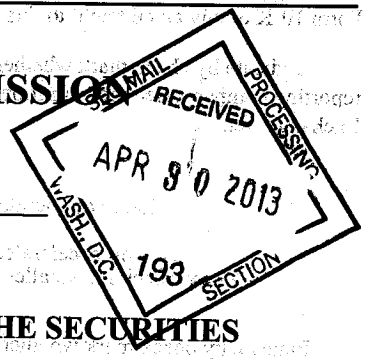
13002358

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




# FORM 10-K

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

**For the fiscal year ended December 31, 2012**

**or**

☐ **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 |

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

**None**

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

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

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

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

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

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

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

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

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, 2012 was $463,771,551 (based upon the closing sales price of such stock as reported on the Nasdaq Global Select Market on such date). Excludes an aggregate of 139,248 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, 2012, the registrant has assumed that a stockholder was an affiliate of the registrant at June 30, 2012 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, 2012. 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 28, 2013, 37,400,135 shares of the registrant's common stock, $0.001 par value, were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the Proxy Statement for the 2013 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, 2012, 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.

**AFFYMAX, INC**
**TABLE OF CONTENTS**

(This page has been left blank intentionally.)

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 our ability to continue our business, operations, and investigation following the recall of OMONTYS, the continuation and success of our collaboration with Takeda Pharmaceutical Company Limited, and the timing, design and results of our clinical trials and drug development program. 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." 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 discovering, developing and delivering innovative therapies that improve the lives of patients with kidney disease and other serious and often life-threatening illnesses. In March 2012, the U.S. Food and Drug Administration, or FDA, approved our first product, OMONTYS® (peginesatide) Injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. OMONTYS is a synthetic, peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Our product is the only once-monthly ESA that has been available to the adult dialysis patient population in the U.S. In 2012, we co-commercialized OMONTYS in the U.S. with our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, the largest pharmaceutical company in Japan.

In February 2013 and in consultation with the FDA, we and Takeda voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS. While we continue to investigate the potential cause of the safety concerns at this time, we face significant challenges to our business. We are unable to estimate the scope or timelines associated with the investigation, which may be costly and time-consuming, and with our limited funds and resources, we may not be able to complete the investigation or ever identify the causes of the safety concerns.

In March 2013, we undertook plans to reorganize our operations in order to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. In addition to transitioning many of the ongoing activities to our collaborator, Takeda, our plans include a significant reduction in force of approximately 230 employees (75% of our workforce), including our commercial and medical affairs field forces as well as other employees throughout the organization. We expect to incur between $8.0 million and $10.0 million in restructuring charges related to the workforce reduction during the first quarter of 2013. As a result of this restructuring and the recall, we may also incur additional charges depending on further review and additional reductions in operations and may also experience impairment changes with respect to our property and equipment and long lived assets in the first quarter of 2013.

We will continue to review our operations as we discuss with Takeda the roles and responsibilities of the parties in addressing our regulatory and other obligations resulting from the OMONTYS recall. In any event, we plan to continue to make efforts to substantially reduce our operating costs, which will likely include further reductions in force as we endeavor to conserve our cash resources. We have been in discussions with, and are planning to seek further assistance and support from Takeda as we transition from a commercial operating company to a company potentially without any product. We are undertaking steps to reduce all of our outstanding obligations to third parties and are dependent on those efforts to continue

operations even in the near term, however, we may not be successful. We are particularly dependent on Takeda's willingness to continue the collaboration in a modified form that reduces our operating expenses and responsibilities under the collaboration, but we may also be required to reduce our share of OMONTYS profits if and when the product may be re-introduced in the future. Even if Takeda is willing to assume additional responsibilities under the collaboration, including the conduct of most or all of the ongoing investigation, the loss of critical personnel and functions means that we may not be able to maintain our operations, support the New Drug Application or NDA, continue as a going concern or ever re-introduce OMONTYS.

In view of our limited resources and funds, we plan to explore various strategic alternatives, including a sale of the company or its assets or a corporate merger. We are considering all possible alternatives, including further restructuring activities, wind-down of operations or even bankruptcy proceedings.

If we and Takeda are unable to rapidly identify and rectify the causes of the safety concerns to the satisfaction of the FDA, which is highly uncertain, OMONTYS may be permanently withdrawn from the market. The recall of OMONTYS has severely harmed our business, financial condition and prospects as a going concern. The recall has also limited our access to funds and the resources that may be required in order to address the safety concerns. As a result, we may be unable to continue our operations. In order to reintroduce OMONTYS, we would have to complete our ongoing thorough investigation, identify the causes of the safety concerns and provide a suitable plan to the FDA for approval. Accordingly, there can be no assurance that we can address the safety concerns and meet the requirements of the FDA for reintroduction. Moreover, even if OMONTYS could be reintroduced, the commercial prospects for this product may be permanently diminished and the product may no longer be commercially viable.

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 registrations or pending applications for the trademarks "Affymax", "Affymax and logo," "OMONTYS," and "OMONTYS and logo" in the U.S. and select foreign countries.

**Our Product: OMONTYS**

In March 2012, the FDA approved our first product, OMONTYS, for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. Although the regulatory approval has not been permanently withdrawn, in February 2013, the product has been recalled nationwide and all promotion and marketing activities have been suspended.

***Anemia Background***

Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. 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 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%. Anemia 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, ESAs are used to treat chemotherapy-induced anemia in cancer patients and to treat anemia due to chronic kidney disease in patients on dialysis and not on dialysis.

***Anemia and Chronic Kidney Disease***

One of the most common forms of chronic anemia occurs in patients with chronic kidney failure. According to the Center for Disease Control, chronic kidney failure affects over 20 million adults in the U.S. 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. According to U.S. Renal Data System, there were approximately 415,000 end-stage renal disease patients on dialysis in the U.S. in 2010.

***Anemia Therapy and Limitations***

Prior to the introduction of OMONTYS, all ESAs were recombinant EPO, or rEPO. 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.

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, one to three times per week or up to every two weeks, to obtain a sustained correction of anemia in chronic kidney disease patients on dialysis.

***OMONTYS Profile***

*Less Frequent Dosing.* OMONTYS is a synthetic peptide-based ESA designed for less frequent dosing compared to other ESAs available to treat dialysis patients in the U.S. 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, OMONTYS requires less frequent dosing than other ESAs in the U.S. for dialysis patients. OMONTYS is designed to be dosed once every four weeks, compared to recombinant products sold in the U.S. that are predominately dosed either one to three times per week or up to every two weeks in the dialysis setting.

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

*Room Temperature Storage.* Based on the product label, OMONTYS can be stored at room temperature in the hands of the health care providers for limited durations after refrigerated distribution. Other ESAs in the U.S. require cold storage conditions throughout the distribution and storage process until administration to patients.

***OMONTYS Voluntary Recall***

In February 2013 and in consultation with the FDA, we and Takeda voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS.

We and Takeda are actively investigating these events. If we are able to identify and address the underlying cause, which is highly uncertain, we will work with Takeda and the FDA to determine the appropriate next steps and direction for the product. During this period, we have undertaken efforts to suspend or terminate our existing third party arrangements relating to the manufacture and commercialization of OMONTYS, and depending on the timing and results of the investigation, we may not be able to reintroduce OMONTYS in a timely manner, if at all.

**Manufacturing and Supply**

In 2012, final OMONTYS drug product was manufactured as a buffered aqueous solution for intravenous or subcutaneous administration. Under our collaboration with Takeda, we are responsible, through our contract manufacturing organizations, or CMOs, for the manufacture and supply of all quantities of OMONTYS active pharmaceutical ingredient, or API, to be used in development and commercialization worldwide, and Takeda is responsible for final drug product manufacture and control. We have established long-term commercial supply agreements with two CMOs for OMONTYS API.

The two CMOs are responsible for procurement of raw materials needed for manufacturing the product, with the exception of bulk poly (ethylene) glycol reagent, or PEG. We have a license, manufacturing and supply agreement with Nektar Therapeutics AL Corporation, or Nektar, who we engaged to manufacture and supply the requirements of PEG.

In connection with the recall and in consultation with Takeda, we have undertaken efforts to suspend or terminate manufacturing activities to the extent practicable pending consideration of next steps with OMONTYS. If we are successful in identifying the cause of the recent safety concerns and addressing them successfully, we and Takeda will determine the appropriate next steps to take with OMONTYS. Prior to such time, we are undertaking strategies to decrease our ongoing manufacturing costs and commitments, including but not limited to, termination of orders and agreements, which may lead to disputes or in any event, negatively impact our ability to reintroduce OMONTYS. If we are able to reintroduce OMONTYS, we intend to continue to rely on third-party manufacturers to produce API, which may require significant effort and validation of new CMOs.

Takeda is responsible for supply chain and distribution management. Specifically, Takeda has sole responsibility for order processing, handling all returns, and manufacturing and distribution of finished goods inventory with regard to sales of OMONTYS. We are unable to predict and do not have control over the decisions of Takeda on these activities resulting from the recall of OMONTYS.

**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. Our issued U.S. patent(s) covering OMONTYS and any U.S. patent(s) that may issue based on pending patent applications containing claims covering OMONTYS including issued claims relating to composition of matter begin expiring no earlier than 2024. We own several pending U.S. patent applications, all of which relate to our core peptide technologies or to particular peptide compounds. 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 OMONTYS 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 |
| 8,106,154 | Nitrogen-Based Linkers for Attaching Modifying Groups to Polypeptides and Other Molecules | 10/5/2029 |
| 8,304,391 | Peptides that Bind to the Erythropoietin Receptor | 5/12/2024 |
| 8,324,159 | Erythropoietin Receptor Peptide Formulations and Uses | 6/26/2026 |

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 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 2015 to 2026.

As a result of uncertainty surrounding OMONTYS and our prospects, we plan to evaluate strategies to decrease our ongoing patent prosecution and maintenance costs, which may result in the abandonment or transfer of any or all of the above patents or applications.

In November 2011, we entered into a settlement and license agreement with Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies under which we obtained a non-exclusive license to the intellectual property in dispute. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations elsewhere in this Annual Report on Form 10-K for more information.

***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 products, product candidates and/or proprietary technologies infringe their intellectual property rights. If one of these patents was found to cover our products, product candidates, proprietary technologies or their uses, we or our collaborators could be required to pay damages and could be restricted from commercializing our products, 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 might 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, litigation expenses, substantial damages, attorney fees, injunction, royalty payments, cross-licensing of our patents, redesign of our products or processes and related fees and costs.

**Research and Development Expenses**

We have made substantial investments in research and development, or R&D. We have conducted clinical trial activities using both our internal staff and third-party contract clinical trial service providers. Except in connection with the recall, we plan to suspend further investment in R&D, including suspending conduct of clinical trials pending consideration of next steps with OMONTYS.

Prior to approval of OMONTYS for commercial sale in March 2012 by the FDA, we had expensed all costs associated with the production of API as R&D expense. R&D expenses were $51.7 million, $76.3 million, and $93.6 million, for the years ended December 31, 2012, 2011, and 2010, respectively.

**Business Relationships**

***Our Collaboration with Takeda***

We entered into a collaboration to develop and commercialize OMONTYS with Takeda pursuant to an agreement in February 2006 and an agreement in June 2006. The February 2006 agreement and the June 2006 agreement are collectively referred to herein as the Arrangement. Under the Arrangement, we and Takeda will co-develop and co-commercialize OMONTYS in the U.S., and Takeda received an exclusive license to develop and commercialize OMONTYS outside of the U.S. Takeda has primary responsibility and bears all costs for OMONTYS clinical development in support of regulatory approval for all territories outside the U.S. and is required to pay us a variable royalty based on annual net sales of OMONTYS outside the U.S.

Revenues in 2012, 2011 and 2010 were derived almost exclusively from collaboration revenue from Takeda. From our inception through December 31, 2012, we have received an aggregate of $534.5 million from Takeda consisting of $122.0 in upfront license fees, $115.3 million in milestone payments and $297.2 million related to profit equalization payments for our share of product profit or loss, the reimbursement of development and commercialization expenses and the purchase of API. We are eligible to receive an aggregate of $357.0 million in additional milestone payments from Takeda upon successful achievement of as yet unmet clinical development and regulatory milestones and sales-based milestones under our Arrangement.

In November 2011, we and Takeda entered into a Commercial API Supply Agreement to formalize our respective responsibilities as they relate to the manufacture and supply of OMONTYS. Under the terms of the agreement, we are responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda is responsible for the fill and finish steps in the manufacture of OMONTYS worldwide.

Finally, in February 2012, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize the terms and conditions relating to our joint U.S. commercialization activities for OMONTYS, including corporate governance structure and division of roles and responsibilities. Under the Co-Promotion Agreement, we deploy the sales and medical affairs field force but share marketing, account management and payor reimbursement related activities with Takeda. We and Takeda split profits or losses 50/50 in the U.S. To implement our profit equalization arrangement, 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. 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.

In connection with the recall and in consultation with Takeda, as appropriate, we plan to evaluate the near-term activities, our respective rights and obligations of the parties under the agreements. including the deployment of resources as part of our efforts to decrease our ongoing costs and commitments, which may negatively impact our ability to reintroduce OMONTYS, if such opportunity arises. We are particularly dependent on Takeda's willingness to continue the collaboration in a modified form that reduces our operating expenses and responsibilities under the collaboration, and we may also be required to reduce our share of OMONTYS profits if and when the product may be reintroduced in the future.

***Our License, Manufacturing and Supply Agreement with Nektar***

In April 2004, we entered into a License, Manufacturing and Supply Agreement with 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 OMONTYS. 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 OMONTYS, which began with the launch of the product in the U.S. in 2012. We also agreed to pay base milestones plus possible additional milestones in connection

with our partnering activities relating to OMONTYS, all of which have been paid. As of December 31, 2012, our remaining milestone obligation is triggered upon acquisition or merger activities.

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**

In 2012, we co-commercialized OMONTYS under our Arrangement with Takeda. The commercial launch of the product occurred in April 2012. We established commercial and medical affairs infrastructures in 2012. The functions of our commercial and medical affairs infrastructures included marketing and sales, medical education, coverage and reimbursement and account management. We marketed our product primarily to dialysis organizations. Associated costs are included in selling, general and administrative, or SG&A, costs in our accompanying financial statements. On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS and we suspended all the promotional activities and marketing of OMONTYS.

Before the voluntary recall of OMONTYS, Takeda was responsible for account management, pricing and contracting. Specifically, Takeda had sole responsibility for invoicing and collection of receivables with regard to sales of OMONTYS. Under our Arrangement with Takeda, Takeda also has the rights and responsibility for establishing and modifying terms and conditions with customers with respect to the sale of OMONTYS in the U.S., including pricing discounts available to third-party payors, price adjustments and other allowable discounts and allowances. Both parties also have shared responsibilities such as joint marketing activities, business analytics and account management allocated by customer segments.

Before the voluntary recall of OMONTYS, Takeda sold primarily to pharmaceutical wholesale distributors in the U.S. and Puerto Rico as the principal means of distributing OMONTYS to healthcare providers, which are primarily large dialysis organizations and to a lesser extent medium and small dialysis organizations. As all product has been recalled and we are undertaking measures including a significant reduction of force involving the commercial and medical affairs resources and field forces, which may negatively impact our ability to reintroduce OMONTYS even if we are able to successfully identify and address the cause of patients' hypersensitivity in the near term, which is highly uncertain.

**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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

If OMONTYS is able to be reintroduced, competing drugs include EPOGEN and potentially Aranesp, which are both marketed by Amgen, Inc., or 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. market, we believe it will be in direct competition with OMONTYS, if we are able to reintroduce the product, because of Mircera's ability to be long-acting; therefore, it could potentially limit the market for OMONTYS.

The introduction of biosimilars into the rEPO market in the U.S. will constitute additional competition for OMONTYS if we are able to reintroduce the product. A biosimilar product is a subsequent version of an existing, branded 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 rEPO, expired in 2004 in the E.U., and the remaining patents expired in 2012 through 2015 in the U.S. Several biosimilar versions of rEPO are available for sale in the E.U. and biosimilar versions of rEPO are currently being studied in clinical trials in the U.S. For example, in January 2012, Hospira, Inc. announced the beginning of its Phase 3 clinical program for its biosimilar with results anticipated in 2013, and in October 2012, Sandoz announced the beginning of its Phase 3 clinical program for its biosimilar with results anticipated in 2014. Upon entry into the U.S. market, biosimilars will

compete with OMONTYS, when and if we reintroduce the product, and will drive down its price and sales volume, which would adversely affect our revenues.

We may also face competition from potential new anemia therapies if and when we reintroduce OMONTYS. There are several product candidates in various stages of active development for anemia indications by potential competitors that may promote the production of naturally-occurring EPO in patients, and some of these product candidates may enter the market as early as 2015. If these product candidates enter the market they may be in direct competition with OMONTYS if and when it is reintroduced. In addition, certain companies are developing potential new therapies for renal-related diseases that could reduce ESA utilization and thus limit the market for OMONTYS if and when it is reintroduced.

If and when we are able to reintroduce OMONTYS, which is highly uncertain, it will be even more challenging for us to compete in view of the recall and related safety concerns particularly due to the long-term experience with currently marketed products and negative perceptions of OMONTYS' safety. These factors present further challenges to compete and enter into long-term supply agreements with the major operators of dialysis clinics in the U.S. In particular, we may not be able to reach a long-term agreement with either of the largest operators of dialysis clinics in the U.S., DaVita Inc., or DaVita, and Fresenius, because both entered into a long-term supply agreement with Amgen that began in January 2012. In July 2012, Fresenius entered into a short-term supply agreement with Takeda Pharmaceuticals America, Inc., or TPA. In February 2013, Fresenius communicated that it decided to pause further expansion of its OMONTYS pilot program.

Even if we are able to successfully address safety issues for OMONTYS with the FDA, we believe it may be more challenging to continue with or expand upon the short-term supply agreement with Fresenius in the near term. In any event, Amgen's long-term supply agreements with DaVita and Fresenius and the potential introduction of Mircera and biosimilars may limit the market opportunity for OMONTYS and adversely impact our ability to generate product sales should we reintroduce the product.

**Government Regulation and Product Approvals**

***FDA and EMA***

OMONTYS is subject to regulation by various authorities in the U.S., the E.U. and other countries, including the FDA in the U.S. and the European Medicines Agency, or EMA, in the E.U. 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, 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 concerns. 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 Marketing Authorization Application, or MAA. In February 2012, Takeda submitted a MAA that was accepted by the EMA. However, in light of the recent OMONTYS recall for safety concerns, there can be no assurance that this application will be approved by the EMA.

***U.S. Approval Process***

OMONTYS is regulated by the FDA as a drug. In the U.S., 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 a NDA generally include:

- preclinical laboratory tests and animal tests conducted in compliance with FDA's good laboratory practice requirements;
- development, manufacture and testing of API and dosage forms suitable for human use in compliance with current good manufacturing practices, or 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.

***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. Approval by the FDA does not ensure approval by the EMA and the recent OMONTYS recall for safety concerns makes approval by the EMA more challenging in the near term.

***Federal and State Healthcare Laws***

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 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.

**Coverage and Reimbursement**

The Centers for Medicare and Medicaid Services, or CMS, the government agency that manages Medicare and is responsible for coverage of OMONTYS for Medicare beneficiaries, has significantly restricted coverage of ESAs in response to the FDA's boxed warning, ESA class labeling changes, and public health advisories. As the costs of the Medicare program continue to grow, CMS may also be compelled to make difficult decisions regarding the trade-offs of certain public health expenditures over others.

Further, prior to January 1, 2011, CMS reimbursed healthcare providers for use of ESAs at average selling price plus 6%. However, under the 2008 Medicare Legislation a new bundled payment system commenced in January 2011 for facilities that furnish renal dialysis services to Medicare beneficiaries with end-stage renal disease. Under the new bundled payment system, providers are reimbursed a fixed amount per patient, including for ESAs such as OMONTYS. In January 2013, Congress enacted legislation to reduce the overall bundled payment to dialysis providers beginning in January 2014. This new capitated reimbursement payment methodology has created incentives for significantly lower utilization or dosing of ESAs, including OMONTYS, and has reduced the commercial potential for the product.

Finally, as a result of CMS coverage and reimbursement changes, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. Third-party payors have begun to follow CMS' restrictive 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 ESAs, which in turn will put pressure on the pricing and utilization of the product. When and if we reintroduce OMONTYS, and coverage and reimbursement are available, which is uncertain, we expect to experience pricing pressures in connection with the sale of OMONTYS due to the trend toward managed health care and the adoption of government coverage and reimbursement policies.

**Employees**

As of December 31, 2012, we had 304 employees. We had 71 employees engaged in research and development, and the remainder of our employees were engaged in other SG&A functions or medical affairs. We have undertaken measures to reduce our workforce by approximately 230 employees and anticipate that further reductions may be in order as we endeavor to conserve our cash resources.

**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 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 have recently recalled OMONTYS nationwide due to safety concerns and OMONTYS may not be reintroduced to the market unless we are able to rapidly identify and successfully address the causes of the safety concerns with the FDA. OMONTYS is our only product and the recall has severely harmed our business. We face significant challenges to our business. We may have to abandon or relinquish some or all of our product rights. Accordingly, we may not be able to continue the business and operations of the company as a result of these safety concerns.***

We recently announced the voluntary nationwide recall of OMONTYS from the market resulting from serious allergic reactions reported in patients receiving OMONTYS, including anaphylaxis related to deaths occurring after first administration of OMONTYS. While we continue to investigate these cases and the nature and causes of the safety concerns, if we are unable to rapidly identify and rectify the causes, the product could be permanently withdrawn from the market and we may be unable to continue as a going concern. The recall has severely harmed our business and financial condition and prospects as a going concern and we may not be able to continue the business and operations of the company.

In order to address the safety concerns resulting in the recall of OMONTYS, we would have to complete our ongoing thorough investigation, identify the causes of the serious allergic reactions and provide a suitable plan to the FDA for approval. We are unable to predict if or when this process may be completed or the associated costs, but we expect that that investigation may be lengthy and are uncertain as to whether our available limited resources, particularly in light of our recent reductions in our workforce, which may not allow us to complete the process in a timely manner. Further, in an effort to continue our operations in the near term with our limited resources, we will need to continue to substantially reduce our operating costs, including further reductions in force of critical personnel and functions, even those directly related to the conduct of the investigation and support of our New Drug Application or NDA for OMONTYS.

There can be no assurance that our business can continue or OMONTYS can be shown to be sufficiently safe to meet the requirements of the FDA for reintroduction. Moreover, even if OMONTYS could be reintroduced, the commercial prospects for this product may be permanently diminished, coverage and reimbursement may not be available, and the product may no longer be commercially viable.

***We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future without revenues from OMONTYS, which was our only product. We have undertaken a reorganization and if we are unable to substantially further reduce our expenses, we may need to cease operations.***

We have experienced significant operating losses since our inception in 2001. At December 31, 2012, we had an accumulated deficit of $543.7 million. Due to the recent recall of OMONTYS and the uncertainty of when or if we may receive any revenues from OMONTYS, we anticipate that we will incur substantial losses in future periods. In particular, we expect to continue to spend substantial amounts in order to:

- investigate the causes of reported patients' hypersensitivity reactions to OMONTYS;
- if we are able to identify and address the safety concerns with OMONTYS, meet the requirements of the FDA in an effort to reintroduce and commercialize OMONTYS;
- support and maintain our organizations and infrastructure to manage and comply with our ongoing regulatory and legal obligations as well as to support our existing and potential future litigation; and
- maintain or manage our ongoing contractual commitments to third parties including to OMONTYS contract manufacturing organizations, or CMOs to reduce our obligations pending the outcome of the investigation.

As a result of the recall and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient cash, cash equivalents, and investments to fund our operations for at least the next 12 months. Even with the recent reorganization, further reductions in our workforce and cash outflows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations and conduct ongoing operations. If we are not able to reintroduce the product or obtain additional funding in the near future, our cash resources will rapidly be depleted and we will be required to significantly reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships. Further, we may be in breach under our loan and security agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or, collectively, the Lenders as the voluntary recall may be considered a material adverse event under the Loan Agreement. Under the Loan Agreement, the Lenders have various rights, including the right to not extend further credit of the remaining $20.0

million under the Loan Agreement, require immediate repayment of the outstanding principal plus accrued and unpaid interest, a final payment fee and prepayment fee of approximately $2.2 million as of February 28, 2013 and other remedies available under the terms of the Loan Agreement. In order to maintain our efforts to identify and address the safety concerns with OMONTYS, we are undertaking a significant restructuring of the business and operations of the company, but we plan to continue to make efforts to substantially reduce our operating costs, which will likely include further reductions in force as we endeavor to conserve our cash resources.

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. Further challenges or delays to potential reintroduction of OMONTYS could require us to raise additional funds to continue our operations. 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. Our current debt financing involves security interests on our assets and 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 identify quickly the causes of the OMONTYS safety concerns or raise additional funds when required or on acceptable terms, we may have to:

- abandon the investigation, NDA, and any potential to reintroduce OMONTYS ;
- significantly delay, scale back, or discontinue operations;
- abandon or relinquish some or all of our existing rights to OMONTYS;
- eliminate or defer manufacturing efforts that may negatively impact OMONTYS; or
- pursue alternatives such as a sale of the company or its assets, a corporate merger, restructuring, winddown of operations or even bankruptcy proceedings.

Our ability to generate product sales and continue as a going concern depends heavily on our ability to successfully reintroduce and commercialize OMONTYS, which is highly uncertain and challenging. OMONTYS will require significant marketing efforts and substantial investment before it can provide us with any meaningful revenue, if ever. We expect to incur substantial expenses associated with the recall and the ongoing investigation. Even if the underlying causes of the safety concerns can be identified, which is uncertain, the timelines associated with the investigation and the feasibility and costs associated with implementing solutions to address the safety concerns to the satisfaction of the FDA are highly uncertain. Our recent reorganization and future reductions in force of critical personnel and functions may substantially impair the investigation and our ability to maintain our operations and support the NDA. Accordingly, we may never be able to reintroduce OMONTYS or generate significant revenues and, even if OMONTYS is reintroduced so as to generate product sales, we may never achieve or sustain profitability.

***Our independent registered public accounting firm has indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.***

Our independent registered public accounting firm has included in their audit opinion on our financial statements for the year ended December 31, 2012, a statement with respect to substantial doubt as to our ability to continue as a going concern. Our financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The reaction of investors to the inclusion of a going concern statement in the report of our independent registered public accounting firm, our lack of cash resources, and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or continue our operations.

***We will be unable to proceed with next steps for OMONTYS without amendment of our collaboration arrangement with Takeda and the cooperation and support of Takeda in the U.S. If we fail to successfully renegotiate our arrangement or otherwise maintain our existing collaboration with Takeda, such termination would have a material adverse effect on our business and operations and our ability to meet our obligations and may result in our having to cease operations.***

The maintenance and successful performance of our strategic collaboration with Takeda for OMONTYS is an important part of our business and operations, in particular with respect to the OMONTYS recall and investigation. Our collaboration with Takeda is extremely complex and we both have obligations to the FDA and one another with respect to the manufacture, development and approval of OMONTYS, including a sharing of the costs associated with the collaboration which have been significantly impacted by the recall of product and related write-offs of assets and third party commitments. The complexity of our collaboration creates significant risk and uncertainty as to how and when we might be in position to address the safety concerns of OMONTYS that resulted in our product recall. In addition, as our cost-sharing arrangement with Takeda proceeds, without significant renegotiation and support from Takeda, we may be unable to continue in the collaboration which may result in our having to cease operations.

Moreover, Takeda has the ability to terminate our collaboration 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 termination in the U.S. would have a material adverse effect on OMONTYS and our business and operations. In the past, events such as the suspension of the OMONTYS 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 increase the possibility that Takeda may elect to terminate the collaboration or limit the resources Takeda is willing to commit to OMONTYS. The safety concerns with OMONTYS combined with the recent U.S. recall may negatively impact the EMA decision and Takeda's view of the collaboration and its overall commitment to OMONTYS, including in the U.S., our major market opportunity.

Under our collaboration, Takeda currently provides funding and performs important functions, including contracting, pricing, accounting for the collaboration revenue and profit equalization and conducting manufacturing activities, all of which are essential to our continuation as a going concern in the near-term. Even in the absence of termination by Takeda, the significant resources and commitment that may be required to successfully address OMONTYS safety concerns with the FDA and to reintroduce and commercialize OMONTYS in the U.S. may result in limited commercial opportunity, and Takeda's failure to provide funding or timely cooperate in our investigation of the causes of the safety concerns with OMONTYS would have a significant adverse effect on our efforts and our business.

***We are currently subject to securities class action litigation and derivative litigation and may be subject to similar or other litigation such as products liability litigation in the future.***

We and certain of our officers as well as Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. have been named defendants in two lawsuits filed in February 2013 in the United States District Court for the Northern District of California, brought on behalf of stockholders of the company that alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants regarding our business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiffs seek to represent a class comprised of purchasers of our common stock during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court.

In addition, in March 2013, a derivative lawsuit was filed purportedly on behalf of the company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuit alleges that certain of our officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding our business health, which was tied to the success of OMONTYS. The lawsuit also asserts claims for unjust enrichment and corporate waste.

While we believe we have meritorious defenses and intend to defend these lawsuits vigorously, we cannot predict the outcome of these lawsuits. We believe that there may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities and we cannot predict how long it may take to resolve these matters. In addition, legal fees and costs incurred in connection with such activities may be significant and we could, in the future, be subject to judgments or enter into settlements of claims for significant monetary damages. A decision adverse to our interests on these actions or resulting from these matters could result in the payment of substantial damages and could have a material adverse effect on our cash flow, results of operations and financial position.

Likewise, if product liability lawsuits are brought against us for injuries or deaths due to patients' adverse reactions to OMONTYS, we may be subject to additional liability. In any event, a potential product liability lawsuit would require significant financial and management resources. Regardless of the outcome, product liability claims may result in injury to our reputation, withdrawal of clinical trial participants, significant costs, diversion of management's attention and

resources, substantial monetary awards, loss of revenue, and additional distractions from our efforts to address safety concerns that may allow us to reintroduce OMONTYS. 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 reintroduction of OMONTYS.

With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuits. Substantial litigation costs or an adverse result in any litigation may adversely impact our business, operating results or financial condition.

***Our success depends on our ability with Takeda to effectively and profitably commercialize OMONTYS, when and if we reintroduce OMONTYS.***

Our success depends on our ability with Takeda to reintroduce OMONTYS and effectively and profitably commercialize OMONTYS when and if we reintroduce OMONTYS. There is no assurance that we can identify and address the underlying cause of the serious hypersensitivity reactions described under the caption "OMONTYS Voluntary Recall" in "Item 1.Business" of this Annual Report on Form 10-K. If we fail to demonstrate the safety of OMONTYS, we will not be able to reintroduce OMONTYS and our business will be materially and adversely affected. When and if we reintroduce OMONTYS, our success will depend on our ability to:

- create market demand for OMONTYS through our education, marketing and sales activities, as well as through our co-promotion agreement with Takeda Pharmaceutical Company Limited, or Takeda, including our ability to establish or demonstrate the safety of OMONTYS;
- re-build a qualified commercial and medical affairs organization and field force;
- achieve market acceptance and generate product sales through Takeda's execution of agreements with the major operators of dialysis clinics on commercially reasonable terms;
- support the efforts of dialysis clinics to safely and effectively administer OMONTYS to dialysis patients on a different treatment plan than for the other approved erythropoiesis stimulating agents, or ESAs;
- receive adequate levels of reimbursement from third-party payors, including government healthcare programs such as Medicare and Medicaid and private insurance programs;
- comply with the post-marketing requirements established by the FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future;
- comply with other healthcare regulatory requirements;
- ensure that the Active Pharmaceutical Ingredient, or API, for OMONTYS and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand; and
- ensure that the entire supply chain for OMONTYS - from API to finished product - efficiently and consistently delivers OMONTYS to our customers.

When and if we are able to reintroduce OMONTYS, which is highly uncertain, it will be even more challenging for us to accomplish these activities in view of the recall and related safety concerns particularly due to the long-term experience with currently marketed products and negative perceptions of OMONTYS' safety. If we are unable to successfully reintroduce and commercialize OMONTYS, we will not receive any sales revenue from the product, which will have a material adverse impact on our business and our prospects.

***Even if we are able to reintroduce OMONTYS, we may not be able to commercialize OMONTYS successfully.***

If we are able to reintroduce OMONTYS, we must have internal sales, marketing, medical affairs, contracting, reimbursement and distribution capabilities. If we are not successful in re-building a commercial and medical affairs organization, then we will have difficulty commercializing OMONTYS when and if it is reintroduced, which would adversely affect our business and financial condition. If we are unable to successfully address these responsibilities ourselves, then we may need to identify third-party providers to support these efforts, which may lead to delays and additional costs as well as potential confusion to our customers. To the extent that we enter into additional co-promotion or other arrangements, any

revenues we receive will depend upon the efforts of both parties, which may not be successful and are only partially in our control. Our product revenues would likely be lower than if we marketed and sold our products directly.

***Even if we are able to reintroduce OMONTYS, we would need to attain significant market acceptance for the product among physicians, patients, health care payors, and the major operators of dialysis clinics, and we would need to reach a long-term agreement with either or both of the largest operators of dialysis clinics.***

Until the approval of OMONTYS, only EPOGEN and Aranesp, the ESAs of our competitor Amgen, Inc., or Amgen, have been used for the treatment of anemia due to chronic kidney disease in adult patients on dialysis in the U.S. This dialysis market is highly established and concentrated, with EPOGEN and Aranesp serving a significant majority of all dialysis patients on Medicare. These two products are the current standard of care, and it may be difficult to encourage healthcare providers to consider OMONTYS, should it be reintroduced, as an alternative to these products with which they and their patients have a longstanding relationship. Physicians, who make the ultimate decision to prescribe a product, may not prescribe OMONTYS, in which case our ability to sell the product would be adversely impacted. Similarly, dialysis clinics using EPOGEN or Aranesp could incur substantial expense in administration and training if they were to convert to OMONTYS. Finally, healthcare providers may not receive adequate levels of reimbursement for OMONTYS from third-party payors, including government healthcare programs such as Medicare and Medicaid and private insurance programs. Some or all of these factors may hinder our efforts to attain significant market acceptance of OMONTYS should it be reintroduced, which would pose a risk to our ability to obtain revenues or favorable margins for the product.

Even if we are able to reintroduce and achieve market acceptance of OMONTYS, if we are unable to reach a long-term supply agreement with either or both of the largest operators of dialysis clinics in the U.S, Fresenius Medical Care North America and DaVita, Inc. or Fresenius and DaVita, respectively, on favorable terms or on a timely basis, then the revenue opportunity for OMONTYS could be significantly reduced. We may not be able to reach a long-term supply agreement with either Fresenius or DaVita because both entered into a long-term supply agreement with Amgen that began in January 2012. In particular, Fresenius entered into a "multi-year" agreement with Amgen whereby Amgen would supply EPOGEN on a "non-exclusive" basis to Fresenius, and DaVita entered into a seven-year agreement with Amgen 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. The specific terms of the Amgen-Fresenius agreement and the Amgen-DaVita agreement have not been publicly disclosed, and we cannot predict how these agreements may impact the commercial opportunity for OMONTYS should it be reintroduced. But these agreements may limit the market opportunity for the product and adversely impact our ability to generate product sales.

In July 2012, Fresenius entered into a short-term supply agreement with Takeda Pharmaceuticals America, Inc., or TPA, a subsidiary of Takeda, whereby TPA supplied OMONTYS to Fresenius for use in certain U.S. dialysis clinics within its organization. On February 13, 2013, Fresenius communicated that it had accumulated experience with OMONTYS in more than 56,600 administrations in over 18,000 patients in its dialysis facilities and that it had decided to pause further expansion of its OMONTYS pilot program. Fresenius indicated that it would analyze the full set of efficacy and safety profile information regarding OMONTYS and that the current scale of their experience with use of the product was adequate to complete this analysis. Even if we are able to successfully address the recent safety concerns for OMONTYS with the FDA, we believe it may be more challenging to continue with or expand upon the short-term supply agreement with Fresenius in the near term. In any event, Amgen's long-term supply agreements with DaVita and Fresenius and the potential introduction of Mircera and biosimilars may limit the market opportunity for OMONTYS and adversely impact our ability to generate product sales should we reintroduce the product.

***The opportunity to reintroduce OMONTYS is highly uncertain and challenging as a result of the negative perception of the safety of OMONTYS.***

The safety concerns resulting in the recent OMONTYS recall and the safety concerns for ESAs as a class may make it challenging to identify and rectify the causes of the safety concerns to the satisfaction of the FDA and may significantly reduce the market for OMONTYS if and when it is reintroduced For example:

- In 2007, as a result of concerns associated with administering ESAs to target higher hemoglobin levels, the FDA required that revised warnings, including boxed warnings, be added to the 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.

- In late 2009, Amgen announced the results from the Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or 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, Aranesp was used to

treat anemia 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 among patients treated with Aranesp compared to the control group. Finally, 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.

- In January 2010, FDA officials published an editorial in the New England Journal of Medicine noting that a number of randomized trials, including TREAT, had attempted to show that using ESAs to raise hemoglobin concentrations to higher targets improves clinical outcomes but rather suggested the opposite. Accordingly, the article indicated 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 the 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, and the manufacturer has reporting and monitoring obligations to ensure compliance.

- 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 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.

- In February 2013, in connection with the recall, the FDA announced that due to the severity of the public health risk, the FDA wanted to be certain that health care providers stop using OMONTYS and that it would investigate products and facilities associated with the recall and would provide updates.

The controversy surrounding ESAs and FDA safety concerns has, and may, further negatively affect OMONTYS. In addition, recent and future FDA actions represent additional challenges to the market for ESAs as a class and may affect the timing or costs associated with implementing a solution to address the cause of patients' hypersensitivity reactions to OMONTYS when and if a cause is available that is satisfactory to the FDA. We cannot predict what additional actions, if any, the FDA may take, which may include 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. Further, regardless of whether or not the FDA takes additional action, the Centers for Medicare and Medicaid Services, or CMS, and other third-party payors may still decide separately to discontinue or limit coverage or lower reimbursement as CMS has recently adopted changes and continues to evaluate coverage and reimbursement policy for ESAs as class. Any of these factors could significantly delay or negatively impact the commercialization of OMONTYS when and if we reintroduce it.

In addition, any negative perception of the safety of OMONTYS relative to other ESAs as a result of our Phase 3 clinical results could significantly reduce the market opportunity for our product when and if we reintroduce it. Specifically, in June 2010, we announced preliminary top-line results from the OMONTYS 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: PEARL 1 and PEARL 2 conducted in non-dialysis patients and EMERALD 1 and EMERALD 2 conducted in dialysis patients. Analysis of efficacy and safety for all of the Phase 3 trials were based primarily on assessments of non-inferiority to the comparator drugs. While OMONTYS 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, 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 OMONTYS group relative to the comparator in non-dialysis patients. Since OMONTYS was launched, over 25,000 patients have been treated with OMONTYS. Serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal, have been recently reported as described under the caption "OMONTYS Voluntary Recall" under "Item 1. Business" of this Annual Report on Form 10-K. On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS and suspended the promotional activities and marketing of OMONTYS. This has severely harmed our business and future financial

results. Any negative perception of OMONTYS' safety relative to other ESAs could further significantly limit any potential opportunity for us to reintroduce and successfully commercialize OMONTYS.

Finally, any negative perception of the safety of OMONTYS relative to other ESAs as a result of any new medical data or product quality issues that suggest new risks or side effects, or increase concern over previously identified risks or side effects would significantly negatively impact the commercial potential as well as any possible reintroduction of OMONTYS.

***We have continuing obligations with respect to OMONTYS and FDA approval remains subject to certain post-marketing requirements that could significantly increase costs or delay or limit our ability to successfully commercialize the product when and if it is reintroduced. If results, data or information with respect to our continuing obligations are negative or we are unable to fulfill our continuing obligations to regulatory authorities or our post-marketing requirements, there may be changes to our product label or we may be required to withdraw the product from the market.***

The FDA approved OMONTYS subject to certain post-marketing requirements. For example, we are required to conduct an observational study and a randomized controlled trial to be completed with final reports submitted in 2018 and 2019, respectively, to evaluate cardiovascular safety and assess safety of long-term use in adult patients on dialysis. We are also required to initiate pediatric studies with target dates for completion between 2016 and 2027. In addition, we are required to comply with a REMS, which includes a requirement to send "Dear Healthcare Provider" letters to nephrology healthcare providers informing them that OMONTYS is not indicated in patients with chronic kidney disease not on dialysis.

Even if we are able to address the safety concerns resulting in our recall of OMONTYS to the satisfaction of the FDA, maintaining regulatory approval for OMONTYS will be increasingly difficult. If we are unable to fulfill the requirements of regulatory authorities or our post-marketing requirements or to the extent there are other unfavorable results, data or other information arising therefrom, then there may be limitations imposed on our product label or we may be required to permanently withdraw the product from the market.

***We have relied on numerous third parties to conduct and complete our development program for OMONTYS, and we will continue to rely on third parties to maintain approval of the product.***

Due to the size and limited experience of our organization, we have relied heavily on third parties to assist us in managing, monitoring and otherwise conducting our clinical trials. Even though we have completed our Phase 3 clinical program and OMONTYS was approved by the FDA, we will continue to require the assistance of third parties in the future, particularly with respect to completing our post-marketing requirements. For example, 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 in connection with conducting our post-marketing trials does not relieve us of these responsibilities and requirements, and regulatory authorities may find remediation efforts by us or such third parties insufficient. In addition, we have had significant difficulties obtaining necessary and quality third-party assistance. 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 commercializing OMONTYS and completing our post-marketing requirements.

***Competition in the pharmaceutical industry is intense. Our recent product recall means that OMONTYS will have to overcome significant competitive issues relative to other approved ESAs on the market.***

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 OMONTYS. Our recent setback with the OMONTYS recall and the uncertainty of whether OMONTYS will be available on the market at all may mean that OMONTYS will be at a significant disadvantage upon the entry of competing products.

When and if OMONTYS is reintroduced, we anticipate that it will compete with EPOGEN and potentially Aranesp, which are both marketed by Amgen, and 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 was on the market in the U.S. prior to OMONTYS. As a result of the patent litigation between Roche and Amgen, Mircera was found to infringe several U.S. patents owned by Amgen and was 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, we believe it will be in direct competition with OMONTYS, if we are able to reintroduce the product, because of Mircera's ability to be long-acting; therefore, it could potentially limit the market for OMONTYS.

The introduction of biosimilars into the ESA market could also prove to be a significant threat if and when we reintroduce OMONTYS as biosimilars could not only limit the market for the product, but could also drive down the price of ESAs.

We may also face competition from potential new anemia therapies if and when we reintroduce OMONTYS. There are several product candidates in various stages of active development for anemia indications by potential competitors that may promote the production of naturally-occurring EPO in patients, and some of these product candidates may enter the market as early as 2015. If these product candidates enter the market they may be in direct competition with OMONTYS if and when it is reintroduced. In addition, certain companies are developing potential new therapies for renal-related diseases that could reduce ESA utilization and thus limit the market for OMONTYS if and when it is reintroduced.

Most of these competitors have substantially greater financial resources and expertise in 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 OMONTYS, which we anticipate to sell on a stand-alone basis when and if we reintroduce it. Established pharmaceutical and large biotechnology companies may invest heavily to discover and develop novel compounds or drug delivery technology that could make OMONTYS 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 or discovering, developing and commercializing products before we do.

***When and if we reintroduce OMONTYS, the U.S. market opportunity for OMONTYS 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 accepted 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. Several biosimilar versions of rEPO are available for sale in the E.U. and biosimilar versions of rEPO are currently being studied in clinical trials in the U.S. For example, in January 2012, Hospira, Inc. announced the beginning of its Phase 3 clinical program for its biosimilar with results anticipated in 2013, and in October 2012, Sandoz announced the beginning of its Phase 3 clinical program for its biosimilar with results anticipated in 2014.

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 OMONTYS if they are able to demonstrate biosimilarity to existing rEPO. Biosimilars will constitute additional competition for OMONTYS should it be reintroduced, and are expected to drive down its price and sales volume, which would adversely affect our revenues.

***The reintroduction and commercial success of OMONTYS in the U.S. depends in significant part on the 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 reintroduce or further commercialize OMONTYS. If our collaborations are unsuccessful, our ability to commercialize products through our collaborations, and to generate future product sales, would be significantly reduced.***

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

Under our collaboration with Takeda, we have co-commercialized OMONTYS in the U.S., and will further co-commercialize the product in the U.S. when and if it is reintroduced. Because we share responsibility with Takeda for 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 OMONTYS 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 OMONTYS 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 the reintroduction and further commercialization of OMONTYS, which may result in a negative impact on our planned timelines, require us to contribute more resources to reintroduce and successfully commercialize OMONTYS and decrease the likelihood of reintroduction and commercial success for OMONTYS in the U.S.

Outside of the U.S., Takeda holds an exclusive license to develop and commercialize OMONTYS 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 decision in December 2011 not to commercialize the product 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 when and if we reintroduce OMONTYS. In addition, Takeda may delay, reduce or terminate development efforts relating to the product elsewhere, independently develop products that compete with the product, or fail to commit sufficient resources to the marketing and distribution of the product. 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 the product.

In the event that Takeda fails to diligently commercialize OMONTYS, 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 OMONTYS, and we may choose not to terminate as we may not be able to find another partner and any new collaboration likely will not provide comparable financial terms to those in our arrangement with Takeda. In the event of our termination, this may require us to commercialize the product 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 our arrangement could materially affect the potential success of the product, including the reintroductionof OMONTYS when and if it occurs.

We have limited ability to control and influence Takeda in its strategic decisions. This is particularly important should we reintroduce and further commercialize OMONTYS 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 reintroduction and commercialization of OMONTYS would be delayed, terminated or negatively impacted. Moreover, if Takeda fails to successfully develop and commercialize OMONTYS outside of the U.S., our potential to generate future revenue in the Takeda territory would be significantly reduced.

***Significant challenges remain with us and Takeda to manufacture OMONTYS on a commercial scale should we reintroduce OMONTYS. Our dependence upon third parties for manufacture and supply may cause delays in, or prevent us from, successfully reintroducing and commercializing OMONTYS. 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. Manufacturing difficulties, disruptions or delays could limit supply of our product sales and have a material adverse effect on our business.***

In connection with the recall and in consultation with Takeda, we plan to suspend manufacturing activities to the extent practicable pending consideration of next steps with OMONTYS. If we are successful in identifying the cause of the recent safety concerns and addressing it, we and Takeda will determine the next appropriate steps to take with OMONTYS. Prior to such time, we plan to evaluate strategies to decrease our ongoing manufacturing costs and commitments, including but not limited to, termination of orders and agreements, which may negatively impact our ability to reintroduce OMONTYS. If we are able to reintroduce OMONTYS, we intend to continue to rely on third-party manufacturers to produce API, which may require significant effort and validation of new CMOs. While we and Takeda are actively investigating to determine the cause of the recent safety concerns, we cannot give any assurances as to whether we can be successful in doing so. Our inability to determine the cause of the recent safety concerns and find and implement a solution to address it may render us unable to reintroduce and manufacture OMONTYS.

Even if we are able to reintroduce OMONTYS, the OMONTYS manufacturing process is complicated and time consuming. Manufacture of OMONTYS API involves long lead times with our CMOs and suppliers. Manufacturing difficulties, disruptions or delays could limit supply of our product. We do not currently have the infrastructure or capability internally to manufacture the OMONTYS needed to conduct our clinical trials or to commercialize the product. We have relied, and will continue to rely, on CMOs to produce our clinical trial materials for the foreseeable future and we expect to continue to rely on CMOs, partners and other third parties to produce sufficient quantities of OMONTYS for all our uses, including commercialization. When and if we reintroduce OMONTYS, if our CMOs or other third parties fail to deliver materials for the manufacture of OMONTYS, or OMONTYS 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 have to delay or suspend future clinical trials or otherwise delay or discontinue commercialization or production.

OMONTYS 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 reintroducing and commercializing OMONTYS, including the following:

- product quality issues;
- cost overruns, process scale-up, process reproducibility;
- changes in demand forecasts that result in inventory write-offs;
- 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.

While we continue to be responsible for the manufacture of API based on Takeda's forecasts, we have transferred responsibility for the manufacture of OMONTYS 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 our, and Takeda's, operations, suppliers and manufacturers are currently, and planned to be, single-sourced, leaving us at greater risk of supply interruptions, potential delays and failure to successfully commercialize.

We, Takeda, and our third-party manufacturers are required to comply with applicable FDA manufacturing practice and other applicable 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 OMONTYS could be interrupted, resulting in delays and additional costs should we reintroduce OMONTYS. Due to the product recall of OMONTYS, manufacturing activities have also been significantly reduced. 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. This could result in further losses and reduced profits that we share from the sale of OMONTYS. Any inability to acquire sufficient quantities of OMONTYS or components thereof in a timely manner from third parties could delay clinical trials or result in product shortages and prevent us from reintroducing and commercializing OMONTYS in a cost-effective manner or on a timely basis. Further, our lack of experience providing reliable supply of product may deter health care providers and dialysis centers from selecting, or switching to, OMONTYS from our competitors' products or from continuing to use OMONTYS should it be reintroduced.

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

Our success will depend in part on obtaining and maintaining patent protection and trade secret protection of OMONTYS 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 OMONTYS 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 applications 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.

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 R&D 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 the ability of our commercial partners, to reintroduce and commercialize OMONTYS 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 OMONTYS 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 OMONTYS 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 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 or reintroducing and commercializing OMONTYS 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.

***We may be unable to continue our operations, meet our obligations, and reintroduce and commercialize OMONTYS as a result of our recent reorganization plan, further reductions in force or any loss of services of senior management and key personnel.***

We are highly dependent upon our senior management and key personnel, however, due to the significant challenges to our business, our recent reorganization and further reductions in force, or the loss of any of their services, for any reason, could negatively impact our operations. We will need to maintain personnel as we investigate the cause of the safety concerns related to OMONTYS, search for and implement a solution to address it, potentially reintroduce and further commercialize OMONTYS and conduct post-marketing studies and trials. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We may not be able to maintain personnel on acceptable terms. In addition, each of our officers and key personnel may terminate his/her employment at any time without notice and without cause or good reason.

**Risks Related to Our Industry**

***Even though OMONTYS approval by the FDA has not been permanently withdrawn, the OMONTYS approval is subject to continued FDA inspection of the safety concerns leading to the recall. Ongoing FDA review may result in significant additional expense and limit our ability to reintroduce and successfully commercialize OMONTYS.***

Although the FDA approval of OMONTYS has not been withdrawn, the FDA may choose to do so as the investigation continues or to subject us to various post-marketing requirements, including additional clinical trials, and the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The recent cases of reported patients' serious hypersensitivity reactions to

OMONTYS and any other subsequent discovery of previously unknown problems with the product, including adverse events of unanticipated severity or frequency, may result in withdrawal or restrictions on the marketing of the product, and could include regulatory actions from the FDA. The actions the FDA may take include, permanent withdrawal, additional studies or label restrictions, the use of informed consents, the addition of more restrictive REMs, further lowering of target hemoglobin levels, or even the removal of indications from the label altogether. In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent or delay successful reintroduction and commercialization of OMONTYS. We cannot predict the likelihood, nature or extent 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 OMONTYS, or any future product, 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;

- the Federal Food, Drug and Cosmetic Act, which prohibits, among other things, individuals or entities from introducing into interstate commerce any food, drug, device or cosmetic that has been adulterated or misbranded; and

- state law equivalents of certain 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.

Many of these laws have not been fully interpreted by applicable regulatory authorities or the courts and their provisions are subject to a variety of interpretations, which increases the risk that we may be found in violation of these laws. 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. The recall has severely harmed our business and financial condition and prospects as a going concern and we may not be able to continue the business and operations of the Company. Accordingly, we may face challenges to maintain operations and a compliance program that are in material compliance with these laws. Because of the far-reaching nature of these laws and the significant disruption to our operations resulting from the recall, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance, or that the occurrence of one or more violations would not result in a material adverse effect on our financial condition and results of operations.

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

We co-marketed OMONTYS in the U.S. before our recent recall of OMONTYS, and have exclusively licensed Takeda to market the product in foreign jurisdictions. When and if we reintroduce OMONTYS, in order to market the product in the E.U. and other foreign jurisdictions, Takeda or a sublicensee 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. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. In addition, there are a number of ESAs available in the E.U. and other foreign markets, and therefore it may be more challenging to obtain regulatory approval in such markets because the risk/benefit analysis for approval may be different than in the U.S. Foreign regulatory approvals may not be obtained on a timely basis, if at all. If we or Takeda, as part of our collaboration, are not able to obtain regulatory approval in any foreign market, then we will not be able to commercialize OMONTYS in any foreign market, and we will not obtain certain regulatory milestones from Takeda.

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

When and if we reintroduce OMONTYS in the U.S., we intend to seek approval to market the product, 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 the product to other available therapies or a clinical trial that studies pharmacoeconomic benefits. If reimbursement of the product 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.

**Risks Related to the Ownership of Our Common Stock**

***We have been named as a defendant in a purported securities class action lawsuit. This lawsuit could result in substantial damages and may divert management's time and attention from our business and operations.***

On February 27, 2013, a purported securities class action complaint was filed in the U.S. District Court for the Northern District of California, naming as defendants us, certain of our officers, Takeda, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. The complaint, filed on behalf of a putative class of persons who purchased our common stock between December 8, 2011 and February 22, 2013, or the Class Period, alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding our company's business practices, financial projections and other disclosures during the Class Period. The complaint seeks damages, costs and expenses and such other relief as determined by the Court, and the complainant seeks to represent a class comprised of purchasers of our common stock during the Class Period. A response to the complaint is not yet due.

Our management believes that we have meritorious defenses and intends to defend this lawsuit vigorously. However, this lawsuit is subject to inherent uncertainties, and the actual cost will depend upon many unknown factors. The outcome of the litigation is necessarily uncertain, we could be forced to expend significant resources in the defense of the suit and we may not prevail. Monitoring and defending against legal actions is time consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with the litigation and, although we believe our company is entitled to coverage under the relevant insurance policies, subject to a retention, coverage could be denied or prove to be insufficient. We are not currently able to estimate the possible cost to us from this matter, as this lawsuit is currently at an early stage and we cannot be certain how long it may take

to resolve this matter or the possible amount of any damages that we may be required to pay. We have not established any reserves for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty of the currently pending litigation could lead to more volatility in our stock price.

***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, 2012, the closing price of our common stock ranged between a high of $27.46 per share and a low of $6.50 per share. The closing price for our common stock as reported by the NASDAQ Global Select Market on February 28, 2013 was $2.65 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:

- our ability to rapidly identify and address the cause of the safety concerns related to OMONTYS;
- our ability to demonstrate safety of OMONTYS to the satisfaction of the FDA and reintroduce such product;
- our ability to fund our operations and continue as a going concern;
- litigation, including the purported securities class action lawsuit pending against us and certain of our officers;
- changes in the market valuations of similar companies;
- actual or anticipated results from, and any delays in, commercialization of OMONTYS should we reintroduce OMONTYS;
- actual or anticipated contractual arrangements for OMONTYS should we reintroduce OMONTYS 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 the FDA and CMS with respect to ESAs generally or OMONTYS specifically;
- 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 OMONTYS;
- 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;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key management or other 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.

***Raising funds through our current credit arrangement may restrict our operations or place further restrictions on our operations.***

In March 2012, we entered into a $30.0 million Loan Agreement with Oxford Finance LLC and Silicon Valley Bank. We initially drew $10.0 million under this agreement and are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions of assets, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under this loan and security agreement, we granted a security interest in substantially all of our assets, other than intellectual property assets, to the lenders. Our failure to comply with the terms of the loan and security agreement, the occurrence of a material impairment in our prospect of repayment or in the perfection or priority of the lender's lien on our assets, as determined by the lenders, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets, and other adverse results. Further, we may be in breach as the voluntary recall may be considered a material adverse event under the Loan Agreement.

***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 have not identified any material weaknesses in our internal controls during the years ended December 31, 2012, 2011 or 2010. We did identify a material weakness in the operation of our internal control over financial reporting that occurred during the second quarter of 2008 which has been fully remediated. We cannot assure you that material weaknesses in our internal controls 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 internal controls 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 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. The recall of OMONTYS has severely harmed our business and financial condition so we may have challenges in maintaining 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". Prior to 2012, we experienced ownership changes as defined by Sections 382 and 383 of the Internal Revenue Code. Due to our announcement of our voluntary recall of OMONTYS in February 2013, there has been an extremely high volume of trading of our stock, which has caused a significant drop in the value of our stock. As a result of the high trading volume, there may be a shift of ownership amongst our 5% stockholders that could result in an ownership change, under Section 382 of the Internal Revenue Code of 1986, as amended. 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.

***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.

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. Approximately 8,000 square feet of this office space has been subleased to a third party under a sublease agreement that terminates in August 2014. In March 2013, we undertook plans to reorganize our operations in order to reduce operating costs, which could include consolidation and further reduction of office space.

**Item 3. Legal Proceedings**

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants Affymax, Inc. or the Company, certain of its officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding the Company's business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court.

On March 19, 2013, a derivative lawsuit was filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuit alleges that certain of the Company's officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding the Company's business health, which was tied to the success of OMONTYS. The lawsuits also asserts claims for unjust enrichment and corporate waste.

Additional complaints may be filed against us and our directors and officers related to our recall of OMONTYS.

Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

**Item 4. Mine Safety Disclosures**

Not applicable.

## 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 Stock Market under the symbol "AFFY" since December 15, 2006. As of February 28, 2013, there were approximately 79 holders of record of our common stock. The following table sets forth, for the periods indicated, the range of high and low intraday sales prices of our common stock as quoted on the NASDAQ Global Select Market.

| | High | Low |
|---|---|---|
| **2012** | | |
| 4th Quarter | $27.74 | $18.28 |
| 3rd Quarter | $22.00 | $11.73 |
| 2nd Quarter | $14.95 | $10.86 |
| 1st Quarter | $16.25 | $6.35 |

| | 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 |

The closing price for our common stock as reported by the NASDAQ Global Select Market on February 28, 2013 was $2.65 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 of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. In March 2012, we entered into a Loan and Security Agreement, or Loan and Security Agreement, with Oxford Finance LLC or Oxford and Silicon Valley Bank, which requires we obtain prior written consent from the lenders before we pay dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of any capital stock.

**Recent Sales of Unregistered Securities**

Except as previously reported in our quarterly reports on Form 10-Q filed with the SEC during the year ended December 31, 2012, there were no unregistered sales of equity securities by us during the year ended December 31, 2012.

**Issuer Purchases of Equity Securities**

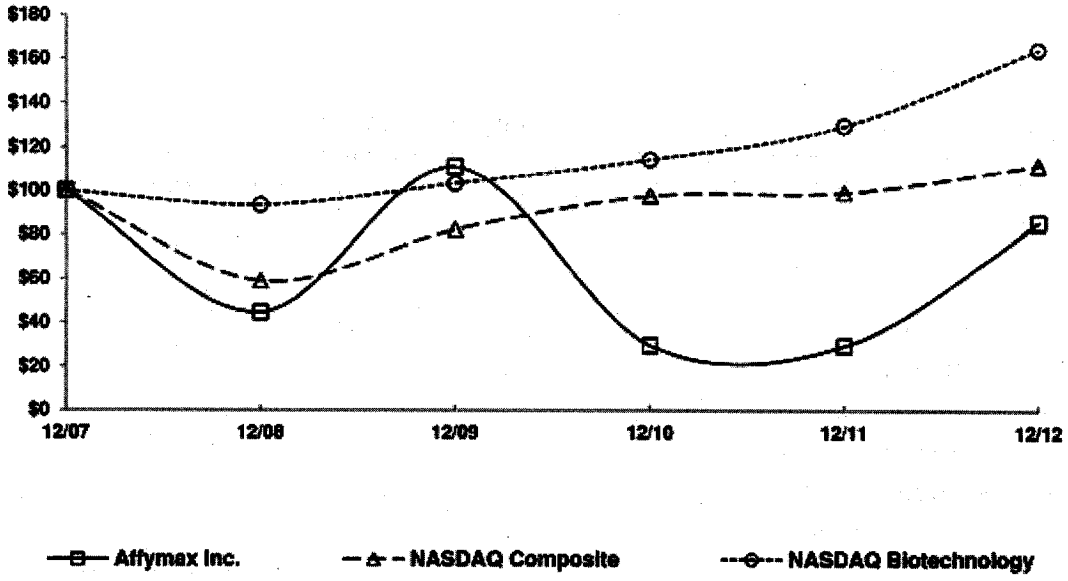
We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2012.

**Performance Graph(1)**

The following graph shows the total stockholder return of an investment of $100 in cash on December 31, 2007, through December 31, 2012 for (i) our common stock, (ii) the Nasdaq Composite Index (U.S.) and (iii) the Nasdaq Biotechnology Index as of December 31, 2012. 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




*$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

(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.

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

| | Year ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2009 | 2008 |
| | (in thousands, except per share data) | | | | |
| **Statements of Operations Data:** | | | | | |
| Revenue: | | | | | |
| Collaboration revenue | $ 94,358 | $ 47,703 | $ 112,503 | $ 114,883 | $ 82,162 |
| License and royalty revenue | 12 | 17 | 18 | 16 | 689 |
| Total revenue | 94,370 | 47,720 | 112,521 | 114,899 | 82,851 |
| Operating expenses: | | | | | |
| Impairment of inventory and losses under firm purchase commitments | 44,957 | — | — | — | — |
| Research and development | 51,738 | 76,308 | 93,638 | 157,125 | 137,492 |
| Selling, general and administrative | 89,714 | 32,818 | 33,331 | 36,716 | 34,090 |
| Total operating expenses | 186,409 | 109,126 | 126,969 | 193,841 | 171,582 |
| Loss from operations | (92,039) | (61,406) | (14,448) | (78,942) | (88,731) |
| Interest income | 77 | 169 | 275 | 934 | 4,545 |
| Interest expense | (1,442) | (144) | (140) | (105) | (609) |
| Other income (expense), net | (34) | 15 | 239 | 171 | (1,433) |
| Loss before provision (benefit) for income taxes | (93,438) | (61,366) | (14,074) | (77,942) | (86,228) |
| Provision (benefit) for income taxes | (26) | 1 | 1 | (1,411) | 282 |
| Net loss | $ (93,412) | $ (61,367) | $ (14,075) | $ (76,531) | $ (86,510) |
| Net loss per common share: | | | | | |
| Basic and diluted (1) | $ (2.57) | $ (1.84) | $ (0.57) | $ (4.06) | $ (5.68) |
| Weighted-average number of common shares used in computing basic and diluted net loss per loss common share | 36,342 | 33,288 | 24,488 | 18,865 | 15,220 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2009 | 2008 |
| | (in thousands) | | | | |
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and short-term investments | $ 77,982 | $ 98,504 | $ 97,081 | $ 160,588 | $ 94,719 |
| Receivable from Takeda | 18,365 | 6,937 | — | 18,561 | 21,688 |
| Long-term investments | 2,323 | — | 19,876 | 7,978 | 22,945 |
| Total assets | 118,217 | 118,995 | 131,387 | 211,510 | 167,720 |
| Payable to Takeda | — | — | 5,958 | — | — |
| Deposit from Takeda | 559 | 1,998 | — | — | — |
| Advance from Takeda | 27,715 | 6,121 | — | — | — |
| Notes payable | 8,844 | — | — | — | — |
| Accumulated deficit | (543,713) | (450,301) | (388,934) | (374,859) | (298,328) |
| Total stockholders' equity | 8,281 | 75,997 | 72,547 | 66,905 | 8,984 |

(1) Please see Note 2 of Notes to 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.

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

### Overview

We are a biopharmaceutical company committed to discovering, developing and delivering innovative therapies that improve the lives of patients with kidney disease and other serious and often life-threatening illnesses. In March 2012, the U.S. Food and Drug Administration, or FDA, approved our first product, OMONTYS® (peginesatide) Injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. OMONTYS is a synthetic, peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Our product is the only once-monthly ESA that has been available to the adult dialysis patient population in the U.S. In 2012, we co-commercialized OMONTYS in the U.S. with our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, the largest pharmaceutical company in Japan.

In early 2013 and in consultation with the FDA, we and Takeda voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS. While we continue to investigate the potential cause of the safety concerns at this time, we face significant challenges to our business. We are unable to estimate the scope or timelines associated with the investigation, which may be costly and time-consuming, and with our limited funds and resources, we may not be able to complete the investigation or ever identify the causes of the safety concerns.

In March 2013, we undertook plans to reorganize our operations in order to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. In addition to transitioning many of the ongoing activities to our collaborator, Takeda, our plans include a significant reduction in force of approximately 230 employees (75% of our workforce), including our commercial and medical affairs field forces as well as other employees throughout the organization. We expect to incur between $8.0 million and $10.0 million in restructuring charges related to the workforce reduction during the first quarter of 2013. As a result of this restructuring and the recall, we may also incur additional charges depending on further review and additional reductions in operations and may also experience impairment changes with respect to our property and equipment and long lived assets in the first quarter of 2013.

We will continue to review our operations as we discuss with Takeda the roles and responsibilities of the parties in addressing our regulatory and other obligations resulting from the OMONTYS recall. In any event, we plan to continue to make efforts to substantially reduce our operating costs, which will likely include further reductions in force as we endeavor to conserve our cash resources. We have been in discussions with, and are planning to seek further assistance and support from Takeda as we transition from a commercial operating company to a company potentially without any product. We are undertaking steps to reduce all of our outstanding obligations to third parties and are dependent on those efforts to continue operations even in the near term, however, we may not be successful. We are particularly dependent on Takeda's willingness to continue the collaboration in a modified form that reduces our operating expenses and responsibilities under the collaboration, but we may also be required to reduce our share of OMONTYS profits if and when the product may be re-introduced in the future. Even if Takeda is willing to assume additional responsibilities under the collaboration, including the conduct of most or all of the ongoing investigation, the loss of critical personnel and functions means that we may not be able to maintain our operations, support the New Drug Application or NDA, continue as a going concern or ever re-introduce OMONTYS.

In view of our limited resources and funds, we plan to explore various strategic alternatives, including a sale of the company or its assets or a corporate merger. We are considering all possible alternatives, including further restructuring activities, wind-down of operations or even bankruptcy proceedings.

If we and Takeda are unable to rapidly identify and rectify the causes of the safety concerns to the satisfaction of the FDA, which is highly uncertain, OMONTYS may be permanently withdrawn from the market. The recall of OMONTYS has severely harmed our business, financial condition and prospects as a going concern. The recall has also limited our access to funds and the resources that may be required in order to address the safety concerns. As a result, we may be unable to continue our operations. In order to reintroduce OMONTYS, we would have to complete our ongoing thorough investigation, identify the causes of the safety concerns and provide a suitable plan to the FDA for approval. Accordingly, there can be no assurance that we can address the safety concerns and meet the requirements of the FDA for reintroduction. Moreover, even if

OMONTYS could be reintroduced, the commercial prospects for this product may be permanently diminished and the product may no longer be commercially viable.

In March 2012, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or, collectively, the Lenders, under which we may borrow up to a total of $30.0 million in two tranches. The first tranche of $10.0 million was borrowed in March 2012. The second tranche of $20.0 million was available for drawdown until March 31, 2013; however, it may no longer be available due to our recent recall of OMONTYS. In connection with the Loan Agreement, we issued the Lenders warrants to purchase 132,855 shares of our common stock, or the Warrants, which are exercisable at $11.855 per share. In September 2012, SVB Financial Group, the parent group of Silicon Valley Bank, exercised its Warrant for a net exercise of 23,453 shares of our common stock. In October 2012, Oxford Finance LLC exercised the remaining Warrants for a net exercise of 36,660 shares of common stock. Both of these Warrants were net exercised on a cashless basis. Since we suspended the marketing activities of OMONTYS and voluntarily recalled OMONTYS, we may be in breach under our Loan Agreement. The voluntary recall may be considered a material adverse event under the Loan Agreement. As a result, we have classified our loan balance as a current liability. Events of default under the Loan Agreement provide the Lenders with various rights, including the right to require immediate repayment of the outstanding principal plus accrued and unpaid interest through the prepayment date, the final payment of $0.5 million and the prepayment fee of $0.5 million. We have not received a notice of default. If we receive a notice of default from the Lenders, in addition to repaying the outstanding balance of our loan. we will also accrue the remaining final interest charge and the full amount of the final payment and the prepayment fee.

In 2012, we co-commercialized OMONTYS with Takeda. The commercial launch of the product occurred in April 2012. To commercialize OMONTYS, we established commercial and medical affairs infrastructures in 2012. The functions of our commercial and medical affairs infrastructures include marketing and sales, medical education, coverage and reimbursement and account management.

In 2012, we marketed our product primarily to dialysis organizations. Associated costs are included in selling, general and administrative costs or SG&A, in our accompanying financial statements.

In 2012, Takeda was responsible for account management, pricing and contracting. Specifically, Takeda had sole responsibility for invoicing and collection of receivables with regard to sales of OMONTYS. Takeda also has the rights and responsibility for establishing and modifying terms and conditions with customers with respect to the sale of OMONTYS in the U.S., including pricing discounts available to third-party payors, price adjustments and other allowable discounts and allowances. Both parties also have shared responsibilities such as joint marketing activities, business analytics and account management allocated by customer segments.

Outside of the U.S., Takeda holds an exclusive license to develop and commercialize OMONTYS and has primary responsibility for filing regulatory submissions and obtaining product approvals in those territories.

Revenues in 2012, 2011 and 2010 were derived almost exclusively from collaboration revenue from Takeda. Collaboration revenue consists of milestone payments, profit equalization revenue related to our share of product profit or loss on OMONTYS, reimbursement of development and commercialization expenses, and revenue for active pharmaceutical ingredient or API, under our agreements with Takeda or collectively, the Arrangement. We derived most of our collaboration revenue in 2012 from milestone payments and profit equalization revenue. From inception to December 31, 2012, we have received $122.0 million of upfront license fees, $115.3 million in milestone payments and $297.2 million related to the profit equalization revenue, the reimbursement of development and commercialization expenses and purchase of API under our Arrangement with Takeda. We are eligible to receive an aggregate of $357.0 million in additional milestone payments from Takeda upon successful achievement of as yet unmet clinical development and regulatory milestones and sales-based milestones. However, timing and amounts are extremely uncertain, due to the recall.

We have experienced significant operating losses since inception. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and API production, license fees, milestone payments and profit equalization revenue from Takeda, issuance of notes payable, capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. As of December 31, 2012, we had an accumulated deficit of $543.7 million. However, due to the recent recall of OMONTYS described under the caption "OMONTYS Voluntary Recall" under "Item 1. Business" of this Annual Report on Form 10-K, we anticipate that we will incur substantial losses in future periods and may continue to incur substantial losses in the long term depending on our success in reintroducing and commercializing OMONTYS. Our operations have consumed substantial amounts of cash since our inception. If we are unable to identify quickly the causes of the OMONTYS safety concerns or raise additional funds when required or on acceptable terms, we may have to:

- abandon the plan to reintroduce OMONTYS;
- assume greater risks and significantly delay, scale back, or discontinue operations;
- relinquish some or all of our existing rights to OMONTYS;
- eliminate or defer manufacturing efforts that may negatively impact OMONTYS; or
- pursue alternatives such as a restructuring or winddown of operations.

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants Affymax, Inc. or the Company, certain of its officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding the Company's business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. On March 19, 2013, a derivative lawsuit was filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuit alleges that certain of the Company's officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding the Company's business health, which was tied to the success of OMONTYS. The lawsuits also asserts claims for unjust enrichment and corporate waste. Additional complaints may be filed against us and our directors and officers related to our recall of OMONTYS. Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

We expect to continue to incur substantial operating losses as we investigate the cause of these safety concerns to OMONTYS, search for and implement solutions to address it and prepare for the potential reintroduction of OMONTYS as well as share in those efforts of Takeda's. When and if we reintroduce OMONTYS, we expect to incur additional operating losses as we add infrastructure and operations to support commercialization of OMONTYS, and potentially begin new R&D programs. Our ability to generate product sales and become profitable depends heavily on our ability to successfully reintroduce and commercialize OMONTYS. OMONTYS will require significant marketing efforts and substantial investment before it can provide us or our partners with any meaningful revenue. Accordingly, we may never generate significant revenues and, even if we do generate revenue in the future, we may never achieve or sustain profitability.

As a result of the February 23, 2013 nationwide voluntary recall of OMONTYS and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient existing cash, cash equivalents and investments to fund our operations for the next 12 months. If we were to reduce cash outflows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations. If we are not able to reintroduce the product or obtain additional funding in the near future, our cash resources will rapidly be depleted and we will be required to materially reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to liquidate our assets, seek bankruptcy protection or other alternatives that would likely result in receiving less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or some of their investment in us. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect our ability to enter into collaborative relationships with business partners, make it more difficult to obtain required financing on favorable terms or at all, negatively affect the market price of our common stock and could otherwise have a material adverse effect on our business, financial condition and results of operations.

If the recall is not lifted and we are not able to reintroduce OMONTYS, this will result in a severe decrease to our profit equalization revenue in future periods. Even if we are successful in reintroducing and commercializing OMONTYS in the future, there can be no assurance that revenues will ramp up rapidly enough to offset operating losses and repayment of debts. Further challenges or delays to potential reintroduction and commercialization of OMONTYS may require us to raise additional funding to successfully reintroduce and commercialize OMONTYS. 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 that may limit our ability to conduct our business and increase our risk of defaults. The market may take into consideration of the recent recall of OMONTYS, which recall is described under the caption "OMONTYS Voluntary Recall" in "Item 1. Business" of this Annual Report on Form 10-K which may negatively affect our ability to obtain additional funding. Market conditions 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 successfully reintroduce and commercialize OMONTYS, and funding may not be available to us on acceptable terms, or at all.

**Results of Operations**

*Revenue*

During the commercialization period, which commenced in June 2011, we receive reimbursement for certain collaboration expenses. Takeda bears responsibility for 70% of third-party expenses related to U.S. development and 50% of third party expenses related to the commercialization of OMONTYS in the U.S. incurred by us and we are responsible for the reciprocal amount of development and commercialization expenses. Certain employee-related expenses supporting preparation for commercialization of OMONTYS in the U.S. are also shared equally. Such employee-related costs include the cost of certain employees that are required to commercialize OMONTYS 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 generally shared equally.

During the development period under the Arrangement with Takeda, which ended in May 2011 upon the submission of our NDA to the FDA for review, collaboration revenue was recognized using the Contingency Adjusted Performance Model, or CAPM. As a result, any payments from Takeda under the Arrangement were recorded as deferred revenue and recognized ratably over the estimated development period. Prior to the approval of OMONTYS, collaboration revenue had consisted of reimbursement of development and commercial expenses, net of Takeda's own eligible expenses, and milestone payments.

OMONTYS sales by Takeda commenced in September 2012. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, our collaboration revenue consisted of profit equalization revenue generated from our collaboration agreement with Takeda, milestone payments, reimbursements of certain eligible development and commercial expenses, net of Takeda's own eligible expenses, and revenue previously deferred related to payments we received associated with previously expensed API, which have been sold by Takeda. Revenue from profit equalization is calculated on a quarterly basis as the amount required so that the profit or loss realized by both Affymax and Takeda on OMONTYS equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS is calculated as gross product sales recorded by Takeda, less the following deductions recorded by Takeda: rebates and discounts, cost of goods and other gross-to-net adjustments incurred by Takeda, royalty expense incurred by us, commercialization expenses (full-time equivalents or FTE, related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by both Takeda and us.

Revenue as compared to prior years is as follows (in thousands):

| | Year ended December 31, | | | Percent Change | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012/2011 | 2011/2010 |
| Collaboration revenue | $ 94,358 | $ 47,703 | $ 112,503 | 98 % | (58)% |
| License and royalty revenue | 12 | 17 | 18 | (29)% | (6)% |
| Total revenue | $ 94,370 | $ 47,720 | $ 112,521 | 98 % | (58)% |

Revenue increased $46.7 million from $47.7 million in 2011 to $94.4 million in 2012. The increase in collaboration revenue for the year ended December 31, 2012 compared to the year ended December 31, 2011 was primarily due to the recognition of $60.3 million in milestone payments from Takeda related to FDA approval of OMONTYS, the European Medicines Agency, or EMA's acceptance for review of the Marketing Authorization Application or MAA submitted by Takeda, and commercial progress on the OMONTYS product launch and our profit equalization revenue[(1)] related to the commencement of OMONTYS sales, and revenue previously deferred related to previously expensed API, which is partially offset by a decrease in amounts eligible for reimbursement under our Arrangement with Takeda.

Revenues decreased $64.8 million from $112.5 million in 2010 to $47.7 million in 2011. The decrease in collaboration revenue for the year ended December 31, 2011 compared to the year ended December 31, 2010 was due to a reduction in overall research and development or R&D 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 $10.0 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 $5.0 million milestone payment from Takeda for the initiation of Phase 3 renal indication in Japan in March 2010 and $30.0 million in milestone payments for the database lock of our non-dialysis and dialysis Phase 3 trials in the second quarter of 2010. Both of these milestones were accounted for under CAPM.

The following table presents our collaboration revenue, by revenue type, for the periods presented (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Profit equalization revenue [1] | $ 26,544 | $ — | $ — |
| Milestone payments | 60,250 | 10,000 | — |
| Revenue previously deferred related to API | 936 | — | — |
| Revenue recognized under CAPM | — | 26,606 | 112,503 |
| Net expense reimbursement after CAPM | 6,628 | 11,097 | — |
| Total collaboration revenue | $ 94,358 | $ 47,703 | $ 112,503 |

[1] Revenue from profit equalization is calculated on a quarterly basis as the amount required such that the profit or loss realized by both Affymax and Takeda on the product equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS is calculated as gross product sales recorded by Takeda, less the following deductions also recorded by Takeda: rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; royalty expense incurred by us, commercialization expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by both Takeda and us. Profit equalization revenue is recognized as revenue in the period product revenue is recognized by Takeda.

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. We and Takeda are actively investigating the cause of these reactions but there can be no assurance that a solution will be found. As a result of the voluntary recall of OMONTYS, all marketing activities have been suspended and there is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. Although we still maintain a license and are actively exploring a cause for the allergic reactions, we do not know when this reintroduction will occur, if at all. If the recall is not lifted and we are not able to reintroduce OMONTYS, this will result in a severe decrease to our profit equalization revenue or potentially profit equalization losses in future periods. The total estimated product returned in the recall all relates to product shipped subsequent to December 31, 2012; as a result there was no impact to the 2012 profit equalization revenue resulting from the recall. Given the uncertainty of any profit equalization revenue in future periods, we have recharacterized our deferred revenue as an Advance from Takeda, which is reflected as a current liability in our December 31, 2012 financial statements. Additionally, although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any, are extremely uncertain due to the recall.

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Research & development | $ 15,480 | $ 22,412 | $ 35,305 |
| Selling, general & administrative | 43,748 | 8,471 | 8,241 |
| Total | $ 59,228 | $ 30,883 | $ 43,546 |

The change in the mix of costs subject to reimbursement in 2012 compared to 2011 was primarily due to our company shifting from being a R&D company to now becoming a commercial company. In 2012, we commercially launched OMONTYS which resulted in much larger commercial-related reimbursements. In 2011, our primary focus was obtaining FDA approval which was more R&D-related. We expect collaboration revenue to fluctuate with changes in revenue related to the profit equalization of the collaboration and with changes in the amount of reimbursable expenses for our direct development. Revenue/

loss from profit equalization is influenced by a number of factors, some of which may impact the sales of OMONTYS and reimbursement of collaboration expenses more significantly than others, including, but not necessarily limited to, our ability to reintroduce OMONTYS following the February 2013 recall and the level of reimbursable costs incurred by us versus those incurred by Takeda including costs associated with the recall, costs of the investigation and potential write offs of API or drug product inventory by Takeda. We do not expect an income statement charge for these as we believe that our exposure is adequately covered under our Advance from Takeda as of December 31, 2012. Although we are eligible to receive future milestones from Takeda, timing and amounts are extremely uncertain due to the recall.

*Cost of Manufacturing API for the Collaboration*

The cost of manufacturing API is not reflected in our statement of operations as we are reimbursed by Takeda for all costs we incur with third parties. At the time of FDA approval in March 2012, we had produced approximately $20.5 million of commercial grade API that had been expensed previously as R&D expenses. As of December 31, 2012, all of the previously expensed API has been shipped to Takeda, of which we have already been reimbursed $18.4 million by Takeda and have a receivable for the remaining balance.

Revenue in the year ended December 31, 2012 was benefited by API material previously expensed. Our collaboration revenue related to API for the year ended December 31, 2012 was $0.9 million, compared to $0.2 million that would have been recorded as revenue if the API were not previously expensed. As of December 31, 2012, we had a remaining balance of $17.8 million in deferred revenue related to previously expensed API. Given the uncertainty of any profit equalization revenue in future periods we have recharacterized our deferred revenue as an Advance from Takeda, which is reflected as a current liability in our December 31, 2012 financial statements. As a result of the recall, we also wrote off $8.4 million of inventory and prepayments made to our contract manufacturing organizations or CMOs. Given the uncertainty in future revenues at this time, we cannot predict if or when we will start recognizing revenues from API.

*Impairment of Inventory and Losses on Firm Purchase Commitments*

Impairment of inventory and losses on firm purchase commitments, as compared to prior years are as follows (in thousands):

| | Year ended December 31, | | | Percent Change | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012/2011 | 2011/2010 |
| Impairment of inventory and losses on firm purchase commitments | $ 44,957 | $ — | $ — | N/A | N/A |

As a result of the voluntary recall of OMONTYS in February 2013, any future collaboration revenue related to API is significantly uncertain as all marketing activities have been suspended and there is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. Dialysis organizations have been instructed to discontinue use and return any unused product to Takeda for a refund. If the recall is not lifted and we are not able to reintroduce, this will result in a severe decrease to our profit equalization revenue or potentially profit equalization losses in future periods.

In connection with the recall and in consultation with Takeda, we have undertaken efforts to suspend manufacturing activities to the extent practicable pending consideration of next steps with OMONTYS. If we are successful in identifying the cause of these safety concerns and addressing it, we and Takeda will determine the next appropriate steps to take with OMONTYS. Prior to such time, we plan to evaluate strategies to decrease our ongoing manufacturing costs and commitments, including but not limited to, termination of orders and agreements, which may negatively impact our ability to reintroduce OMONTYS. If we are able to reintroduce OMONTYS, we intend to continue to rely on third-party manufacturers to produce API, which may require significant effort and validation of new CMOs.

We initiate orders for API with our CMOs based on forecasts from Takeda, which are based on expected demand for OMONTYS. Orders generally have commenced once there was a contractual commitment for the API from Takeda. As of December 31, 2012, we have future purchase commitments amounting to $34.6 million covering CMO costs for API through 2013, assuming we continue manufacturing API according to plan. These future commitments are comprised of $5.8 million for firm purchase commitments of bulk poly(ethylene) glycol reagent, or PEG, and the remaining $28.8 million of manufacturing obligations relate to API, and are based on firm forecasts from Takeda and therefore may be subject to reimbursement under the API Supply Agreement with Takeda. If we elect to terminate one or more of our CMO contracts then the amount of the purchase commitment could be substantially reduced, and in lieu of termination, we may be able to negotiate a reduced obligation with our CMOs under existing agreements.

In addition to the binding CMO purchase commitments, we also had $10.4 million in inventory and prepayments made to our CMOs on our balance sheet as of December 31, 2012. As a result of the the inability to sell OMONTYS and the uncertainty of future revenues, we have written down our API inventory and prepayments for API being produced by our CMOs to a net realizable value of zero and have recorded an $10.4 million impairment charge related to this writedown. We have also recorded a $34.6 million loss on firm purchase commitments by applying the same lower of cost or market approach that is used to value inventory. If actual net realizable values of the underlying inventory are subsequently more favorable as a result of a reintroduction of the product, we may experience favorable effects on our operating results if any inventory impairment and losses on firm purchase commitments that have been recorded are reversed, potentially resulting in a gain. Of the total $45.0 million charge for impairment of inventory and loss on CMO purchase commitments, we have the right under the Arrangement to submit to Takeda for reimbursement $18.4 million of such expenses. However because of uncertainty of future amounts to be received, we have not recorded a receivable from Takeda. At the time we and Takeda identify the cause of the safety concern, or if no cause is determined and both parties agree on an expense distribution, we would then expect to submit the amounts to Takeda for reimbursement.

Takeda capitalizes inventory costs associated with the production of OMONTYS and enters into purchase commitments for goods associated with this manufacturing. The write down or write off of such inventory and any charges for purchase commitments by Takeda would be subject to the profit equalization revenue or loss calculation of the Arrangement. We estimate that inventory charges of $2.5 million may be billed to us during the first quarter of 2013 based on the manufacturing costs incrred by Takeda as of December 31, 2012. With respect to purchase commitments, Takeda may request reimbursement for a portion of the costs associated with Takeda's firm purchase commitment of $9.3 million with Baxter for pre-filled syringes. Our exposure is limited to the portion of the Baxter agreement that relates to the U.S. We have no liability related to the E.U. or Japan because in those countries we receive only a royalty on product sales and the collaboration profit split does not apply to operations in those countries. The amount of our exposure is estimated to be $0.7 million which we expect to incur in the first quarter of 2013.

Per the Arrangement, the allocation of expenses incurred in connection with a recall is based on the source of the defect if determinable. We believe the total costs of recalling the product, which is primarily composed of costs to a third-party to gather, store, and return the product to Takeda, to be incurred in 2013, will range from $2.0 million to $3.0 million. The Arrangement provides that the allocation of expenses incurred in connection with a recall is to be based on the source of the defect, if determinable. If the recall is determined to be due to manufacturing defect of bulk API, then we are required to bear all such recall expenses. If the recall is determined to be due to manufacturing defect of finished product, then Takeda is required to bear all such recall expenses. If the recall is determined to be due to both manufacturing defects of the API and the manufacturing of the final drug product, then we and Takeda are required to share recall expenses proportionally. Given the ongoing nature of the investigation, the cause of the recall is not yet known and the range of recall costs that we may ultimately be responsible for may be up to the full amount of the costs incurred.

*Research and Development Expenses*

The major components of R&D expenses include clinical trial expenses, consulting and other third-party costs, API manufacturing costs incurred prior to FDA approval, salaries and employee benefits, license fees paid to third parties for use of their intellectual property, supplies and allocations of various overhead and occupancy costs. Clinical trial expenses include, but are not limited to, contract research organization, or CRO, and investigator fees, site costs, comparator drug costs and clinical research organization costs. All R&D expenses are expensed as incurred. R&D expenses, as compared to prior years are as follows (in thousands):

| | Year ended December 31, | | | Percent Change | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012/2011 | 2011/2010 |
| Research and development expenses | $ 51,738 | $ 76,308 | $ 93,638 | (32)% | (19)% |

R&D expenses declined $24.6 million from 2011 to 2012. The decrease in R&D expenses in 2012 compared to 2011 was primarily due to reduced consultant costs as a result of both the completion of our filing of our NDA in May 2011 and of the preparation for our FDA advisory committee meeting which occurred in December 2011 and reduced personnel related costs related to the reduction in force implemented in the third quarter of 2011. This was partially offset by ongoing clinical trial activity on our Phase 3b trial, and a Phase 2 study in Pure Red Cell Aplasia, or PRCA patients.

R&D expenses declined $17.3 million from 2010 to 2011. The decrease in R&D expenses in 2011 compared to 2010 was primarily due to 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 related to a change in estimate in

our clinical trial accrual regarding final close-out activities with both of our major CROs on the Phase 3 studies. This decrease was partially offset by $8.0 million of fixed payments related to the 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, which we collectively refer to as Janssen (see Note 4 of Notes to Financial Statements), costs related to our Phase 3b study commenced in the third quarter of 2011 and $0.9 million in employee-related restructuring costs related to a reduction in force incurred in 2011.

We expect to critically evaluate the level of R&D expenses we incur in future periods as a result of the voluntary recall of OMONTYS in February 2013 and the uncertainty as to when or if we will be able to reintroduce OMONTYS. Except in connection with the investigation of the cause of the recall, we plan to suspend further investment in R&D, including conduct of clinical trials pending consideration of next steps with OMONTYS.

*Selling, General and Administrative Expenses*

SG&A expenses consist principally of salaries, employee benefits, consulting, professional fees for legal, auditing and tax services, marketing and commercial support for OMONTYS, allocation for overhead and occupancy costs and royalty expense. SG&A, expenses as compared to prior years are as follows (in thousands):

| | Year ended December 31, | | | Percent Change | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012/2011 | 2011/2010 |
| Selling, general and administrative expenses | $ 89,714 | $ 32,818 | $ 33,331 | 173% | (2)% |

SG&A expenses increased $56.9 million from 2011 to 2012. The increase in SG&A expenses in 2012 compared to 2011 was primarily due to higher commercialization expenses related to expansion of our commercial capabilities, including the establishment of a field sales force and other activities to support our commercialization efforts. In addition, as a result of our FDA approval, we also expensed a one-time milestone payment of $2.0 million to Nektar Therapeutics AL Corporation, or Nektar, during the three months ended March 31, 2012 and also incurred $1.8 million in royalty expense resulting from the introduction of OMONTYS in 2012.

SG&A expenses declined $0.5 million from 2010 to 2011. The decrease in SG&A expenses in 2011 as compared to 2010 was primarily due to lower legal costs. This decrease was partially offset by higher commercial expenses related to expansion of our commercial capabilities as we prepared for potential FDA approval of OMONTYS, a facilities-related restructuring charge of $0.9 million related to idle and excess office space, and increased employee compensation costs.

As a result of the voluntary recall of OMONTYS, all product has been recalled and all marketing activities have been suspended. There is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. We are unlikely to be able to maintain the commercial and medical affairs resources and capabilities we had established prior to the recall, which would reduce our SG&A expenses; however this could negatively impact our ability to reintroduce OMONTYS even if we are able to successfully identify and address the cause of these safety concerns in the near term, which is highly uncertain.

*Interest Income (Expense), Net*

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

| | Year ended December 31, | | | Percent Change | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012/2011 | 2011/2010 |
| Interest income | $ 77 | $ 169 | $ 275 | (54)% | (39)% |
| Interest expense | $ (1,442) | $ (144) | $ (140) | 901 % | 3 % |
| Interest income (expense), net | $ (1,365) | $ 25 | $ 135 | (5,560)% | (81)% |

The decrease from interest income, net to interest expense, net was due primarily to interest expense related to our notes payable with the Lenders and our launch allowance with Takeda and lower interest rates and lower average cash balance during the year ended December 31, 2012 compared to the same period in 2011. The decrease in interest income (expense), net in 2011 as compared to 2010 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.

Since we suspended the marketing activities of OMONTYS and voluntarily recalled OMONTYS, we may be in breach under our Loan Agreement. The voluntary recall may be considered a material adverse event under the Loan Agreement that may result in an event of default. If there is a notice of default from the Lenders, interest expense may increase in 2013 because of the acceleration of interest expense for interest payments due at maturity. Events of default under the Loan Agreement provides the Lenders various rights, including the right to require immediate repayment of the outstanding principal plus accrued and unpaid interest through the prepayment date, the final payment of $0.5 million and the prepayment fee of $0.5 million. Additionally, the default may increase the interest rate by an additional 500 basis points (5.0)% applied to the outstanding loan balance.

*Other Income (Expense), Net*

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

| | Year ended December 31, | | | Percent Change | |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012/2011 | 2011/2010 |
| Other income (expense), net | $ (34) | $ 15 | $ 239 | (327)% | (94)% |

Other expense, net, for the year ended December 31, 2012 includes a $30,000 loss on disposal of fixed assets. Other income, net, for year ended December 31, 2011 includes a $13,000 insurance refund. 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.

*Provision for Income Taxes*

We are subject to federal and state income taxes. While we did generate net income during the first quarter of 2012 due to significant milestone payments received in the period, we were in a net operating loss position for 2012 and therefore have not recorded any federal or state taxes, other than a benefit of federal statute of limitations lapsing on a previously reserved tax benefit and the minimum statutory California tax, for the year ended December 31, 2012. We also did not record any tax liability for the year ended December 31, 2011 and 2010 other than the minimum statutory California tax due to the anticipated tax loss position for the year ended December 31, 2011 and 2010.

As of December 31, 2012 and 2011, 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 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, 2012 and 2011 are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Cash and cash equivalents | $68,265 | $54,339 |
| Short-term investments | $9,717 | $44,165 |
| Long-term investments | $2,323 | — |

As of December 31, 2012, we had $81.4 million in cash, cash equivalents, restricted cash and marketable securities. Our cash and investment balances are held in a variety of interest bearing instruments, including corporate debt securities, and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation. As of December 31, 2012, we had total debt of $8.8 million, which consists of the face value of the notes payable less the net debt discount associated with the issuance of warrants to our Lenders.

*Working Capital.* Working capital was $3.4 million at December 31, 2012, a decrease of $83.9 million from working capital as of December 31, 2011. This decrease was primarily attributable to:

- a decline of $20.5 million in cash, cash equivalents and marketable securities
- an increase of $38.5 million in accrued liabilities, primarily related to accrued potential losses on firm purchase commitments
- an increase of $27.7 million in Advance from Takeda

- an increase of $8.8 million in the current portion of debt.
- The decrease was partially offset by an increase of $11.4 million in accounts receivable from Takeda.

As a result of the February 23, 2013 nationwide voluntary recall of OMONTYS and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient existing cash, cash equivalents and investments to fund our operations for the next 12 months. If we were to reduce cash outflows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations. If we are not able to reintroduce the product or obtain additional funding in the near future, our cash resources will rapidly be depleted and we will be required to materially reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to liquidate our assets, including relinquish some or all of our existing rights to OMONTYS, seek bankruptcy protection or other alternatives that would likely result in receiving less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or some of their investment in us. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect our ability to enter into collaborative relationships with business partners, make it more difficult to obtain required financing on favorable terms or at all, negatively affect the market price of our common stock and could otherwise have a material adverse effect on our business, financial condition and results of operations.

In March 2013, we undertook plans to reorganize our operations in order to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. In addition to transitioning many of the ongoing activities to our collaborator, Takeda, our plans include a significant reduction in force of approximately 230 employees (75% of our workforce), including our commercial and medical affairs field forces as well as other employees throughout the organization. We expect to incur between $8.0 million and $10.0 million in restructuring charges related to the workforce reduction during the first quarter of 2013. As a result of this restructuring and the recall, we may also incur additional charges depending on further review and additional reductions in operations and may also experience impairment changes with respect to our property and equipment and long lived assets in the first quarter of 2013.

We will continue to review our operations as we discuss with Takeda the roles and responsibilities of the parties in addressing our regulatory and other obligations resulting from the OMONTYS recall. In any event, we plan to continue to make efforts to substantially reduce our operating costs, which will likely include further reductions in force as we endeavor to conserve our cash resources. We have been in discussions with, and are planning to seek further assistance and support from Takeda as we transition from a commercial operating company to a company potentially without any product. We are undertaking steps to reduce all of our outstanding obligations to third parties and are dependent on those efforts to continue operations even in the near term, however, we may not be successful. We are particularly dependent on Takeda's willingness to continue the collaboration in a modified form that reduces our operating expenses and responsibilities under the collaboration, but we may also be required to reduce our share of OMONTYS profits if and when the product may be re-introduced in the future. Even if Takeda is willing to assume additional responsibilities under the collaboration, including the conduct of most or all of the ongoing investigation, the loss of critical personnel and functions means that we may not be able to maintain our operations, support the NDA, continue as a going concern or ever re-introduce OMONTYS.

In view of our limited resources and funds, we plan to explore various strategic alternatives, including a sale of the company or its assets or a corporate merger. We are considering all possible alternatives, including further restructuring activities, wind-down of operations or even bankruptcy proceedings.

If the recall is not lifted and we are not able to reintroduce OMONTYS, this will result in a severe decrease to our profit equalization revenue in future periods. Even if we are successful in reintroducing and commercializing OMONTYS in the future, there can be no assurance that revenues will ramp up rapidly enough to offset operating losses and repayment of debts. Further challenges or delays to potential reintroduction and commercialization of OMONTYS may require us to raise additional funding to successfully reintroduce and commercialize OMONTYS. 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 that may limit our ability to conduct our business and increase our risk of defaults. The market may take into consideration of the recent recall of OMONTYS, which recall is described under the caption "OMONTYS Voluntary Recall" in "Item 1. Business" of this Annual Report on Form 10-K which may negatively affect our ability to obtain additional funding. Market conditions 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 successfully reintroduce and commercialize OMONTYS, and funding may not be available to us on acceptable terms, or at all. Since we suspended the marketing activities of OMONTYS and voluntarily recalled OMONTYS, we may be in breach under our Loan Agreement with the Lenders. The voluntary recall may be considered a material adverse event under the Loan

Agreement which may result in an event of default. Therefore, the remaining $20.0 million under the Loan Agreement may no be longer available to us.

Our independent registered public accounting firm, in their audit report on our financial statements for the year ended December 31, 2012, expressed substantial doubt about our ability to continue as a going concern.

Since our inception, we have financed our operations through sale of capital stock, license fees, milestone payments, reimbursement for development and commercial expenses, profit equalization revenue for OMONTYS, and manufacturing costs from collaborative partners, issuance of notes payable, capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through December 31, 2012, we have received net proceeds of $458.5 million from the issuance of equity 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.

Due to our announcement of our voluntary recall of OMONTYS in February 2013, there has been an extremely high volume of trading of our stock, which has caused a significant drop in the value of our stock. As a result of the high trading volume, there may be a shift of ownership amongst our 5% stockholders that could result in an ownership change, under Section 382 of the Internal Revenue Code of 1986, as amended. Under Section 382, a corporation that undergoes an ownership change, as defined by the Internal Revenue Code, may be subject to significant limitations on its ability to utilize its net operating losses or NOLs, and tax credits accumulated prior to the ownership change to offset future taxable income or tax liabilities. We are currently in the process of assessing the impact. At December 31, 2012, deferred tax assets were offset by a valuation allowance except to the extent of possible taxable income in an earlier period.

*Financing Agreements*

*Loan Agreement.* In March 2012, we entered into the Loan Agreement, with the Lenders, under which we may borrow up to a total of $30.0 million in two tranches for general corporate purposes. The first tranche of $10.0 million was borrowed in March 2012. The second tranche of $20.0 million was available for drawdown until March 31, 2013; however, it may no longer be available due to our recent recall of OMONTYS. Events of default include failure to deliver financial statements and reports to the Lenders on a timely basis, failure to file all required tax returns on a timely basis, failure to maintain insurance on collateral, and other routine and customary requirements under a loan agreement. The Loan Agreement also contains negative covenants that restrict our ability to incur additional debt financing, change in business purpose, merge or consolidate, or encumbrance of assets without prior written consent of the Lenders. The interest rate for the first tranche will be fixed upon drawdown of the respective tranche at a per annum rate equal to the greater of 8.95% or 8.57% plus the then effective U.S. Treasury note yield to maturity for a 36 month term determined three (3) business days prior to the funding date of the tranche (but in any event not less than thirty-eight basis points (0.38%)). The interest rate related to the drawdown of the first tranche is 9.11%. Payments under the Loan Agreement for the first tranche are interest-only through February 1, 2013, followed by equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2015. In addition to the monthly principal and interest payments, a final payment equal to 5% of the aggregate amount drawn, or $0.5 million for the first tranche, will be due on the earliest to occur of (1) the last amortized payment, (2) the acceleration of the loan or (3) prepayments of the loan, as specified in the Loan Agreement (See Note 8 of Notes to Financial Statements). Since we suspended the marketing activities of OMONTYS and voluntarily recalled OMONTYS, we may be in breach under our Loan Agreement. The voluntary recall may be considered a material adverse event under the Loan Agreement which may result in an event of default. Events of default under the Loan Agreement provide the Lenders with various rights, including the right to require immediate repayment of the outstanding principal plus accrued and unpaid interest through the prepayment date, the final payment of $0.5 million and the prepayment fee of $0.5 million. We have not received a notice of default. If we receive a notice of default from the Lenders, in addition to repaying the outstanding balance of our loan, we will also accrue the remaining final interest charge and the full amount of the final payment and the prepayment fee.

*Funding from our Collaboration Partner*

We have received cumulative amounts of $122.0 million of upfront license fees, $115.3 million in milestone payments and $297.2 million related to profit equalization revenue, the reimbursement of development and commercialization expenses and purchase of API under our Arrangement with Takeda. Takeda has the right to terminate the June 2006 collaboration agreement in its entirety, upon written notice to Affymax by at least six months written notice prior to the effective date of the termination.

In early 2013 and in consultation with the FDA, we and Takeda voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS. While we continue to investigate the potential cause of the safety concerns, we are unable to estimate the scope or timelines associated

with the investigation. If we are unable to identify and rectify the causes of the safety concerns to the satisfaction of the FDA, OMONTYS may be withdrawn from the market and we may be unable to continue our operations as a going concern.

*Eligible Profit Equalization Profit and Loss from our Collaboration Partner.*

In connection with the recall and in consultation with Takeda, as appropriate, we plan to evaluate the near-term activities, our respective rights and obligations of the parties under the agreements including the deployment of resources as part of our efforts to decrease our ongoing costs and commitments, which may negatively impact our ability to reintroduce OMONTYS, if such opportunity arises.

Takeda capitalizes inventory costs associated with the production of OMONTYS and enters into purchase commitments for goods associated with this manufacturing. The write down or write off of such inventory and any charges for purchase commitments by Takeda would be subject to the profit equalization revenue or loss calculation of the Arrangement. We estimate that inventory charges of $2.5 million may be billed to us during the first quarter of 2013 based on the manufacturing costs incurred by Takeda as of December 31, 2012. With respect to purchase commitments, Takeda may request reimbursement for a portion of the costs associated with Takeda's firm purchase commitment of $9.3 million with Baxter for pre-filled syringes. Our exposure is limited to the portion of the Baxter agreement that relates to the U.S. We have no liability related to the E.U. or Japan because in those countries we receive only a royalty on product sales and the collaboration profit split does not apply to operations in those countries. The amount of our exposure is estimated to be $0.7 million which we expect to incur in the first quarter of 2013.

We believe the total costs of recalling the product, which is primarily composed of costs to a third-party to gather, store, and return the product to Takeda will range from $2.0 million to $3.0 million. These costs are expected to be primarily incurred in the first quarter of 2013 and have not been accrued as of December 31, 2012. The Arrangement provides that the allocation of expenses incurred in connection with a recall is to be based on the source of the defect, if determinable. If the recall is determined to be due to manufacturing defect of bulk API, then we are required to bear all such recall expenses. If the recall is determined to be due to manufacturing defect of finished product, then Takeda is required to bear all such recall expenses. If the recall is determined to be due to both manufacturing defects of the API and the manufacturing of the final drug product, then we and Takeda are required to share recall expenses proportionally. Given the ongoing nature of the investigation, the cause of the recall is not yet known and the range of recall costs that we may ultimately be responsible for may be up to the full amount of the costs incurred.

In the first quarter of 2013, we believe Takeda will record an impairment charge for certain long lived assets associated with OMONTYS. Under the profit/loss equalization, we are responsible for half of these charges. We estimate our exposure related to this impairment to be approximately $7.0 million. This amount has not been accrued as of December 31, 2012.

*Profit Equalization Revenue/Loss.* While Takeda is responsible for the sale of OMONTYS and accordingly Takeda records product revenue, we and Takeda share equally in the net profits and losses of OMONTYS in the U.S. The profit equalization revenue is calculated on a quarterly basis as the amount required so that the profit or loss realized by both Affymax and Takeda on the product equates to 50% of the total product profit or loss. In determining the OMONTYS net profit or loss, OMONTYS product revenue is reduced by rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; royalty expense incurred by us, commercialization expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by Takeda and us. The profit equalization amount is recognized as revenue in the period the product sales occur and product revenue is recognized by Takeda.

*Launch Allowance.* Takeda funded the first $20.0 million of U.S. commercial expenses. Amounts received under the launch allowance are non-refundable. As part of the launch allowance, 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 $11.0 million (see Note 3 of Notes to Financial Statements). In 2012, Takeda deducted a total of $2.8 million against the profit equalization and are eligible to deduct the balance against future profit equalization revenue.

*API Payments.* Under the terms of the API Supply Agreement, we are responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda reimburses us for our cost of API plus 20%. During the year ended December 31, 2012, we received $13.5 million in payments for API, substantially all of which is recorded as a liability in our balance sheet as an Advance from Takeda as of December 31, 2012.

*Milestone Payments.* Additionally, we are eligible to receive a total of $357.0 million in additional milestone payments, which include the milestones below. Upon the successful achievement of as yet unmet clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate amount of $95.0 million of substantive milestone payments relating to the renal program of which $20.0 million is associated with the first approval in either pre-dialysis or

dialysis indication in the first major European Union or E.U. country. The remaining $75.0 million in payments for the renal program under the worldwide agreement are aggregated as they do not have estimated dates of achievement in the near- or medium-term. In addition, we are eligible to receive from Takeda an aggregate of $112.0 million of substantive milestone payments related to oncology for unmet clinical development and regulatory milestones and only a portion of these payments relate to the U.S. The collaboration is not pursuing the oncology program; accordingly, future payment of this aggregate amount is unlikely. In addition, we are eligible to receive up to $150.0 million of sales-based milestones. Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any, are extremely uncertain due to the recall.

*Expense Reimbursement Payments.* We are eligible to receive reimbursement from Takeda for 70% of all third-party expenses related to U.S. development in the U.S. (See Note 3 of Notes to Financial Statements).

*Settlement and License Agreement*

In November 2011, we entered into the Settlement and License Agreement with Janssen, which required us to make two fixed payments to Janssen of $6.0 million, which was paid in December 2011, and $2.0 million which was paid in June 2012. The Settlement and License Agreement required us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of OMONTYS, and requires us to make a $2.5 million milestone payment to Janssen upon regulatory approval of OMONTYS in the first major European country. In addition, Janssen will be entitled to royalties on sales of OMONTYS in Europe, Japan and certain other countries outside of the U.S. 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. Upon FDA approval of OMONTYS in March 2012, we capitalized $2.5 million related to the first milestone payment during the first quarter of 2012. The resulting asset will be amortized over the expected life of the related patent family, the last-expiring patent of which expires in June 2016. This $2.5 million milestone payment to Janssen was paid in April 2012.

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 agreed to pay up to $6.5 million in additional milestones to us in consideration of the upfront and milestone payments that we are required to make to Janssen under the Settlement and License Agreement (see Note 4 of Notes to Financial Statements). These milestones were substantive and at risk at the time that we entered into the amendment with Takeda. $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 June 30, 2012, $3.0 million of these milestones had been earned as a result of FDA approval of OMONTYS, which we received payment in the second quarter of 2012. In July 2012, we earned an additional $2.25 million milestone as a result of commercial progress on the OMONTYS product launch, which was recognized as revenue in the third quarter of 2012. There are no royalties to Janssen on U.S. sales of OMONTYS, but we are solely responsible for the royalty payment to Janssen on sales of OMONTYS in certain regions outside the U.S. when and if it is approved in those regions.

*Cash Flows during the Years Ended December 31, 2012, 2011, and 2010*

In summary, our cash flows for the periods presented are as follows (in thousands):

| | December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Net cash used in operating activities | $ (37,180) | $ (71,966) | $ (49,234) |
| Net cash provided by (used in) investing activities | 27,995 | 8,001 | (11,479) |
| Net cash provided by (used in) financing activities | 23,111 | 54,805 | (1,084) |

Net cash used in operating activities for the years ended December 31, 2012, 2011, and 2010, was $37.2 million, $72.0 million, and $49.2 million, respectively. Net cash used in operations for all periods reflects our net loss partially offset by the benefit of payments received from Takeda related to milestone payments, profit equalization revenue, and reimbursement for development and commercial expense and purchases of API by Takeda. Cash used in operating activities in 2012 as compared to 2011 decreased by $34.8 million primarily due to higher noncash expenses related to impairment of inventory and losses on firm purchase commitments in 2012 compared to 2011. Cash used in operating activities in 2011 as compared to 2010 increased by $22.7 million primarily due to a higher net loss in 2011 compared to 2010.

Net cash provided by investing activities for the year ended December 31, 2012 of $28.0 million was primarily due to maturities of investments, partially offset by the purchases of investments and property and equipment and payments related to OMONTYS intellectual property. Net cash provided by investing activities for the year ended December 31, 2011 of $8.0

million 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, 2012 was primarily attributable to proceeds of $10.0 million received from the issuance of a notes payable and $13.1 million received from the issuance of common stock upon exercise of stock options and our employee stock purchase plan. 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 secondary public offering in March 2011 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 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 Opportunity, Ltd. during the year.

In early 2013 and in consultation with the FDA, we and Takeda, voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS. While we continue to investigate the potential cause of the safety concerns, we are unable to estimate the scope or timelines associated with the investigation. If we are unable to identify and rectify the causes of the safety concerns to the satisfaction of the FDA, OMONTYS may be withdrawn from the market and we may be unable to continue our operations as a going concern.

**Contractual Obligations and Significant Commitments**

Our future contractual obligations, including financing costs, at December 31, 2012, are as follows (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **2013** | **2014 - 2015** | **2016 -2017** | **Thereafter** |
| Operating lease obligations (1) | $ 7,495 | $ 4,229 | $ 3,266 | $ — | $ — |
| Notes payable (2) | 10,000 | 3,730 | 6,270 | — | — |
| Interest payments on notes payable, fixed rate (2) | 1,719 | 758 | 961 | — | — |
| Manufacturing obligations (3) | 34,599 | 34,004 | 595 | | |
| Total fixed contractual obligations (4) | $ 53,813 | $ 42,721 | $ 11,092 | $ — | $ — |

(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) Relates to Loan Agreement with the Lenders which includes interest due on the loan and $0.5 million related to the final payment. If we receive a notice of default from the Lenders, we will be obligated to pay the remaining final interest charge and the prepayment fee of $0.5 million.

(3) Relates to significant non-cancelable orders and minimum commitments under our agreements with CMOs relating to the manufacturing of OMONTYS API.

(4) These fixed contractual obligations do not include the Advance from Takeda that may have to be refunded to Takeda.

Takeda capitalizes inventory costs associated with the production of OMONTYS and enters into purchase commitments for goods associated with this manufacturing. The write down or write off of such inventory and any charges for purchase commitments by Takeda would be subject to the profit equalization revenue or loss calculation of the Arrangement. We estimate that inventory charges of $2.5 million may be billed to us during the first quarter of 2013 based on the manufacturing costs incurred by Takeda as of December 31, 2012. With respect to purchase commitments, Takeda may request reimbursement for a portion of the costs associated with Takeda's firm purchase commitment of $9.3 million with Baxter for pre-filled syringes. Our exposure is limited to the portion of the Baxter agreement that relates to the U.S. We have no liability related to the E.U. or Japan because in those countries we receive only a royalty on product sales and the collaboration profit split does not apply to operations in those countries. The amount of our exposure is estimated to be $0.7 million which we expect to incur in the first quarter of 2013.

In the first quarter of 2013, we believe Takeda will record an impairment charge for certain long lived assets associated with OMONTYS. Under the profit/loss equalization, we are responsible for half of these charges. We estimate our exposure related to this impairment to be approximately $7.0 million. This amount has not been accrued as of December 31, 2012.

In April 2004, we entered into a License, Manufacturing and Supply Agreement with 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 OMONTYS. In consideration of the license grant, we agreed to pay royalties on the sales of OMONTYS. We also agreed to pay base milestones plus possible additional milestones in connection with our partnering activities relating to OMONTYS or merger and acquisition activities. As of December 31, 2012, no further milestone obligations remain.

Under the agreement, we also engaged Nektar for the manufacture and supply of our requirements of bulk PEG for the manufacture of OMONTYS. 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 PEG. 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.

**Going Concern**

Our financial statements have been presented on the basis that we continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The lack of financial resources due to the recall of OMONTYS raises substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

**Off-Balance Sheet Arrangements**

At December 31, 2012, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the Securities and Exchange Commission, or SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in our financial condition, revenues, or expenses, results of operations, liquidity, capital expenditures, or capital resources that is material to investors.

**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, 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.

**Product Recall**

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. We have evaluated this subsequent event to determine the accounting impacts of this particular event and related effects on our financial statements as of December 31, 2012. Based on our analysis that is ongoing, we have not discovered any indication that a condition existed as of December 31, 2012 and we believe that this event relates to conditions that did not exist as of December 31, 2012. Given the nature and significance of this event, we have provided additional disclosure as appropriate. We also reviewed account balances subject to estimation at December 31, 2012, including inventory and inventory purchase commitment obligations, for which we perform a lower of cost or market analysis, to determine if those account balances should be updated based on revised estimates with information available prior to the date the financial statements were issued. As of the result of the recall, we recorded financial statement adjustments to reflect changes in our estimates through the filing date of our Annual Report on Form 10-K as to the recoverability of inventory and deposits made to our CMOs, loss on firm purchase commitments and changes in the short term and long-term classification of certain liabilities. See Notes 1, 2, 3, 5, and 8 of the Notes to the Financial Statements.

**Revenue Recognition**

***Collaboration Revenue***

We recognize revenue for contracts entered into prior to 2011 in accordance with the SEC, Staff Bulletin No. 101, *Revenue Recognition in Financial Statements*, 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. 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(s) 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 (e.g. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the company. We recognize revenue for contracts entered into or modified after January 1, 2011, in accordance with 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 or modified agreements.

We account for our Arrangement with Takeda under ASC 605-25 and currently are operating in the commercialization period as defined in the Arrangement. Before the recall, we were performing commercialization services such as promotions and marketing as well as development work related to OMONTYS post approval. In return for these services, we receive a 50/50 share of operating profit from the sale and distribution of OMONTYS (as described below), certain milestone payments and contingent payments due under the Arrangement. We also continue to receive reimbursement of costs for commercial and development costs as described in the Arrangement. Prior to approval of OMONTYS, our primary source of revenue consisted of milestone payments and Takeda's reimbursement of commercialization and development costs.

According to the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to commercialization services such as pre-marketing, launch promotions and marketing of OMONTYS as well as development work related to OMONTYS post approval. In return for these services, we receive a 50/50 share of operating profit from the sale and distribution of OMONTYS (as described below), certain milestone and contingent payments due under the Arrangement. We also continue to receive reimbursement of costs for commercial and development costs as described in the Arrangement. Prior to approval of OMONTYS, our primary source of revenue had consisted of milestone payments and Takeda's reimbursement of commercialization and development costs.

In addition to the profit sharing and reimbursement of the costs described above, the Arrangement provides us the potential to earn substantive at risk milestone payments upon achievement of contractual criteria (see Note 3 of Notes to Financial Statements).

During the commercialization period, our obligations include ongoing regulatory work to obtain and maintain FDA approval and commercialization efforts related to our product launch and promotion and marketing of OMONTYS.

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

- *Expense reimbursement revenue.* Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercialization expenses (shared 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. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, reimbursement of commercialization expenses and development costs (both FTE and out of pocket costs) associated with post-marketing development activities, will be incorporated into the profit equalization revenue as required under the Arrangement in order to effect the 50/50 profit split, as described below.

- *Profit equalization revenue/loss.* Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, Takeda allocates the quarterly profit equalization revenue/loss to us in order to effect the 50/50 profit/loss split from the sale of OMONTYS, as called for by the Arrangement. Profit equalization revenue/loss is calculated as the amount required so that the profit or loss realized by both us and Takeda on the product equates to 50% of the total product profit or loss. The profit equalization revenue/loss allocated to us from Takeda for the year ended December 31, 2012 was $26.5 million. Total product profit or loss on OMONTYS is calculated on a quarterly basis as gross product sales recorded by Takeda, less the following deductions also recorded by Takeda: rebates and discounts, cost of goods and other gross-to-net adjustments incurred by Takeda; royalty expenses incurred by us, commercialization expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by both Takeda and us. Profit equalization revenue is recognized as revenue in the period product revenue is recognized by Takeda. As a result of the voluntary recall of OMONTYS in February 2013, all marketing activities have been suspended and there is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. If the recall is not lifted and we are not able to reintroduce, this will result in a severe decrease to our profit equalization revenue or potentially, profit equalization losses, in future periods.

- *API revenue.* Takeda reimburses us for 120% of the external costs incurred by us to manufacture and ship commercial API for their ultimate manufacture of OMONTYS. We record the balance in deferred revenue until the earnings process is complete, which occurs when the finished goods produced from each batch of API are sold by Takeda to the end customer. As of December 31, 2012, we had a remaining balance of $17.8 million in deferred revenue related to previously expensed API. Given the uncertainty of the effects of the recall in future periods, we have recharacterized our deferred revenue as an Advance from Takeda, which is reflected as a current liability in our December 31, 2012 financial statements.

- *Milestone revenue.* 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. Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any, are extremely uncertain due to the recall.

***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.

***Inventory***

We value our inventories at the lower of cost or net realizable value which is contractually determined in our collaboration with Takeda to be our cost plus a markup. We determine the cost of inventory using the specific identification method. We record API as inventory when the title transfers to us from the CMO, until the point of acceptance by Takeda. We initiate orders for API with our CMOs based on forecasts from Takeda. To date all orders have generally commenced once there was a contractual commitment for the API from Takeda.

We analyze our inventory levels quarterly and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value, as well as any inventory quantities in excess of expected requirements at December 31, 2012. Any expired inventory is disposed of and the related costs are recognized as expense. The voluntary recall of OMONTYS in February 2013, impacted the recoverability of our inventories based on assumptions about expected demand and net realizable value. Given the significant uncertainty of demand following the recall we have written down our API inventory and prepayments made to our CMOs to the net realizable value of zero and have recorded an $10.4 million impairment charge related to this writedown. We have also established an accrual for estimated losses on firm inventory purchase commitments of $34.6 million by applying the same lower of cost or market approach that is used to value inventory.

Neither charge reflects any future contractual reimbursements due under our collaboration arrangement with Takeda. If actual net realizable values are more favorable subsequently as a result of a reintroduction of the product, we may have favorable operating results in the future due to costs being already incurred.

We expensed costs relating to the production of API as R&D expense in the period incurred until we receive FDA approval for a new product or product configuration, and begin to capitalize the subsequent inventory costs relating to that product or product configuration. Prior to approval of OMONTYS for commercial sale in March 2012 by the FDA, we had expensed all costs associated with the production of API as R&D expense. Subsequent to receiving FDA approval of OMONTYS, we commenced capitalization of third party costs which are incurred to manufacture the API used in the production of OMONTYS.

***Stock-Based Compensation***

Our stock-based compensation expense for stock options is estimated at the grant date based on the award's fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite service period. The Black-Scholes option pricing model requires various highly judgmental assumptions including expected volatility and expected term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. We estimate the forfeiture rate based on historical experience and our expectations regarding future pre-vesting termination behavior of employees. To the extent our actual forfeiture rate is different from our estimate, stock-based compensation expense is adjusted accordingly.

***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. 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 $73.0 million, $70.6 million, and $13.1 million of unrecognized tax benefits as of December 31, 2012, 2011, and 2010, respectively.

Prior to 2012, 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 or NOL and credit carryforwards. Accordingly, we had reduced our gross deferred tax asset for the expiring carryforwards by $59.6 million as of December 31, 2011. Due to our announcement of our voluntary recall of OMONTYS in February 2013, there has been an extremely high volume of trading of our stock, which may trigger a shift of ownership amongst our 5% stockholders that could result in an ownership change (greater than 50%) as defined by the Internal Revenue Code. This could result in a significant impairment of our NOLs and potential elimination of our gross deferred tax asset, which is currently subject to our valuation allowance as it had been previously determined by management that it is more likely than not that the deferred tax asset would not be realized. We are currently in the process of assessing the impact.

At December 31, 2012, we had federal and state net operating loss carryforwards of $402.0 million and $416.0 million, respectively, before taking into consideration the annual Section 382 limitation. The federal net operating loss carryforwards begin to expire in 2028 and state net operating loss carryforwards begin to expire in 2018, if not utilized. At December 31, 2012, we had federal and state research credit carryforwards of $8.7 million and $7.0 million, respectively. The federal credits begin to expire, if not utilized, in 2022 and state credits are carried forward indefinitely.

At December 31, 2012 and 2011, our liability for uncertain income tax positions was $10.1 million and $10.4 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, 2012, 2011, and 2010, we recognized $(322,000), $144,000 and $140,000, respectively, of interest expense related to our liability for uncertain income tax positions. For the years ended December 31, 2012, 2011 and 2010, there were no penalties related to uncertain income tax positions. At December 31, 2012 and 2011, $664,000 and $986,000 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.

**Recent Accounting Pronouncements**

Effective January 1, 2012, we adopted revised guidance related to fair value measure disclosure that increases comparability between U.S. GAAP and International Financial Reporting Standards. This guidance clarifies the application of existing fair value measurement and disclosure and changes certain principles or requirements for fair value measures and disclosure. The adoption of this revised guidance requires expanded disclosure in our consolidated financial statements but did not impact financial results.

Effective January 1, 2012, we adopted revised guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and International Financial Reporting Standards. We have elected to disclose comprehensive income in a separate statement in our annual report and a single continuous statement during interim reporting periods.

## 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 have market risk for our debt since our outstanding debt obligations are fixed interest rate of 9.11% plus a default increase in the interest rate by an additional 500 basis points (5.0)% that may be applied to the outstanding loan balances upon the occurrence of an event of default. 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. The effect of a hypothetical decrease or increase of 10% in the average yield earned on cash, cash equivalents and investments would have resulted in an immaterial change in our interest income for the year ended December 31, 2012.

The table below presents the weighted-average interest rates and related carrying amounts (in thousands) of our investment portfolio as of December 31, 2012 and 2011:

| | 2012 | | 2011 | |
|---|---|---|---|---|
| | Weighted-average Interest Rate | Carrying Amount | Weighted-average Interest Rate | Carrying Amount |
| Cash equivalents | 0.04% | $45,999 | 0.01% | $45,244 |
| Short-term investments | 0.36% | $9,717 | 0.14% | $44,165 |
| Long-term investments | 0.49% | $2,323 | N/A | N/A |

**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. However, the effect of an immediate 10% change in foreign currency rates would have no material impact on our financial condition, results of operations or cash flows as of December 31, 2012.

## Item 8. Financial Statements and Supplementary Data.

Our financial statements and notes thereto appear on pages 55 to 84 of this Annual Report on Form 10-K.

## REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Affymax, Inc.

We have audited the accompanying balance sheets of Affymax, Inc. as of December 31, 2012 and 2011, and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring operating losses with nearly all of the Company's revenues to date resulting from the collaboration with Takeda Pharmaceutical Company Limited, or Takeda, related to the development and commercialization of OMONTYS. On February 23, 2013, the Company and Takeda announced a nationwide voluntary recall of OMONTYS. The voluntary recall may be considered a material adverse event under the Company's loan agreement with its lenders that may result in an event of default. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated April 1, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California
April 1, 2013

**AFFYMAX, INC.**
**BALANCE SHEETS**
**(in thousands, except share data)**

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 68,265 | $ 54,339 |
| Short-term investments | 9,717 | 44,165 |
| Receivable from Takeda | 18,365 | 6,937 |
| Deferred tax assets | 363 | 351 |
| Prepaid expenses | 2,731 | 1,490 |
| Other current assets | 3,069 | 338 |
| Total current assets | 102,510 | 107,620 |
| Property and equipment, net | 2,981 | 3,013 |
| Restricted cash | 1,135 | 1,135 |
| Long-term investments | 2,323 | — |
| Deferred tax assets, net of current | 6,876 | 6,888 |
| Other assets | 2,392 | 339 |
| Total assets | $ 118,217 | $ 118,995 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 6,591 | $ 941 |
| Accrued liabilities | 52,522 | 13,999 |
| Accrued clinical trial expenses | 2,844 | 3,365 |
| Deposit from Takeda | 559 | 1,998 |
| Advance from Takeda, current | 27,715 | — |
| Notes payable, current | 8,844 | — |
| Total current liabilities | 99,075 | 20,303 |
| Long-term income tax liability | 10,062 | 10,411 |
| Advance from Takeda, net of current | — | 6,121 |
| Deferred revenue, net of current | — | 5,174 |
| Other long-term liabilities | 799 | 989 |
| Total liabilities | 109,936 | 42,998 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity | | |
| Preferred Stock, $0.001 par value, 10,000,000 shares authorized, none issued and outstanding | — | — |
| Common stock: $0.001 par value, 100,000,000 shares authorized, 37,369,717 and 35,733,181 shares issued and outstanding at December 31, 2012 and 2011, respectively | 37 | 36 |
| Additional paid-in capital | 551,959 | 526,244 |
| Accumulated deficit | (543,713) | (450,301) |
| Accumulated other comprehensive income | (2) | 18 |
| Total stockholders' equity | 8,281 | 75,997 |
| Total liabilities and stockholders' equity | $ 118,217 | $ 118,995 |

The accompanying notes are an integral part of these financial statements. See subsequent event in Note 1.

**AFFYMAX, INC.**
**STATEMENTS OF OPERATIONS**
**(in thousands, except per share data)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Revenue: | | | |
| Collaboration revenue | $ 94,358 | $ 47,703 | $ 112,503 |
| License and royalty revenue | 12 | 17 | 18 |
| Total revenue | 94,370 | 47,720 | 112,521 |
| Operating expenses: | | | |
| Impairment of inventory and losses on firm purchase commitments | 44,957 | — | — |
| Research and development | 51,738 | 76,308 | 93,638 |
| Selling, general and administrative | 89,714 | 32,818 | 33,331 |
| Total operating expenses | 186,409 | 109,126 | 126,969 |
| Loss from operations | (92,039) | (61,406) | (14,448) |
| Interest income | 77 | 169 | 275 |
| Interest expense | (1,442) | (144) | (140) |
| Other income (expense), net | (34) | 15 | 239 |
| Loss before provision (benefit) for income taxes | (93,438) | (61,366) | (14,074) |
| Provision (benefit) for income taxes | (26) | 1 | 1 |
| Net loss | $ (93,412) | $ (61,367) | $ (14,075) |
| Net loss per share: | | | |
| Basic and diluted | $ (2.57) | $ (1.84) | $ (0.57) |
| Weighted-average number of shares used in computing basic and diluted net loss per share | 36,342 | 33,288 | 24,488 |

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

**AFFYMAX, INC.**
**STATEMENTS OF COMPREHENSIVE LOSS**
**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Net loss | $ (93,412) | $ (61,367) | $ (14,075) |
| Other comprehensive income (loss): | | | |
| Change in unrealized gains (losses) on investments | (20) | (13) | 183 |
| Reclassification adjustment for (gains) losses on investments recognized in earnings | — | — | (97) |
| Other comprehensive income (loss) | $ (20) | $ (13) | $ 86 |
| Comprehensive loss | $ (93,432) | $ (61,380) | $ (13,989) |

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

# AFFYMAX, INC.
# STATEMENTS OF STOCKHOLDERS' EQUITY
# (in thousands, except share data)

| | Shares | Amount | Additional Paid-In Capital | Deferred Stock-Based Compensation | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholder's Equity |
|---|---|---|---|---|---|---|---|
| **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) |
| Other comprehensive income | — | — | — | — | — | 86 | 86 |
| Net loss | — | — | — | — | (14,075) | — | (14,075) |
| **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 |
| Issuance of common stock related to the employee stock purchase plan | 184,382 | 1 | 807 | — | — | — | 808 |
| 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 |
| Change in unrealized loss on marketable securities | — | — | — | — | — | (13) | (13) |
| Net loss | — | — | — | — | (61,367) | — | (61,367) |
| **Balance at December 31, 2011** | 35,733,181 | 36 | 526,244 | — | (450,301) | 18 | 75,997 |
| Issuance of common stock upon exercise of stock options | 1,129,422 | 1 | 12,028 | — | — | — | 12,029 |
| Issuance of common stock upon vesting of restricted stock units | 222,093 | — | — | — | — | — | — |
| Issuance of common stock related to the employee stock purchase plan | 224,908 | — | 1,082 | — | — | — | 1,082 |
| Issuance of warrants related to Loan and Security Agreement | — | — | 1,394 | — | — | — | 1,394 |
| Issuance of common stock upon net exercise of warrants | 60,113 | — | — | — | — | — | — |
| Deferred stock-based compensation | — | — | 87 | (87) | — | — | — |
| Amortization of deferred stock-based compensation | — | — | — | 87 | — | — | 87 |
| Employee stock-based compensation | — | — | 11,055 | — | — | — | 11,055 |
| Nonemployee stock-based compensation | — | — | 69 | — | — | — | 69 |
| Change in unrealized loss on marketable securities | — | — | — | — | — | (20) | (20) |
| Net loss | — | — | — | — | (93,412) | — | (93,412) |
| **Balance at December 31, 2012** | 37,369,717 | $ 37 | $ 551,959 | $ — | $ (543,713) | $ (2) | $ 8,281 |

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

# AFFYMAX, INC.
# STATEMENTS OF CASH FLOWS
## (in thousands)

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| **Cash flows from operating activities** | | | |
| Net loss | $ (93,412) | $ (61,367) | $ (14,075) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Impairment of inventory and losses on firm purchase commitments | 44,957 | — | — |
| Depreciation and amortization | 1,987 | 2,182 | 2,212 |
| Amortization of premium on investments | 75 | 55 | 650 |
| Stock-based compensation expense | 11,211 | 10,025 | 11,523 |
| Loss on disposal of property and equipment | 30 | 11 | 2 |
| Noncash interest expense | 827 | 144 | 140 |
| Changes in operating assets and liabilities: | | | |
| Receivable from Takeda | (9,600) | (6,937) | 18,561 |
| Income tax receivable | — | — | 1,443 |
| Inventory | (4,515) | — | — |
| Prepaid expenses | (5,085) | 272 | 1,069 |
| Other current assets | (2,732) | (77) | 5,612 |
| Other noncurrent assets | (2) | (289) | 342 |
| Accounts payable | 5,650 | 620 | (143) |
| Accrued liabilities | 3,849 | 2,405 | (1,000) |
| Accrued clinical trial expenses | (521) | (7,882) | (28,252) |
| Payable to Takeda | — | (5,958) | 5,958 |
| Deferred revenue | (5,174) | (13,322) | (53,475) |
| Deposit from Takeda | (1,438) | 1,998 | — |
| Long-term income tax liability | (27) | 18 | — |
| Advance from Takeda | 17,767 | 6,121 | — |
| Other long-term liabilities | (1,027) | 15 | 199 |
| Net cash used in operating activities | (37,180) | (71,966) | (49,234) |
| **Cash flows from investing activities** | | | |
| Purchases of property and equipment | (1,562) | (1,265) | (730) |
| Payments for of intellectual property license | (2,500) | — | — |
| Purchases of investments | (13,233) | (35,799) | (128,650) |
| Proceeds from sale of investments | — | — | 16,042 |
| Proceeds from maturities of investments | 45,265 | 45,024 | 101,857 |
| Proceeds from sale of property and equipment | 25 | 41 | 2 |
| Net cash provided by (used in) investing activities | 27,995 | 8,001 | (11,479) |
| **Cash flows from financing activities** | | | |
| Proceeds from issuance of common stock upon exercise of stock options | 12,029 | 371 | 2,243 |
| Proceeds from issuance of common stock under employee stock purchase plan | 1,082 | 809 | 982 |
| Proceeds from common stock issued upon private placement, net of issuance costs | — | — | 4,883 |
| Proceeds from common stock issued upon public offering, net of issuance costs | — | 53,625 | — |
| Repayment of UBS loan | — | — | (9,192) |
| Proceeds from notes payable | 10,000 | — | — |
| Net cash provided by (used in) financing activities | 23,111 | 54,805 | (1,084) |
| Net increase (decrease) in cash and cash equivalents | 13,926 | (9,160) | (61,797) |
| Cash and cash equivalents at beginning of the period | 54,339 | 63,499 | 125,296 |
| Cash and cash equivalents at end of the period | $ 68,265 | $ 54,339 | $ 63,499 |
| **Supplemental disclosures of cash flow information:** | | | |
| Income taxes paid | $ 1 | $ 1 | $ 1 |
| Interest paid | $ 615 | $ — | $ — |
| **Supplemental schedule of non-cash financing activities:** | | | |
| Advance from Takeda | $ 1,828 | $ — | $ — |
| Change in unrealized gain (loss) on investments | $ (20) | $ (13) | $ 86 |
| Deferred stock-based compensation, net of cancellations | $ 87 | $ (5) | $ (379) |
| Warrants issued in connection with notes payable | $ 1,394 | $ — | $ — |

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

## 1. The Company

Affymax, Inc., a Delaware corporation, was incorporated in July 2001. We are a biopharmaceutical company committed to discovering, developing and delivering innovative therapies that improve the lives of patients with kidney disease and other serious and often life-threatening illnesses. In March 2012, the U.S. Food and Drug Administration, or FDA, approved the company's first product, OMONTYS® (peginesatide) Injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. OMONTYS is a synthetic, peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells and is the only once-monthly ESA currently available to the adult dialysis patient population in the U.S. We are co-commercializing OMONTYS with our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda and we launched the product in April 2012. In February 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of safety concerns. See further discussion below.

We have experienced significant operating losses since inception. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and active pharmaceutical ingredient, or API, production, license fees, milestone payments and profit equalization revenue payments from our collaborative partner Takeda, issuance of notes payable, operating and capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. As of December 31, 2012, we had an accumulated deficit of $543.7 million.

**Subsequent Event**

*Product Recall*

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. We and Takeda are actively investigating the cause of these reactions but there can be no assurance that a solution will be found. As a result of the voluntary recall of OMONTYS, all marketing activities have been suspended and there is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. Although we still maintain a license and are actively exploring a cause for the allergic reactions, we do not know when this reintroduction will occur, if at all. If the recall is not lifted and we are not able to reintroduce, this will result in a severe decrease to our profit equalization revenue.

In connection with the recall and in consultation with Takeda, we have undertaken efforts to suspend manufacturing activities to the extent practicable pending consideration of next steps with OMONTYS. If we are successful in identifying the cause of these recent safety concerns and addressing it, we and Takeda will determine the next appropriate steps to take with OMONTYS. Prior to such time, we plan to evaluate strategies to decrease our ongoing manufacturing costs and commitments, including but not limited to, termination of orders and agreements. However, in order to reintroduce OMONTYS, we would have to complete our ongoing and thorough investigation, identify the causes of the safety concerns and provide a suitable plan to the FDA for approval. Accordingly, there can be no assurance that we can address the safety concerns and meet the requirements of the FDA for reintroduction. Moreover, even if OMONTYS could be reintroduced, the commercial prospects for this product may be permanently diminished and the product may no longer be commercially viable.

Given the nature and significance of the product recall, in connection with the preparation of our 2012 financial statements we have reviewed account balances subject to estimation at December 31, 2012, including inventory and inventory purchase commitment obligations, for which we perform a lower of cost or market analysis. We have recorded adjustments to our financial statements to reflect changes in our estimates as to the recoverability of inventory and deposits made to our contract manufacturing organizations, or CMOs, loss on firm purchase commitments and changes in the short-term and long-term classification of certain liabilities. We have provided additional disclosure as appropriate. See Notes 2, 3, 5, and 8 of the Notes to the Financial Statements.

*Restructuring*

In March 2013, we commenced a re-organization plan to reduce operating costs, which included a reduction in force of approximately 230 employees. We expect to incur between $8.0 million and $10.0 million in restructuring charges, all of which are related to expenditures for one-time employee termination benefits. We expect to incur most of the charges during the first quarter of 2013. As a result of this restructuring and the recall, we may also experience impairment changes with respect to our property and equipment and long lived assets our license from Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies, collectively referred to as Janssen, in the first quarter of 2013.

**Going Concern**

The accompanying financial statements have been prepared on a going concern basis that contemplates the realization of assets and liabilities. Operating losses have been incurred each year since inception, resulting in an accumulated deficit of $543.7 million as of December 31, 2012. Nearly all of our revenues to date have come from our collaboration with Takeda. As a result of the February 23, 2013 nationwide voluntary recall of OMONTYS and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient existing cash, cash equivalents and investments to fund our operations for the next 12 months. Even with the recent reorganization, further reductions in our workforce and cash flows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations and conduct ongoing operations. If we do not have sufficient funds to continue operations, we could be required to liquidate our assets, seek bankruptcy protection or other alternatives. Further, we may be in breach under our loan and security agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or the Lenders, as the voluntary recall may be considered a material adverse event under the Loan Agreement. Under the loan agreement the Lenders have various rights including the ability to require immediate repayment of the outstanding principal plus accrued and unpaid interest, a final payment fee and a prepayment fee (see further discussion in Note 8 of the Notes to the Financial Statements below). We expect to incur substantial expenses associated with the recall and the ongoing investigation. Even if the underlying causes of the safety concerns can be identified, which is uncertain, the timelines associated with the investigation and the feasibility and costs associated with implementing solutions to address the safety concerns to the satisfaction of the FDA are highly uncertain. Accordingly, we may never be able to reintroduce OMONTYS or generate significant revenues and, even if OMONTYS is reintroduced so as to generate product sales, we may never achieve or sustain profitability. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect our ability to enter into collaborative relationships with business partners. These matters raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

**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 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.

**Reclassifications**

Certain amounts in prior period financial statements have been reclassified to conform to the current period presentation. We reclassified $537,000 to accrued liabilities from other long-term liabilities in the 2011 balance sheet. These reclassifications did not change previously reported net loss, total assets, or stockholders' equity.

**Concentration of Risk**

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 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.

As of December 31, 2012 and December 31, 2011 our accounts receivable balance with Takeda was $18.4 million and $6.9 million, respectively. The receivable is comprised of the amounts due from Takeda under our Arrangement with them. We have not experienced any credit losses from our receivables with Takeda and none are expected. We do not require collateral on our receivable. The receivable balance as of December 31, 2012 has been collected in full subsequent to year end.

To achieve profitable operations, we and Takeda must successfully manufacture and commercialize OMONTYS. There can be no assurance that OMONTYS can be manufactured at an acceptable cost and with appropriate performance characteristics on a consistent and reliable basis, or that OMONTYS will be successfully commercialized, when and if OMONTYS is reintroduced. These factors could have a material adverse effect on our future financial results.

Further, some of our and Takeda's operations, suppliers and manufacturing arrangements are currently single-sourced, leaving us at greater risk of supply interruptions, potential delays and failure to commercialize, when and if OMONTYS is reintroduced. Due to the product recall of OMONTYS, we have undertaken efforts to suspend or terminate manufacturing activities to the extent practicable pending consideration of next steps with OMONTYS. 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. Any inability to acquire sufficient quantities of OMONTYS or components thereof in a timely manner from third parties could result in product shortages, delays in clinical trials and could prevent us from commercializing OMONTYS in a cost-effective manner or on a timely basis. This could result in further losses and reduced profits that we share in from the sale of OMONTYS.

**Revenue Recognition**

***Collaboration Revenue***

We recognize revenue for contracts entered into prior to 2011 in accordance with the SEC Staff Bulletin No. 101, *Revenue Recognition in Financial Statements*, 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. 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(s) 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 (e.g. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the company. We recognize revenue for contracts entered into or materially modified after January 1, 2011, in accordance with 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 or modified agreements.

We account for our Arrangement with Takeda under ASC 605-25 and currently, are operating in the commercialization period as defined in the Arrangement. Before the recall, we were performing commercialization services such as promotions and marketing as well as development work related to OMONTYS post approval. In return for these services, we receive a 50/50 share of operating profit from the sale and distribution of OMONTYS (as described below), certain milestone payments and contingent payments due under the Arrangement. We also continue to receive reimbursement of costs for commercial and

development costs as described in the Arrangement. Prior to approval of OMONTYS, our primary source of revenue consisted of milestone payments and Takeda's reimbursement of commercialization and development costs.

In addition to the profit sharing and reimbursement of the costs described above, the Arrangement provides us the potential to earn substantive at risk milestone payments upon achievement of contractual criteria (see Note 3 of Notes to Financial Statements). However, timing and amounts of these milestones are extremely uncertain due to the recall.

During the commercialization period, our obligations include ongoing regulatory work to obtain and maintain FDA approval and commercialization efforts related to our product launch and promotion and marketing of OMONTYS.

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

- *Expense reimbursement revenue.* Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercialization expenses (shared 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 equivalents, 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. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, reimbursement of commercialization expenses and development costs (both FTE and out of pocket costs) associated with post-marketing development activities, is incorporated into the profit equalization revenue as required under the Arrangement in order to effect the 50/50 profit split, as described below.

- *Profit equalization revenue/loss.* Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, Takeda allocates the quarterly profit equalization revenue/loss to us in order to effect the 50/50 profit/loss split from the sale of OMONTYS, as called for by the Arrangement. Profit equalization revenue/loss is calculated as the amount required so that the profit or loss realized by both usand Takeda on the product equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS is calculated on a quarterly basis as gross product sales recorded by Takeda, less the following deductions also recorded by Takeda: rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; royalty expenses incurred by us, commercialization expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by both Takeda and us. Profit equalization revenue is recognized as revenue in the period product revenue is recognized by Takeda. As a result of the voluntary recall of OMONTYS in February 2013, all marketing activities have been suspended. If the recall is not lifted and we are not able to reintroduce, this will result in a severe decrease to our profit equalization revenue or potentially, profit equalization losses, in future periods.

- *API revenue.* Takeda reimburses us for 120% of the external costs incurred by us to manufacture and ship commercial API for their ultimate manufacture of OMONTYS. Werecord the balance in deferred revenue until the earnings process is complete, which occurs when the finished goods produced from each batch of API are sold by Takeda to the end customer. As of December 31, 2012 we had a remaining balance of $17.8 million in deferred revenue related to previously expensed API. Given the uncertainty of the effects of the recall and the return of product containing the API that followed the recall, we have recharacterized our deferred revenue as an Advance from Takeda, which is reflected as a current liability in our December 31, 2012 financial statements.

- *Milestone revenue.* 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. Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any are extremely uncertain due to the recall.

During the development period under the Arrangement with Takeda, which ended upon the submission of our New Drug Application or NDA to the FDA for review, collaboration revenue was recognized using the Contingency Adjusted Performance Model or CAPM. As a result, any 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, 2012, 2011, and 2010 (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Profit equalization revenue | $ 26,544 | $ — | $ — |
| Milestone payments | 60,250 | 10,000 | — |
| Revenue previously deferred related to API | 936 | — | — |
| Revenue recognized under CAPM | — | 26,606 | 112,503 |
| Net expense reimbursement after CAPM | 6,628 | 11,097 | — |
| Total collaboration revenue | $ 94,358 | $ 47,703 | $ 112,503 |

***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 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.

**Inventory**

We value our inventories at the lower of cost or net realizable value which is contractually determined in our collaboration with Takeda to be our cost plus a markup. We determine the cost of inventory using the specific identification method. We record API as inventory when the title transfers to us from the CMO, until the point of acceptance by Takeda. We initiate orders for API with our CMOs based on forecasts from Takeda. To date all orders have generally commenced once there was a contractual commitment for the API from Takeda.

We analyze our inventory levels quarterly and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value, as well as any inventory quantities in excess of expected requirements at December 31, 2012. Any expired inventory is disposed of and the related costs are recognized as expense. The voluntary recall of OMONTYS in February 2013, impacted the recoverability of our inventories based on assumptions about expected demand and net realizable value. As of the filing date, given the significant uncertainty of demand following the recall we have written down our API inventory and prepayments made to our CMOs to the net realizable value of zero and have recorded an $10.4 million impairment charge related to this writedown. We have also established an accrual for estimated losses on firm inventory purchase commitments of $34.6 million by applying the same lower of cost or market approach that is used to value inventory. Neither charge reflects any future contractual reimbursements due under our collaboration arrangement with Takeda. If actual net realizable values are more favorable subsequently as a result of a reintroduction of the product, we may have favorable operating results in the future due to costs being already incurred.

We expense costs relating to the production of API as research and development or R&D expense in the period incurred until we receive FDA approval for a new product or product configuration and began to capitalize the subsequent inventory costs relating to that product or product configuration. Prior to approval of OMONTYS for commercial sale in March 2012 by the FDA, we had expensed all costs associated with the production of API as R&D expense. Subsequent to receiving FDA approval of OMONTYS, we commenced capitalization of third party costs which are incurred to manufacture the API used in the production of OMONTYS.

**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 component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Debt securities are 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. These costs consist primarily of salaries and other personnel-related expenses, including associated stock-based compensation, facility-related expenses, depreciation of facilities and equipment, lab consumables and services performed by clinical research organizations, research institutions and other outside service providers.

**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.

**Valuation of Long-Lived Assets**

Long-lived assets to be held and used are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When an asset's expected future undiscounted cash flows are less than its carrying value, an impairment loss is recognized and the asset is written down to its estimated value. Long-lived assets to be disposed of are reported at the lower of the carrying amount of fair value less cost to dispose. There were no indicators of impairment as of December 31, 2012.

**Segment Information**

We operate in one business segment with principal operations in the U.S. Collaboration revenue was from our partner headquartered in Japan. 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. Adjustments due to changes in estimate are recorded in the period when the change occurs.

**Shipping and Handling Costs**

We acquire poly(ethylene) glycol reagent, or PEG, and API to support Takeda's manufacturing process. Shipping and handling costs incurred for PEG purchases are recorded in selling, general & administrative, or SG&A, expense in the statement of operations because they are not directly reimbursed by Takeda. Shipping and handling costs incurred for API purchases are reimbursed by Takeda and are recorded as a receivable until they are reimbursed.

**Net Loss Per Common Share**

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Stock options, warrants, restricted stock units or RSUs, and common stock issuable pursuant to the 2006 Employee Stock Purchase Plan were not included in the diluted net loss per common share calculation for the periods presented because the inclusion of such shares would have had an antidilutive effect.

The computations for basic and diluted net loss per share are as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Numerator: | | | |
| Net loss | $ (93,412) | $ (61,367) | $ (14,075) |
| Denominator: | | | |
| Weighted-average number of common shares used in computing basic and diluted net loss per common share | 36,342 | 33,288 | 24,488 |
| Basic and diluted net loss per common share | $ (2.57) | $ (1.84) | $ (0.57) |

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Options to purchase common stock | 4,858 | 4,262 | 3,890 |
| Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan | 40 | 41 | 29 |
| Restricted stock units | 297 | 362 | 503 |
| Warrant to purchase common stock | 424 | 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 RSUs. Stock options are valued using the Black-Scholes valuation model while the fair value of RSUs is equivalent to the market 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.

**New Accounting Standards Recently Adopted**

Effective January 1, 2012 we adopted revised guidance related to fair value measure disclosure that increases comparability between U.S. GAAP and International Financial Reporting Standards. This guidance clarifies the application of existing fair value measurement and disclosure and changes certain principles or requirements for fair value measures and disclosure. We have expanded disclosure in our financial statements to reflect this adoption. It did not impact our financial results.

Effective January 1, 2012, we adopted revised guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and International Financial Reporting Standards. We have elected to disclose comprehensive income in a separate statement in our annual report and in a single continuous statement during interim reporting periods.

**3. Development and Commercialization Agreements with Takeda**

We entered into two separate collaboration agreements with Takeda in February 2006 and June 2006 related to the co-development and co-commercialization of OMONTYS, which have been combined for accounting purposes due to their proximity of negotiation. We amended these arrangements in November 2011 concurrent with the settlement and license agreement, or Settlement and License Agreement, with Janssen (see further discussion below and Note 4 of Notes to Financial

Statements). These arrangements and amendment are collectively referred to as the Arrangement. Takeda has the right to terminate the June 2006 collaboration agreement in its entirety, upon written notice to Affymax by at least six months written notice prior to the effective date of the termination.

Collaboration revenue reported on our statement of operations consists of the nonrefundable upfront license fees, reimbursement for the sale of API net of costs incurred, net reimbursement of certain development and commercial expenses, revenues from product profit sharing, and milestone payments. We recognized $94.4 million, $47.7 million, and $112.5 million of collaboration revenue during the year ended December 31, 2012, 2011, and 2010, respectively. The amount receivable from Takeda as of December 31, 2012 and December 31, 2011 was $18.4 million and $6.9 million, respectively.

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis. We and Takeda are actively investigating the cause of these reactions but there can be no assurance that a solution will be found. As a result of the voluntary recall of OMONTYS, all marketing activities have been suspended and there is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. Although we still maintain a license and are actively exploring a cause for these safety concerns, we do not know when this reintroduction will occur, if at all.

In connection with the recall and in consultation with Takeda, as appropriate, we plan to evaluate the near-term activities, our respective rights and obligations of the parties under the agreements including the deployment of resources as part of our efforts to decrease our ongoing costs and commitments.

*Development and Commercialization of OMONTYS in the U.S.*

Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to U.S. commercialization. Certain employee-related expenses supporting the commercialization of OMONTYS in the U.S. are also shared equally. In addition, costs of certain employees in clinical, regulatory and other development functions supporting any post-marketing development activities such as additional clinical trials required by the FDA as a condition of the approval of OMONTYS in March 2012 or other activities separately agreed to by the parties in the U.S. are shared equally.

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 OMONTYS including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We are responsible for deployment of the sales force and the medical affairs field force but share marketing, account management and payor reimbursement related activities with Takeda. Takeda is responsible for manufacturing and distribution of the finished drug product to the customer and records product sales of OMONTYS. Specifically, Takeda has sole responsibility for handling all returns, order processing, invoicing and collection of receivables with regard to sales of OMONTYS. Takeda also has the rights and responsibility for establishing and modifying terms and conditions with respect to the sale of OMONTYS in the U.S., including pricing discounts available to third party payers, price adjustments and other allowable discounts and allowances. 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.

While Takeda is responsible for the sale of OMONTYS and accordingly Takeda records product revenue, we and Takeda share equally in the net profits and losses of those sales of OMONTYS in the United States. In determining the OMONTYS net profit or loss, OMONTYS product revenue is reduced by rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; royalty expense incurred by us, commercialization expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by both Takeda and us. We review the revenue, related deductions and expenses provided by Takeda and prepare an invoice to Takeda for our portion of the OMONTYS net profit after factoring in applicable costs incurred by us and Takeda at the end of each quarter. The profit equalization amount is recognized as revenue in the period the product sales occur and product revenue is recognized by Takeda.

As a result of the voluntary recall of OMONTYS in February 2013, all marketing activities have been suspended and there is significant uncertainty as to when or if we will be able to reintroduce OMONTYS. Although we still maintain a license and are actively exploring a cause for these safety concerns, we do not know when this reintroduction will occur, if at all.

*Development and Commercialization of OMONTYS outside of the U.S.*

In February 2006, we granted an exclusive license to Takeda for development and commercialization of OMONTYS in Japan. In December 2011, Takeda announced that it had decided not to commercialize OMONTYS in Japan. We and Takeda have explored other options for the commercialization rights for OMONTYS in the Japanese market, including potentially licensing it to a third party. If Takeda or its licensee is successful in clinical development and regulatory milestones, we are eligible to receive contingent payments from Takeda which aggregate up to $33.0 million relating to the Japan renal program and $5 million for a third indication that neither we or Takeda is pursuing.

In June 2006, Takeda subsequently received an exclusive license to develop and commercialize the product outside of the U.S. Takeda bears all costs for product 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 the product outside the U.S. In February 2012, Takeda announced the acceptance for assessment from the EMA of a MAA for OMONTYS for the treatment of symptomatic anemia associated with chronic kidney disease in adult patients on dialysis. The application is currently under review by that agency.

*Launch Allowance*

As noted above, Takeda bears responsibility for 50% of all third party expenses related to the commercialization of OMONTYS in the U.S. Takeda also provided a launch allowance to help fund the initial costs associated with preparing to launch under which it committed to fund the first $20.0 million of U.S. commercial expenses incurred in total by us and Takeda. Amounts received under the launch allowance are non-refundable; however, Takeda is entitled to deduct up to 8% of net sales from the profit equalization revenue, which would have otherwise been due to us each period until they have recouped an amount equal to $11.0 million ($10.0 million plus a $1.0 million fixed amount that represents interest). During the year ended December 31, 2012, $2.8 million was deducted by Takeda from profit equalization revenue under this arrangement. As of December 31, 2012 our liability balance under the launch allowance is $7.9 million.

Due to voluntary recall of OMONTYS in February 2013, all marketing activities have been suspended and there is no certainty as to when those activities will restart. The launch allowance will remain as a liability until we can determine, if at all, the timing of when that liability will be extinguished or if the collaboration is terminated. If our collaboration with Takeda is terminated prior to Takeda's recoupment of the balance, there is no obligation that we repay these amounts.

*Milestones*

During 2012 we earned the following milestone payments from Takeda, a $50.0 million milestone upon FDA approval of OMONTYS in the dialysis indication, a $5.0 million milestone upon acceptance for review of the MAA, filing for OMONTYS by the EMA, and a $3.0 million and $2.25 million milestone related to an amendment to the Arrangement or the November 2011 Amendment, described below. As of December 31, 2012, we are eligible to receive a total of $357.0 million in additional milestone payments, which include the milestones below. Upon the successful achievement of as yet unmet clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate amount of $95.0 million of substantive milestone payments relating to the renal program, of which $20.0 million is associated with the first approval in either pre-dialysis or dialysis indication in the first major European Union or E.U. country. The remaining $75.0 million in payments for the renal program under the worldwide agreement are aggregated as they do not have estimated dates of achievement in the near- or medium-term. In addition, we are eligible to receive from Takeda an aggregate of $112.0 million of substantive milestone payments related to oncology for unmet clinical development and regulatory milestones and only a portion of these payments relate to the U.S. The collaboration is not pursuing the oncology program; accordingly future payment of this aggregate amount is unlikely. In addition, we are eligible to receive up to $150.0 million of sales-based milestones of $10.0 million, $20.0 million, $30.0 million, $40.0 million and $50.0 million for worldwide net sales, excluding Japan, reached and recorded by Takeda during a fiscal year of the arrangement of $0.5 billion, $1.0 billion, $1.5 billion, $2.0 billion and $3.0 billion, respectively. We are also entitled to certain milestone payments related to the Settlement and License Agreement with Janssen (see further discussion below and in Note 4 of Notes to Financial Statements). Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any, are extremely uncertain due to the recall.

*API Supply Agreement*

In November 2011, as contemplated under the Arrangement, we and Takeda executed a Commercial API Supply Agreement. Under the terms of the API Supply Agreement, we are responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda reimburses us for our cost of

API plus 20%. Takeda remains responsible for the fill and finish steps in the manufacture of OMONTYS worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda agreed to pay an aggregate of $10.8 million in deposits for commercial API manufactured by us, all of which had been received as of December 31, 2012. In addition, during the year ended December 31, 2012, Takeda also paid us another deposit of $0.5 million to be applied to future purchases of commercial API. Through December 31, 2012, we have received $11.3 million and shipped $10.8 million of API that reduced the deposit balance to $0.5 million. Any amounts received from Takeda under the API Supply Agreement in excess of book value of the API were originally recorded as deferred revenue in the account named Deposit from Takeda until the related product had been sold through to the end customer by Takeda. For the year ended December 31, 2012, we recognized revenue of $0.9 million related to API. $2.3 million of API was shipped to Takeda prior to December 31, 2012 and is pending acceptance.

Given the uncertainty of the recall and the return of product containing API that followed the recall, we have recharacterized our deferred revenue as an Advance from Takeda, which is reflected as a current liability in our December 31, 2012 financial statements. Given the significant uncertainty in future revenues at this time, we cannot predict if or when OMONTYS sales will recommence.

*Impairment of Inventory and Firm Purchase Commitments*

We initiate orders for API with our CMOs based on forecasts from Takeda, which are based on expected demand for OMONTYS. Orders generally have commenced once there was a contractual commitment for the API from Takeda. As of December 31, 2012, we have future purchase commitments amounting to $34.6 million. These future commitments are comprised of $5.8 million for firm purchase commitments of PEG, and the remaining $28.8 million of manufacturing obligations relate to API, and were based on firm demand forecasts from Takeda and therefore may be subject to reimbursement under the API Supply Agreement with Takeda.

In addition to the binding CMO purchase commitments, we also had $10.4 million in inventory and prepayments made to our CMOs on our balance sheet as of December 31, 2012. As a result of the inability to sell OMONTYS and the uncertainty of future revenues, we have written down our API inventory and prepayments for API being produced by our CMOs to a net realizable value of zero and have recorded an $10.4 million impairment charge related to this writedown. We have also recorded a $34.6 million loss on firm purchase commitments by applying the same lower of cost or market approach that is used to value inventory. Of the total $45.0 million charge for impairment of inventory and loss on CMO purchase commitments, we have the right under the Arrangement to submit to Takeda for reimbursement $18.4 million of such expenses. However because we have not presented such amounts to Takeda for reimbursement, and such reimbursements would be subject to Takeda's approval, we have not recorded a receivable for such amounts as of December 31, 2012.

*Cost of Recall*

We believe the total costs of recalling the product, which is primarily composed of costs to a third-party to gather, store, and return the product to Takeda will range from $2.0 million to $3.0 million. These costs are expected to be primarily incurred in the first quarter of 2013 and have not been accrued as of December 31, 2012. The Arrangement provides that the allocation of expenses incurred in connection with a recall is to be based on the source of the defect, if determinable. If the recall is determined to be due to manufacturing defect of bulk API, then we are required to bear all such recall expenses. If the recall is determined to be due to manufacturing defect of finished product, then Takeda is required to bear all such recall expenses. If the recall is determined to be due to both manufacturing defects of the API and the manufacturing of the final drug product, then we and Takeda are required to share recall expenses proportionally. Given the ongoing nature of the investigation, the cause of the recall is not yet known and the range of recall costs that we may ultimately be responsible for may be up to the full amount of the costs incurred.

Takeda capitalizes inventory costs associated with the production of OMONTYS and enters into purchase commitments for goods associated with this manufacturing. The write down or write off of such inventory and any charges for purchase commitments by Takeda would be subject to the profit equalization revenue or loss calculation of the Arrangement. We estimate that inventory charges of $2.5 million may be billed to us during the first quarter of 2013 based on the manufacturing costs incurred by Takeda as of December 31, 2012. With respect to purchase commitments, Takeda may request reimbursement for a portion of the costs associated with Takeda's firm purchase commitment of $9.3 million with Baxter for pre-filled syringes. Our exposure is limited to the portion of the Baxter agreement that relates to the U.S. We have no liability related to the E.U. or Japan because in those countries we receive only a royalty on product sales and the collaboration profit split does not apply to operations in those countries. The amount of our exposure is estimated to be $0.7 million which we expect to incur in the first quarter of 2013.

In the first quarter of 2013, we believe Takeda will record an impairment charge for certain long lived assets associated with OMONTYS. Under the profit/loss equalization we are responsible for half of these charges. We estimate our exposure related to this impairment to be approximately $7.0 million. This amount has not been accrued as of December 31, 2012.

*November 2011 Amendment*

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. We recognized $3.0 million of these milestones in the first quarter of 2012 as it was earned as a result of FDA approval in March 2012. An additional $2.25 million of these milestones was earned in July 2012 as a result of progress on the commercial launch of OMONTYS, and recognized in the third quarter of 2012.

## 4. Contractual Arrangements

*Our 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 OMONTYS. 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 OMONTYS, which began with the launch of the product in the U.S. in 2012 and was suspended on February 26, 2013. We also agreed to pay base milestones plus possible additional milestones in connection with our partnering activities relating to OMONTYS or merger and acquisition activities. As of December 31, 2012 no further milestone obligations remain.

*Settlement and License Agreement with Janssen*

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 required us to make two fixed payments to Janssen, $6.0 million, which was paid in December 2011, and $2.0 million, which was paid in June 2012. 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 Settlement and License Agreement also required us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of OMONTYS, and requires us to make a $2.5 million milestone payment to Janssen upon regulatory approval of OMONTYS in the first major European country. Upon FDA approval in March 2012, we capitalized $2.5 million related to the first milestone payment during the first quarter of 2012 as an other asset. The resulting asset will be amortized over the expected life of the related patent family, the last-expiring patent of which expires in June 2016. This $2.5 million milestone payment was paid to Janssen in April 2012. For the year ended December 31, 2012, we recognized $0.4 million of amortization expense. In the first quarter we expect to incur $2.1 million in charges related to the impairment if the remaining balance of this asset as a result of the recall. This amount has not been accrued as of year-end.

In addition, Janssen will be entitled to low, single-digit royalties on sales of OMONTYS in Europe, Japan and certain other countries outside of the United States until mid-2016. This royalty payment is not reimbursable under our collaboration with Takeda.

## 5. Balance Sheet Components

### Property and Equipment, Net

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

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| Leasehold improvements | $ 2,501 | $ 2,303 |
| Equipment | 9,794 | 8,748 |
| Software | 3,064 | 2,428 |
| Construction in progress | 9 | 630 |
| | 15,368 | 14,109 |
| Less: Accumulated depreciation and amortization | (12,387) | (11,096) |
| | $ 2,981 | $ 3,013 |

Depreciation and amortization expense for the years ended December 31, 2012, 2011, and 2010, was $2.0 million, $2.2 million, and $2.2 million, respectively.

### Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| Accrued potential losses related to firm purchase commitments [1] | $ 34,599 | $ — |
| Compensation-related expenses | 12,837 | 7,971 |
| SG&A related costs [2] | 3,633 | 1,228 |
| R&D related costs | 830 | 1,659 |
| Janssen Biotech installment payment accrual | — | 2,000 |
| Other | 623 | 1,141 |
| | $ 52,522 | $ 13,999 |

(1) See Note 3 of Notes to Financial Statements.
(2) Includes accruals relating to FDA fee, commercial and medical affairs, IT related and other miscellaneous accruals.

## 6. Investments

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

| | As of December 31, 2012 | | | | |
|---|---|---|---|---|---|
| | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Other-Than Temporary Impairment | Fair Value |
| Short-term investments: | | | | | |
| Certificates of deposit | $ 1,300 | $ — | $ — | $ — | $ 1,300 |
| Corporate debt securities | 8,416 | 1 | — | — | 8,417 |
| Total short-term investments | $ 9,716 | $ 1 | $ — | $ — | $ 9,717 |
| | | | | | |
| Long-term investments: | | | | | |
| Corporate debt securities | $ 2,326 | $ — | $ (3) | $ — | $ 2,323 |
| Total long-term investments | $ 2,326 | $ — | $ (3) | $ — | $ 2,323 |

| | 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 agency securities | 41,906 | 23 | (5) | — | 41,924 |
| Total short-term investments | $ 44,147 | $ 23 | $ (5) | $ — | $ 44,165 |

The investments mature between January 2013 and July 2014. No other-than-temporary impairments were identified for the investment securities held by us as of December 31, 2012.

## 7. Fair Value Measurements

We measure certain financial assets and liabilities 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 our own assumptions.

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 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, under 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.

Financial instruments that are not recorded at fair value are measured at fair value on a quarterly basis for disclosure purposes. The fair value of the notes payable are based on the present value of expected future cash flows, assumptions about current interest rates and the creditworthiness of Affymax. Market risk associated with our fixed rate debt relates to the potential reduction in fair value. The carrying amounts of our notes payable approximates fair value.

The carrying amounts of certain financial instruments, such as cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximates fair value due to their relatively short maturities, and low market interest rates if applicable.

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, 2012 | | | |
|---|---|---|---|---|
| | | Fair Value Measurements Using | | |
| | Total | Level 1 | Level 2 | Level 3 |
| Money market funds | $ 45,999 | $ 45,999 | $ — | $ — |
| Short-term investments: | | | | |
| Certificates of deposit | $ 1,300 | $ — | $ 1,300 | $ — |
| Corporate debt securities | 8,417 | — | 8,417 | — |
| Total short-term investments | $ 9,717 | $ — | $ 9,717 | $ — |
| Long term investments: | | | | |
| Corporate debt securities | $ 2,323 | $ — | $ 2,323 | $ — |
| Total long-term investments | $ 2,323 | $ — | $ 2,323 | $ — |

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

## 8. Loan and Security Agreement

In March 2012, we entered into he Loan Agreement with Oxford Finance LLC and Silicon Valley Bank, or, collectively, the Lenders, under which we may borrow up to a total of $30.0 million in two tranches.

The first tranche of $10.0 million was borrowed in March 2012. The second tranche of $20.0 million was available for drawdown until March 31, 2013; however, it may no longer be available due to our recent recall of OMONTYS. The interest rate for the first tranche is fixed upon drawdown at a per annum rate equal to the greater of 8.95% or 8.57% plus the then effective U.S. Treasury note yield to maturity for a 36 month term but in any event not less than thirty-eight basis points (0.38)%. The interest rate related to the drawdown of the first tranche is 9.11%.

Payments under the Loan Agreement for the first tranche are interest-only through February 1, 2013, followed by equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2015. In addition to the monthly principal and interest payments, a final payment equal to 5% of the aggregate amount drawn, or $0.5 million for the first tranche, will be due on the earliest to occur of (1) the last amortized payment, (2) the acceleration of the loan or (3) prepayments of the loan, as specified in the Loan Agreement.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We have also agreed not to pledge or otherwise encumber our intellectual property assets, except for permitted licenses, as defined in the Loan Agreement.

We have paid the Lenders a facility fee of $150,000. In addition, if we repay all or a portion of the first tranche prior to maturity, we will pay the Lenders a prepayment fee, based on a percentage of the then outstanding principal balance, equal to: 5.00% if the prepayment occurs prior to or on the first anniversary of the respective funding date, 4.00% if the prepayment occurs after the first anniversary of the respective funding date but prior to or on the second anniversary of the respective funding date, or 2.00% if the prepayment occurs after the second anniversary of the respective funding date.

To secure our performance of our obligations under this loan and security agreement, we granted a security interest in substantially all of our assets, other than intellectual property assets, to the lenders. Our failure to comply with the terms of the

loan and security agreement, the occurrence of a material impairment in our prospect of repayment or in the perfection or priority of the lender's lien on our assets, as determined by the lenders, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets, and other adverse results.

The Loan Agreement includes customary affirmative and negative covenants, but does not include any covenants to attain or maintain certain financial metrics or thresholds. The covenants include required financial reporting, requirement to maintain inventory in good and marketable conditions, limitations on certain dispositions of assets, limitations on the incurrence of additional debt, limitations on change in business purpose, merge or consolidate, or encumbrance of assets without prior written consent of the Lenders. The Loan Agreement also includes customary events of default, including payment defaults; breaches of covenants following any applicable cure period, failure to deliver financial statements and reports to the lender on a timely basis, failure to file all required tax returns on a timely basis, failure to maintain insurance on collateral, and other routine and customary requirements under a loan agreement; and a material adverse change which is defined as follows: (a) a material impairment in the perfection or priority of Lenders' security interest or in the value of the collateral; (b) a material adverse change in our business, operations or financial condition (or otherwise); or (c) a material impairment of the prospect of repayment of any portion of the loans. Upon the occurrence of an event of default and following any applicable cure periods, a default increase in the interest rate by an additional 500 basis points (5.0)% may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

Since we suspended the marketing activities of OMONTYS and voluntarily recalled OMONTYS, we have classified all of our loan balance as a current liability and treated it as callable. Events of default under the Loan Agreement, provide the Lenders with various rights, including the right to require immediate repayment of the outstanding principal plus accrued and unpaid interest through the prepayment date, the final payment of $0.5 million and the prepayment fee of $0.5 million. We have not received a notice of default. If we receive a notice of default from the Lenders, in addition to repaying the outstanding balance of our loan we will also accrue the remaining final interest charge and the full amount of the final payment and the prepayment fee.

In connection with the Loan Agreement, we issued the Lenders warrants to purchase 132,855 shares of our common stock, or the Warrants, at an exercise price of $11.855 per share. Each Warrant may be exercised on a cashless basis in whole or in part. The exercise period of the Warrants will terminate on the earlier of seven years from March 26, 2012, the issuance date or the closing of certain merger or consolidation transactions in which the consideration is cash or stock of a publicly traded acquiror, or a combination thereof. Using the Black Scholes valuation model, we estimated the fair value of these Warrants to be approximately $1.4 million. The following assumptions were used to estimate the fair value: expected volatility of 83.4%, risk-free interest rate of 1.65%, and expected term of seven years. These Warrants are considered to be costs incurred as part of the loan and have been recorded as a debt discount, which is offset against the loan, and is amortized over the term life of Loan Agreement based on the effective interest method to interest expense. In September 2012, SVB Financial Group, parent of Silicon Valley Bank, exercised its Warrant for a net exercise and issuance of 23,453 shares of our common stock. In October 2012, Oxford Finance LLC exercised the remaining Warrants for a net exercise and issuance of 36,660 shares of our common stock. Both of these Warrants were net exercised on a cashless basis.

Our future minimum principal payments under the Loan Agreement as of December 31, 2012 are as follows (in thousands):

| | |
|---|---|
| 2013 | $ 3,730 |
| 2014 | 4,084 |
| 2015 | 2,186 |
| Total minimum principal payments | 10,000 |
| Less debt discount, net of amortization | (1,156) |
| Balance at December 31, 2012 | $ 8,844 |

## 9. Commitments and Contingencies

*Operating Leases*

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.

In March 2012, we entered into a sublease agreement with a third party to sublease a portion of one of our Palo Alto buildings. The sublease began on May 1, 2012 and will end on August 31, 2014. Under the agreement we will receive future minimum payments of $0.4 million and $0.3 million in 2013 and 2014, respectively, which offsets the rent payments noted below.

Rent expense for the years ended December 31, 2012, 2011, and 2010 was $3.6 million, $3.2 million and $2.8 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, 2012 are as follows (in thousands):

| | |
|---|---|
| 2013 | $ 4,229 |
| 2014 | 3,246 |
| 2015 | 20 |
| Total minimum lease payments | $ 7,495 |

*Legal Proceedings*

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants Affymax, Inc. or the Company, certain of its officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding the Company's business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court.

On March 19, 2013, a derivative lawsuit was filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuit alleges that the certain of the Company's officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding the Company's business health which was tied to the success of OMONTYS. The lawsuits also asserts claims for unjust enrichment and corporate waste.

Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

Additionally, in light of the recall, a product liability claim could potentially arise, although no claim has been filed to date.

We assess litigation to determine if an unfavorable outcome would lead to a probable loss or reasonable possible loss, which could be estimated. We accrue for losses that are both probable and reasonably estimable. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range. In the cases where we believe that a reasonable possible loss exists, we disclose the facts and circumstances of the litigation, including an estimable range, if possible. Substantially all of these contingencies are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonable possible loss. Accordingly, no loss accrual has been established for the above. While it is not possible to accurately predict or determine the eventual outcome of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our financial condition, results of operations or cash flows.

**10. 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, none of which were issued and outstanding as of December 31, 2012 and 2011. The rights, preferences and privileges of any preferred 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, 2012.

***Common Stock***

Our Certificate of Incorporation authorizes us to issue 100,000,000 shares of $0.001 par value common stock. As of December 31, 2012, and 2011, respectively we had 37,369,717 and 35,733,181 shares of common stock issued and outstanding.

No dividends on common stock have been declared since inception through December 31, 2012.

***Warrants***

In connection with the Loan Agreement, in March 2012, we issued the Lenders warrants to purchase 132,855 shares of our common stock, or the Warrants, at an exercise price of $11.855 per share. In September 2012, SVB Financial Group, the parent of Silicon Valley Bank, exercised its Warrant for a net exercise of 23,453 shares of our common stock and subsequently sold these shares in December 2012. In October 2012, Oxford Finance LLC exercised the remaining Warrants for a net exercise of 36,660 shares of our common stock. Both of these Warrants were net exercised on a cashless basis.

In addition, warrants to purchase an aggregate of 423,971 shares of common stock, at an exercise price of $16.78 per share, were issued in March 2009, which was related to a private placement. The warrants are exercisable immediately and expire in March 2014.

***Significant Equity Transactions***

In September 2012, our amended agreement with Azimuth Opportunity Ltd., or Azimuth, dated as of September 25, 2009 and amended in September 2010, expired. The agreement provided that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth was 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. No equity was issued in 2012 or 2011 under this agreement.

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 options under the 2001 Plan may be granted with a maximum life of 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 an individual that holds 10% or more of our outstanding stock 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, which was amended and restated in June 2012, 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 RSUs, 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 with a maximum life of 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 RSUs granted by us to date provide for vesting and delivery of shares of common stock generally over three years or are subject to performance based vesting upon milestones (described below). As of December 31, 2012, we reserved 6,908,443 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 shares reserved, 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 312,214 total shares available for grant, combined, under the 2001 and 2006 Plans as of December 31, 2012.

*2006 Employee Stock Purchase Plan*

Upon the effectiveness of our initial public offering in December 2006, we adopted the 2006 Employee Stock Purchase Plan or the Purchase Plan. As of December 31, 2012 , we reserved a total of 748,158 for issuance under the Purchase Plan of which 21,723 shares are available to be issued. 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, 2012, 2011, and 2010, 224,908, 184,382 and 130,315 shares of common stock, respectively, were purchased under the Purchase Plan.

## 11. Stock-Based Compensation

Stock-based compensation was recorded in the statements of operations as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Research and development | $ 4,324 | $ 4,632 | $ 4,521 |
| Selling, general and administrative | 6,887 | 5,393 | 7,002 |
| Total | $ 11,211 | $ 10,025 | $ 11,523 |

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

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2012 | | 2011 | | 2010 | |
| | 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 | 2,142,286 | $ 8.26 | 1,110,924 | $ 4.41 | 1,999,999 | $ 9.64 |
| Restricted stock units | 184,963 | $ 7.99 | 220,856 | $ 6.96 | 460,158 | $ 6.03 |

As of December 31, 2012, there was unrecognized compensation cost of $22.2 million related to these stock options and RSUs. The unrecognized compensation cost as of December 31, 2012 is expected to be recognized over a weighted-average amortization period of 2.7 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, 2012, 2011, and 2010:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Expected volatility | 81% | 80% | 81% |
| Risk-free interest rate | 0.89% | 1.86% | 2.10% |
| Dividend yield | 0.00% | 0.00% | 0.00% |
| Expected term (in years) | 5.5 | 5.6 | 5.5 |

The expected term of stock options represents the average period the stock options are expected to remain outstanding. For the year ended December 31, 2012, the expected term was based on our historical information on employee exercise and post-vesting employment termination behavior. For the years ended December 31, 2011 and 2010, the expected term was 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 year ended December 31, 2012 was based on our historical volatility of our common stock. The expected stock price volatility for our stock options for the years ended December 31, 2011 and 2010 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. 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 RSUs using the closing price of our stock on the grant date. The fair value of RSUs is being amortized on a straight-line basis over the requisite service period of the awards.

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, 2012, 2011, and 2010 was $4.36, $2.63, and $3.64 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, 2012, 2011 and 2010:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Expected volatility | 50%-106% | 50%-157% | 85%-193% |
| Risk-free interest rate | 0.04%-0.57% | 0.04%-1.00% | 0.16%-1.44% |
| Dividend yield | —% | —% | —% |
| Expected term (in months) | 6-24 | 6-24 | 6-24 |

The expected term of employee stock purchase rights represents the period the employee stock purchase rights are expected to remain outstanding. The Purchase Plan permits eligible employees to purchase common stock at 6 month intervals at a discount through payroll deductions during defined offering periods. The expected stock price volatility for the year ended December 31, 2012 was based on our historical volatility of our common stock. The expected stock price volatility for the years ended December 31, 2011 and 2010 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. The risk-free interest rate assumption is based on the U.S. Treasury

instruments whose term was consistent with the expected term of our employee stock purchase rights. The expected dividend assumption is based on our history and expectation of dividend payouts.

There were no tax benefits related to employee stock-based compensation for the years ended December 31, 2012, 2011, and 2010.

***Stock Option and Restricted Stock Unit Activity***

The following tables summarize information about stock option and RSU activity for the year ended December 31, 2012:

| | Number of Shares | Weighted-Average Exercise Price (Per Share)(1) | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) (2) |
|---|---|---|---|---|
| ***Stock Options:*** | | | | |
| **Balances at December 31, 2011** | **4,261,509** | **$ 14.12** | | |
| Granted | 2,142,286 | 11.99 | | |
| Exercised (3) | (1,129,422) | 10.65 | | |
| Forfeited | (184,387) | 10.44 | | |
| Cancelled | (232,450) | 27.55 | | |
| **Balances at December 31, 2012** | **4,857,536** | **$ 13.49** | **7.73** | **$ 33,848** |
| **Options exercisable at December 31, 2012** | **1,914,542** | **$ 16.98** | **6.05** | **$ 9,393** |
| **Options vested and expected to vest at December 31, 2012** | **4,767,241** | **$ 13.51** | **7.70** | **$ 33,178** |

| | Number of Shares | Weighted-Average Grant Date Fair Value (Per Share)(1) | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) (2) |
|---|---|---|---|---|
| ***Restricted Stock Units:*** | | | | |
| **Balances at December 31, 2011** | **361,691** | **$ 6.58** | | |
| Granted (time-based) | 184,963 | 7.99 | | |
| Vested | (222,093) | 6.35 | | |
| Forfeited | (27,838) | 7.47 | | |
| **Balances at December 31, 2012** | **296,723** | **$ 7.54** | **1.12** | **$ 5,635** |

(1) The weighted average price per share is determined using exercise price per share for stock options and fair value per share on grant 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, 2012.
- 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, 2012.

(3) The total intrinsic value of stock options exercised was $10.6 million, $0.3 million, and $6.9 million during the years ended December 31, 2012, 2011, and 2010, respectively, and was determined at the date of each exercise.

During 2010, the Board of Directors approved the grant of 225,000 performance-based RSUs, or PRSUs, to certain executive officers. These units vest 50% upon FDA acceptance of our NDA submission for review for OMONTYS and 50% upon product launch of OMONTYS. During 2011, 50% of these units vested when the FDA accepted our submission and filed the NDA for review. During 2012, the remaining 50% of these units vested upon product launch of OMONTYS.

The total fair value of stock options that vested during the years ended December 31, 2012, 2011 and 2010 was $6.2 million, $7.2 million and $8.9 million, respectively. The total fair value of RSUs and PRSUs that vested during the years ended December 31, 2012, 2011 and 2010 was $0.8 million, $0.9 million and $0.2 million, respectively.

The stock options outstanding and exercisable by exercise price at December 31, 2012 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 | 2,018,770 | 8.21 | $6.74 | 589,990 | $6.37 |
| $10.06 - 20.22 | 1,623,844 | 8.12 | $13.39 | 480,085 | $14.96 |
| $20.22 - 30.27 | 1,053,997 | 6.81 | $23.47 | 683,542 | $23.60 |
| $30.27 - 36.43 | 160,925 | 3.78 | $33.76 | 160,925 | $33.76 |
| $0.80 - 36.43 | 4,857,536 | 7.73 | $13.49 | 1,914,542 | $16.98 |

***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, 2012, the fair value of the common stock was $18.99 per share and approximately 167 repriced stock options remained outstanding. During the years ended December 31, 2012, 2011, and 2010, we have recorded deferred stock-based compensation (benefit) related to these stock options of $87,000, $(5,000), and $(379,000), respectively, and recorded stock-based compensation (income) expense of $87,000, $(5,000), and $(379,000), 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 $69,000, $(10,000), and $(291,000), respectively, for the years ended December 31, 2012, 2011, and 2010.

## 12. 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. Given these plans and the fact that this space is adequately separable from our existing facilities, we recorded total restructuring charges of $869,000 during the year ended December 31, 2011, which represents the present value of the estimated future facility costs for which we expected 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 SG&A expenses in the statement of operations.

The estimates underlying the fair value of the lease-related restructuring liability involved significant assumptions regarding the time required to contract with a subtenant, the amount of space we would be able to sublease, the range of potential sublease rates and the level of leasehold improvement expenditures that would be incurred to sublease the property.

In March 2012, we entered into a sublease agreement with a third party to sublease approximately 8,000 of the 16,000 square feet of the available office space. The sublease has a twenty-eight month term that begins on May 1, 2012 and ends on August 31, 2014, which is near the end of our lease term of September 30, 2014. In March, management concluded that the remaining excess office space could not effectively be sub-leased due to the sublease of only a portion of the broader space, prevailing market conditions, and our assessment of the marketability of the remaining space given the size and remaining term. As a result of this determination, and due to other developments in our operations, management elected to reconfigure the remaining space to make it available for use by the Company as needed. As a result, we reversed a net amount of $336,000 relating solely to the new sublease and the related space during the three months ended March 31, 2012.

In August 2011, we initiated a restructuring plan to lower annual operating expenses that included a planned reduction in force of 22 positions.

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 charge accrued | 869 | 975 | 1,844 |
| Cash payments | (431) | (710) | (1,141) |
| Accretion | 72 | — | 72 |
| Balance as of December 31, 2011 | 510 | 265 | 775 |
| Restructuring charges accrued | 77 | 6 | 83 |
| Adjustments | (413) | (62) | (475) |
| Cash payments | (214) | (209) | (423) |
| Accretion | 11 | — | 11 |
| Balance at December 31, 2012 | (29) | — | (29) |
| Less Current Portion | (16) | — | (16) |
| Long-term portion as of December 31, 2012 | $ (13) | $ — | $ (13) |

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.

## 13. Income Taxes

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Provision (benefit) for income taxes: | | | |
| Current provision (benefit) for income taxes: | | | |
| Federal | $ (27) | $ — | $ — |
| State | 1 | 1 | 1 |
| Total current provision (benefit) for income taxes | (26) | 1 | 1 |
| Deferred tax benefit: | | | |
| Federal | — | — | — |
| State | — | — | — |
| Total deferred tax benefit | — | — | — |
| Provision (benefit) for income taxes | $ (26) | $ 1 | $ 1 |

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, 2012, 2011 and 2010. For the year ended December 31, 2012, a tax benefit was recognized due to changes in tax reserves.

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, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Federal statutory income tax rate | (35.00)% | (35.00)% | (35.00)% |
| State income taxes, net of federal benefit | — | — | 0.01 |
| Stock-based compensation expense | 3.04 | 4.15 | 9.61 |
| Change in valuation allowance | 32.52 | (56.26) | 37.17 |
| Change in federal rates and prior year true ups | (0.64) | 0.70 | (0.32) |
| Permanent differences true ups | 0.08 | 0.08 | 0.11 |
| Tax credits | — | 2.66 | (11.58) |
| Changes in tax reserves | (0.03) | — | — |
| Impairment of tax attributes due to ownership change | — | 83.67 | — |
| Provision (benefit) for income taxes | (0.03)% | 0.00 % | 0.00 % |

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

| | December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Net operating loss carryforwards | $ 113,956 | $ 93,282 |
| Federal and State credit carryforwards | 4,249 | 3,552 |
| Depreciation and amortization | 11,866 | 15,938 |
| Capitalized start-up costs | 1,185 | 1,333 |
| Accrued liabilities and allowances | 35,955 | 17,720 |
| Gross deferred tax assets | 167,211 | 131,825 |
| Deferred tax liability | — | — |
| Net deferred tax asset | 167,211 | 131,825 |
| Less: Valuation allowance | (159,971) | (124,585) |
| 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 increased $35.4 million during the year ended December 31, 2012 and decreased $40.6 million during the year ended December 31, 2011. As of December 31, 2012 and 2011, we have a net deferred tax asset balance of $7.2 million and $7.2 million, respectively, in consideration of the uncertainty in income taxes liability recorded for the same amount.

Prior to 2012, 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 or NOL and credit carryforwards. Accordingly, we had reduced our gross deferred tax asset for the expiring carryforwards by $59.6 million as of December 31, 2011. Due to our announcement of our voluntary recall of OMONTYS in February 2013, there has been an extremely high volume of trading of our stock and a significant drop in the value of our stock. As a result of the high trading volume, there may be a shift of ownership amongst our 5% stockholders that could result in an ownership change, under Section 382 of the Internal Revenue Code of 1986, as amended. Under Section 382, a corporation that undergoes an ownership change, as defined by the Internal Revenue Code, may be subject to significant limitations on its ability to utilize its net operating losses or NOLs, and tax credits accumulated prior to the ownership change to offset future taxable income or tax liabilities. We are currently in the process of assessing the impact. At December 31, 2012, deferred tax assets were offset by a valuation allowance except to the extent of possible taxable income in an earlier period.

At December 31, 2012, we had federal and state net operating loss carryforwards of $402.0 million and $416.0 million, respectively. The federal net operating loss carryforwards begin to expire in 2028 and state net operating loss carryforwards begin to expire in 2018, if not utilized. At December 31, 2012, we had federal and state research credit carryforwards of $8.7 million and $7.0 million, respectively. The federal credits begin to expire, if not utilized, in 2022 and state credits are carried forward indefinitely.

If our assumptions change and we determine we will be able to realize these net operating losses, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets as of December 31, 2012, will be accounted for as follows: approximately $4.6 million will be recorded as an increase in equity, while the remaining benefit will be recognized as a reduction of income tax expense.

At December 31, 2012 and 2011, our liability for uncertain income tax positions was $10.1 million and $10.4 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, 2012, 2011, and 2010, we recognized $(322,000), $144,000, and $140,000, respectively, of interest (benefit) expense related to our liability for uncertain income tax positions. As of December 31, 2012 and 2011, we had accrued $664,000 and $986,000, respectively, of interest expense related to our liability for uncertain income tax positions. For the years ended December 31, 2012, 2011, and 2010, there were no 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.

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 $73.0 million, $70.6 million, and $13.1 million of unrecognized tax benefits as of December 31, 2012, 2011, and 2010, respectively.

As of December 31, 2012 and 2011, $65.8 million and $63.4 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, 2012, 2011, and 2010, is as follows (in thousands):

| | December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Balance at beginning of year | $ 70,613 | $ 13,100 | $ 12,366 |
| Additions for current year tax positions | — | 59,419 | 734 |
| Additions for prior year tax positions | 2,437 | — | — |
| Reductions for statute of limitations | (27) | — | — |
| Reductions for prior year tax positions | (6) | (1,906) | — |
| Balance at end of year | $ 73,017 | $ 70,613 | $ 13,100 |

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 remains 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.

**14. 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 $895,000, $407,000, and $460,000, for the years ended December 31, 2012, 2011, and 2010, respectively.

## 15. 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):

| | 2012 Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, | June 30, | September 30, | December 31, |
| Collaboration revenue | $ 63,205 | $ 2,754 | $ 13,603 | $ 14,796 |
| Total revenue | 63,209 | 2,755 | 13,607 | 14,799 |
| Income (loss) from operations | 31,520 | (31,381) | (23,990) | (68,188) |
| Net income (loss) | 31,453 | (31,956) | (24,638) | (68,271) |
| Basic net income (loss) per common share | $ 0.88 | $ (0.89) | $ (0.68) | $ (1.85) |
| Weighted-average number of common shares used in computing basic net income (loss) per common share calculation | 35,772 | 36,075 | 36,350 | 36,846 |
| Diluted net income (loss) per common share | $ 0.87 | $ (0.89) | $ (0.68) | $ (1.85) |
| Weighted-average number of common shares used in computing diluted net income (loss) per common share calculation | 36,338 | 36,075 | 36,350 | 36,846 |

As a result of the uncertainty of future revenues resulting from the product recall, our fourth quarter of 2012 includes charges related to the impairment of inventory and losses on firm purchase commitments. We have written down our API inventory and prepayments made to our CMOs to a net realizable value of zero and have recorded an $10.4 million impairment charge related to this writedown. We have also recorded a $34.6 million loss on firm purchase commitments by applying the same lower of cost or market approach that is used to value inventory, given the uncertainty of demand following the recall.

Our fourth quarter of 2012 also includes adjustments relating to estimates for compensation and Medicaid accruals previously recorded in our expenses for the third quarter of 2012. The net favorable impact to our statement of operations in the fourth quarter for these changes in estimates was $2.3 million or $0.06 per share for the quarter ended December 31, 2012.

| | 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 calculation | 26,354 | 35,388 | 35,578 | 35,704 |

**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, 2012, 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, 2012, there were no changes in our internal control over financial reporting that occurred during the year 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, 2012. 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, 2012, 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.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Affymax, Inc.

We have audited Affymax Inc.'s internal control over financial reporting as of December 31, 2012, 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, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2012 financial statements of Affymax, Inc. and our report dated April 1, 2013 expressed an unqualified opinion thereon that included an explanatory paragraph regarding Affymax, Inc.s' ability to continue as a going concern.

/s/ Ernst & Young LLP

Redwood City, California
April 1, 2013

*Changes in Internal Control over Financial Reporting*

We completed the implementation of a new Enterprise Resource Planning system during the second quarter of 2012. This implementation was not undertaken in response to any identified deficiency or weakness to our internal controls over financial reporting. It was undertaken to establish a scalable foundation for our core business processes. We also received FDA approval for OMONTYS in March 2012, resulting in our implementation of new accounting policies during the year ended December 31, 2012 with respect to revenue recognition, capitalization of inventory and certain accruals related to incentive compensation for our commercialization team. These new accounting policies caused changes in certain of our business processes and associated internal controls over financial reporting.

**Item 9B. Other Information.**

Not applicable.

## PART III.

Certain information required by Part III is omitted from this Annual Report on Form 10-K and incorporated by reference to our definitive proxy statement for our 2013 annual meeting of shareholders to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended. If such definitive proxy statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed no later than the end of such 120-day period.

### 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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 security ownership of certain beneficial owners and management is included in our proxy statement for our 2013 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 by reference to the information included in our proxy statement for our 2013 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 2013 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 Comprehensive Loss
- 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:

| Exhibit number | | Description |
|---|---|---|
| 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 Oxford Finance Corporation to Purchase shares of Common Stock(4) |
| 4.6 | | Form of Warrant to Silicon Valley Bank to Purchase shares of Common Stock(4) |
| 4.7 | | Form of Warrant to Purchase shares of Common Stock(5) |
| 10.1 | + | Form of Indemnity Agreement for Directors and Executive Officers(3) |
| 10.2 | + | 2001 Stock Option/Stock Issuance Plan(1) |
| 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(6) |
| 10.4 | + | Form of Stock Issuance Agreement under 2001 Stock Option/Stock Issuance Agreement(7) |
| 10.5 | + | Amended and Restated 2006 Equity Incentive Plan, as amended March 2, 2011(8) |
| 10.6 | + | Amended and Restated 2006 Equity Incentive Plan, as amended June 13, 2012(9) |
| 10.7 | + | Form of Option Grant Notice and Form of Option Agreement under 2006 Equity Incentive Plan(10) |
| 10.8 | + | 2006 Employee Stock Purchase Plan(11) |
| 10.9 | + | Form of Offering Document under 2006 Employee Stock Purchase Plan(12) |
| 10.10 | + | Form of Restricted Stock Unit Notice and Form of Restricted Stock Unit under 2006 Equity Incentive Plan (13) |
| 10.11 | + | Summary of Non-Employee Director Compensation Program(14) |
| 10.12 | + | Reserved |
| 10.13 | | Research and Development/Office Lease, dated May 30, 1990, by and between Miranda Associates and Affymax Research Institute(15) |
| 10.14 | | 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(16) |

| | | |
|---|---|---|
| 10.15 | | Second Amendment to Lease, dated December 20, 1999, by and between Spieker Properties, L.P. and Affymax Research Institute(17) |
| 10.16 | | 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(18) |
| 10.17 | * | EPO Receptor License Agreement, dated September 5, 1996, by and between the Registrant and Genetics Institute, Inc.(19) |
| 10.18 | * | 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.(20) |
| 10.19 | * | License, Manufacturing, and Supply Agreement, dated April 8, 2004, by and between the Registrant and Nektar Therapeutics AL, Corporation(21) |
| 10.20 | * | Collaboration and License Agreement, dated February 13, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(22) |
| 10.21 | * | Collaboration and License Agreement, dated June 27, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(23) |
| 10.22 | | Research and Development Agreement, dated April 2, 1992, by and between the Registrant and The R.W. Johnson Pharmaceutical Research Institute(24) |
| 10.23 | | Sublease Agreement, dated September 1, 2006, by and between the Registrant and TIBCO Software Inc.(25) |
| 10.24 | | First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between Registrant and Takeda Pharmaceutical Company Limited(26) |
| 10.25 | | Fourth Amendment to Lease, dated November 30, 2006, by and between Registrant and CA-Foothill Research Center L.P.(27) |
| 10.26 | | Second Amendment to Collaboration and License Agreements between Registrant and Takeda Pharmaceutical Company Limited effective January 1, 2008(28) |
| 10.27 | | 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(29) |
| 10.28 | | 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(30) |
| 10.29 | + | Executive Employment Agreement, as amended January 31, 2013, by and between the Registrant and Anne-Marie Duliege |
| 10.30 | + | Executive Employment Agreement, as amended January 31, 2013, by and between the Registrant and Robert Venteicher |
| 10.31 | | Common Stock Purchase Agreement, dated September 25, 2009 by and between the Registrant and Azimuth Opportunity Ltd.(31) |
| 10.32 | | Form of Credit Line and related documentation effective as of December 8, 2009 by and between the Registrant and UBS Financial Services, Inc.(32) |
| 10.33 | + | Executive Employment Agreement, dated February 19, 2010, by and between the Registrant and John A. Orwin.(33) |
| 10.34 | | Fifth Amendment, dated May 20, 2010, by and between the Registrant and EOP-Foothill Research Center, L.L.C.(34) |
| 10.35 | | Amendment No. 1 to Common Stock Purchase Agreement, dated September 17, 2010, between the Registrant and Azimuth Opportunity Ltd.(35) |
| 10.36 | + | Amendment to Employment Agreement between the Registrant and John A. Orwin effective as of September 23, 2010.(36) |
| 10.37 | + | Amendment to Employment Agreement between the Registrant and Anne-Marie Duliege effective as of September 23, 2010.(37) |
| 10.38 | + | Amendment to Employment Agreement between the Registrant and Robert F. Venteicher effective as of September 23, 2010.(38) |
| 10.39 | + | Amended and Restated Executive Employment Agreement, dated February 1, 2011, by and between the Registrant and John A. Orwin.(39) |
| 10.40 | + | Executive Employment Agreement, dated March 4, 2011, by and between the Registrant and Herb Cross.(40) |
| 10.41 | | Sixth Amendment to Lease, dated December 21, 2010 by and between Registrant and CA-Foothill Research Center L.P.(41) |
| 10.42 | | Amendment No. 2 to Common Stock Purchase Agreement, dated as of May 2, 2011 by and between the Registrant and Azimuth Opportunity Ltd.(42) |

| | | |
|---|---|---|
| 10.43 | | Settlement and License Agreement, dated as of November 7, 2011, by and between the Registrant and Janssen Biotech, Inc. (43) |
| 10.44 | | Third Amendment to Collaboration and License Agreements, effective as of November 7, 2011, by and between the Registrant and Takeda Pharmaceutical Company Limited (44) |
| 10.45 | * | U.S. Co-Promotion Agreement, dated February 24, 2012, by and between the Registrant and Takeda Pharmaceuticals U.S.A., Inc.(45) |
| 10.46 | | Loan and Security Agreement, dated March 26, 2012, by and between the Registrant, Oxford Finance Corporation and Silicon Valley Bank(46) |
| 10.47 | + | Executive Employment Agreement, effective as of October 1, 2012, by and between the Registrant and Karin L. Walker(47) |
| 10.48 | + | Executive Employment Agreement, dated January 31, 2013, by and between the Registrant and Jeffrey H. Knapp. |
| 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 in 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 in 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 10-Q as filed with the Securities and Exchange Commission on May 9, 2012.

(5) Incorporated by reference to Exhibit 4.5 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(6) Incorporated by reference to Exhibit 10.3 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(7) Incorporated by reference to Exhibit 10.4 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(8) Incorporated by reference to Exhibit 10.5 in our Form 10-Q as filed with the Securities and Exchange Commission on May 9, 2011.

(9) Incorporated by reference to Exhibit 10.6 in our Form 10-Q as filed with the Securities and Exchange Commission on August 8, 2012.

(10) Incorporated by reference to Exhibit 10.6 in 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 10.7 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(12) Incorporated by reference to Exhibit 10.8 in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

(13) Incorporated by reference to Exhibit 10.9 in our Form 10-K as filed with the Securities and Exchange Commission on March 13, 2008.

(14) Incorporated by reference to Exhibit 10.13 in our Form 10-K as filed with the Securities and Exchange Commission on March 12, 2009.

(15) Incorporated by reference to Exhibit 10.14 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(16) Incorporated by reference to Exhibit 10.15 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(17) Incorporated by reference to Exhibit 10.16 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(18) Incorporated by reference to Exhibit 10.17 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(19) Incorporated by reference to Exhibit 10.18 in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

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

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

(22) Incorporated by reference to Exhibit 10.24 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2009.

(23) Incorporated by reference to Exhibit 10.25 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2009.

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

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

(26) Incorporated by reference to Exhibit 10.28 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2009.

(27) Incorporated by reference to Exhibit 10.35 in our Form 10-K as filed with the Securities and Exchange Commission on April 2, 2007.

(28) Incorporated by reference to Exhibit 10.30 in our Form 10-K as filed with the Securities and Exchange Commission on March 13, 2008.

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

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

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

(32) Incorporated by reference to Exhibit 10.33 in our Form 10-K as filed with the Securities and Exchange Commission on March 4, 2010.

(33) Incorporated by reference to Exhibit 10.34 in our Form 10-Q as filed with the Securities and Exchange Commission on May 6, 2010.

(34) Incorporated by reference to Exhibit 10.35 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2010.

(35) Incorporated by reference to Exhibit 10.36 in our Form 8-K as filed with the Securities and Exchange Commission on September 20, 2010.

(36) Incorporated by reference to Exhibit 10.38 in our Form 10-Q as filed with the Securities and Exchange Commission on November 5, 2010.

(37) Incorporated by reference to Exhibit10.40 in our Form 10-Q as filed with the Securities and Exchange Commission on November 5, 2010.

(38) Incorporated by reference to Exhibit 10.41 in our Form 10-Q as filed with the Securities and Exchange Commission on November 5, 2010.

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

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

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

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

(43) Incorporated by reference to Exhibit 10.47 in our Form 10-K as filed with the Securities and Exchange Commission on March 14, 2012.

(44) Incorporated by reference to Exhibit 10.48 in our Form 10-K as filed with the Securities and Exchange Commission on March 14, 2012.

(45) Incorporated by reference to Exhibit 10.49 in our Form 10-Q/A as filed with the Securities and Exchange Commission on July 2, 2012.

(46) Incorporated by reference to Exhibit 10.50 in our Form 10-Q as filed with the Securities and Exchange Commission on May 9, 2012.

(47) Incorporated by reference to Exhibit 10.51 in our Form 10-Q as filed with the Securities and Exchange Commission on November 9, 2012.

+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.

## 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<br>John Orwin | Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer) | April 1, 2013 |
| /s/ HERB CROSS<br>Herb Cross | Chief Financial Officer (Principal Financial Officer) | April 1, 2013 |
| /s/ KARIN L. WALKER<br>Karin L. Walker | Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer) | April 1, 2013 |
| /s/ HOLLINGS C. RENTON<br>Hollings C. Renton | Member of the Board of Directors | April 1, 2013 |
| /s/ KATHLEEN LAPORTE<br>Kathleen LaPorte | Member of the Board of Directors | April 1, 2013 |
| /s/ KEITH R. LEONARD<br>Keith R. Leonard | Member of the Board of Directors | April 1, 2013 |
| /s/ TED W. LOVE<br>Ted W. Love | Member of the Board of Directors | April 1, 2013 |
| /s/ DANIEL K. SPIEGELMAN<br>Daniel K. Spiegelman | Member of the Board of Directors | April 1, 2013 |

| Signature | Title | Date |
|---|---|---|
| /s/ CHRISTI VAN HEEK<br>Christi van Heek | Member of the Board of Directors | April 1, 2013 |
| /s/ JOHN P. WALKER<br>John P. Walker | Member of the Board of Directors | April 1, 2013 |

## EXHIBIT INDEX

| Exhibit number | | Description |
|---|---|---|
| 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 Oxford Finance Corporation to Purchase shares of Common Stock(4) |
| 4.6 | | Form of Warrant to Silicon Valley Bank to Purchase shares of Common Stock(4) |
| 4.7 | | Form of Warrant to Purchase shares of Common Stock(5) |
| 10.1 | + | Form of Indemnity Agreement for Directors and Executive Officers(3) |
| 10.2 | + | 2001 Stock Option/Stock Issuance Plan(1) |
| 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(6) |
| 10.4 | + | Form of Stock Issuance Agreement under 2001 Stock Option/Stock Issuance Agreement(7) |
| 10.5 | + | Amended and Restated 2006 Equity Incentive Plan, as amended March 2, 2011(8) |
| 10.6 | + | Amended and Restated 2006 Equity Incentive Plan, as amended June 13, 2012(9) |
| 10.7 | + | Form of Option Grant Notice and Form of Option Agreement under 2006 Equity Incentive Plan (10) |
| 10.8 | + | 2006 Employee Stock Purchase Plan(11) |
| 10.9 | + | Form of Offering Document under 2006 Employee Stock Purchase Plan(12) |
| 10.10 | + | Form of Restricted Stock Unit Notice and Form of Restricted Stock Unit under 2006 Equity Incentive Plan(13) |
| 10.11 | + | Summary of Non-Employee Director Compensation Program(14) |
| 10.12 | + | Reserved |
| 10.13 | | Research and Development/Office Lease, dated May 30, 1990, by and between Miranda Associates and Affymax Research Institute(15) |
| 10.14 | | 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(16) |
| 10.15 | | Second Amendment to Lease, dated December 20, 1999, by and between Spieker Properties, L.P. and Affymax Research Institute(17) |
| 10.16 | | 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(18) |
| 10.17 | * | EPO Receptor License Agreement, dated September 5, 1996, by and between the Registrant and Genetics Institute, Inc.(19) |
| 10.18 | * | 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.(20) |
| 10.19 | * | License, Manufacturing, and Supply Agreement, dated April 8, 2004, by and between the Registrant and Nektar Therapeutics AL, Corporation(21) |
| 10.20 | * | Collaboration and License Agreement, dated February 13, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(22) |
| 10.21 | * | Collaboration and License Agreement, dated June 27, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(23) |

| | | |
|---|---|---|
| 10.22 | | Research and Development Agreement, dated April 2, 1992, by and between the Registrant and The R.W. Johnson Pharmaceutical Research Institute(24) |
| 10.23 | | Sublease Agreement, dated September 1, 2006, by and between the Registrant and TIBCO Software Inc.(25) |
| 10.24 | | First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between Registrant and Takeda Pharmaceutical Company Limited(26) |
| 10.25 | | Fourth Amendment to Lease, dated November 30, 2006, by and between Registrant and CA-Foothill Research Center L.P.(27) |
| 10.26 | | Second Amendment to Collaboration and License Agreements between Registrant and Takeda Pharmaceutical Company Limited effective January 1, 2008(28) |
| 10.27 | | 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(29) |
| 10.28 | | 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(30) |
| 10.29 | + | Executive Employment Agreement, as amended January 31, 2013, by and between the Registrant and Anne-Marie Duliege |
| 10.30 | + | Executive Employment Agreement, as amended January 31, 2013, by and between the Registrant and Robert Venteicher |
| 10.31 | | Common Stock Purchase Agreement, dated September 25, 2009 by and between the Registrant and Azimuth Opportunity Ltd.(31) |
| 10.32 | | Form of Credit Line and related documentation effective as of December 8, 2009 by and between the Registrant and UBS Financial Services, Inc.(32) |
| 10.33 | + | Executive Employment Agreement, dated February 19, 2010, by and between the Registrant and John A. Orwin.(33) |
| 10.34 | | Fifth Amendment, dated May 20, 2010, by and between the Registrant and EOP-Foothill Research Center, L.L.C.(34) |
| 10.35 | | Amendment No. 1 to Common Stock Purchase Agreement, dated September 17, 2010, between the Registrant and Azimuth Opportunity Ltd.(35) |
| 10.36 | + | Amendment to Employment Agreement between the Registrant and John A. Orwin effective as of September 23, 2010.(36) |
| 10.37 | + | Amendment to Employment Agreement between the Registrant and Anne-Marie Duliege effective as of September 23, 2010.(37) |
| 10.38 | + | Amendment to Employment Agreement between the Registrant and Robert F. Venteicher effective as of September 23, 2010.(38) |
| 10.39 | + | Amended and Restated Executive Employment Agreement, dated February 1, 2011, by and between the Registrant and John A. Orwin.(39) |
| 10.40 | + | Executive Employment Agreement, dated March 4, 2011, by and between the Registrant and Herb Cross.(40) |
| 10.41 | | Sixth Amendment to Lease, dated December 21, 2010 by and between Registrant and CA-Foothill Research Center L.P.(41) |
| 10.42 | | Amendment No. 2 to Common Stock Purchase Agreement, dated as of May 2, 2011 by and between the Registrant and Azimuth Opportunity Ltd.(42) |
| 10.43 | | Settlement and License Agreement, dated as of November 7, 2011, by and between the Registrant and Janssen Biotech, Inc. (43) |
| 10.44 | | Third Amendment to Collaboration and License Agreements, effective as of November 7, 2011, by and between the Registrant and Takeda Pharmaceutical Company Limited (44) |
| 10.45 | * | U.S. Co-Promotion Agreement, dated February 24, 2012, by and between the Registrant and Takeda Pharmaceuticals U.S.A., Inc.(45) |
| 10.46 | | Loan and Security Agreement, dated March 26, 2012, by and between the Registrant, Oxford Finance Corporation and Silicon Valley Bank(46) |
| 10.47+ | | Executive Employment Agreement, effective as of October 1, 2012, by and between the Registrant and Karin L. Walker(47) |
| 10.48+ | | Executive Employment Agreement, dated January 31, 2013, by and between the Registrant and Jeffrey H. Knapp. |
| 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 in 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 in 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 10-Q as filed with the Securities and Exchange Commission on May 9, 2012.

(5) Incorporated by reference to Exhibit 4.5 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(6) Incorporated by reference to Exhibit 10.3 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(7) Incorporated by reference to Exhibit 10.4 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(8) Incorporated by reference to Exhibit 10.5 in our Form 10-Q as filed with the Securities and Exchange Commission on May 9, 2011.

(9) Incorporated by reference to Exhibit 10.6 in our Form 10-Q as filed with the Securities and Exchange Commission on August 8, 2012.

(10) Incorporated by reference to Exhibit 10.6 in 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 10.7 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(12) Incorporated by reference to Exhibit 10.8 in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

(13) Incorporated by reference to Exhibit 10.9 in our Form 10-K as filed with the Securities and Exchange Commission on March 13, 2008.

(14) Incorporated by reference to Exhibit 10.13 in our Form 10-K as filed with the Securities and Exchange Commission on March 12, 2009.

(15) Incorporated by reference to Exhibit 10.14 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(16) Incorporated by reference to Exhibit 10.15 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(17) Incorporated by reference to Exhibit 10.16 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(18) Incorporated by reference to Exhibit 10.17 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.

(19) Incorporated by reference to Exhibit 10.18 in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.

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

(21) Incorporated by reference to Exhibit 10.23 in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on December 11, 2006.
(22) Incorporated by reference to Exhibit 10.24 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2009.
(23) Incorporated by reference to Exhibit 10.25 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2009.
(24) Incorporated by reference to Exhibit 10.34 in our registration statement on Form S-1, registration no. 333-136125, filed with the Securities and Exchange Commission on July 28, 2006.
(25) Incorporated by reference to Exhibit 10.32 in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on November 30, 2006.
(26) Incorporated by reference to Exhibit 10.28 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2009.
(27) Incorporated by reference to Exhibit 10.35 in our Form 10-K as filed with the Securities and Exchange Commission on April 2, 2007.
(28) Incorporated by reference to Exhibit 10.30 in our Form 10-K as filed with the Securities and Exchange Commission on March 13, 2008.
(29) Incorporated by reference to Exhibit 10.31 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.
(30) Incorporated by reference to Exhibit 10.32 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.
(31) Incorporated by reference to Exhibit 10.35 in our Form 8-K as filed with the Securities and Exchange Commission on September 25, 2009.
(32) Incorporated by reference to Exhibit 10.33 in our Form 10-K as filed with the Securities and Exchange Commission on March 4, 2010.
(33) Incorporated by reference to Exhibit 10.34 in our Form 10-Q as filed with the Securities and Exchange Commission on May 6, 2010.
(34) Incorporated by reference to Exhibit 10.35 in our Form 10-Q as filed with the Securities and Exchange Commission on August 5, 2010.
(35) Incorporated by reference to Exhibit 10.36 in our Form 8-K as filed with the Securities and Exchange Commission on September 20, 2010.
(36) Incorporated by reference to Exhibit 10.38 in our Form 10-Q as filed with the Securities and Exchange Commission on November 5, 2010.
(37) Incorporated by reference to Exhibit10.40 in our Form 10-Q as filed with the Securities and Exchange Commission on November 5, 2010.
(38) Incorporated by reference to Exhibit 10.41 in our Form 10-Q as filed with the Securities and Exchange Commission on November 5, 2010.
(39) Incorporated by reference to Exhibit 10.41 in our Form 10-Q as filed with the Securities and Exchange Commission on May 9, 2011.
(40) Incorporated by reference to Exhibit 10.42 in our Form 10-K as filed with the Securities and Exchange Commission on March 11, 2011.
(41) Incorporated by reference to Exhibit 10.43 in our Form 10-K as filed with the Securities and Exchange Commission on March 11, 2011.
(42) Incorporated by reference to Exhibit 10.45 in our Form 10-Q as filed with the Securities and Exchange Commission on August 8, 2011
(43) Incorporated by reference to Exhibit 10.47 in our Form 10-K as filed with the Securities and Exchange Commission on March 14, 2012.
(44) Incorporated by reference to Exhibit 10.48 in our Form 10-K as filed with the Securities and Exchange Commission on March 14, 2012.
(45) Incorporated by reference to Exhibit 10.49 in our Form 10-Q/A as filed with the Securities and Exchange Commission on July 2, 2012.
(46) Incorporated by reference to Exhibit 10.50 in our Form 10-Q as filed with the Securities and Exchange Commission on May 9, 2012.
(47) Incorporated by reference to Exhibit 10.51 in our Form 10-Q as filed with the Securities and Exchange Commission on November 9, 2012.

+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.