obtain no future economic benefit over the term of our lease, net of estimated future sublease income. The $869,000 charge, as well as $72,000 of accretion was recorded during the year ended December 31, 2011 in selling, general and administrative or SG&A expenses in the statement of operations.

The estimates underlying the fair value of the lease-related restructuring liability involve significant assumptions regarding the time required to contract with a subtenant, the amount of space we may be able to sublease, the range of potential future sublease rates and the level of leasehold improvements expenditures that we may incur to sublease the property. We have evaluated a number of potential sublease scenarios with differing assumptions and have probability weighted these scenarios and calculated the present value of cash flows based on management's judgment. We will continue to monitor and update the liability balance when future events impact our cash flow estimates related to this excess space.

In August 2011, we initiated a restructuring plan to lower annual operating expenses that included a planned reduction in force of 22 positions. As a result, we recorded a restructuring charge in the year ended December 31, 2011 of $975,000 related to severance and benefits, of which $932,000 was reflected as R&D expense and $43,000 as SG&A expense in the statement of operations.

The following table summarizes the accrual balance and utilization by type for the restructuring (in thousands):

	Facilities Related	Employee Related	Total
Balance as of January 1, 2011	$	$	$
Restructuring charges accrued	869	975	1,844
Cash payments	(431)	(710)	(1,141)
Accretion	72		72
Balance at December 31, 2011	510	265	775
Less Current Portion	391	265	656
Long-term portion as of December 31, 2011	$ 119	$	$ 119

The current portion of the total restructuring accrual balance is included in the caption "Accrued liabilities" and the non-current portion is included in the caption "Other long-term liabilities" on the balance sheet.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

11. Income Taxes

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Provision (benefit) for income taxes:			
Current provision (benefit) for income taxes:			
Federal	$	$	$ (1,412)
State	1	1	1
Total current provision (benefit) for income taxes	1	1	(1,411)
Deferred tax benefit:			
Federal			
State			
Total deferred tax benefit			
Provision (benefit) for income taxes	$ 1	$ 1	$ (1,411)

We recorded a provision for minimum statutory state tax and provided no federal tax as a result of our net operating loss for the year ended December 31, 2011 and 2010.

We recorded a benefit for income taxes for the year ended December 31, 2009 of $1.4 million, consisting largely of a federal tax benefit that primarily resulted from the Worker, Homeownership and Business Assistance Act of 2009 enacted in November 2009, which allowed us to carryback our 2008 net operating loss to 2007 and recover $1.3 million in alternative minimum taxes previously paid for the year ended December 31, 2007. We also recorded a $100,000 federal benefit related to refundable R&D credits available to us pursuant to a provision within the Housing Assistance Tax Act of 2008, which was effective for tax years ended after March 31, 2008 and December 31, 2009.

We incurred significant operating losses since inception and anticipate that we may incur continued losses in the future.

A reconciliation of the federal statutory income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,		
	2011	2010	2009
Federal statutory income tax rate	(35.00)%	(35.00)%	(35.00)%
State income taxes, net of federal benefit		0.01	
Stock-based compensation expense	4.15	9.61	0.84
Change in valuation allowance	(56.26)	37.17	33.76
Change in federal rates and prior year true ups	0.70	(0.32)	0.64
Permanent differences true ups	0.08	0.11	0.03
Tax credits	2.66	(11.58)	(2.09)
Impairment of tax attributes due to ownership change	83.67		
Provision (benefit) for income taxes	0.00%	0.00%	(1.82)%

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

11. Income Taxes (Continued)

Deferred tax assets consist of the following (in thousands):

	December 31,	
	2011	**2010**
Net operating loss carryforwards	$ 93,282	$ 118,654
Federal and State credit carryforwards	3,552	12,233
Depreciation and amortization	15,938	20,147
Capitalized start up costs	1,333	1,481
Accrued liabilities and allowances	17,720,	20,094
Gross deferred tax assets	131,825	172,609
Deferred tax liability		(216)
Net deferred tax asset	131,825	172,393
Less: Valuation allowance	(124,585)	(165,153)
Net deferred tax assets	$ 7,240	$ 7,240

Management establishes a valuation allowance for those deductible temporary differences when it is more likely than not that some or all of the benefit of such deferred tax assets will not be recognized. The ultimate realization of deferred tax assets is dependent upon our ability to generate taxable income during the periods in which the temporary differences are deductible. Management considers the historical level of taxable income, projections for future taxable income, taxable income in carryback years and tax planning strategies in making this assessment. Management's assessment in the near term is subject to change if estimates of future taxable income during the carryforward period are increased. The valuation allowance decreased $40.6 million during the year ended December 31, 2011 and increased $6.7 million during the year ended December 31, 2010. As of December 31, 2011 and 2010, we have a net deferred tax asset balance of $7.2 million each in consideration of the uncertainty in income taxes liability recorded for the same amount.

We considered the following positive and negative factors in determining that it was more likely than not that the $7.2 million of the net deferred tax asset as of December 31, 2011 and 2010 would be realized:

Net deductible temporary differences that were expected to reverse in 2011 and 2012;

There were no relevant tax strategies available that we would consider feasible; and

Uncertainties, such as regulatory approval of peginesatide would adversely affect our future operations.

We have experienced ownership changes as defined by Sections 382 and 383 of the Internal Revenue Code which establishes an annual limit on the deductibility of pre-ownership change net operating loss and credit carryforwards. As a result of the ownership change and underlying annual limitation, some of our pre-ownership change net operating loss and all of our federal pre-ownership change credit carryforwards will expire unutilized. Accordingly, we have reduced our gross deferred tax asset for the expiring carryforwards by $59.6 million as of December 31, 2011.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

11. Income Taxes (Continued)

At December 31, 2011, we had federal and state net operating loss carryforwards of $345 million and $360 million, respectively. The federal net operating loss carryforwards begin to expire in 2029 and state net operating loss carryforwards begin to expire in 2019, if not utilized.

At December 31, 2011 and 2010, our liability for uncertain income tax positions was $10.4 million and $10.2 million, respectively, which is reflected as long-term income tax liabilities on our balance sheet. Our policy is to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. For the years ended December 31, 2011, 2010, and 2009, we recognized $144,000, $140,000, and $105,000, respectively, of interest expense related to our liability for uncertain income tax positions. As of December 31, 2011 and 2010, we had accrued $986,000 and $842,000 , respectively, of interest expense related to our liability for uncertain income tax positions. For the years ended December 31, 2011, 2010 and 2009, there were no penalties related to uncertain income tax positions.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The guidance prescribes a minimum recognition threshold and measurement process for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We do not believe any such uncertain tax positions currently pending will have a material adverse effect on our financial statements, although an adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period. We had $70.6 million, $13.1 million, and $12.4 million and of unrecognized tax benefits as of December 31, 2011, 2010, and 2009, respectively.

As of December 31, 2011 and 2010, $63.4 million and $5.9 million, respectively of the unrecognized tax benefits would affect our income tax provision and effective tax rate if recognized. However, as we would currently need to increase the valuation allowance for any additional amounts benefited, the effective tax rate would not be impacted until the valuation allowance was removed.

A reconciliation of the unrecognized tax benefits for the years ended December 31, 2011, 2010, and 2009 is as follows (in thousands):

	December 31,		
	2011	**2010**	**2009**
Balance at beginning of year	$ 13,100	$ 12,366	$ 11,770
Additions for current year tax positions	59,419	734	759
Additions for prior year tax positions			
Reductions for prior year tax positions	(1,906)		(163)
Balance at end of year	$ 70,613	$ 13,100	$ 12,366

We file federal and California income tax returns. For U.S. federal and California income tax purposes, the statute of limitation with regards to all returns remain open due to carryforward of net operating losses and R&D credits generated in prior years. There are no tax years under examination by any jurisdiction at this time.

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

12. Retirement Savings Plan

We have a retirement savings plan, commonly known as a 401(k) plan, that allows all full time employees to contribute from 1% to 50% of their salary, subject to IRS limits. Beginning in 2008, we made matching contributions equal to 50% of the employee deferral contributions during the fiscal year up to $4,000. Employees who met the period of service requirement minimum of 500 hours and remained employed on the last day of the fiscal year were eligible for the matching contribution. Our contributions to the 401(k) plan were $407,000, $460,000, and $453,000 for the years ended December 31, 2011, 2010, and 2009, respectively.

13. Quarterly Financial Data (unaudited)

The following tables summarize the unaudited quarterly financial data for the last two fiscal years (in thousands, except per share data):

	2011 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Collaboration revenue	$ 16,679	$ 14,146	$ 13,204	$ 3,674
Total revenue	16,683	14,151	13,209	3,677
Loss from operations	(9,632)	(12,531)	(9,826)	(29,417)
Net loss	(9,591)	(12,519)	(9,816)	(29,441)
Basic and diluted net loss per common share	$ (0.36)	$ (0.35)	$ (0.28)	$ (0.82)
Weighted-average number of common shares used in computing basic and diluted net loss per common share calculations	26,354	35,388	35,578	35,704

During the year ended December 31, 2011, we continued to work with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. During the year, we received notification from both of our major CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trials which resulted in a $1.8 million reversal of our clinical trial accrual in the third and fourth quarter of 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate

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AFFYMAX, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

13. Quarterly Financial Data (unaudited) (Continued)

change in estimate during the period decreased R&D expense by $2.5 million for the year ended December 31, 2011.

	2010 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Collaboration revenue	$ 34,646	$ 54,341	$ 16,784	$ 6,732
Total revenue	34,650	54,346	16,790	6,735
Income (loss) from operations	(7,862)	17,265	(12,109)	(11,742)
Net income (loss)	(7,866)	17,312	(12,030)	(11,491)
Basic net income (loss) per common share	$ (0.33)	$ 0.71	$ (0.49)	$ (0.45)
Diluted net income (loss) per common share	$ (0.33)	$ 0.70	$ (0.49)	$ (0.45)
Weighted-average number of common shares used in computing basic and diluted net income (loss) per common share				
Basic	23,932	24,219	24,369	25,274
Diluted	23,932	24,736	24,369	25,274

As a result of finalizing amendments for clinical trial activities completed in 2009, our fourth quarter of 2010 includes adjustments relating to estimates previously recorded in our expenses for the years ended December 31, 2008 and 2009. The adjustments decreased clinical trial expense by $12.1 million. As this change in estimate was comprised of development costs charged to Takeda at a 70% reimbursement rate, this amount was a payable due back to Takeda. The reimbursement received from Takeda in prior periods was recorded as deferred revenue and collaboration revenue under our CAPM revenue recognition model. This change in estimate resulted in a reduction of $8.4 million of deferred revenue and a reversal of $7.8 million of collaboration revenue. The net impact to our statement of operations for this change in estimate was a $4.3 million decrease to our net loss or $0.18 per share for the year ended December 31, 2010.

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Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as defined in the Rules 13(a)-15(e) of the Securities Exchange Act of 1934, as amended or the Exchange Act. Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2011, our disclosure controls and procedures were effective at the reasonable assurance level.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our procedures or our internal controls will prevent or detect all error and all fraud. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Management determined that, as of December 31, 2011, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission or COSO in Internal Control Integrated Framework. Our management has concluded that, as of December 31, 2011, our internal control over financial reporting was effective based on these criteria.

Ernst & Young LLP, an independent registered public accounting firm, has audited out financial statements included herein and has issued and audit report on the effectiveness of our internal control over financial reporting, which report is included below.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Affymax, Inc.

We have audited Affymax Inc.'s 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). Affymax's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed 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, Affymax Inc. 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 2011 financial statement of Affymax, Inc. and our report dated March 14, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, CA
March 14, 2012

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Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

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PART III.

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we intend to file our definitive proxy statement for our 2011 annual meeting of stockholders, pursuant to Regulation 14A of the Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item with respect to our executive officers may be found under the section, "Executive Officers and Key Employees" appearing in our proxy statement for our 2012 annual meeting of stockholders and is incorporated herein by reference. The information required by this item relating to our directors and nominees, including information with respect to audit committee financial experts, may be found under the section entitled "Proposal 1 Election of Directors" appearing in the proxy statement for our 2012 annual meeting of stockholders and is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Exchange Act may be found under the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in our proxy statement for our 2012 annual meeting of stockholders and is incorporated herein by reference.

In 2006, we adopted a code of ethics that applies to our employees, officers and directors and incorporates guidelines designed to deter wrongdoing and to promote the honest and ethical conduct and compliance with applicable laws and regulations. In addition, the code of ethics incorporates our guidelines pertaining to topics such as conflicts of interest and workplace behavior. We have posted the text of our code of ethics on our website at www.affymax.com in connection with "Investor Relations/Corporate Governance" materials. In addition, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

The information required by this item concerning director and executive compensation is included in our proxy statement for our 2012 annual meeting of stockholders under the section entitled "Executive Compensation" and is incorporated herein by reference. The information required by this item concerning Compensation Committee interlocks and insider participation is included in our proxy statement for our 2012 annual meeting of stockholders under the section entitled "Compensation Committee Interlocks and Insider Participation" and is incorporated herein by reference. The information required by this item concerning our Compensation Committee's review and discussion of our Compensation Discussion and Analysis is included in our proxy statement for our 2012 annual meeting of stockholders under the section entitled "Compensation Committee Report" and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item with respect to securities authorized for issuance under our equity compensation plans is included in our proxy statement for our 2012 annual meeting of stockholders under the section entitled "Securities Authorized for Issuance under Equity Compensation Plans" and is incorporated herein by reference. The information required by this item relating to

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security ownership of certain beneficial owners and management is included in our proxy statement for our 2012 annual meeting of stockholders under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this item is incorporated herein by reference to the information included in our proxy statement for our 2012 annual meeting of stockholders under the sections entitled "Information Regarding The Board of Directors and Corporate Governance" and "Transactions With Related Persons."

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated herein by reference to the information included in our proxy statement for our 2012 annual meeting of stockholders under the section entitled "Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV.

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements (included in Part II of this report):

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

Balance Sheets

Statements of Operations

Statements of Stockholders' Equity

Statements of Cash Flows

Notes to Financial Statements

(2) Financial Statement Schedules

All other financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

The following exhibits are included herein or incorporated herein by reference:

3.3 Amended and Restated Certificate of Incorporation(1)

3.5 Amended and Restated Bylaws(2)

4.1 Reference is made to exhibits 3.3 and 3.5

4.2	Specimen Common Stock Certificate(1)
4.4	Amended and Restated Investor Rights Agreement, dated September 7, 2006, by and between the Registrant and certain of its stockholders(3)
4.5	Form of Warrant to Purchase shares of Common Stock(4)
10.1+	Form of Indemnity Agreement for Directors and Executive Officers(3)
10.2+	2001 Stock Option/Stock Issuance Plan(1)

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10.3+	Form of Notice of Grant of Stock Option, Form of Stock Option Agreement and Form of Stock Purchase Agreement under 2001 Stock Option/Stock Issuance Plan(5)
10.4+	Form of Stock Issuance Agreement under 2001 Stock Option/Stock Issuance Agreement(5)
10.5+	Amended and Restated 2006 Equity Incentive Plan, as amended March 2, 2011(6)
10.6+	Form of Option Grant Notice and Form of Option Agreement under 2006 Equity Incentive Plan(5)
10.7+	2006 Employee Stock Purchase Plan(5)
10.8+	Form of Offering Document under 2006 Employee Stock Purchase Plan(7)
10.9+	Form of Restricted Stock Unit Notice and Form of Restricted Stock Unit under 2006 Equity Incentive Plan(8)
10.10+	Employment Agreement, dated December 17, 2008, by and between the Registrant and Arlene M. Morris(9)
10.11+	Executive Employment Agreement, dated December 17, 2008, by and between the Registrant and Paul B. Cleveland(9)
10.13+	Summary of Non-Employee Director Compensation Program(9)
10.14	Research and Development/Office Lease, dated May 30, 1990, by and between Miranda Associates and Affymax Research Institute(5)
10.15	First Amendment to Lease, dated November 16, 1999, by and between Spieker Properties, L.P., successor in interest to Miranda Associates, and Affymax Research Institute(5)
10.16	Second Amendment to Lease, dated December 20, 1999, by and between Spieker Properties, L.P. and Affymax Research Institute(5)
10.17	Third Amendment, dated December 31, 2001, by and between EOP-Foothill Research Center, L.L.C., successor by merger to Spieker Properties L.P., and the Registrant(5)
10.18*	EPO Receptor License Agreement, dated September 5, 1996, by and between the Registrant and Genetics Institute, Inc.(7)
10.19*	License Agreement, dated July 27, 2001, by and between the Registrant, Glaxo Group Limited, SmithKline Beecham Corporation, Affymax N.V., Affymax Research Institute and Affymax Technologies N.V.(10)
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10.21*	Collaboration and License Agreement, dated February 13, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(12)
10.22*	Collaboration and License Agreement, dated June 27, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(13)
10.23	Research and Development Agreement, dated April 2, 1992, by and between the Registrant and The R.W. Johnson Pharmaceutical Research Institute(14)
10.24	Sublease Agreement, dated September 1, 2006, by and between the Registrant and TIBCO Software Inc.(15)

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10.25	First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between Registrant and Takeda Pharmaceutical Company Limited(16)
10.26	Fourth Amendment to Lease, dated November 30, 2006, by and between Registrant and CA-Foothill Research Center L.P.(17)
10.27	Second Amendment to Collaboration and License Agreements between Registrant and Takeda Pharmaceutical Company Limited effective January 1, 2008(18)
10.28	Securities Purchase Agreement to purchase shares of Common Stock dated February 13, 2009 by and among Registrant and the purchasers identified on the signature pages thereto(19)
10.29	Securities Purchase Agreement to purchase shares of Common Stock and Warrants to purchase shares of Common Stock dated February 13, 2009 by and among Registrant and the purchasers identified on the signature pages thereto(20)
10.30+	Executive Employment Agreement, dated December 17, 2008 by and between the Registrant and Anne-Marie Duliege(21)
10.31+	Executive Employment Agreement, dated December 17, 2008 by and between the Registrant and Robert Venteicher(22)
10.32	Common Stock Purchase Agreement, dated September 25, 2009 by and between the Registrant and Azimuth Opportunity Ltd.(23)
10.33	Form of Credit Line and related documentation effective as of December 8, 2009 by and between the Registrant and UBS Financial Services, Inc.(24)
10.34+	Executive Employment Agreement, dated February 19, 2010, by and between the Registrant and John A. Orwin.(25)
10.35	Fifth Amendment, dated May 20, 2010, by and between the Registrant and EOP-Foothill Research Center, L.L.C.(26)
10.36	Amendment No. 1 to Common Stock Purchase Agreement, dated September 17, 2010, between the Registrant and Azimuth Opportunity Ltd.(27)
10.37+	Amendment to Employment Agreement between the Registrant and Arlene M. Morris effective as of September 23, 2010.(28)
10.38+	Amendment to Employment Agreement between the Registrant and John A. Orwin effective as of September 23, 2010.(28)
10.39+	Amendment to Employment Agreement between the Registrant and Paul B. Cleveland effective as of September 23, 2010.(28)
10.40+	Amendment to Employment Agreement between the Registrant and Anne-Marie Duliege effective as of September 23, 2010.(28)
10.41+	Amendment to Employment Agreement between the Registrant and Robert F. Venteicher effective as of September 23, 2010.(28)
10.42+	Amended and Restated Executive Employment Agreement, dated February 1, 2011, by and between the Registrant and John A. Orwin.(29)
10.43+	Executive Employment Agreement, dated March 4, 2011, by and between the Registrant and Herb Cross.(30)

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10.44	Sixth Amendment to Lease, dated December 21, 2010 by and between Registrant and CA-Foothill Research Center L.P.(31)
10.45+	Separation Agreement, dated January 5, 2011, by and between the Registrant and Arlene M. Morris.(32)
10.46	Amendment No. 2 to Common Stock Purchase Agreement, dated as of May 2, 2011 by and between the Registrant and Azimuth Opportunity Ltd.(33)
10.47	Settlement and License Agreement, dated as of November 7, 2011, by and between the Registrant and Janssen Biotech, Inc.
10.48	Third Amendment to Collaboration and License Agreements, effective as of November 7, 2011, by and between the Registrant and Takeda Pharmaceutical Company Limited
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney. Reference is made to the signature page
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)
101.INS#	XBRL Instance
101.SCH#	XBRL Taxonomy Extension Schema
101.CAL#	XBRL Taxonomy Extension Calculation
101.LAB#	XBRL Taxonomy Extension Labels
101.PRE#	XBRL Taxonomy Extension Presentation
101.DEF#	XBRL Taxonomy Extension Definition

(1) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on November 30, 2006.

(2) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on September 10, 2007.

(3) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on October 2, 2006.

(4) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(5) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(6) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on May 9, 2011.

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(7) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

(8) Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission.

(9) Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

(10) Incorporated by reference to Exhibit 10.21 of our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(11) Incorporated by reference to Exhibit 10.23 of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

(12) Incorporated by reference to Exhibit 10.24 in our Form 10-Q, as filed with the Securities and Exchange Commission on August 4, 2009.

(13) Incorporated by reference to Exhibit 10.25 in our Form 10-Q, as filed with the Securities and Exchange Commission on August 4, 2009.

(14) Incorporated by reference to Exhibit 10.34 of our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(15) Incorporated by reference to Exhibit 10.32 of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on November 30, 2006.

(16) Incorporated by reference to Exhibit 10.28 in our Form 10-Q for the quarter ended June 30, 2009 as filed with the Securities and Exchange Commission.

(17) Incorporated by reference to Exhibit 10.35 in our Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission.

(18) Incorporated by reference to Exhibit 10.30 in our Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission.

(19) Incorporated by reference toExhibit 10.31in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(20) Incorporated by reference toExhibit 10.32 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(21) Incorporated by reference to Exhibit 10.33 in our Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

(22)

Incorporated by reference to Exhibit 10.34 in our Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

(23)

Incorporated by reference to Exhibit 10.35 in our Form 8-K as filed with the Securities and Exchange Commission on September 25, 2009.

(24)

Incorporated by reference to the indicated exhibit in our Form 10-K, as filed with the Securities and Exchange Commission on March 4, 2010.

(25)

Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on May 6, 2010.

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(26) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on August 5, 2010.

(27) Incorporated by reference to the indicated exhibit in our Form 8-K, as filed with the Securities and Exchange Commission on September 20, 2010.

(28) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on November 5, 2010.

(29) Incorporated by reference to Exhibit 10.41 in our Form 10-Q, as filed with the Securities and Exchange Commission on May 9, 2011.

(30) Incorporated by reference to Exhibit 10.42 in our Form 10-K, as filed with the Securities and Exchange Commission on March 11, 2011.

(31) Incorporated by reference to Exhibit 10.43 in our Form 10-K, as filed with the Securities and Exchange Commission on March 11, 2011.

(32) Incorporated by reference to Exhibit 10.44 in our Form 10-Q, as filed with the Securities and Exchange Commission on May 9, 2011.

(33) Incorporated by reference to Exhibit 10.45 in our Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2011.

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

The certification attached as Exhibit 32.1 accompany this Annual Report on Form 10-K, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Affymax, Inc., under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AFFYMAX, INC.

By: /s/ JOHN A.ORWIN

John A. Orwin
Chief Executive Officer and
Member of the Board of Directors

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John Orwin and Herb Cross, and each of them, as his true and lawful attorneys-in-fact and agents, each with the full power of substitution for him, and in his name and in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents, and any of them or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ JOHN A. ORWIN John Orwin	Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	March 14, 2012
/s/ HERB CROSS Herb Cross	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2012
/s/ HOLLINGS C. RENTON Hollings C. Renton	Member of the Board of Directors	March 14, 2012
/s/ KATHLEEN LAPORTE Kathleen LaPorte	Member of the Board of Directors	March 14, 2012

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Signature	Title	Date
/s/ KEITH R. LEONARD Keith R. Leonard	Member of the Board of Directors	March 14, 2012
/s/ TED W. LOVE Ted W. Love	Member of the Board of Directors	March 14, 2012
/s/ DANIEL K. SPIEGELMAN Daniel K. Spiegelman	Member of the Board of Directors	March 14, 2012
Christi van Heek	Member of the Board of Directors	March 14, 2012
/s/ JOHN P. WALKER John P. Walker	Member of the Board of Directors	March 14, 2012

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101.LAB#	XBRL Taxonomy Extension Labels
101.PRE#	XBRL Taxonomy Extension Presentation
101.DEF#	XBRL Taxonomy Extension Definition

(1) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on November 30, 2006.

(2) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on September 10, 2007.

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(3) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on October 2, 2006.

(4) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(5) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(6) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on May 9, 2011.

(7) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

(8) Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission.

(9) Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

(10) Incorporated by reference to Exhibit 10.21 of our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(11) Incorporated by reference to Exhibit 10.23 of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

(12) Incorporated by reference to Exhibit 10.24 in our Form 10-Q, as filed with the Securities and Exchange Commission on August 4, 2009.

(13) Incorporated by reference to Exhibit 10.25 in our Form 10-Q, as filed with the Securities and Exchange Commission on August 4, 2009.

(14) Incorporated by reference to Exhibit 10.34 of our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(15) Incorporated by reference to Exhibit 10.32 of our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on November 30, 2006.

(16) Incorporated by reference to Exhibit 10.28 in our Form 10-Q for the quarter ended June 30, 2009 as filed with the Securities and Exchange Commission.

(17) Incorporated by reference to Exhibit 10.35 in our Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission.

(18)

Incorporated by reference to Exhibit 10.30 in our Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission.

(19)

Incorporated by reference toExhibit 10.31in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(20)

Incorporated by reference toExhibit 10.32 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(21)

Incorporated by reference to Exhibit 10.33 in our Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

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(22) Incorporated by reference to Exhibit 10.34 in our Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

(23) Incorporated by reference to Exhibit 10.35 in our Form 8-K as filed with the Securities and Exchange Commission on September 25, 2009.

(24) Incorporated by reference to the indicated exhibit in our Form 10-K, as filed with the Securities and Exchange Commission on March 4, 2010.

(25) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on May 6, 2010.

(26) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on August 5, 2010.

(27) Incorporated by reference to the indicated exhibit in our Form 8-K, as filed with the Securities and Exchange Commission on September 20, 2010.

(28) Incorporated by reference to the indicated exhibit in our Form 10-Q, as filed with the Securities and Exchange Commission on November 5, 2010.

(29) Incorporated by reference to Exhibit 10.41 in our Form 10-Q, as filed with the Securities and Exchange Commission on May 9, 2011.

(30) Incorporated by reference to Exhibit 10.42 in our Form 10-K, as filed with the Securities and Exchange Commission on March 11, 2011.

(31) Incorporated by reference to Exhibit 10.43 in our Form 10-K, as filed with the Securities and Exchange Commission on March 11, 2011.

(32) Incorporated by reference to Exhibit 10.44 in our Form 10-Q, as filed with the Securities and Exchange Commission on May 9, 2011.

(33) Incorporated by reference to Exhibit 10.45 in our Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2011.

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

The certification attached as Exhibit 32.1 accompany this Annual Report on Form 10-K, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Affymax, Inc., under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

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In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.