

**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, 2008

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**

(State or other jurisdiction of  
incorporation or organization)

**77-0579396**

(I.R.S. Employer  
Identification Number)

**4001 Miranda Avenue  
Palo Alto, CA 94304  
(650) 812-8700**

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, par value \$0.001 per share	The NASDAQ Stock Market LLC (NASDAQ Global Market)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition 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  Smaller reporting company   
(do not check if a  
smaller reporting  
company)

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

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, 2008 was \$145,046,697 (based upon the closing sales price of such stock as reported on the Nasdaq Global Market on such date). Excludes an aggregate of 6,100,230 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, 2008, the registrant has assumed that a stockholder was an affiliate of the registrant at June 30, 2008 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, 2008. 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 March 2, 2009, the registrant had outstanding 18,811,970 shares of Common Stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the Proxy Statement for the 2009 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the Commission within 120 days of the end of the fiscal year ended December 31, 2008, are incorporated by reference into Part III of this Report. Except with respect to information specifically incorporated by reference into this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

**AFFYMAX, INC.**  
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*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “potential” and similar expressions intended to identify forward-looking statements. These forward-looking statements include statements regarding the timing, design and results of our clinical trials and drug development program, the continuation and success of our collaboration with Takeda, and the timing and likelihood of the commercialization of Hematide. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K under Item 1A “Risk Factors,” including risks relating to the continued safety and efficacy of Hematide in clinical development, the potential for once per month dosing and room temperature stability, the cardiovascular event rate in our phase 3 clinical program, the timing of patient accrual in ongoing and planned clinical studies, regulatory requirements and approvals, research and development efforts, industry and competitive environment, reimbursement coverage, intellectual property rights and disputes and other matters. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.*

## **PART I.**

### **Item 1. Business.**

#### **Overview**

We are a biopharmaceutical company developing novel peptide-based drug candidates to improve the treatment of serious and often life-threatening conditions. Our product candidate, Hematide™, is designed to treat anemia associated with chronic renal failure. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic renal failure, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may lead to chronic fatigue or increase the risk of other diseases or death. Currently recombinant EPO, or rEPO, is used to manage the anemia of dialysis, pre-dialysis and cancer patients. According to IMS Health Incorporated, rEPO generated \$11.5 billion in worldwide revenues for 2008, of which we believe approximately \$6.8 billion was generated in the U.S. Of this \$6.8 billion, we estimate that over one-half is attributable to use of rEPO in patients with chronic renal failure, and the remainder is attributable to other indications, primarily cancer patients. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Hematide is designed to be longer acting than currently marketed ESAs in the U.S. and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers.

We are conducting Phase 3 clinical trials in patients suffering from chronic renal failure, on dialysis and not on dialysis (“pre-dialysis”). We are conducting four open-label, randomized controlled clinical trials. Of these trials, two trials are being conducted in pre-dialysis patients and are designed to evaluate the safety and efficacy of Hematide compared to darbepoetin alfa to correct anemia and

maintain hemoglobin in a corrected range over time. The other two trials are being conducted in dialysis patients and are designed to evaluate the safety and efficacy of Hematide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to Hematide. Enrollment of our Phase 3 clinical program was completed in 2008. Analysis of efficacy and safety for all of the Phase 3 studies will be based on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint will be the mean change in hemoglobin from baseline. Each study is planned to continue until the last patient has been treated for approximately 52 weeks. In addition, the assessment of safety will include a composite cardiovascular endpoint from a pooled safety database.

Currently, we expect to release results from the Phase 3 clinical program in the first quarter of 2010, however, the rate of accrual of cardiovascular events could affect the duration of the studies. If the cardiovascular events accrue at a lower rate than estimated, the outcome of the composite safety endpoint analysis may not meet the pre-defined non-inferiority criteria due to insufficient events, causing a possible failure of our clinical program. In order to obtain additional data to compensate for a lower than estimated cardiovascular event rate, the Phase 3 clinical program may need to be extended or additional studies may need to be conducted, if even feasible, which could delay the development of Hematide and the achievement of milestones from our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda. Even if the cardiovascular events accrue at the estimated rate, we could still fail to establish that Hematide is non-inferior to the comparator drugs upon analysis of the data from our Phase 3 clinical program. Further, our Phase 3 clinical program could be suspended or terminated prior to completion based on safety or other concerns, including recommendations of the data monitoring committee, which will be meeting periodically to review the interim safety data from our trials.

In August 2008, we and Takeda, agreed to suspend the development of Hematide to treat chemotherapy-induced anemia and to focus all development efforts for Hematide on the treatment of chronic renal failure anemia.

In February and June 2006, we entered into two separate agreements with Takeda, the largest pharmaceutical company in Japan, which resulted in a worldwide collaboration to develop and commercialize Hematide. Under our collaboration, the companies will co-develop and co-commercialize Hematide in the U.S. Takeda received an exclusive license to develop and commercialize Hematide outside of the U.S. Beginning January 1, 2007, Takeda was responsible for the first \$50 million of third party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Of the first \$50 million of third party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of \$36.3 million was incurred by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda bears 70% of the third party U.S. development expenses, while we are responsible for 30% of the expenses. Each company retains responsibility for 100% of its internal development expenses. Under the agreements, Takeda paid us upfront license fees of \$122 million and purchased approximately \$10 million of our preferred stock. In December 2006, Takeda completed a Phase 1 trial of Hematide in Japan for which Takeda paid us a milestone payment of \$10 million in January 2007. Upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive additional payments from Takeda of up to a total of \$345 million across all indications, the majority of which relate to the renal program, including milestone payments upon completion of database lock of the Phase 3 clinical trials of \$15 million for dialysis and \$15 million for pre-dialysis, \$20 million milestone payments upon FDA acceptance of the submission of the new drug application, or NDA, and \$95 million of milestone payments upon approval by the FDA in dialysis and pre-dialysis indications. Further, we may receive from Takeda up to an aggregate of \$150 million upon the achievement of certain worldwide annual net sales milestones. We and Takeda will share equally in the net profits and losses of Hematide in the U.S. which include expenses related to the marketing and launch of Hematide. Takeda will pay us royalties based on the annual net sales of Hematide outside the U.S.

## **Our Product Candidate: Hematide**

Hematide is a synthetic peptide-based ESA designed for less frequent dosing compared to currently marketed ESAs in the U.S. It is currently in Phase 3 clinical trials for treatment of anemia associated with chronic renal failure. Hematide is designed to be dosed once every four weeks, compared to recombinant products sold in the U.S. that are dosed either several times a week, every week to two weeks, or up to every three weeks for some patients. In addition, we believe that Hematide can be further developed to be stable at room temperature, compared to the cold storage conditions needed for recombinant products.

### ***Anemia Background***

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

Anemia generally exists in men when the hemoglobin level in blood, which is a measure of red blood cells, is less than 12 g/dL, or the hematocrit, which is a ratio of the volume packed red blood cells to the volume of whole blood, is less than 37%, and in women when hemoglobin is less than 11 g/dL or hematocrit is less than 33%. The Food and Drug Administration, or FDA, the medical community and others have recently raised significant safety concerns relating to currently marketed ESAs as a result of reports of increased mortality and side effects from a number of clinical trials. Some of these safety concerns relate to targeting and maintaining high hemoglobin levels for extended periods of time. The FDA recently required revised warnings, including black box warnings, be added to labels of currently marketed ESAs advising physicians to monitor hemoglobin levels and to use the lowest dose of ESA to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions. Black box warnings for currently marketed ESAs also note increased risk of death and serious cardiovascular events when administered to target higher hemoglobin levels.

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

Over time, chronic renal failure usually progresses to irreversible end-stage renal disease, the most severe stage of the disease. End-stage renal disease patients require either lifetime dependence on renal dialysis, a medical procedure in which blood is cleansed of impurities, or a kidney transplant. Patients with end-stage renal disease are nearly always moderately to severely anemic unless treated with an ESA like rEPO. According to the Centers for Medicare and Medicaid Services, or CMS, there are approximately 380,000 end-stage renal disease patients on dialysis in the U.S. served by approximately 5,000 dialysis facilities. Funding and reimbursement for this care are predominately through the Medicare End Stage Renal Disease Program. In 2005, according to the CMS, reimbursement for many drugs, including ESAs, was at a rate of 106% of the average ESA sales price.

This allows the dialysis facilities to realize a profit on the purchase and administration of ESAs, which constitutes an important component of their economic viability.

We estimate that approximately two-thirds of pre-dialysis patients with anemia are not treated with an ESA prior to progression to stage 5, end-stage renal disease, and initiating dialysis. While in the U.S. currently marketed ESAs are indicated for up to every two week dosing in pre-dialysis patients, these patients often require much less frequent visits to their nephrologists or primary care physicians for treatment of their underlying disease. Because of the incongruity between the optimal dose scheduling of these ESAs and the timing of pre-dialysis patient office visits, we believe that the pre-dialysis market for ESAs is underserved by existing therapy and could be better served with a product that can be dosed once every four weeks.

*Anemia associated with Cancer and Other Conditions.* Anemia in cancer patients may be caused by chemotherapy or the cancer itself. For patients undergoing chemotherapy, the destruction of progenitor stem cells and precursor cells in the bone marrow by chemotherapy often leads to anemia. Anemia can also occur in any person with a chronic disease that causes significant inflammation, infection, or bleeding, such as rheumatoid arthritis or cardiovascular disease, and it can therefore be considered a characteristic disease of the elderly. We are testing Hematide in chronic renal failure, but are not currently testing Hematide's effectiveness in treating anemia due to other conditions.

#### *Current Therapy and Limitations*

According to IMS Health Incorporated, rEPO generated \$11.5 billion in worldwide revenues for 2008, of which we believe approximately \$6.8 billion was generated in the U.S. Of this \$6.8 billion, we estimate that over one-half is attributable to use of rEPO in patients with chronic renal failure, and the remainder is attributable to other indications, primarily cancer patients. ESAs, in the form of rEPO variants, have been used successfully to manage the anemia of dialysis, pre-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 may also exist among rEPOs with regard to frequency of dosing, duration of effect and rate of rise in hemoglobin. Stability in the blood and circulating half-life, which measure the time it takes the compound to disappear from the blood, generally correlate with less frequent dosing. One of our objectives is to develop a product with a duration of effect that results in a well-controlled hemoglobin response while still allowing optimal dosing, ideally once every four weeks.

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

*Frequency of Dosing.* In the U.S., currently marketed ESAs are hampered by short duration of effect resulting in the need for frequent dosing. We believe that the need for frequent dosing has limited the use of ESAs in treatment settings such as pre-dialysis, where patient visits for the purpose of treating underlying disease are less frequent than for patients undergoing dialysis multiple times per week. The population of pre-dialysis patients who may benefit from anemia management far outnumbers the population of patients who have reached end-stage renal disease. We believe the

requirement for relatively frequent dosing has historically limited the use of ESAs in pre-dialysis and that, with its longer acting profile, Hematide has the potential to expand this market.

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

#### *Potential Hematide Advantages*

Hematide is a relatively small synthetic peptide-based ESA which we are developing for the treatment of anemia patients with chronic renal failure. 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 cost of manufacture, and specificity of effect. Further, because they are composed of naturally-occurring amino acids, peptide-based therapeutics theoretically also carry the general advantage of reduced toxicity relative to small molecule drugs. 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, Hematide has the potential to require less frequent dosing than currently marketed ESAs in the U.S. As a long-acting ESA, we believe that Hematide may overcome many of the patient care limitations of currently marketed rEPOs in the U.S. We believe that flexibility of dosing based on duration of effect may allow many patients to receive anemia management therapy concurrently with therapy for their underlying disease.

Hematide is being developed for room temperature stability, ease-of-handling, and long shelf life in order to overcome many of the limitations which hamper the cost effectiveness, and thus the physician adoption, of rEPOs.

Our early clinical trials have shown similar positive effects on red blood cell formation when Hematide is given at equivalent doses either intravenously or subcutaneously. These results suggest that Hematide may be equally effective in humans when administered by either route. Additional clinical trials are underway to confirm this observation. We believe it may be easier to use Hematide than some forms of rEPO, which often have different clinical effects when given subcutaneously versus intravenously.

Although Hematide has the erythropoietic activity characteristic of naturally occurring EPO, its amino acid sequence is unrelated to EPO, rEPO or any other known naturally-occurring erythropoietic protein. Because Hematide does not appear to display immunologic cross-reactivity to naturally-occurring EPO, we believe that Hematide will not cause PRCA. We have conducted preclinical studies which have demonstrated that Hematide can stimulate reticulocytes and elevate hemoglobin levels in an animal model of EPO antibody mediated PRCA. An ongoing Phase 2 clinical trial of Hematide in a small number of patients with PRCA has shown supportive results to date. These results suggest that

Hematide is not neutralized by antibodies to rEPO and thus may be effective in rescuing patients that have developed PRCA.

Based on preclinical and clinical studies to date, we believe that the risk of developing antibodies to Hematide will be low. Thus far, we have observed that Hematide-induced antibodies do not appear to cross-react with rEPO and do not generally have any apparent effect on clinical response to the drug.

### ***Hematide Development Program***

We are currently conducting multiple Phase 3 clinical trials of Hematide in patients with anemia due to chronic renal failure and have suspended our development efforts to treat chemotherapy-induced anemia.

To date, over 400 patients have received Hematide in our Phase 1 and 2 clinical studies. We believe the pharmacokinetics and pharmacodynamics of Hematide have been shown from these trials to be appropriate for extended dose intervals and desired drug activity. We anticipate that Hematide will be dosed once every four weeks in most chronic renal failure patients. Data from our ongoing Phase 2 open-label human clinical trials indicate that Hematide induces a consistent, appropriately rapid, prolonged, dose-dependent increase in reticulocytes and hemoglobin. The type and frequency of adverse events, including serious adverse events associated with Hematide, in these clinical trials appear to be similar to those events that have been reported for currently marketed ESAs in studies targeting similar hemoglobin levels.

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

### ***Chronic Renal Failure***

#### ***Current Phase 2 Clinical Trials***

We and Takeda are currently conducting multiple Phase 2 clinical trials of Hematide at sites in the U.S. and Europe in dialysis patients, pre-dialysis patients, peritoneal dialysis patients and patients with PRCA. These trials are designed to determine the safety, pharmacodynamics and pharmacokinetics of Hematide when administered to patients suffering from anemia. Our Phase 2 trials are not designed to establish sufficient safety or efficacy to obtain regulatory approval, and no observations from these trials should be taken as conclusive evidence of Hematide's safety and/or efficacy in any patient population.

The primary objectives of our ongoing roll-over Phase 2 clinical trials are to evaluate dosing and the long-term safety of Hematide. In patients on dialysis whose hemoglobin values have already been corrected by three times a week rEPO therapy, we are seeking to maintain hemoglobin values in the corrected range by administering Hematide once every four weeks. In trials involving pre-dialysis, we are seeking to correct patients' anemia as measured by increased hemoglobin values. Secondary endpoints of our clinical trials include frequency of red blood cell transfusions.

Recently, two Phase 2 clinical trials have been initiated that are intended to evaluate the use of Hematide to treat anemic patients in additional segments of the chronic renal failure patient population. One of the studies is focused on evaluating Hematide in patients undergoing peritoneal dialysis, a special form of dialysis that allows the process to be performed in the patient's home. The other trial will evaluate the conversion of Aranesp-treated chronic renal patients (on dialysis and not on dialysis) to once-monthly Hematide.

### ***Current Phase 3 Clinical Trials***

We are conducting Phase 3 clinical trials in approximately 2,600 dialysis and pre-dialysis patients suffering from chronic renal failure. Based on our discussions with the FDA on the design of our Phase 3 program, we are conducting four open-label, randomized controlled clinical trials. Of these trials, two trials are being conducted in pre-dialysis patients and are designed to evaluate the safety and efficacy of Hematide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials are being conducted in dialysis patients and are designed to evaluate the safety and efficacy of Hematide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to Hematide. Analysis of efficacy and safety for all of the Phase 3 studies will be based on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint will be the mean change in hemoglobin from baseline. Each study is planned to continue until the last patient has been treated for 52 weeks. In addition, the assessment of safety will include a composite cardiovascular endpoint from a pooled safety database.

Currently, we expect to release results from the Phase 3 clinical program in the first quarter of 2010, however, the rate of accrual of cardiovascular events could affect the duration of the studies. If the cardiovascular events accrue at a lower rate than estimated, the outcome of the composite safety endpoint analysis may not meet the pre-defined non-inferiority criteria due to insufficient events, causing a possible failure of our clinical program. In order to obtain additional data to compensate for a lower than estimated cardiovascular event rate, the Phase 3 clinical program may need to be extended or additional studies may need to be conducted, if even feasible, which could delay the development of Hematide and the achievement of milestones from Takeda. Even if the cardiovascular events accrue at the estimated rate, we could still fail to establish that Hematide is non-inferior to the comparator drugs upon analysis of the data from our Phase 3 clinical program. Further, our Phase 3 clinical program could be suspended or terminated prior to completion based on safety or other concerns, including recommendations of the data monitoring committee, which will be meeting periodically to review the interim safety data from our trials.

### **Manufacturing and Supply**

All of our current good manufacturing practices, or GMP, manufacturing is outsourced to third parties with oversight by our internal managers. We have limited non-GMP manufacturing capacity in-house. We rely on third-party manufacturers to produce sufficient quantities of drug substance and product for use in clinical trials. We intend to continue this practice for any future clinical trials and large-scale commercialization of Hematide and for any other potential products for which we retain significant development and commercialization rights. All of our current product candidates are chemically synthesized and peptide-based.

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

Final Hematide drug product is currently manufactured as a buffered aqueous solution for intravenous or subcutaneous administration. Takeda has assumed responsibility for final drug product manufacture and control as part of our worldwide collaboration for Hematide.

### **Intellectual Property**

We protect our technology through the use of patents, trade secrets and proprietary know-how. We have more than 20 issued U.S. patents, including claims covering compositions of compounds comprising peptides of a broad genus of ESA peptide sequences, methods of treating EPO disorders using these compounds and methods of synthesizing these types of ESA peptide compounds. We own several pending U.S. patent applications, all of which relate to our core peptide technologies or to particular peptide compounds. Our issued U.S. patent(s) covering Hematide and any U.S. patent(s) that may issue based on pending patent applications containing claims covering Hematide begin expiring no earlier than 2024. We own foreign equivalent patents and patent applications based on our U.S. patents and patent applications. We also retain technical information related to manufacture and analysis of Hematide as trade secrets. We are currently involved in binding arbitration with Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc., or, collectively, J&J, over the ownership of certain patents and applications currently assigned to J&J, three of our issued U.S. patents and a number of foreign patents and patent applications. See “Risk Factors—Risks Related to Our Business” and “Legal Proceedings” elsewhere in this Annual Report on Form 10-K.

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.

#### ***Third-Party Intellectual Property***

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

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

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

- infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;

- substantial damages for infringement, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- a court prohibiting us from selling or licensing the product or using the proprietary technology unless the third party licenses its technology to us, which it is not required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross licenses to our technology; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

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

### **Research and Development Expenses**

We have made substantial investments in research and development. Research and development costs consist of salaries, stock-based compensation, employee benefits, license fees, laboratory supplies, costs associated with clinical trials, including amounts paid to clinical research organizations, other professional services and facility costs. Research and development expenses were \$137.5 million, \$69.4 million, and \$54.3 million, for the years ended December 31, 2008, 2007 and 2006, respectively.

### **Our Strategic Alliances**

#### *June 2006 Development and Commercialization Agreement with Takeda*

In June 2006, we entered into a Development and Commercialization Agreement with Takeda to develop and commercialize Hematide worldwide. Under our collaboration, the companies will co-develop and co-commercialize Hematide in the U.S. Takeda received an exclusive license to develop and commercialize Hematide outside of the U.S. As contemplated by this agreement, the February 2006 agreement that we have also entered into with Takeda was harmonized to address the worldwide arrangement between the parties.

We will share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of Hematide. Specifically, we will have primary responsibility for Hematide's clinical development plan and clinical trials in the dialysis and pre-dialysis indications, while Takeda will have primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the extent any such indication is developed. Beginning January 1, 2007, Takeda was responsible for the first \$50 million of third party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Of the first \$50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of \$36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda bears 70% of the third party U.S. development expenses, while we are responsible for 30% of the expenses. Each company retains responsibility for 100% of its internal development expenses. Takeda will have primary responsibility and bear all costs for Hematide's clinical development in support of regulatory approval for all territories outside the United States.

Under the June 2006 agreement, Takeda paid an upfront license fee of \$105 million, and upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda up to an aggregate of \$280 million across all indications, the majority of which relate to

the renal program, including milestone payments upon completion of database lock of the Phase 3 clinical trials of \$15 million for dialysis and \$15 million for pre-dialysis, \$20 million milestone payments upon FDA acceptance of the submission of the new drug application, or NDA, and \$95 million of milestone payments upon approval by the FDA in dialysis and pre-dialysis indications. Further, we may receive from Takeda up to an aggregate of \$150 million upon the achievement of certain worldwide annual net sales milestones. We and Takeda will share equally in the net profits and losses of Hematide in the United States, which include expenses related to the marketing and launch of Hematide. Takeda will pay us a variable royalty based on annual net sales of Hematide outside the United States.

We will own and have responsibility for United States NDAs in the dialysis, pre-dialysis, chemotherapy-induced anemia and anemia of cancer indications to the extent any such NDA is filed. Takeda will own and have responsibility for regulatory filings outside the United States. Takeda will also be responsible for creating and maintaining a global safety database.

We will also be responsible, through our contract manufacturers, for the manufacture and supply of all quantities of Hematide API to be used in the development and commercialization of Hematide worldwide. Takeda will be responsible for the fill and finish steps in the manufacture of Hematide worldwide.

The parties have agreed to jointly develop the initial commercial marketing plan for Hematide in the United States pursuant to which we and Takeda will divide Hematide promotional responsibilities in the U.S. We will be primarily responsible for commercialization activities within the dialysis and pre-dialysis markets, and Takeda primarily responsible for oncology-related markets. We and Takeda will jointly decide on promotional responsibility for markets outside of these initial indications. Takeda will control price, terms of sale and booking of sales of Hematide.

With respect to existing third-party license agreements relevant to Hematide, fees and milestones payments related to these existing third-party licenses will be shared between us and Takeda as development expenses, provided that an upfront fee in the amount of \$17.6 million to a third-party licensor of certain technology related to Hematide paid in 2006 was the sole responsibility of us. For all territories outside the U.S., any royalty payments to a third party for a license will be borne solely by Takeda and other fees or payments will be borne by us and Takeda jointly.

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

#### ***February 2006 Development and Commercialization Agreement with Takeda***

In February 2006, we entered into a collaboration with Takeda to develop and commercialize Hematide in Japan. Under our agreement, Takeda obtained the exclusive right to develop and commercialize Hematide in Japan for the treatment of anemia in patients with chronic renal failure and cancer, while we retained the rights to develop and commercialize Hematide in the rest of the world, either alone or with third-party partners. Takeda has granted to us a fully paid, royalty-free, sublicenseable, non-exclusive license under its own related technology to develop and commercialize Hematide in the rest of the world.

Takeda also obtained a right of first negotiation to any backup products for Hematide developed by us or our third-party partners. Specifically, during the first ten years of the agreement, if we develop, or our third-party partners develop within an Affymax collaboration, a product that advances to

Phase 2 clinical trials and competes with Hematide in the renal or oncology indications, we are obligated to offer to Takeda the right to develop and commercialize such product in Japan before offering the product opportunity in Japan to any other third party.

Takeda is obligated to use diligent efforts to develop and commercialize Hematide in Japan. The agreement establishes a joint committee to oversee the development, regulatory approval and commercialization of Hematide. While the joint committee will operate by consensus of the parties, Takeda will generally have the final decision-making authority on matters pertaining to the development and commercialization of Hematide in Japan.

Takeda is responsible for commercializing Hematide in Japan and will have the discretion to set the price of Hematide in Japan. Under the agreement, Takeda will provide us with progress reports on its commercialization activities and we will have the opportunity to review and comment on the significant marketing decisions including strategy and launch dates.

We provide Takeda with Hematide API and Takeda is responsible for the fill and finish of the product. Our pre-clinical and clinical supply of Hematide API to Takeda is governed under the terms of this agreement, while the supply for Takeda's requirements for commercial quantities of Hematide API will be governed by a separate manufacturing agreement that the parties will enter into prior to the earlier of the Phase 3 clinical trials or the stability studies for Takeda's finished product formulation of Hematide.

Pursuant to this agreement, Takeda has paid us approximately \$37 million to date, consisting of \$17 million in upfront licensing fees, approximately \$10 million equity investment in our Series E preferred stock, and in January 2007, a \$10 million cash milestone payment for the completion of the first Phase 1 trial of Hematide in Japan. Upon Takeda's successful achievement of clinical development and regulatory milestones, we may receive from Takeda up to an additional total of \$65 million across all indications, the majority of which relate to the renal program, together with royalties based on a percentage of the sales of Hematide in Japan.

Under the agreement, each party will solely own all inventions made by such party alone, and will jointly own all inventions made by the parties jointly, including all intellectual property rights therein. Such solely-owned inventions and jointly-owned inventions will be subject to the cross-licenses between the parties for the development and commercialization of Hematide in each party's territory. We are obligated to maintain our third-party license agreements that may contain technology that is the subject of the license to Takeda under this agreement.

Each party will be responsible for the worldwide filing, prosecution and maintenance (including defense against third-party opposition claims) of patents solely owned by such party and the filing, prosecution and maintenance of jointly-owned patents each in its own territory. The parties will share the responsibility for enforcing patents against third-party infringement, and the allocation of responsibilities and sharing of recoveries will depend on where the claims arise, and which patents are involved. We have the first right, but not the obligation, to defend against patent infringement claims or bring patent opposition claims relating to Hematide in Japan, and Takeda has the backup right to do so. Neither party can settle any patent infringement claim without the prior consent of the other party, if the settlement will negatively affect the other party's rights.

Each party is obligated to indemnify the other party for third-party claims and losses resulting from the development and commercialization activities involving Hematide in its territory, a breach of its representations, warranties or obligations under the agreement, or its willful misconduct or negligent acts, except to the extent such losses are subject to the indemnification obligations of the other party.

Absent early termination, the agreement will expire when all of Takeda's payment obligations expire. Either party may terminate the agreement early upon prior written notice if the other party commits an uncured material breach of the agreement. Takeda also has the option to terminate the

agreement early, without cause, upon six months' prior written notice. We may convert Takeda's license to be non-exclusive or terminate the agreement entirely if Takeda promotes certain products that compete with Hematide. If Takeda terminates without cause or if we terminate for Takeda's material breach, Takeda will transfer to us the right to develop and commercialize Hematide in Japan.

#### ***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 Hematide. 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 Hematide. We also agreed to pay milestone payments totaling up to an additional \$7 million, plus possible additional milestones in connection with our partnering activities relating to Hematide or merger and acquisition activities.

In July 2006, we paid Nektar a \$17.6 million milestone payment triggered by our receipt of a \$105 million upfront payment from Takeda.

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

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

#### **Marketing and Sales**

We currently do not have sales and marketing capabilities. Our business model is to become a fully integrated biopharmaceutical company and we intend to develop commercial capabilities in the renal market in order to co-commercialize Hematide under our collaboration agreements with Takeda.

#### **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 renal failure and oncology research, some in direct competition with us. We also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

According to IMS Health, rEPO generated \$11.5 billion in worldwide revenues for 2008, of which we believe approximately \$6.8 billion was generated in the U.S. Of this \$6.8 billion in U.S. revenue, the leaders, PROCIT, marketed by J&J, and Aranesp and EPOGEN, both marketed by Amgen, represented the entire market. Aranesp, introduced in 2001, has significant market share, particularly in the oncology market. In late 2005, U.S. quarterly sales of Aranesp surpassed those of PROCIT. Aranesp is approved for once-monthly dosing for treatment of anemia in pre-dialysis patients in Europe. In the U.S., Amgen reportedly is in the process of seeking approval for once-monthly dosing of Aranesp for treatment of anemia in pre-dialysis patients. In 2005, Amgen submitted a biologics license supplement to include a once-monthly dosing regimen for pre-dialysis patients in the label for Aranesp. In October 2006, the FDA responded to Amgen's filing with a request for additional clinical data for the once-monthly dosing regimen, including an additional clinical study.

Roche has obtained regulatory approval to market and has launched a PEGylated ESA, called Mircera, in Europe. 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 the expiration of these patents in 2013. If Mircera enters the U.S. markets before Hematide or upon its entry, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide, because of its ability to be longer acting than currently marketed ESAs in the U.S. In addition to marketed ESAs, there are several ESA product candidates in various stages of active development, including small molecules, by a potential competitor, FibroGen, Inc., that may promote the production of naturally-occurring EPO in patients. In addition, Merck recently announced plans to develop its own version of EPO in yeast cells instead of mammalian cells which, if successful, may permit Merck to launch its product prior to the expiration of Amgen's U.S. patents.

In addition, several biosimilar versions of short-acting rEPO have recently been launched or are expected to launch in Europe in the near term. Biosimilar EPOGEN products are generally not expected to enter the U.S. market until 2013, when the last patent in Amgen's U.S. EPO patent estate expires.

### **Government Regulation and Product Approvals**

The clinical development, manufacturing and potential marketing of our products are subject to regulation by various authorities in the U.S., the E.U. and other countries, including, in the U.S., the FDA, and, in the E.U., the European Agency for the Evaluation of Medical Products, or EMEA. The Federal Food, Drug, and Cosmetic Act and the Public Health Service Act in the U.S., and numerous directives, regulations, local laws, and guidelines in the E.U. govern testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Product development and approval within these regulatory frameworks takes a number of years, and involves the expenditure of substantial resources.

Regulatory approval will be required in all major markets in which we, or our licensors, seek to test our products 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 preclinical data, chemical data and a proposed clinical study protocol, as described above, 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 European Union, or 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. The regulatory authorities in the E.U. typically have between one and three months in which to raise any objections to the proposed clinical trial, and they often have the right to extend this review period at their discretion. In the U.S., following completion of Phase 1 trials, further submissions to regulatory authorities are necessary in relation to Phase 2 and 3 trials to update the existing IND. Authorities may require additional data before allowing the trials to commence and could demand discontinuation of studies at any time if there are significant safety issues. In addition to regulatory review, a clinical trial involving human subjects has to be approved by an independent body. The exact composition and responsibilities of this body differ from country to country. In the U.S., for example, each clinical trial is conducted under the auspices of an Institutional Review Board at the institution at which the clinical trial is conducted. This board considers among other things, the design of the clinical trial, ethical factors, the safety of the human subjects and the possible liability risk for the institution. Equivalent rules apply in each member state of the E.U., where one or more independent ethics committees that typically operate similarly to an Institutional Review Board, will review the ethics of conducting the proposed research. Other authorities elsewhere in the world have slightly differing requirements involving both execution of clinical trials and import or export of pharmaceutical products. It is our responsibility to ensure that we conduct our business in accordance with the regulations of each relevant territory.

Information generated in this 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. There can be no assurance that if clinical trials are completed, either we or our collaborative partners will submit applications for required authorizations to manufacture or market potential products, including a marketing authorization application or an NDA, or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all.

In order to gain marketing approval, we must submit a dossier to the relevant authority for review, which is known in the U.S. as an NDA and in the E.U. as a marketing authorization application (MAA). The format is usually specified by each authority, although in general it will include information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product and non-clinical and clinical data. The FDA undertakes such reviews for the U.S. 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 EMEA. The EMEA 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 studies 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.

### **Employees**

As of December 31, 2008, we had 147 employees. We had 105 employees engaged in research and development, and our remaining employees are management or administrative staff. In February 2009, we reduced our workforce by approximately 12 percent primarily in research, management and administrative areas. None of our employees is subject to a collective bargaining agreement. We believe that we have good relations with our employees.

### **About Affymax**

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

We have a registration for the trademark “Affymax” in the U.S. We have applied in the U.S. to register the trademarks: “Adeptide,” “Angiotide,” “Avisis,” “Gematide,” “Hematide,” “Innotide” and “Affymax and logo.” We have applied in certain other countries to register the trademarks: “Avisis,” “Hematide” and “Innotide.”

### **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](http://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](http://www.sec.gov).

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

*You should carefully consider the risks described below, which we believe are the material risks of our business before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. 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.*

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

*We are dependent on the success of Hematide, and we cannot give any assurance that it will receive regulatory approval. Recent safety concerns surrounding the use of ESAs may limit the ability to develop or successfully commercialize Hematide.*

Hematide, an ESA, is a new chemical entity and currently our only product candidate. We are conducting Phase 3 clinical trials for the treatment of anemia associated with chronic renal failure. In order to commercialize Hematide, we will be required to conduct clinical trials to establish that Hematide is safe and effective which may not succeed and to obtain regulatory approvals which we may fail to do. We do not know, and are unable to predict, whether we will be able to successfully execute and complete the Phase 3 clinical trials in a timely or effective manner.

The FDA, the medical community, and others have recently raised significant safety concerns relating to commercially available ESAs as a result of reports of increased mortality and side effects from a number of clinical trials. These concerns have resulted in a number of negative actions affecting the market for ESAs, particularly in oncology, including the following:

- As a result of concerns associated with administering ESAs to target higher hemoglobin levels, the FDA required revised warnings, including black box warnings, be added to labels of currently marketed ESAs advising physicians to monitor hemoglobin levels and to use the lowest dose of ESA to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions.
- The FDA also issued a public health advisory re-evaluating the safe use of the ESA class and convened its Oncology Drugs Advisory Committee (ODAC) in May 2007 to consider recent information on risks associated with ESAs for use in the treatment of anemia in cancer patients. The ODAC recommended that the FDA institute restrictions on the usage of currently marketed ESAs, including limitations on the treatment of certain types of cancer and the duration of treatment.
- The FDA also convened a joint meeting in September 2007 of the Cardiovascular and Renal Drugs advisory committee and the Drug Safety and Risk Management advisory committee to review the risks and benefits of ESAs.
- The FDA approved revised black box warnings and other safety-related product labeling changes for commercially available ESAs during 2007 and 2008.
- In addition, the FDA convened another ODAC meeting in March 2008 to review data from more recent clinical trials with breast cancer patients and cervical cancer patients using currently marketed ESAs, and to consider additional action. The ODAC recommended the use of informed consents and further restrictions on the use of currently marketed ESAs for the treatment of chemotherapy-induced anemia, including the exclusion of patients with metastatic breast or head and neck cancer as well as those cancer patients potentially receiving curative treatment.
- In July 2008, the FDA announced additional safety-related label restrictions for the use of commercially available ESAs including revisions to the black box warnings to provide that ESAs

are not indicated for patients undergoing chemotherapy expected to cure their cancer. In addition, the FDA required new prescribing information to assure that ESA therapy is not initiated until the hemoglobin level drops below 10 g/dL.

In 2008, these factors and the uncertain regulatory climate resulted in our and Takeda's decision to suspend the development of Hematide to treat chemotherapy-induced anemia, which may have a material adverse effect on our business and future financial results.

We cannot predict what further action, if any, the FDA may take, which may include, among others, additional label restrictions, the use of informed consents, further lowering of target hemoglobin levels, or even the removal of indications from the label altogether. Further, regardless of whether the FDA takes additional action or not, CMS and private payors may still decide separately to lower or discontinue reimbursement.

The controversy surrounding ESAs and FDA concerns has, and may, further negatively affect patient enrollment and the cost, scope, size, risk, or timing of our clinical trials, increase the risk of achieving regulatory approval, and significantly delay commercialization of Hematide. The market for ESAs has been significantly reduced and is likely to negatively impact the commercial potential of Hematide.

Our clinical development program for Hematide may not lead to a commercial drug either because we fail to demonstrate that it is safe and effective in clinical trials and we therefore fail to obtain necessary approvals from the FDA, and similar foreign regulatory agencies, or because we have inadequate financial or other resources to advance Hematide through the clinical trial process. Any failure to obtain approval of Hematide would have a material and adverse impact on our business as we would have to incur substantial expense and it would take a significant amount of time and resources to bring any future product candidate to market, if ever.

***We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future requiring substantial additional financing. If we fail to obtain additional financing, we will be unable to complete the development and commercialization of Hematide and may need to cease operations. Even if we obtain additional financing, we may never achieve or sustain profitability***

We have experienced significant operating losses since our inception in 2001. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. At December 31, 2008, we had an accumulated deficit of \$298.3 million. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to:

- complete the Phase 3 clinical trials for the Hematide renal program and other clinical development of Hematide;
- prepare the submission of the New Drug Application, or NDA, for Hematide;
- validate the manufacturing process for Hematide at our contract manufacturers; and
- prepare to launch and commercialize Hematide, including building our own commercial organization, sales force and infrastructure to address renal markets.

We believe that existing cash, cash equivalents and investments and the interest thereon, will enable us to maintain our currently planned operations through at least 12 months. However, we expect that additional capital will need to be raised to complete the development and commercialization of Hematide. The current capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Securing funding has been particularly difficult for companies of our size with limited capital resources. Continuation of this market may significantly limit our ability to raise funds such that that there can be no assurance we can

raise the additional funds to support our continuing operations and maintain current development and commercialization timelines for Hematide.

To date, our sources of cash have been limited primarily to the proceeds from the sale of our securities to private and public investors and payments by Takeda under our collaboration agreements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to raise additional funds when required or on acceptable terms, we may have to:

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

We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials, prepare for the NDA and add infrastructure and operations to support commercialization of Hematide, and potentially begin new research and development programs. Our ability to generate revenue depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our product candidate, Hematide. If due to lengthy and complicated development, clinical and regulatory requirements or any other reason, we are unable to commercialize Hematide, it will be a long time before we will be able to commercialize any future product candidates, if ever.

Even if we receive regulatory approval of Hematide, we must successfully commercialize Hematide before we can become profitable. We anticipate that it will be at least several years before we can commercialize Hematide and we expect to incur substantial expenses associated with our commercialization efforts as well as share in those of Takeda's even prior to obtaining approval of Hematide as well as thereafter. Accordingly, we may never generate significant revenues and, even if we do generate revenues, we may never achieve or sustain profitability.

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

***A portion of our investments consists of auction rate securities, or ARS, and the market for those securities has recently failed to provide liquidity, and if such illiquidity continues, may negatively impact our operations. Although we have received ARS rights from UBS AG, we may not be able to recover the value of our ARS under our settlement with UBS AG.***

Since the filing of our Form 10-K for the year ended December 31, 2007, the overall ARS market has continued to deteriorate and our ARS have failed in all but a single auction. Accordingly, we recorded a \$3.6 million net reduction of fair value of ARS which was recorded as an impairment charge for the year ended December 31, 2008. As of December 31, 2008, the fair value balance of our ARS totaled \$17.6 million. Our valuation analysis is based on dynamic market conditions and further

deterioration in the ARS markets or changes in our assumptions could lead to significant reductions in determined value thus resulting in additional impairments in future periods. We may also be required to sell these investments at prices significantly below par or assessed fair value. There can be no assurance as to the timing of when, or if the market for ARS will recover in a manner that will allow us to receive a return of some or all of our principal or to meet our liquidity needs. If we are unable to liquidate our ARS to obtain funds when needed we may be unable to fund our operations. We have entered into a settlement agreement with UBS AG relating to the failed auctions of our ARS through which UBS AG and its affiliates may provide us with additional funds based on these ARS. However, if we are unable to access the funds underlying or secured by these investments in a timely manner, we may need to find alternate sources of funding for certain of our operations, which may not be available on favorable terms, or at all, and our business could be adversely affected.

In accepting the settlement offer from UBS AG relating to the failed auctions of our ARS, we agreed to give up certain rights and accept certain risks. Under this settlement, UBS AG issued us Series C-2 Auction Rate Securities Rights (the “ARS Rights”). The ARS Rights are not transferable and give us the option to require UBS to repurchase at par our ARS beginning on June 30, 2010, and prior to such date, UBS has the option to buy, at par, the ARS.

While we entered into the settlement in expectation that UBS AG will fulfill its obligations in connection with the ARS Rights, UBS AG may not have sufficient financial resources to satisfy these obligations. The U.S. and worldwide financial markets have recently experienced unprecedented volatility, particularly in the financial services sector. While UBS AG has stated that it believes it has the financial resources necessary to perform its obligations under the ARS Rights, UBS AG may not be able to maintain the financial resources necessary to satisfy its obligations with respect to the ARS Rights in a timely manner or at all. The obligations of UBS AG under the ARS Rights are not secured by the assets of UBS AG or otherwise and are not guaranteed by any other entity. UBS AG is not required to obtain any financing to support its obligations. If UBS AG is unable to perform its obligations under the settlement, we may have no source of liquidity or means of obtaining value for our ARS. In addition, UBS AG is a Swiss bank and all or a substantial portion of its assets are located outside the U.S. As a result, it may be difficult for us to serve legal process on UBS AG or its management or have any of them appear in a U.S. court. Judgments based solely on the U.S. securities laws may not be enforceable in Switzerland. As a result, if UBS AG fails to fulfill its obligations, we may not be able to effectively seek recourse against it while the release of claims provided to UBS and its affiliates may still be held to be enforceable.

***We have initiated binding arbitration and related litigation with Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc., or collectively, J&J, over ownership of intellectual property related to erythropoietin receptor, or EPO-R, agonists. An adverse result in this binding arbitration or litigation, together with adverse results in subsequent litigation J&J might then bring, could prevent us from manufacturing or commercializing Hematide in a number of countries in accordance with our current plans or could limit our ability to license third parties to do so.***

We have initiated binding arbitration and related litigation with J&J over the ownership of a number of U.S. and international patents and patent applications related to EPO-R agonists, or the “intellectual property in dispute.” We believe that we are the sole owner or co-owner of the intellectual property in dispute. J&J, on the other hand, alleges that it is the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which we are currently named as sole owner that relate to specified peptide compounds. Although we believe our position in this dispute is meritorious and that we have substantial defenses to J&J’s counterclaims, litigation is time consuming and expensive and the outcome is inherently uncertain. A number of outcomes in the dispute are possible, including, without limitation, the possibility that we lose or do not acquire specific patents and patent rights in the ESA field, J&J obtains or retains specific patents and patent rights in the ESA field or we become liable for damages, attorneys’ fees and costs. Moreover, if the arbitration panel were to

determine that J&J is the sole owner of one or more of the disputed patents, J&J may seek to assert such patents against us in the U.S., Europe and elsewhere.

We believe the U.S. intellectual property in dispute does not encompass Hematide and that we can manufacture, commercialize and sell Hematide in the U.S. regardless of the outcome of this arbitration. However, if, through the ongoing arbitration or otherwise, J&J or another potential competitor obtains or possesses patents or patent rights that are deemed to encompass one or more elements of Hematide, that party could initiate proceedings, an adverse result in which could prevent us from manufacturing or commercializing Hematide, either for ourselves or with Takeda, in the U.S.

If the intellectual property in dispute is deemed broad enough to cover Hematide, then under the laws applicable to most relevant jurisdictions outside the U.S., a finding of joint ownership would permit us to manufacture and sell Hematide, but may not allow us to license third parties to do so. Because our strategy is to commercialize Hematide worldwide through our partnership with Takeda, a finding of joint ownership of the patents and applications in question could materially affect our business plans outside the U.S. Within the U.S., joint ownership of a patent gives each joint owner the right to license third parties, so even if the patents in question are held to be jointly owned by us and J&J we do not believe we would be prevented from pursuing our partnership strategy for Hematide in the U.S. If the arbitration panel determines that J&J is the sole owner of one or more of the U.S. patents in the dispute that are assigned to us, J&J may seek to assert such patent against us in the U.S.

Although J&J's ownership of its European patent application relating to agonist peptide dimers is subject to the pending arbitration, a patent could be issued from this application to J&J by the European Patent Office in the near future. In the J&J arbitration proceeding, we have claimed that we should be at least joint owner of this European application. If this patent issues, J&J could seek to enforce this patent against us in Europe. In many European countries, a patent cannot be asserted to stop clinical trials, but in some, a patent holder can seek to enjoin clinical trials. We are seeking to minimize the effect this might have on our development plans, but there can be no assurance that our clinical trial and manufacturing plans would not be delayed if a European patent issues to J&J.

The outcome of any arbitration or litigation proceeding is inherently unpredictable. The claims and underlying facts at issue in this dispute are complex, and could necessitate prolonged discovery. Since we acquired assets from Affymax N.V. (a different company from us), discovery could uncover documents and other evidence of which we are not currently aware that are adverse to our position. We have incurred significant expense in pursuing this matter to date, and because a final decision on the arbitration and related litigation may not be reached for years, we expect we will continue to incur significant and increasing expenses for several more years, likely totaling in the millions of dollars as this matter progresses toward resolution. In addition, the efforts of our technical, legal and management personnel have been and will continue to be diverted as a result of this dispute. The arbitration panel ruling permitting the scope of discovery to include certain information relating to Hematide could increase our legal expenses significantly and may further divert the efforts of our technical, legal and management personnel.

***Our commercial success depends upon attaining significant market acceptance of Hematide among physicians, patients, health care payors and, in the renal market, acceptance by the major operators of dialysis clinics.***

Hematide has not been approved or commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Hematide, in which case we would not generate revenue or become profitable. In particular, the therapeutic indications targeted by Hematide have been served by our competitors' products for many years. These products may now be said to be the standard of care, and it may be difficult to encourage healthcare providers to switch from products with which they and their patients have become comfortable.

The dialysis market, which is one of the largest and most established markets that Hematide will attempt to penetrate, is highly concentrated, with two companies serving a significant majority of all dialysis patients on Medicare. In addition, dialysis clinics using ESAs could incur substantial expense in administration and training if they were to switch from current ESAs to Hematide. The concentration of customers for ESAs within the dialysis market may pose a risk to our ability to obtain revenues or favorable margins on Hematide, if approved. If we cannot come to agreements with one or more of the major companies operating dialysis clinics in the U.S. or even if we do, we cannot do so prior to product launch, the revenue opportunity of Hematide could be significantly reduced. In October 2006, Amgen Inc., or Amgen, marketer of the ESAs EPOGEN and Aranesp, and Fresenius Medical Care, or Fresenius, one of the two largest operators of dialysis clinics in the U.S., announced an agreement whereby Amgen would be the sole supplier of EPO products for Fresenius' dialysis business effective immediately through the end of 2011. We are not aware of the specific terms of the Amgen-Fresenius agreement, and cannot project how it may impact the commercial opportunity for Hematide if and when it is launched. However, agreements between operators of dialysis facilities and marketers of competing ESA products could potentially limit the market opportunity for Hematide, and adversely impact our ability to generate revenues.

Currently, CMS reimburses healthcare providers for use of ESAs at a rate of average sales price plus a 6% margin to the provider, or ASP plus 6%. These reimbursement rates have been declining and have been subject to concerns over the rates that will be subject to future reimbursement. In addition, Congress has recently enacted legislation entitled "Medicare Improvements for Patients and Providers Act of 2008," or 2008 Medicare Legislation, that adopts a bundled payment system covering the cost of drugs, including ESAs, as well as dialysis services effective January 2011. Significant aspects of the 2008 Medicare Legislation and the details of the bundled payment system will be determined through additional rulemaking. We cannot be certain what reimbursement policies will be in effect at the time we seek to enter the chronic renal failure market or any other indication in the U.S., or the effect these policies may have on our ability to compete effectively, if we are ever successful in reaching the market.

In addition, recent studies by manufacturers of ESAs indicate that the higher levels of hemoglobin achieved through administration of ESAs can result in a statistically significant increase in cardiovascular events. This may in turn reduce the growth or cause contraction of the market for ESAs and reduce the potential revenues for Hematide.

In the pre-dialysis market, one challenge is that patients suffering from anemia may not access health care resources to treat their condition for some time following its onset. As a result, the available pre-dialysis market may be limited by the overall proportion of patients who are diagnosed with the condition, how early these patients are diagnosed, and at what point they begin treatment. Additionally, reaching and educating the doctors who treat pre-dialysis patients may be difficult, as these patients are spread thinly across a variety of treatment settings. Primary care physicians that treat pre-dialysis patients may not be comfortable with reimbursement procedures for injectible products and thus delay or restrict treatment with ESAs.

In addition, market acceptance of Hematide by physicians, healthcare payors and patients will depend on a number of additional factors, including:

- the clinical indications for which Hematide is approved;
- acceptance by physicians and patients of Hematide as a safe and effective treatment;
- perceived advantages over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement by third parties;

- the continued use of ESA treatments generally for anemia;
- relative convenience and ease of administration; and
- the prevalence and severity of side effects.

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

We face competition from established and emerging pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. 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 Hematide or any other future products that we may develop and commercialize. In addition, significant delays in the development of Hematide could allow our competitors to bring new products to market before we do and impair our ability to commercialize Hematide. Competitors may also reduce the price of their ESAs in order to gain market share. These price reductions could force us to lower the price of Hematide in order to compete effectively, resulting in lower revenues and reduced margins on the sales of Hematide.

We anticipate that, if approved, Hematide would compete with EPOGEN and Aranesp, which are both marketed by Amgen, PROCrit, which is marketed by Ortho Biotech Products, L.P. (a subsidiary of J&J), NeoRecormon and Mircera, which are currently marketed outside the U.S. by Roche. Aranesp is approved for once-monthly dosing for treatment of anemia in pre-dialysis patients in Europe. In the U.S., Amgen is reportedly in the process of seeking approval for once-monthly dosing of Aranesp for treatment of anemia in pre-dialysis patients. If Amgen is successful in obtaining approval for once-monthly dosing or our competitors' products are administered in practice on a less frequent basis than prescribed by their labels, the market for Hematide may be decreased. In addition, Roche's Mircera has recently launched in Europe. Mircera reportedly has greater plasma stability and is longer acting than any rEPO product that is currently on the market. As a result of the patent litigation between Roche and Amgen, Mircera has been found to infringe several U.S. patents owned by Amgen and has been enjoined from being sold in the U.S. until the expiration of these patents in 2013. If Mircera enters the U.S. market before Hematide or upon its entry, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide, because of its ability to be longer acting. In addition, Merck recently announced plans to develop its own version of EPO in yeast cells instead of mammalian cells which, if successful, may permit Merck to launch its product prior to the expiration of Amgen's U.S. patents. Another potential competitor, FibroGen, Inc., or FibroGen, is developing small molecules designed to promote the production of greater levels of naturally-occurring EPO in patients. The introduction of biosimilars into the ESA market, or new market entrants, could also prove to be a significant threat to us as it could not only limit the market for Hematide, but could also drive down the price of ESAs.

Most of these competitors have substantially greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Current marketers of ESAs also have the ability to bundle sales of existing ESA products with their other products, potentially disadvantaging Hematide, which we plan to sell on a stand-alone basis. Established pharmaceutical and large biotechnology companies may invest heavily to discover and develop novel compounds or drug delivery technology that could make Hematide obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through strategic partnerships with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well

as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Our competitors may succeed in obtaining patent or other intellectual property protection, receiving FDA approval, or discovering, developing and commercializing products before we do.

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

The last significant U.S. patent for epoetin alfa, a version of short-acting rEPO, expires in 2013. Patents related to epoetin alfa expired in the E.U. in 2004. Biosimilars of short-acting rEPO are currently being developed or launched in and for various markets outside the U.S., including the E.U. Short-acting rEPO biosimilars are already being sold in various territories outside the U.S. and the E.U. We expect that biosimilars, including rEPO, will be sold at a significant discount to existing branded products when they are launched in the U.S. and the E.U. The introduction of biosimilars into the ESA market could prove to be a significant threat to Hematide if they are able to demonstrate bioequivalence to existing ESAs. Biosimilars will constitute additional competition for Hematide and could drive its price and sales volume down, which may adversely affect our revenues.

***Any failure or delay in completing clinical trials or the submission of our NDA for Hematide could severely harm our business.***

Hematide, as well as any other product candidate we choose to pursue, must undergo extensive preclinical studies and clinical trials as a condition to submission of an NDA and regulatory approval. Preclinical studies and clinical trials are expensive, complicated, and take many years to complete.

The rate of accrual of cardiovascular events could affect the duration of our Phase 3 clinical program, which is currently planned for 52 week treatment period of the last patient. If the cardiovascular events accrue at a lower rate than estimated, the outcome of the safety endpoint analysis may not meet the pre-defined non-inferiority criteria due to insufficient events causing a possible failure of our clinical program. In order to obtain additional data to compensate for a lower than estimated cardiovascular event rate, the Phase 3 clinical program may need to be extended or additional studies may need to be conducted, if even feasible, which could delay the development of Hematide and the achievement of milestones from Takeda. Even if the cardiovascular events accrue at the estimated rate, we could still fail to establish that Hematide is non-inferior to the comparator drugs upon analysis of the data from our Phase 3 clinical program. Further, our Phase 3 clinical program could be suspended or terminated prior to completion based on safety or other concerns, including recommendations of the data monitoring committee, which will be meeting periodically to review the interim safety data from our trials. In addition, the completion of clinical trials for Hematide and the submission of our NDA may be delayed or fail for many other reasons, including:

- safety issues, including serious adverse events associated with Hematide, and concerns surrounding use of ESAs generally;
- difficulties of executing our Phase 3 clinical program, for Hematide, which is large and complex, involving numerous third parties, approximately 2,600 patients and 400 sites in the U.S. and Europe, compliance with a variety of government regulations, and a number of significant new initiatives and systems for which we do not have any prior experience implementing, including the adjudication of cardiovascular events by an independent review committee;
- regulators or institutional review boards may not authorize us to continue clinical trials or we may suspend or terminate such trials for various reasons, including recommendations of the data monitoring committee, exposure of the participating patients to unacceptable health risks or noncompliance with regulatory requirements;

- our inability, or the inability of our collaborators or licensees, to manufacture or obtain from third parties materials of a quality or quantity sufficient to complete our preclinical studies, clinical trials or registration stability studies;
- risks associated with non-inferiority trial designs, which are studies devised and statistically powered to show that the test drug is not inferior to the control drug;
- risks associated with data integrity and difficulty in obtaining complete and accurate data on a timely basis which may result from our unusual Phase 3 trial design whereby all patients end treatment in each trial in the same timeframe or for a variety of other reasons, including shortage of resources, failure to follow the clinical trial protocols, inadequate monitoring or training of sites, or problems maintaining contact with patients after treatment;
- poor effectiveness or safety concerns during clinical trials;
- the failure of patients to complete clinical trials due to the length of our clinical program, side effects, dissatisfaction with Hematide or other reasons;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by FDA and similar foreign regulatory agencies.

Patients participating in the trials may not live through completion of the trial or may suffer adverse medical effects unrelated to treatment with Hematide. The results from earlier preclinical testing and prior clinical trials may not be predictive of results obtained in other preclinical models, which we are continuing to conduct, or later and larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. Our failure to adequately demonstrate the safety and effectiveness of Hematide will prevent us from receiving regulatory approval and will have a material adverse impact our business.

It is possible that Hematide will not complete clinical trials in any markets. We also do not know and are unable to predict whether the data arising from the clinical trials for Hematide will be satisfactory to the FDA and, if not, whether the FDA will require us to conduct additional trials or alter the scope, size or design of such trials, which could result in additional delays in bringing Hematide to market, if ever. Accordingly, we may not receive the regulatory approvals needed to market Hematide. Any failure or delay in completing clinical trials or submitting our NDA to the FDA would delay commercialization of Hematide and severely harm our business and financial condition.

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

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

- the financial and internal resources may be insufficient and are needed for Hematide;

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

***The success of Hematide is dependent upon the strength and performance of our collaboration with Takeda. If we fail to maintain our existing collaboration with Takeda, such termination would likely have a material adverse effect on our ability to continue to develop Hematide and our business. If we fail to enter into new, strategic collaborations with other future product candidates we pursue, we may have to reduce or delay our product candidate development efforts or increase our expenditures.***

The maintenance and successful performance of our strategic collaboration with Takeda for development of Hematide is an important part of our business model. Our collaboration with Takeda is extremely complex particularly with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties with respect to decision making. Accordingly, significant aspects of the development and commercialization of Hematide require Takeda's agreement or approval prior to implementation, which can cause delays. Further, if we are not able to reach agreement with Takeda or maintain our existing collaboration with Takeda to develop and commercialize Hematide, our business could be severely adversely affected. Takeda has the ability to terminate each of the collaboration agreements upon an uncured material breach by us or even in the absence of a material breach with six-months' notice. Currently, Takeda could provide us notice of termination of either or both of our collaboration agreements, which would likely have a material adverse effect on the advancement of our Hematide program and our business. The suspension of the Hematide oncology program may increase the likelihood that Takeda terminates the collaboration or affect the resources Takeda is willing to commit to Hematide. Through the collaboration, Takeda currently provides development funding and performs important functions, including conduct of certain clinical trials and manufacturing activities, and is expected to pay us milestone payments upon the completion of certain events, all of which would be unavailable to us in the case of an early termination of the collaboration. Even in the absence of a termination, Takeda's failure to provide funding or perform its obligations on a timely basis may have a material adverse effect on our business and the success of Hematide.

In addition, if we fail to maintain the Takeda collaboration or establish and maintain additional strategic collaborations for any other potential product candidates that we may pursue:

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

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

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

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

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell Hematide profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has recently been enacted. In particular, in December 2003, then President Bush signed into law new Medicare prescription drug coverage legislation that changed the methodology used to calculate reimbursement for certain drugs such as Hematide. In addition, the legislation directed the Secretary of Health and Human Services to contract with procurement organizations to purchase physician-administered drugs from the manufacturers and provided physicians with the option to obtain drugs through these organizations as an alternative to purchasing from the manufacturers, which some physicians may find advantageous.

In addition, in response to the FDA's recent black box warning and public health advisories, CMS has recently significantly restricted coverage of ESAs. In July 2007, CMS issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Neoplastic Conditions, or the National Coverage Decision, that determined that ESA treatment was not reasonable or necessary for certain medical conditions, including any anemia of cancer not related to cancer treatment, among others. The National Coverage Decision also established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia and contains a coverage restriction for hemoglobin levels greater than 10g/dL, which has had a material adverse effect on the use of ESAs. In July 2007, CMS also issued revisions to its reimbursement policies for the use of ESAs for end stage renal disease in cases where hemoglobin levels exceed 13 g/dL and also decreased the monthly dosing limits. In July 2008, CMS announced that ESAs are a potential topic for another National Coverage Decision citing adverse effects in cancer and chronic kidney disease patients, including dialysis patients while noting the large costs but uncertain benefits. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage which could have a materially negative impact on the size of the ESA market in the United States and reduce the overall size of the market Hematide is expected to compete in at the time of launch.

As a result of these reimbursement and other legislative proposals and the trend towards managed health care in the U.S., third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of approved products for medical indications other than those for which the FDA has granted market approvals. In addition, major third-party payors have begun to follow CMS's restrictive reimbursement policies, which has further decreased the market for ESAs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

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

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

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

CMS currently reimburses healthcare providers for use of ESAs at ASP plus 6%. However, the 2008 Medicare Legislation replaces ASP plus 6% reimbursement with a new bundled payment system to be implemented commencing in January 2011. Although significant aspects of the bundled payment system have yet to be established, providers are expected to be reimbursed a fixed amount per patient. We cannot guarantee that Hematide will be reimbursed by CMS in a method that will support physician adoption and depending upon the details of the bundled payment system that are ultimately implemented, may not be favorable to the entry of new ESAs such as Hematide. In fact, a capitated reimbursement payment methodology may create incentives for significantly lower utilization or dosing of ESAs, including Hematide, and reduce the commercial potential for Hematide.

*We rely on third parties to conduct preclinical and clinical trials for Hematide, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain the necessary regulatory approvals.*

We rely on contract research organizations, contractors and other third parties to assist us in managing, monitoring and otherwise conducting clinical trials. We compete with larger companies for the resources of these third parties.

Although we rely on these third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements.

We may not be able to maintain our relationships with these contract research organizations or contractors on acceptable terms. These third parties generally may terminate their engagements with us at any time and having to enter into alternative arrangements would delay development and

commercialization of Hematide. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to Hematide.

If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of Hematide.

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

The Hematide manufacturing process is a complicated, time-consuming process. Manufacture of Hematide active pharmaceutical ingredient, or API, involves long lead times. We do not currently have the infrastructure or capability internally to manufacture the Hematide needed to conduct our clinical trials or to commercialize Hematide. We are and will continue to rely upon contract manufacturers to produce our clinical trial materials and in the future commercial supplies of Hematide. For the foreseeable future, we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of Hematide for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver materials for the manufacture of Hematide or Hematide itself for clinical use or for our registration stability studies on a timely basis, with sufficient quality and at commercially reasonable prices, and if we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or our planned NDA filing or otherwise discontinue development and production.

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

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

We have transferred responsibility of manufacture of Hematide finished product to Takeda and we therefore have limited control and ability to address risks associated with that portion of the manufacturing process. Further, some of suppliers and manufacturing arrangements, including the provision of bulk poly(ethylene) glycol reagent for the manufacture of Hematide from Nektar Therapeutics AL, Corporation, or Nektar, are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

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

*The commercial success of Hematide depends in part on the development and marketing efforts of Takeda, over which we have limited control. If our collaborations are unsuccessful, our ability to develop and commercialize products through our collaborations, and to generate future revenue from the sale of these products, would be significantly reduced.*

Our dependence on Takeda for our global collaboration with Hematide and our other collaboration arrangements, subjects us to a number of risks. Our ability to develop and commercialize drugs that we develop with our collaboration partners depends on our collaboration partners' abilities to establish the safety and efficacy of Hematide, obtain and maintain regulatory approvals and achieve market acceptance of Hematide once commercialized. Under our collaboration with Takeda, we co-develop and co-commercialize Hematide in the U.S. Because we share responsibility with Takeda for clinical development activities in the U.S., the progress of the Hematide program is dependent on the efforts of Takeda of which we have no control. In fact, during 2008, Takeda has taken responsibility for conducting several clinical trials including among others, a study in patients with peritoneal dialysis and a study involving the conversion of Aranesp-treated chronic renal patients (on dialysis and not on dialysis). Accordingly, failure of Takeda to act in a timely manner may delay our ability to develop Hematide in accordance with our timelines. Takeda holds an exclusive license to develop and commercialize Hematide outside of the U.S. and any progress and commercial success in those territories is dependent solely on Takeda's efforts and commitment to the program. Takeda may delay, reduce or terminate development efforts relating to Hematide, independently develop products that compete with Hematide, or fail to commit sufficient resources to the marketing and distribution of Hematide. 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 Hematide.

In the event that Takeda fails to diligently develop or commercialize Hematide, we may have the right to terminate our partner's rights but we may choose not to as we will not receive any future revenue from Hematide or even if we do, we may not be able to find another partner requiring us to commercialize Hematide on our own, which is likely to result in significant additional expense and delay. Business combinations, significant changes in business strategy, litigation and/or financial difficulties may also adversely affect the willingness or ability of Takeda to complete its obligations under our collaboration agreements. If Takeda fails to perform in the manner we expect, our potential to develop and commercialize products Hematide and to generate future revenue would be significantly reduced. If a conflict of interest arises between us and Takeda, it may act in its own self-interest and not in the interest of our company or our stockholders. If Takeda were to breach or terminate the collaboration agreements with us or otherwise fail to perform its obligations thereunder in a timely

manner, the preclinical or clinical development or commercialization of Hematide could be delayed or terminated.

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of Hematide 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 Hematide from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

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

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

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

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

- the patents of others may have an adverse effect on our business.

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

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

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

Our ability, and that of our commercial partners, to commercialize any approved product will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and foreign counterparts related to Hematide 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 are currently involved in binding arbitration with J&J, which could result in one or more patents being issued to these parties for technology that we jointly or solely own. 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 Hematide 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.

Our ongoing litigation is described in the sections entitled “Business—Intellectual Property” and “Legal Proceedings.” We have incurred substantial expense as a result of our litigation and arbitration proceedings and we expect to incur even greater expense in the future. In addition, 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, developing or commercializing Hematide or from developing, manufacturing and selling any future products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses. If it is determined that we have infringed an issued patent, we could be compelled to pay significant damages, including punitive damages.

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

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

We currently have no sales, marketing or distribution capabilities. To commercialize Hematide, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services. If we decide to market Hematide directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize Hematide directly or indirectly with Takeda include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

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

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Arlene Morris, our President and Chief Executive Officer, and Dr. Anne-Marie Duliege, our Chief Medical Officer. The loss of services of Ms. Morris, Dr. Duliege, or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of Hematide.

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

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

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

*Our operations may be adversely impacted by our exposure to risks related to foreign currency exchange rates.*

Some of our costs and expenses associated with our clinical trials are denominated in foreign currencies. We are primarily exposed to changes in exchange rates with Europe due to agreements with third-party vendors and clinical sites located in Europe. When the United States dollar weakens against these currencies, the dollar value of the foreign-currency denominated expense increases, and when the dollar strengthens against these currencies, the dollar value of the foreign-currency denominated expense decreases. Accordingly, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations. We currently do not hedge against our foreign currency risks.

### **Risks Related to Our Industry**

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

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and

regulations may differ from country to country. Neither we nor Takeda is permitted to market Hematide in the U.S. until we receive approval of a New Drug Application, or NDA, from the FDA. We have not received marketing approval for Hematide. Further, we have not previously prepared an NDA submission, which involves compliance with governmental regulations and successful completion of a number of significant and complicated undertakings for which we do not have any prior experience implementing. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs.

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

- a drug candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- The FDA might not approve our or our third-party manufacturer's processes or facilities; or
- The FDA may change its approval policies or adopt new regulations.

***Even if we receive regulatory approval for Hematide, we will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize Hematide.***

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

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of Hematide. 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 our future products and we may not achieve or sustain profitability.

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

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

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

We intend to seek approval to market Hematide in the U.S. and, through our Takeda collaboration, in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some foreign countries, particularly in the European Union, 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 Hematide to other available therapies or a clinical trial that studies pharmacoeconomic benefits. If reimbursement of Hematide is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

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

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

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

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

- decreased demand for Hematide;
- injury to our reputation;

- withdrawal of clinical trial participants;
- costs of related litigation;
- diversion of management's attention and resources;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize Hematide.

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

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

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

The trading price of our common stock has been highly volatile. For the 52 weeks ended March 2, 2009, the price ranged between a high of \$22.62 per share and a low of \$8.52 per share. Our stock is expected to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results from, and any delays in, our clinical trials;
- actual or anticipated changes in our capital resources and our ability to obtain financing and the terms thereof;
- actual or anticipated actions taken by regulatory agencies with respect to ESAs generally or specifically as to Hematide;
- new products or services introduced or announced by us or our collaboration partners, or our competitors, including Roche's Mircera, and the timing of these introductions or announcements;
- issuance of patents to competitors, including the expected issuance of patents to J&J in Europe;
- developments in and the outcome of our litigation with J&J, including both substantive and procedural rulings by the arbitration panel;
- actual or anticipated regulatory approvals of Hematide or competing products;
- actions taken by regulatory agencies with respect to clinical trials, manufacturing process or sales and marketing activities;
- changes in laws or regulations applicable to Hematide, including but not limited to clinical trial requirements for approvals;
- the success of our development efforts and clinical trials;
- the success of our efforts to discover, acquire or in-license additional products or product candidates;

- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- actual or anticipated variations in our quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- actual or anticipated changes in earnings estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;
- changes in the market valuations of similar companies;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- developments relating to proprietary rights held by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- trading volume of our common stock; and
- sales of our common stock by us or our stockholders.

*In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition. Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.*

As of March 2, 2009, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 59% of our voting stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

*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. During our review of the results of operations for the quarter ended June 30, 2008, we identified a material weakness in the operation of our internal controls over financial reporting, as defined in Public Company Accounting

Oversight Board Standard No. 5, in connection with the completeness and accuracy of clinical trial expense. As of December 31, 2008, this material weakness has been fully remediated.

While no material weaknesses were identified as of December 31, 2008, we cannot assure you that material weaknesses will not be identified in future periods. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting in future periods. If we do experience a material weakness in future periods, then investor confidence, our stock price and our ability to obtain additional financing on favorable terms could be adversely affected.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

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

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

***We are at risk of securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we were to face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders.

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.**

We received a comment letter from the Securities and Exchange Commission (“SEC”) on December 17, 2008 relating to the Company’s Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2007. The SEC requested additional information and provided comments related to (i) our revenue recognition policies, (ii) our income taxes, and (iii) our remediation efforts related to enhancement of our financial controls. We responded to the SEC on January 9, 2009 and received a follow-up letter from the SEC on February 19, 2009 requesting additional information and clarification relating our revenue recognition policies and our income taxes. As we only recently submitted another response to the SEC on March 10, 2009 immediately prior to the filing of this Form 10-K, we will be continuing to work with the SEC to resolve the remaining comments.

#### **Item 2. Properties.**

We currently lease approximately 84,460 square feet of laboratory and office space in Palo Alto, California under lease agreements that terminate in September 2014. We believe that our facilities adequately meet our present needs.

#### **Item 3. Legal Proceedings.**

##### *J&J Intellectual Property Dispute*

We have initiated binding arbitration and related litigation with certain subsidiaries of Johnson & Johnson, or J&J, over ownership of intellectual property related to erythropoietin receptor, or EPO-R, agonists (compounds capable of binding to and activating the EPO-R). This intellectual property is the subject of a number of U.S. and international patents and patent applications assigned to Affymax and J&J, including a U.S. patent currently assigned to J&J, several U.S. patents currently assigned to us and a European patent application currently assigned to J&J. See “Risk Factors—Risk Related to Our Business.” In this section, we refer to the patents and patent applications subject to the arbitration collectively as the “intellectual property in dispute”. We believe that we are the sole owner or co-owner of the intellectual property in dispute, including a European patent application currently naming J&J as sole owner that may issue in the near future and relates to specified ESA peptide compounds. J&J, on the other hand, alleges that they are the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which we are currently named as sole owner that relate to specified peptide compounds.

We believe the U.S. intellectual property in dispute does not encompass Hematide and that we can manufacture, commercialize and sell Hematide in the U.S. regardless of the outcome of this arbitration. However, if, through the ongoing arbitration or otherwise, J&J or another potential competitor obtains or possesses patents or patent rights that are deemed to encompass one or more elements of Hematide, that party could initiate proceedings, an adverse result in which could prevent us from manufacturing or commercializing Hematide, either for ourselves or with Takeda, in the U.S.

If the intellectual property in dispute is deemed broad enough to cover Hematide, then under the laws applicable to most relevant jurisdictions outside the U.S., a finding of joint ownership would permit us to manufacture and sell Hematide, but may not allow us to license third parties to do so. We have entered into a collaboration agreement with Takeda to commercialize Hematide worldwide, so a finding of joint ownership of the patents and applications in question could materially affect our business plans outside the U.S. In the U.S., joint ownership of a patent gives each joint owner the right to license third parties, so even if the patents in question are held to be jointly owned by us and J&J, we do not believe we would be prevented from pursuing our partnership strategy for Hematide in the U.S. If the arbitration panel determines that J&J is the sole owner of one or more of the U.S. patents in the dispute that are assigned to us, J&J may seek to assert such patent against us in the U.S.; however, we believe that we have strong defenses to any assertion that Hematide infringes any claims of these U.S. patents.

#### *The Research and Development Agreement with J&J*

In April 1992, Affymax N.V. (a different company from us) entered into a three-year Research and Development Agreement, which we refer to as the “R&D Agreement,” with a division of Ortho Pharmaceutical Corporation, a subsidiary of J&J. In 2001, we assumed the rights and obligations of Affymax N.V. under the R&D Agreement and acquired rights to patents and patent applications that comprise much of the intellectual property in dispute.

Under the R&D Agreement, J&J provided Affymax N.V. research funding and Affymax N.V. sought to discover compounds directed at the EPO receptor. The R&D Agreement provided for us to retain rights to our existing technology and identified as our technology our methodologies for creating peptide sequence “libraries”, each of which contained billions of different peptide sequences, and methodologies that could be used to determine which if any of the peptide sequences contained in a library would bind to an identified receptor. The R&D Agreement further provided for any invention made by either party to be the property of the party making the invention and that joint inventions would be jointly owned.

Our position is based on the following chronology: From 1992 through 1995, a group of scientists working for Affymax N.V., performed extensive research under the R&D Agreement and discovered numerous peptides and peptide dimers that bind to and activate the EPO-R. These Affymax N.V. scientists started with the Affymax N.V. peptide sequence libraries, conducted numerous tests, experiments and analyses and discovered and identified a set of active peptides that bind to and activate the EPO-R. The Affymax scientists disclosed the inventions and the results of their research to J&J. In November 1993, Affymax N.V., through Affymax Technologies, N.V., a related entity, filed U.S. Patent Application No. 08/155,940, or the ‘940 application, claiming various of the Affymax N.V. scientists’ inventions and identifying four Affymax scientists, and no J&J scientists, as the inventors. Affymax N.V. provided J&J with a draft copy of the ‘940 application before filing it. The Affymax scientists’ research gave rise to numerous other patent applications, including continuation-in-part applications based on and claiming priority from the ‘940 application, a continuation of one of those applications, and numerous foreign and international patent applications based on one or more of these applications. Ultimately, the ‘940 application was abandoned in favor of these other applications. In 2001, we acquired the rights, previously held by Affymax N.V. and Affymax Technologies, N.V., to these patents and patent applications. Some of the applications have issued as patents, and these patents and patent applications comprise much of the intellectual property in dispute. Based on the inventions of the Affymax N.V. scientists, we believe we are the sole owner or a co-owner of the intellectual property in dispute.

J&J, however, alleges that it discovered the idea of searching peptide sequence libraries, such as Affymax N.V.’s libraries, to find peptides that bind to and activate the EPO-R, and that the Affymax N.V. scientists did not make inventive contributions when they discovered and identified the

specific peptides that bind to and activate the EPO-R. J&J also alleges that it discovered the idea of, and methodology for, dimerizing these peptides to make them more biologically active, and that it provided Affymax with reagents and control substances for use in research under the R&D Agreement, as well as instructions on how to use them. J&J further alleges that Affymax N.V. improperly removed the names of the J&J employees who had been identified as inventors on the parties' joint applications pending before the U.S. Patent and Trademark Office without notifying or consulting J&J. For these reasons, J&J claims that it should be granted sole ownership or joint ownership of the intellectual property in dispute.

#### *Post-R&D Agreement Development Activities*

In March 1995, Affymax N.V., Affymax Technologies, N.V. and Affymax Research Institute, or the Affymax Entities, were acquired by Glaxo Wellcome plc. In July 2001, we acquired specified assets from Glaxo Wellcome plc and related entities, including the rights to the R&D Agreement and the rights to specified patents and patent applications that had previously been held by Affymax N.V. and Affymax Technologies, N.V. After the termination of the R&D Agreement in 1995, the Affymax Entities pursued efforts to create a synthetic compound that activated the EPO-R and had the biological and physical properties needed to be a commercially viable pharmaceutical product. Our efforts culminated in the first chemical synthesis of Hematide in 2003.

#### *Patent Applications Filed During and After the R&D Agreement*

The intellectual property in dispute relates primarily to the following patents and patent applications: U.S. Patent No. 5,767,078; U.S. Patent Application No. 08/484,135; PCT Application No. PCT/US96/09469 (International Publication No. WO96/40772); European Patent Office application EP96/918,317; Canadian Patent Application No. CA 2228277; Japanese Patent Application No. JP 09-(1997) 501781; Australian Patent No. 732,294; Australian Patent Application AU01/054,337; Australian Patent Application AU04/203,690; U.S. Patent No. 5,773,569; U.S. Patent No. 5,830,851; U.S. Patent No. 5,986,047; European Patent No. EP 0 886,648; PCT Application No. PCT/US96/09810 (International Publication No. WO96/40749); U.S. Patent Application No. 08/155/940; U.S. Patent Application No. 08/484,631; U.S. Patent Application No. 08/484,635; and U.S. Patent Application No. 08/827,570.

In November 1993, the Affymax Entities filed a U.S. patent application (U.S.S.N. 08/155,940), or the '940 application, identifying four of their scientists as inventors. In June 1995, the Affymax Entities filed U.S. Patent Application Nos. 08/484,631 and 08/484,635, or the '631 and '635 applications. These applications were continuation-in-part applications based on and claiming priority from the '940 application. They also included certain subject matter that J&J specifically requested be added. At the time of filing, the '631 and '635 applications listed certain J&J employees as inventors in addition to the Affymax scientists. Prior to filing the '940, '631, and '635 applications, the Affymax Entities provided J&J with drafts and/or copies of the applications or informed them of their intent to file them. On or about June 7, 1996, the Affymax Entities filed PCT Application No. PCT/US96/09810, which was based on and claimed priority from the '631 and '635 applications and has given rise to a European patent (EP 0 866 648), which has been assigned jointly to us and J&J.

On the same day in June 1995 that the Affymax Entities filed the '631 and '635 applications, J&J separately filed U.S. Patent Application No. 08/484,135, or the '135 application, which identified J&J employees as the sole inventors of the described subject matter and J&J as the sole assignee. J&J later filed a PCT application (PCT Application No. PCT/US96/09810) based on and claiming priority from the '135 application, and various foreign patent applications (including in Europe, Canada, Japan and Australia) based on the PCT application. The parties dispute whether J&J informed the Affymax Entities prior to filing these applications. U.S. Patent No. 5,767,078 and Australian Patent No. 732,294 issued to J&J based on these applications, and other applications are pending, including European

patent application EP96/918,317. We claim in the arbitration that we are the sole or joint owner of these patents and applications and any U.S., foreign or international patents or applications based on, claiming priority from or relating to them.

On March 28, 1997, the Affymax Entities filed U.S. Patent Application No. 08/827,570, or the '570 application, a continuation of the '635 application. That day, the Affymax Entities also filed a preliminary amendment and a petition for correction of inventorship in connection with the '570 application, as well as supplemental responses and petitions for correction of inventorship in connection with the '631 and '635 applications. The '631, '635, and '570 applications have now issued to Affymax as U.S. Patents Nos. 5,773,569; 5,830,851; and 5,986,047. J&J alleges that the Affymax Entities filed the '570 application and the above-referenced petitions, preliminary amendment and supplemental responses without notifying or consulting with J&J. J&J claims in the arbitration that it is the sole or joint owner of these patents and applications and any U.S., foreign, or international patents or applications based on, claiming priority from, or relating to them.

J&J's European patent application EP96/918,317, which relates to agonist peptide dimers, could result in a patent being issued to J&J in the near future. In the J&J arbitration proceeding, we have claimed that we should be at least joint owner of this European application. If the patent issues, J&J could seek to enforce this patent against us in Europe. In many European countries, a patent cannot be asserted to stop clinical trials, but in some, a patent holder can seek to enjoin clinical trials.

#### *Litigation and Arbitration Chronology*

On June 9, 2004, we filed a civil complaint in the Munich Regional Court in the Federal Republic of Germany against J&J alleging that we are an owner or co-owner of J&J's European patent application relating to agonist peptide dimers (European Patent Application EP96/918,317). In October 2005, J&J filed its response to our complaint, denying our claims of inventorship and ownership. In April 2006, we requested the court to dismiss the complaint so that the issues it raised could be resolved pursuant to the arbitration proceeding described below. The court has done so.

On September 23, 2004, we filed a civil complaint in the U.S. District Court for the Northern District of Illinois, or the Illinois case, against J&J alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, and for unjust enrichment and constructive trust. The complaint alleges that the Affymax N.V. scientists are sole or co-inventors of the intellectual property in dispute, including the above-referenced J&J patents and patent applications, and that we are the sole or co-owner of them. The complaint also alleges that J&J breached the R&D Agreement by, among other things, engaging in a course of conduct designed to obtain patents for itself and to deny us patents on the Affymax scientists' inventions. The complaint further alleges that we have suffered damages as a result of J&J's breaches and that J&J has been unjustly enriched through its misconduct and should be subject to the imposition of a constructive trust.

J&J denied all material claims in our complaint and, among other things, counterclaimed that its employees are the true inventors of the intellectual property in dispute and that it is therefore entitled to sole or co-ownership of the above-referenced patents and patent applications assigned solely or jointly to us (including U.S. Patent Nos. 5,986,047, 5,773,569, and 5,830,851, which are solely assigned to us, and European Patent No. EP 0 866 648, which is assigned jointly to us and J&J). J&J also brought related claims for breach of contract, breach of fiduciary duty, unjust enrichment and constructive trust. J&J alleges, among other things, that the Affymax Entities filed in their own name certain patent applications allegedly claiming inventions of J&J employees without notifying or consulting with J&J, that during patent prosecution the Affymax Entities improperly removed the names of J&J employees from certain patent applications on which those employees had been

identified as inventors, and that these and other alleged breaches entitle J&J to damages and waive all rights we may have had to the intellectual property in dispute.

J&J requested that the Illinois case be dismissed and the matter decided under the R&D Agreement's arbitration provisions. On February 28, 2006, the Illinois court entered an order that the appropriate forum for us and J&J to resolve the inventorship, ownership, breach of contract and related claims was binding arbitration under the American Arbitration Association, or AAA, rules in Illinois. The Illinois court held that the claims pending in the German court were also subject to arbitration and required us to dismiss the German complaint, which we have done. The Illinois court further stated that it will retain jurisdiction over the subject matter during the arbitration in Illinois.

On April 12, 2006, we filed a demand for arbitration with the AAA claiming that we are the owner or co-owner of the intellectual property in dispute and alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, for unjust enrichment and constructive trust, and for breach of fiduciary duty. On May 8, 2006, J&J filed its answer and counterclaims, substantially restating their allegations made in the U.S. and German courts. In April 2007, the Company filed an amended demand for arbitration. In June 2007, J&J filed an amended counterdemand. The AAA has appointed a panel of arbitrators, and the arbitrators have established a schedule for the arbitration. The parties have commenced discovery. In June 2007, J&J filed a motion to compel discovery of information relating to Hematide and then filed a substitute motion to compel. In July 2007, the Company filed an opposition to J&J's motion to compel and a motion for protective order. In September 2007, the arbitrators ruled that J&J can obtain limited discovery on Hematide, but that J&J cannot obtain discovery on Hematide product formulas, sequences, laboratory notebooks containing such information, experimental results, clinical trial results and strategies, or internal business planning. The arbitration hearing has been delayed and has been rescheduled to occur during the second half of 2009. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on the Company because of legal costs, diversion of management resources and other factors.

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

**Item 4. Submission of Matters to a Vote of Security Holders.**

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 Global Market under the symbol “AFFY” since December 15, 2006. As of March 2, 2009, there were approximately 128 holders of record of our common stock. The following table sets forth, for the periods indicated, the range of high and low closing sales prices of our common stock as quoted on the NASDAQ Global Market.

	High	Low
<b>2008</b>		
4th Quarter . . . . .	\$20.22	\$ 9.03
3rd Quarter . . . . .	\$22.12	\$15.38
2nd Quarter . . . . .	\$17.69	\$13.35
1st Quarter . . . . .	\$22.99	\$13.78
	<b>High</b>	<b>Low</b>
<b>2007</b>		
4th Quarter . . . . .	\$30.99	\$20.35
3rd Quarter . . . . .	\$28.76	\$21.77
2nd Quarter . . . . .	\$39.40	\$26.96
1st Quarter . . . . .	\$40.47	\$31.69

The closing price for our common stock as reported by the NASDAQ Global Market on March 2, 2009 was \$12.44 per share.

#### Dividend Policy

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

#### Recent Sales of Unregistered Securities

Not applicable.

#### Issuer Purchases of Equity Securities

The following table provides information relating to repurchases of our common stock in the three months ended December 31, 2008:

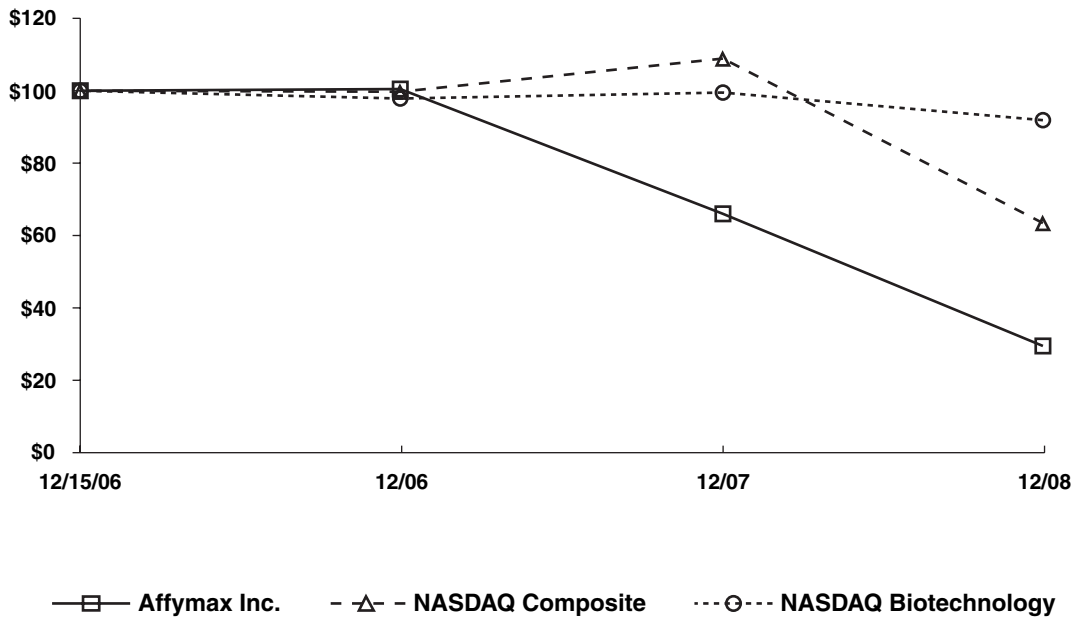
Period	Total Number of Shares Purchased(1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Program
October 1, 2008 - October 31, 2008 . . . . .	250	\$0.80	N/A	N/A
November 1, 2008 - November 30, 2008 . . . . .	—	—	N/A	N/A
December 1, 2008 - December 31, 2008 . . . . .	—	—	N/A	N/A
Total . . . . .	250	\$0.80	N/A	N/A

(1) The 250 shares of our common stock were repurchased by us from an employee upon termination of services pursuant to the terms and conditions of our 2001 Stock Option/Stock Issuance Plan, which permits us to elect to purchase such shares at the original issuance price.

**Performance Graph(1)**

The following graph shows the total stockholder return of an investment of \$100 in cash on December 15, 2006, the date our common stock first started trading on the NASDAQ Global Market, through December 31, 2008 for (i) our common stock, (ii) the Nasdaq Composite Index (U.S.) and (iii) the Nasdaq Biotechnology Index as of December 31, 2008. 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 25 MONTH CUMULATIVE TOTAL RETURN\***  
 Among Affymax Inc., The NASDAQ Composite Index  
 And The NASDAQ Biotechnology Index



\* \$100 invested on 12/15/06 in stock & 11/30/08 in 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.

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
<b>Statements of Operations Data:</b>					
Collaboration revenue . . . . .	\$ 82,162	\$ 44,303	\$ 11,688	\$ —	\$ —
License and royalty revenue . . . . .	689	33	38	74	151
Total revenue . . . . .	<u>82,851</u>	<u>44,336</u>	<u>11,726</u>	<u>74</u>	<u>151</u>
<b>Operating expenses:</b>					
Research and development . . . . .	137,492	69,398	54,347	24,051	17,338
General and administrative . . . . .	34,090	24,075	11,089	10,032	4,931
Total operating expenses . . . . .	<u>171,582</u>	<u>93,473</u>	<u>65,436</u>	<u>34,083</u>	<u>22,269</u>
Loss from operations . . . . .	(88,731)	(49,137)	(53,710)	(34,009)	(22,118)
Interest income . . . . .	4,545	11,393	5,549	1,413	439
Interest expense . . . . .	(609)	(14)	(84)	(29)	—
Other income (expense), net . . . . .	(1,433)	46	(43)	49	281
Net loss before provision for income taxes . . . . .	<u>(86,228)</u>	<u>(37,712)</u>	<u>(48,288)</u>	<u>(32,576)</u>	<u>(21,398)</u>
Provision for income taxes . . . . .	282	5,357	—	—	—
Net loss(2) . . . . .	<u>(86,510)</u>	<u>(43,069)</u>	<u>(48,288)</u>	<u>(32,576)</u>	<u>(21,398)</u>
Accretion of mandatorily redeemable convertible preferred stock . . . . .	—	—	(815)	(597)	(105)
Net loss attributable to common stockholders . . . . .	<u>\$(86,510)</u>	<u>\$(43,069)</u>	<u>\$(49,103)</u>	<u>\$(33,173)</u>	<u>\$(21,503)</u>
Net loss per common share:					
Basic and diluted(1)(2) . . . . .	<u>\$ (5.68)</u>	<u>\$ (2.88)</u>	<u>\$ (32.56)</u>	<u>\$(101.65)</u>	<u>\$ (70.39)</u>
Weighted-average number of common shares used in computing basic and diluted net loss per loss common share . . . . .					
	<u>15,220</u>	<u>14,941</u>	<u>1,508</u>	<u>326</u>	<u>305</u>
	December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments . . . . .	\$ 94,719	\$ 168,337	\$ 224,292	\$ 57,893	\$ 24,720
Receivable from Takeda . . . . .	21,688	15,331	10,191	—	—
Long-term investments . . . . .	22,945	15,655	6,133	—	—
Total assets . . . . .	<u>167,720</u>	<u>225,792</u>	<u>249,988</u>	<u>60,960</u>	<u>27,728</u>
Capitalized lease obligations, net of current . . . . .	—	8	140	310	—
Mandatorily redeemable convertible preferred stock . . . . .	—	—	—	168,784	112,396
Accumulated deficit . . . . .	<u>(298,328)</u>	<u>(211,818)</u>	<u>(168,749)</u>	<u>(120,461)</u>	<u>(87,885)</u>
Total stockholders’ equity (deficit) . . . . .	<u>8,984</u>	<u>84,185</u>	<u>116,899</u>	<u>(113,691)</u>	<u>(87,162)</u>

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

(2) In 2008, 2007 and 2006, loss from operations, net loss and basic and diluted net loss per common share include the impact of SFAS No. 123(R) stock-based compensation charges, which were not present in prior years. Please see Notes 2 and 8 to the notes to our audited financial statements.

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

### **Overview**

We are a biopharmaceutical company developing novel peptide-based drug candidates to improve the treatment of serious and often life-threatening conditions. Our product candidate, Hematide, is designed to treat anemia associated with chronic renal failure. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic renal failure, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may increase the risk of other diseases or death. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Hematide is designed to be longer acting than currently marketed ESAs in the U.S., and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers.

We are conducting Phase 3 clinical trials in patients suffering from chronic renal failure, on dialysis and pre-dialysis. We are conducting four open-label, randomized controlled clinical trials. Of these trials, two trials are being conducted in pre-dialysis patients and are designed to evaluate the safety and efficacy of Hematide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials are being conducted in dialysis patients and are designed to evaluate the safety and efficacy of Hematide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to Hematide. Analysis of efficacy and safety for all of the Phase 3 studies will be based on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint will be the mean change in hemoglobin from baseline. Each study is planned to continue until the last patient has been treated for approximately 52 weeks. In addition, the assessment of safety will include a composite cardiovascular endpoint from a pooled safety database.

Currently, we expect to release results from the Phase 3 clinical program in the first quarter of 2010, however, the rate of accrual of cardiovascular events could affect the duration of the studies. If the cardiovascular events accrue at a lower rate than estimated, the outcome of the composite safety endpoint analysis may not meet the pre-defined non-inferiority criteria due to insufficient events, causing a possible failure of our clinical program. In order to obtain additional data to compensate for a lower than estimated cardiovascular event rate, the Phase 3 clinical program may need to be extended or additional studies may need to be conducted, if even feasible, which could delay the development of Hematide and the achievement of milestones from our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda. Even if the cardiovascular events accrue at the estimated rate, we could still fail to establish that Hematide is non-inferior to the comparator drugs upon analysis of the data from our Phase 3 clinical program. Further, our Phase 3 clinical program could be suspended or terminated prior to completion based on safety or other concerns, including recommendations of the data monitoring committee, which will be meeting periodically to review the interim safety data from our trials.

In August 2008, we and Takeda agreed to suspend development of Hematide to treat chemotherapy induced anemia and to focus all development efforts on our renal program.

To date, we have not generated any product revenue. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and active pharmaceutical ingredient, or API, production, license fees and milestone payments from collaborative partners, operating and capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. Since inception, we have incurred net losses and expect to incur substantial and increasing losses for the next several years in order to complete the development and commercialization of Hematide. As of December 31, 2008, we had an accumulated deficit of \$298.3 million.

In March 2009, we completed a private placement raising an estimated \$41.6 million of net proceeds through the issuance of common stock and warrants exercisable for common stock. We believe that the existing cash, cash equivalents and investments together with the interest thereon, will enable us to maintain our currently planned operations through at least 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide. The current worldwide capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs even some activities related to the support of Hematide. If we are unable to raise additional funds when needed we could be required to further delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

***Research and Development Expenses***

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

Although we cannot predict the total amount our future research and development expenses with any degree of certainty, we expect to incur substantially increasing research and development expenses in 2009, particularly expenses arising from clinical development activities including continuation of our Phase 3 clinical trials for Hematide. In addition, we may conduct more research and perform additional preclinical studies and clinical trials to obtain additional data for Hematide in future periods.

The table below sets out our research and development expenses excluding stock-based compensation expenses by project since 2006 as a percentage of total research and development expenses for the applicable period. We commence tracking the costs for a project when we are working with another company or when the related prototype peptide demonstrates significant biological activity, typically in a cell-free assay, and merits substantial increase in the level of effort.

	<u>Hematide</u>	<u>Other Research Programs(1)</u>	<u>Total</u>
<b>2006</b> .....	90%	10%	100%
<b>2007</b> .....	91%	9%	100%
<b>2008</b> .....	99%	1%	100%

(1) Does not include any projects where the expense is 10% or greater of total research and development expenses excluding stock-based compensation expense.

Under the worldwide agreement with Takeda, we and Takeda will co-develop and co-commercialize Hematide in the U.S. Beginning January 1, 2007, Takeda was responsible for the first \$50 million of third party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Of the first \$50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of \$36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda bears 70% of the third party U.S. development expenses, while we are responsible for 30% of the expenses. We retain responsibility for 100% of our internal development expenses. Takeda will have primary responsibility and bear all costs for Hematide clinical development in support of regulatory approval for all territories outside the U.S.

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

#### ***General and Administrative Expenses***

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, accounting, business and commercial development, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, prosecution and defense costs and professional fees for legal, consulting, auditing and tax services. We expect to incur increasing general and administrative expense in future periods to support our research and development activities, preparation for the New Drug Application for Hematide, costs associated with our J&J litigation and development of commercial capabilities.

#### **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. The preparation of these financial statements requires us to make estimates and assumptions 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.

While our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

## ***Revenue Recognition***

### *Collaboration Revenue*

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* ("SAB 104"). When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). Application of this standard 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.

In February and June 2006, we entered into two separate collaboration agreements with Takeda, or the Arrangement, which have been combined for accounting purposes due to their proximity of negotiation. We evaluated the multiple elements under the combined single arrangement in accordance with the provisions of EITF 00-21. We determined the deliverables do not have value to the customer on a stand alone basis and we were unable to obtain verifiable objective evidence to determine the fair value of the undelivered elements. Accordingly, we concluded that there was a single unit of accounting.

Effective January 1, 2008, we entered into an amendment to the Arrangement with Takeda. The amendment provides us the ability to opt-out of our obligation to participate on the joint steering committee and any related subcommittees at any time beginning January 1, 2011 without any other modifications. As a result, the obligation to participate in the joint steering committee and any related subcommittee is no longer indefinite. Accordingly, we determined that we can separate the performance obligations that occur over the development period from the performance obligations that will occur during the commercialization period. We do not expect the development period obligations to extend past January 1, 2011. As a result of the change in performance period from indefinite to approximately 4.5 years (i.e., the inception of the Arrangement to January 1, 2011), beginning on January 1, 2008, we recognized revenue during the development period using the Contingency-Adjusted Performance Model ("CAPM"). Under the CAPM, revenue is initially recognized in the period the payment is earned under the arrangement including amounts that are either received or due from Takeda. Revenue initially recognized is based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment is earned in relation to the total projected development period. The remaining portion of the payment is then recognized on a straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period include amounts due for upfront license fees, milestone payments earned, purchases of API and reimbursement of development and commercial expenses. The cumulative effect adjustment totaling \$1.4 million for the change of estimate, which results from now being able to estimate the period of performance, was recognized as additional revenue during the three months ended March 31, 2008. Through the period of the joint steering committee obligation, we expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods. Included in the reimbursable expense is the cost of API that we manufacture and supply to Takeda during the development period, which we will also supply during the commercialization period. A change in the estimated term of the development period could materially affect the amount of collaboration revenue recognized in future periods.

Prior to January 2008, we were unable to determine the period of its performance obligations under the Arrangement as our required participation on the joint steering committee extends for as long as products subject to the collaboration with Takeda are being sold by either of the parties. Accordingly, the contractual term of our joint steering committee obligations was considered indefinite.

As a result, revenue for the single unit of accounting was recorded on a proportional performance basis as long as the overall Arrangement was determined to be profitable during the years ended December 31, 2007 and 2006. We accounted for the Arrangement using a zero profit proportional performance model (i.e., revenue was recognized equal to direct costs incurred, but not in excess of cash received or receivable assuming that the overall Arrangement was expected to be profitable). We used an input based measure, specifically direct costs, to determine proportional performance because we believed that the inputs were representative of the value being conveyed to Takeda through the research and development activities and delivery of the API. We believed that using direct costs as the unit of measure of proportional performance also most closely reflected the level of effort related to our performance under the Arrangement. Direct costs were those costs that directly resulted in the culmination of an earnings process for which Takeda received a direct benefit. The nature of these costs were third party and internal costs associated with conducting clinical trial activities for dialysis and pre-dialysis indications, costs associated with the manufacturing of API and API stability testing, allocated payroll-related costs for representatives participating on the joint steering committee and sales and marketing costs during the co-commercialization period. Direct costs specifically excluded costs of a general and administrative nature, upfront payments to manufacturers unrelated to specific product manufactured such as reservation of capacity, cost for API not yet delivered to Takeda, travel and expense related costs, sales and marketing costs during the development period, any research and development costs not associated with Hematide, interest, depreciation and amortization expense. Revenue was recognized equal to direct costs incurred, but not in excess of cash received or receivable. Amounts resulting from payments received in advance of revenue recognized were recorded as deferred revenue until the earlier of (i) when we could meet the criteria for separate recognition of each element under the guidance of EITF 00-21 or (ii) after we had fulfilled all of its contractual obligations under the Arrangement.

We were required to assess the profitability of the overall Arrangement on a periodic basis throughout the life of the Arrangement when events or circumstances indicated a potential change in facts. Profitability was defined as a net cash inflow resulting from the Arrangement over its life. Such assessment was based on estimates to determine the most likely outcome based on available facts and circumstances at each assessment date. The estimates included the consideration of factors such as the progress and timing of clinical trials, competitive ESAs in the market, drug related serious adverse events and other safety issues in the clinical trials, pricing reimbursement in relevant markets and historical costs incurred compared to original estimates. When the periodic assessment or other events or circumstances indicated a loss would result from performance under the Arrangement, costs would continue to be recognized as they were incurred. However, revenue would be deferred until either: (i) the Arrangement became profitable, at which point revenue would continue to be recognized, or (ii) the end of the Arrangement.

#### *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 the Company in the 2001 spin out from GlaxoSmithKline (“Glaxo”) are recorded net of the 50% that the Company is required to remit to Glaxo.

#### *Clinical Trial Expense*

We record expense for estimated clinical study external costs, which are a significant component of research and development (“R&D”) expenses. These clinical trial costs were \$77.8 million, \$26.8 million and \$9.4 million for the years ended December 31, 2008, 2007 and 2006, respectively. Clinical studies are administered by third-party contract research organizations (“CROs”). CROs typically perform most of the total start-up activities for the trials, including document preparation, site

identification pre-study visits, training as well as on-going program management. For the Phase 3 studies, which represent the vast majority of the clinical trial expense, the expense recorded is based on reporting received from CROs and internal analyses. We accrue costs for work performed by CROs based on the achievement of contracted activities during the period. Expense for investigator fees, which include patient costs, is based on internal estimates of activities using patient enrollment and contractual or estimated rates. For the Phase 2 studies, the expense is activities based such as patient monitoring as reported by the CROs and achievement of milestones. Other costs such as testing and drug materials are expensed as incurred.

For all studies, CRO reporting is reviewed by us for appropriateness and adjustments are made as deemed necessary to ensure that the expenses reflect the actual effort incurred by the CROs. However, if we do not receive complete and accurate information from the vendors or underestimates activity levels associated with a study at a given point in time, we may have to record adjustments, including potentially significant additional R&D expenses in subsequent periods.

During the quarter ended June 30, 2008, we identified an overstatement of clinical trial expense and collaboration revenue of \$1.3 million in the year ended December 31, 2007. As a result, clinical trial expense and collaboration revenue, which includes reimbursement for these costs, includes an out of period reduction of \$1.3 million and \$0.4 million, respectively, in the year ended December 31, 2008.

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

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment*, or SFAS No. 123(R), which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value. SFAS No. 123(R) revises SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123*, and supersedes APB No. 25, *Accounting for Stock Issued to Employees*. We adopted SFAS No. 123(R) using the prospective transition method. Under this method, compensation cost is measured and recognized for all share-based payments granted, modified and settled subsequent to December 31, 2005. In accordance with the prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

We account for stock-based compensation arrangements with nonemployees in accordance with SFAS No. 123, as amended by SFAS No. 148, and EITF, No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. For stock options granted to nonemployees, the fair value of the stock options is estimated using the Black-Scholes valuation model. This model utilizes the estimated fair value of common stock and requires that, at the date of grant, we make assumptions with respect to the remaining contractual term of the option, the volatility of the fair value of our common stock, risk free interest rates and expected dividend yields of our common stock. Different estimates, most notably volatility and expected term, of the option could materially change the value of an option and the resulting expense.

#### ***Investments***

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. In February 2008, the FASB issued Staff Position No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP No. 157-2, which delays the effective date of SFAS No. 157 for all nonfinancial assets and liabilities except for those

recognized or disclosed at least annually. In October 2008, the FASB issued Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, or FSP No. 157-3. FSP No. 157-3 clarifies the application of SFAS No. 157 in a market that is not active. We adopted the provisions of SFAS No. 157 with respect to our financial assets and liabilities only.

Effective January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 159, which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option under SFAS No. 159, except for the Series C-2 ARS Rights, as more fully described in the section entitled "Liquidity and Capital Resources."

Our investments, other than auction rate securities, or ARS, are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker quotations or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Our investments in ARS are classified within Level 3 of the fair value hierarchy because of the lack of observable inputs. As a result, we determined the value of these ARS at December 31, 2008 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization, credit risk and an illiquidity discount factor. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer's credit risk.

#### *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.

Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, that prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. The cumulative effect of adopting FIN 48 resulted in no adjustment to retained earnings as of January 1, 2007. We had \$11.8 million and \$10.7 million, respectively, of unrecognized tax benefits as of December 31, 2008 and 2007.

As of December 31, 2008 and 2007, our FIN 48 liability for uncertain income tax positions was \$9.6 million and \$9.4 million, respectively, which was reflected as long-term income tax liabilities on our balance sheet. We adopted a policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. For the year ended December 31, 2008, we recognized \$596,000 of interest expense related to the \$9.6 million FIN 48 liability for uncertain income tax positions as of December 31, 2008. For the years ended December 31, 2007 and 2006, no interest expense related to uncertain income tax positions was required or recognized. For the years ended December 31, 2008, 2007 and 2006, \$81,000, \$0 and \$0, respectively, of penalties related to uncertain income tax positions were required and recognized. We do not anticipate that any of the unrecognized tax benefits will increase or decrease significantly over the next twelve months.

## Results of Operations

### Comparison of Years Ended December 31, 2008 and 2007

	Year Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2008	2007		
	(in thousands, except percentages)			
Revenue . . . . .	\$ 82,851	\$ 44,336	\$ 38,515	87%
Research and development expenses . . .	137,492	69,398	68,094	98
General and administrative expenses . . .	34,090	24,075	10,015	42
Interest income (expense), net . . . . .	3,936	11,379	(7,443)	(65)
Other income (expense), net . . . . .	(1,433)	46	(1,479)	(3,215)
Provision for income taxes . . . . .	282	5,357	(5,075)	(95)
Net loss . . . . .	(86,510)	(43,069)	(43,441)	101

*Revenue.* We recognized \$82.2 million of collaboration revenue under the CAPM for the year ended December 31, 2008, which included a \$1.4 million cumulative adjustment resulting from an amendment to the collaboration agreements with Takeda, as discussed in the notes to our audited financial statements, and an out of period reduction of \$0.4 million. Collaboration revenue under CAPM includes expenses that are eligible for reimbursement from Takeda, net of Takeda's own eligible expenses. We recognized \$44.3 million of collaboration revenue under the zero profit proportional performance model for the year ended December 31, 2007. The increase in collaboration revenue in 2008, which we expect to continue through 2009, was primarily due to the growth in third-party development expenses reimbursed by Takeda related to our Phase 3 clinical trials which commenced enrollment in late 2007, and the continued amortization of revenue under the CAPM from expense reimbursements and milestones received from Takeda in prior periods.

We recognized \$689,000 and \$33,000 of license and royalty revenue for the years ended December 31, 2008 and 2007, respectively. The increase in license and royalty revenue in 2008 was due to payments received under a license agreement that we acquired in the 2001 spin out from Glaxo, net of the 50% that we are required to remit to Glaxo.

*Research and Development Expenses.* The increase in research and development expenses was primarily due to an increase of \$61.9 million in clinical trial costs resulting principally from additional clinical trials, manufacturing of clinical supplies and enrollment of higher number of patients and an increase of \$5.0 million in personnel costs resulting from increased headcount and stock-based compensation expenses. We expect to incur substantially increasing research and development expenses in 2009, particularly expenses arising from clinical development activities related to our Phase 3 clinical trials.

*General and Administrative Expenses.* The increase in general and administrative expenses was primarily due to an increase of \$8.0 million in legal and consulting fees and an increase of approximately \$2.5 million in personnel costs resulting from higher headcount and stock-based compensation expenses. We expect to incur increasing general and administrative expenses in future periods to support our research and development activities, preparation for the New Drug Application for Hematide, costs associated with our J&J litigation and expansion of commercial capabilities.

*Interest Income (Expense), Net.* The decrease in interest income, net, was due primarily to lower level of cash, cash equivalents and investments and lower interest rates during the year.

*Other Income (Expense), Net.* Other income (expense), net, for the year ended December 31, 2008 includes a \$3.6 million other-than-temporary impairment charge related to the net decrease in fair value of our investments in ARS partially offset by a \$2.4 million gain from the Series C-2 ARS Rights

received from UBS AG, as more fully described in the section entitled “Liquidity and Capital Resources.”

*Provision for Income Taxes.* We are subject to federal and California state income tax. We recorded a provision for income taxes for the years ended December 31, 2008 and 2007.

For the year ended December 31, 2008, we recorded a provision for income taxes of \$282,000 consisting of \$107,000 of federal tax benefit and \$389,000 of net California state income tax expense. The \$107,000 of federal tax benefit was primarily due to a research and development credits refund available to us pursuant to a provision within the Housing Assistance Tax Act of 2008, which was signed into law in July 2008. The California state income tax expense of \$389,000 was primarily related to an out of period reduction to our California research and development credits that was partially offset by additional California research and development credits that were identified.

We recorded a provision for income taxes for the year ended December 31, 2007 of \$5.4 million consisting of \$15.4 million of current income taxes net of a \$10.0 million of deferred tax benefit. The current income taxes of \$15.4 million resulted primarily from the inclusion in 2007 taxable income of \$120.3 million of the upfront license fees received from Takeda during 2006 that, for tax purposes, were deferred in 2006 and recognized in 2007 and resulted in U.S. federal and state taxable income for the year ended December 31, 2007. The upfront license fees from Takeda were recorded as deferred revenue for financial reporting purposes and are being recognized as revenue over a period of approximately 4.5 years, as more fully described in the “Critical Accounting Policies and Significant Judgments and Estimates” section in this Annual Report on Form 10-K. The \$10.0 million net deferred tax benefit, and the related net deferred tax asset as of December 31, 2007 in the same amount, were recorded to reflect our ability to carry back tax losses generated in 2008 and 2009 as a result of certain reversing tax deductible temporary differences from December 31, 2007. We intend to carry back our 2008 federal taxable loss to reduce our 2007 federal income tax liability to the alternative minimum income tax liability as determined under the current U.S. federal income tax statutes.

We considered the following positive and negative factors in determining that it was more likely than not that the \$7.2 million and \$10.0 million, respectively, of net deferred tax asset as of December 31, 2008 and 2007 would be realized:

- Net deductible temporary differences that were expected to reverse in 2008 and 2009 and that we would generate losses in those years that could be carried back to reduce the 2007 federal income tax liability.
- There were no relevant tax strategies available that we would consider feasible.
- Uncertainties, such as regulatory approval of Hematide and binding arbitration and litigation with certain subsidiaries of Johnson & Johnson, that if unfavorably resolved, would adversely affect our future operations.
- We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future, and therefore the net deferred tax assets were limited to the amount available to be realized with the carry back enumerated above.

*Comparison of Years Ended December 31, 2007 and 2006*

	Year Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2007	2006		
	(in thousands, except percentages)			
Revenue . . . . .	\$ 44,336	\$ 11,726	\$32,610	278%
Research and development expenses . . .	69,398	54,347	15,051	28
General and administrative expenses . . .	24,075	11,089	12,986	117
Interest income (expense), net . . . . .	11,379	5,465	5,914	108
Other income (expense), net . . . . .	46	(43)	89	(207)
Provision for income taxes . . . . .	5,357	—	5,357	100
Net loss . . . . .	(43,069)	(48,288)	5,219	(11)
Accretion of mandatorily redeemable convertible preferred stock . . . . .	—	815	(815)	(100)

*Revenue.* We recognized \$44.3 million and \$11.7 million of revenue under our Arrangement with Takeda for the years ended December 31, 2007 and 2006, respectively, under the zero profit proportional performance model, as discussed in the notes to our audited financial statements. The increase in revenue was primarily due to the growth in direct costs associated with the increase in clinical trial activity and headcount in connection with Hematide. We recognized immaterial revenues for the years ended December 31, 2007 and 2006 from royalty payments.

*Research and Development Expenses.* The increase in research and development expenses of \$15.1 million was primarily due to an increase of \$25.0 million in clinical trial costs resulting principally from additional clinical trials and enrollment of more patients, an increase of \$6.1 million in personnel costs resulting from increased headcount and stock-based compensation expenses and a \$875,000 technology license fee for which the technological feasibility had not been established and there is no alternative future use. The increase in research and development expenses from the year ended December 31, 2007 to 2006 was lowered by a milestone payment of \$17.6 million in connection with the Nektar license that was expensed during the year ended December 31, 2006.

*General and Administrative Expenses.* The increase in general and administrative expenses was primarily due to an increase of approximately \$7.8 million in personnel costs resulting from higher headcount, and stock-based compensation expenses and an increase of \$4.3 million in Sarbanes-Oxley, legal and other consulting fees.

*Interest Income (Expense), Net.* The increase in interest income, net, was due primarily to higher level of cash, cash equivalents and short-term investments during the year.

*Other Income (Expense), Net.* Other income (expense), net, was immaterial for the years ended December 31, 2007 and 2006.

*Provision for Income Taxes.* We are subject to federal and California state income tax. We recorded a provision for income taxes for the year ended December 31, 2007. We were in a net operating loss position in 2006 and all prior periods and therefore did not record a provision for income taxes for the year ended December 31, 2006.

*Accretion of Mandatorily Redeemable Convertible Preferred Stock.* Our convertible preferred stock was redeemable at the request of the holders on or after July 11, 2010. We were accreting the carrying value of the preferred stock to the mandatory redemption amount using the effective interest method through periodic charges to additional paid in capital. We recorded accretion on the preferred stock through the date of the automatic conversion of all of our outstanding preferred stock into common stock upon the closing of our initial public offering in December 2006.

## Liquidity and Capital Resources

Since our inception, we have financed our operations through sale of capital stock, license fees, milestone payments and reimbursement for development and commercial expenses and manufacturing costs from collaborative partners, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through December 31, 2008, we have received net proceeds of \$258.8 million from the issuance of common stock and convertible preferred stock and \$122 million of upfront license fees, a \$10 million milestone payment and \$94.3 million for the reimbursement of development and commercial expenses and purchase of API from our collaboration agreements with Takeda. Of the first \$50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda under the Arrangement, a total of \$36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda bears 70% of the third-party U.S. development expenses, while we are responsible for 30% of the expenses.

As of December 31, 2008, we had \$117.7 million in unrestricted cash, cash equivalents and short-term and long-term investments. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, corporate bonds, commercial paper, auction rate securities, or ARS, 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, 2008, we had fair value of ARS totaling \$17.6 million that were comprised of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, closed end preferred issuances and another municipal issuance. The ARS held by us are rated AAA by a major credit rating agency, except for one ARS that is rated AA by a major credit rating agency. ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days but have stated or contractual maturities that are generally greater than one year. Through mid-February 2008, every auction reset date of the ARS held by us was successful. In mid-February, overall market liquidity concerns resulted in the failure of a majority of the auctions in the ARS markets. In the following month, approximately one-fifth of the auctions for ARS we held were successful. However, the overall ARS market has continued to deteriorate and the ARS held by us have failed in all but a single auction since mid-March 2008. During this period through December 31, 2008, the par value of ARS held by us decreased by \$8.5 million to \$21.3 million primarily due to redemptions at par value by the issuers.

We determined the fair value of our ARS at December 31, 2008 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization and credit risk. In addition, we included in our analysis an illiquidity factor to estimate the discount necessary to sell a security for which there is no active market. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer's credit risk. Our analysis resulted in a net decrease in fair value of ARS totaling \$3.6 million as of December 31, 2008. The decrease in fair value was deemed to be other-than-temporary and recorded as an impairment charge to other expense for the year ended December 31, 2008. Our analysis is based on dynamic market conditions and further deterioration in the ARS markets or changes in our assumptions could lead to significant reductions in determined value thus resulting in impairments in future periods.

As a result of a settlement between various regulatory agencies, including the Securities and Exchange Commission, and UBS entities relating to sales and marketing practices of ARS, in October 2008, we received an offer from UBS AG of Series C-2 ARS Rights in connection with the \$15.0 million of par value of ARS that were purchased through UBS and we continue to hold through

December 31, 2008. In November 2008, we accepted the terms of the Series C-2 ARS Rights and delivered the required legal release of claims against the UBS entities. The Series C-2 ARS Rights give us the option to require UBS to repurchase, at par, the ARS beginning on June 30, 2010, and prior to such date, UBS has the option to buy, at par, the ARS. In connection with the ARS Rights, UBS is also making available to eligible borrowers, loans potentially up to 75% of the value of the ARS. We determined that the ARS Rights do not meet the definition of a derivative security under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* (“SFAS No. 133”), because the ARS Rights are non-transferable and we must tender the related ARS to receive the cash settlement. Therefore, we elected to measure the ARS Rights separately under the fair value option of SFAS No. 159 in order to partially offset the changes in the fair value of the related ARS. We determined the value of the ARS Rights was \$2.4 million as of December 31, 2008 using a discounted cash flow analysis based on, among other things, the timing and likelihood of the recovery of the par value of the ARS from UBS. We recorded the fair value of the ARS Rights as a long-term other asset with a corresponding credit to other income (expense), partially offsetting the unrecognized losses incurred to date on the related ARS, during the year ended December 31, 2008. The recognition of the ARS Rights and the other-than-temporary impairment on the related ARS resulted in a net impact of \$214,000 to other income (expense) for the year ended December 31, 2008. We anticipate that future changes in the fair value of the ARS Rights will be offset by the changes in the fair value of related ARS with no material net impact to net loss.

Based on our expected cash usage and our balance of cash and other investments, we do not anticipate the current illiquidity of these investments will affect our ability to operate our business as usual for at least 12 months. However, there can be no assurance as to the timing of when, or if the market for ARS will recover in a manner that will allow us to receive a return of some or all of our principal or to meet our liquidity needs. Although our ARS continue to pay interest according to their stated terms, if the illiquidity continues, these investments may be subject to a further decline in value, which would require us to recognize additional impairments in future periods. We may also be required to sell these investments at prices significantly below par or assessed fair value. If we are unable to liquidate our ARS to obtain funds when needed we may be unable to fund our operations. UBS AG may not be able to maintain the financial resources necessary to satisfy its obligations with respect to the ARS Rights in a timely manner or at all.

	<u>Year Ended</u> <u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
	(in thousands)	
Cash, cash equivalents and short-term investments . . . . .	\$94,719	\$168,337
Working capital . . . . .	\$33,730	\$139,114
Long-term investments . . . . .	\$22,945	\$ 15,655

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(in thousands)		
Cash provided by (used in):			
Operating activities . . . . .	\$(62,631)	\$(45,539)	\$ 68,209
Investing activities . . . . .	\$(22,630)	\$ 5,175	\$(42,889)
Financing activities . . . . .	\$ 1,092	\$ 1,038	\$107,822
Capital expenditures (included in investing activities above). . . . .	\$ (3,778)	\$ (3,525)	\$ (1,452)

Net cash used in operating activities for the year ended December 31, 2008 primarily reflects the net loss for the period, which was reduced in part by non-cash activities including stock-based compensation, an other-than-temporary impairment charge related to our investments in ARS,

depreciation and amortization, as well as a decrease in prepaid expenses and other current assets, and changes in operating assets and liabilities due to timing of payments made in connection with our Phase 3 clinical trials for Hematide. Net cash used in operating activities for the year ended December 31, 2007 primarily reflects the development of Hematide and other product candidates partially offset by a milestone payment and direct cost reimbursements from Takeda. Cash used in the period includes the net loss, which was reduced in part by non-cash expenses including stock-based compensation, depreciation and amortization, as well as an increase in prepaid expenses, other current assets and other assets primarily as a result of payments made at the initiation of our Phase 3 clinical trials for Hematide. Cash provided by operations includes a \$10 million milestone payment, \$23.7 million for the reimbursement of development and commercial expenses and purchase of API by Takeda and an increase in accounts payable, long-term income tax liability and other long term liabilities due to the timing of payments. Net cash provided by operating activities for the year ended December 31, 2006 primarily reflects the \$122 million of upfront license fees received from Takeda, which was partially offset by the net loss for the period.

Net cash used in investing activities for the year ended December 31, 2008 was primarily related to net purchases of investments and, to a lesser extent, purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2007 primarily reflects net maturities of investments, which was offset by purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2006 was primarily related to net purchases of investments and, to a lesser extent, purchases of property and equipment.

Net cash provided by financing activities for the years ended December 31, 2008 and 2007 was primarily attributable to the proceeds from issuance of common stock upon exercise of stock options and proceeds from the purchase of common stock under our Employee Stock Purchase Plan, which was offset by principal payments under the capital lease obligations. Net cash provided by financing activities for the year ended December 31, 2006 was primarily attributable to the net proceeds of our initial public offering of \$96.1 million and the issuance of Series E preferred stock to Takeda.

Our future contractual obligations, including financing costs, at December 31, 2008 were as follows:

Contractual Obligations	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Capitalized lease obligations . . . . .	\$ 7	\$ 7	\$ —	\$ —	\$ —
Operating lease obligations . . . . .	16,266	2,583	5,472	5,907	2,304
Long-term income tax liability(1) . . . . .	9,400	—	—	—	—
Total fixed contractual obligations . . . . .	<u>\$25,673</u>	<u>\$2,590</u>	<u>\$5,472</u>	<u>\$5,907</u>	<u>\$2,304</u>

(1) With respect our long-term income tax liability as of December 31, 2008, we were unable to make a reasonably reliable estimate of the period of cash settlement, if any, with the respective taxing authorities.

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

Nektar a \$17.6 million milestone payment triggered by the collaboration agreements signed with Takeda in February and June 2006.

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

In September 2006, we entered into an operating lease for additional office space in Palo Alto, California. The lease commenced in November 2006 and terminates in December 2010. The total square footage covered by the new lease is 30,630 square feet, of which we leased 15,315 square feet starting in November 2006 and the remaining 15,315 square feet starting in September 2007.

In December 2006, we entered into an extension of the operating lease for office space in Palo Alto, California. The lease extension commences in October 2007 and terminates in September 2014. The total square footage covered by the lease extension is 84,460 square feet, of which we lease 53,830 square feet starting in October 2007 and the remaining 30,630 square feet starting in January 2011. Our future capital requirements will depend on many forward looking factors and are not limited to the following:

- the initiation, progress, timing and completion of preclinical studies and clinical trials for Hematide;
- our ability to maintain and achieve milestones under our collaboration agreements with Takeda;
- costs of litigation;
- outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the number of drug candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- cost of procuring clinical and commercial supplies of Hematide and future product candidates, if any; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

In March 2009, we completed a private placement raising an estimated \$41.6 million of net proceeds through the issuance of common stock and warrants exercisable for common stock. We believe that the existing cash, cash equivalents and investments together with the interest thereon, will enable us to maintain our currently planned operations through at least 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide even after taking into account the potential milestone payments that may be received under our collaboration with Takeda. The current worldwide capital markets have been extremely volatile and

inaccessible, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Securing funding has been particularly difficult for small companies of our size with limited capital resources. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Hematide is the main focus of our business, which we expect to be the case for the foreseeable future. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs even some activities related to support of Hematide. If we are unable to raise additional funds when needed we could be required to further delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

### **Recent Accounting Pronouncements**

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (“EITF No. 07-1”), which defines collaborative arrangements and establishes reporting and disclosure requirements for transactions between participants in a collaborative arrangement and between participants in the arrangements and third parties. EITF No. 07-1 is effective retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date for fiscal years beginning after December 15, 2008. We are currently assessing the potential impact that the adoption of EITF No. 07-1 will have on our financial statements.

Effective January 1, 2008, we adopted the provisions of EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (“EITF No. 07-3”). EITF No. 07-3 requires us to defer and capitalize nonrefundable advance payments for research and development activities. Such amounts will be recognized as expenses as the goods are delivered or the services are performed. If we do not expect the goods to be delivered or the services to be performed, the capitalized amounts should be expensed. The adoption of EITF No. 07-3 did not have a significant impact on our financial statements.

In June 2008, the EITF reached a consensus on EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity’s Own Stock* (“EITF No. 07-05”). EITF No. 07-5 provides guidance on how to determine if certain instruments (or embedded features) are considered indexed to our own stock, including instruments similar to our issued warrants to purchase our stock. EITF No. 07-5 requires companies to use a two-step approach to evaluate an instrument’s contingent exercise provisions and settlement provisions in determining whether the instrument is considered to be indexed to its own stock and exempt from the application of SFAS No. 133. Although EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008, any outstanding instrument at the date of adoption will require a retrospective application of the accounting through a cumulative effect adjustment to retained earnings upon adoption. We are currently assessing the potential impact that the adoption of EITF No. 07-5 will have on our financial statements.

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

There were no significant off-balance sheet arrangements at December 31, 2008.

## Item 7A. Quantitative and Qualitative Disclosure of Market Risks

### Interest Rate Risk

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

As of December 31, 2008, we had fair value of ARS totaling \$17.6 million that were comprised of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, closed end preferred issuances and another municipal issuance. The ARS held by us are rated AAA by a major credit rating agency, except for one ARS that is rated AA by a major credit rating agency. Based on overall market liquidity concerns, we determined that there was a net decrease in fair value of ARS totaling \$3.6 million as of December 31, 2008.

The table below presents the weighted-average interest rates and related carrying amounts of our investment portfolio as of December 31, 2008 and 2007:

	2008		2007	
	Weighted-average Interest Rate	Carrying Amount	Weighted-average Interest Rate	Carrying Amount
		(in thousands)		(in thousands)
Cash equivalents . . . . .	0.20%	\$20,643	4.91%	\$106,282
Short-term investments . . . . .	2.30%	\$70,673	5.37%	\$ 60,122
Long-term investments . . . . .	1.84%	\$22,945	6.14%	\$ 15,655

### 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.

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

Our financial statements and notes thereto appear on pages 65 to 101 of this Annual Report on Form 10-K.

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

The Board of Directors and Stockholders  
Affymax, Inc.

We have audited the accompanying balance sheet of Affymax, Inc. as of December 31, 2008, and the related statements of operations, stockholders' equity, and cash flows for the year then ended. 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 audit. The financial statements of Affymax, Inc. for the year ended December 31, 2007, were audited by other auditors whose report dated March 12, 2008, expressed an unqualified opinion on those statements and included an explanatory paragraph that disclosed the change in the Company's manner in which it accounts for uncertainty in income taxes as discussed in Note 2 to those financial statements.

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 2008 financial statements referred to above present fairly, in all material respects, the financial position of Affymax, Inc. at December 31, 2008, and the results of its operations and its cash flows for year ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Affymax, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, CA  
March 12, 2009

**REPORT OF PRICEWATERHOUSECOOPERS LLP,  
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Affymax, Inc.:

In our opinion, the balance sheet as of December 31, 2007 and the related statements of operations, of stockholders' equity, and of cash flows for each of two years in the period ended December 31, 2007 present fairly, in all material respects, the financial position of Affymax, Inc. (the "Company") at December 31, 2007, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America. 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 of these statements 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the financial statements, effective January 1, 2007, the Company changed the manner in which it accounts for uncertainty in income taxes.

/s/ PricewaterhouseCoopers LLP

San Jose, California  
March 12, 2008

**AFFYMAX, INC.**  
**BALANCE SHEETS**

(in thousands, except share and per share data)

	December 31,	
	2008	2007
<b>Assets</b>		
Current assets		
Cash and cash equivalents . . . . .	\$ 24,046	\$ 108,215
Restricted cash . . . . .	11	11
Short-term investments . . . . .	70,673	60,122
Receivable from Takeda . . . . .	21,688	15,331
Income taxes receivable . . . . .	2,665	—
Deferred tax assets . . . . .	1,351	1,810
Prepaid expenses and other current assets . . . . .	6,647	9,323
Total current assets . . . . .	127,081	194,812
Property and equipment, net . . . . .	6,952	4,470
Restricted cash . . . . .	1,135	1,135
Long-term investments . . . . .	22,945	15,655
Deferred tax assets, net of current . . . . .	5,889	8,272
Other assets . . . . .	3,718	1,448
Total assets . . . . .	\$ 167,720	\$ 225,792
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable . . . . .	\$ 614	\$ 9,348
Accrued liabilities . . . . .	9,831	3,517
Accrued clinical trial expenses . . . . .	27,806	2,473
Income taxes payable . . . . .	163	739
Deferred revenue . . . . .	54,930	39,488
Capitalized lease obligations, current . . . . .	7	133
Total current liabilities . . . . .	93,351	55,698
Deferred revenue, net of current . . . . .	54,915	75,911
Long-term income tax liability . . . . .	9,400	9,434
Capitalized lease obligations, net of current . . . . .	—	8
Other long-term liabilities . . . . .	1,070	556
Total liabilities . . . . .	158,736	141,607
Commitments and contingencies (Note 5)		
Stockholders' equity		
Common stock: \$0.001 par value, 100,000,000 shares authorized; 15,304,419 and 15,128,959 shares issued and outstanding at December 31, 2008 and 2007, respectively . . . . .	15	15
Additional paid-in capital . . . . .	306,828	296,035
Deferred stock-based compensation . . . . .	(4)	(28)
Accumulated deficit . . . . .	(298,328)	(211,818)
Accumulated other comprehensive income (loss) . . . . .	473	(19)
Total stockholders' equity . . . . .	8,984	84,185
Total liabilities and stockholders' equity . . . . .	\$ 167,720	\$ 225,792

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

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

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Collaboration revenue . . . . .	\$ 82,162	\$ 44,303	\$ 11,688
License and royalty revenue . . . . .	689	33	38
Total revenue . . . . .	<u>82,851</u>	<u>44,336</u>	<u>11,726</u>
Operating expenses			
Research and development . . . . .	137,492	69,398	54,347
General and administrative . . . . .	34,090	24,075	11,089
Total operating expenses . . . . .	<u>171,582</u>	<u>93,473</u>	<u>65,436</u>
Loss from operations . . . . .	(88,731)	(49,137)	(53,710)
Interest income . . . . .	4,545	11,393	5,549
Interest expense . . . . .	(609)	(14)	(84)
Other income (expense), net . . . . .	(1,433)	46	(43)
Net loss before provision for income taxes . . . . .	(86,228)	(37,712)	(48,288)
Provision for income taxes . . . . .	282	5,357	—
Net loss . . . . .	(86,510)	(43,069)	(48,288)
Accretion of mandatorily redeemable convertible preferred stock . . . . .	—	—	(815)
Net loss attributable to common stockholders . . . . .	<u>\$(86,510)</u>	<u>\$(43,069)</u>	<u>\$(49,103)</u>
Net loss per common share:			
Basic and diluted . . . . .	<u>\$ (5.68)</u>	<u>\$ (2.88)</u>	<u>\$ (32.56)</u>
Weighted-average number of common shares used in computing basic and diluted net loss per common share . . . . .	<u>15,220</u>	<u>14,941</u>	<u>1,508</u>

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

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

	<u>Common</u>	<u>Stock</u>	<u>Additional</u>	<u>Deferred</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Stock-Based</u>	<u>Deficit</u>	<u>Other</u>	<u>Stockholders'</u>
			<u>Capital</u>	<u>Compensation</u>		<u>Comprehensive</u>	<u>Equity (Deficit)</u>
						<u>Income (Loss)</u>	
<b>Balance at December 31, 2005</b> . . . . .	332,731	\$—	\$ 7,200	\$(409)	\$(120,461)	\$(21)	\$(113,691)
Issuance of common stock upon exercise of stock options . . . . .	202,401	1	150	—	—	—	151
Conversion of Series A preferred stock . . . . .	848,293	1	22,999	—	—	—	23,000
Conversion of Series C preferred stock . . . . .	6,626	—	100	—	—	—	100
Revision of allocated fair value of warrants . . . . .	—	—	(247)	—	—	—	(247)
Accretion on mandatorily redeemable convertible preferred stock . . . . .	—	—	(815)	—	—	—	(815)
Deferred stock-based compensation . . . . .	—	—	(809)	809	—	—	—
Amortization of deferred stock-based compensation . . . . .	—	—	—	(476)	—	—	(476)
Employee stock-based compensation under SFAS No. 123(R) . . . . .	—	—	2,152	—	—	—	2,152
Reversal of deferred stock-based compensation due to cancellations . . . . .	—	—	18	(18)	—	—	—
Nonemployee stock-based compensation . . . . .	—	—	346	—	—	—	346
Repurchase of common stock . . . . .	(880)	—	(1)	—	—	—	(1)
Conversion of Series C warrant to common stock warrant . . . . .	—	—	56	—	—	—	56
Conversion of preferred stock to common stock upon IPO . . . . .	8,993,572	9	156,719	—	—	—	156,728
Issuance of common stock upon exercise of warrant for cash . . . . .	107,268	—	1,824	—	—	—	1,824
Issuance of common stock upon cashless exercise of warrants . . . . .	133,293	—	—	—	—	—	—
Proceeds from common stock issued upon IPO, net of issuance costs . . . . .	4,255,000	4	96,081	—	—	—	96,085
Elimination of fractional shares resulting from reverse stock split . . . . .	—	—	(2)	—	—	—	(2)
Components of other comprehensive loss:							
Net loss . . . . .	—	—	—	—	(48,288)	—	(48,288)
Change in unrealized gain (loss) on marketable securities . . . . .	—	—	—	—	—	(23)	(23)
Total comprehensive loss . . . . .	—	—	—	—	—	—	(48,311)
<b>Balance at December 31, 2006</b> . . . . .	<u>14,878,304</u>	<u>\$15</u>	<u>\$285,771</u>	<u>\$( 94)</u>	<u>\$(168,749)</u>	<u>\$(44)</u>	<u>\$ 116,899</u>

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

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount					
<b>Balance at December 31, 2006</b>	14,878,304	\$15	\$285,771	\$ (94)	\$(168,749)	\$(44)	\$116,899
Issuance of common stock upon exercise of stock options	213,454	—	507	—	—	—	507
Issuance of common stock related to the employee stock purchase plan	42,228	—	905	—	—	—	905
Deferred stock-based compensation	—	—	(445)	445	—	—	—
Amortization of deferred stock-based compensation	—	—	—	(413)	—	—	(413)
Employee stock-based compensation under SFAS No. 123(R)	—	—	7,082	—	—	—	7,082
Reversal of deferred stock-based compensation due to cancellations	—	—	(34)	34	—	—	—
Nonemployee stock-based compensation	—	—	159	—	—	—	159
Repurchase of common stock	(5,027)	—	(15)	—	—	—	(15)
Tax benefits related to employee stock-based compensation	—	—	2,135	—	—	—	2,135
Capitalized IPO costs	—	—	(30)	—	—	—	(30)
Components of other comprehensive loss:							
Net loss	—	—	—	—	(43,069)	—	(43,069)
Change in unrealized gain (loss) on marketable securities	—	—	—	—	—	25	25
Total comprehensive loss	—	—	—	—	—	—	(43,044)
<b>Balance at December 31, 2007</b>	<u>15,128,959</u>	<u>\$15</u>	<u>\$296,035</u>	<u>\$ (28)</u>	<u>\$(211,818)</u>	<u>\$(19)</u>	<u>\$ 84,185</u>

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

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount					
<b>Balance at December 31, 2007</b>	15,128,959	\$15	\$296,035	\$ (28)	\$(211,818)	\$(19)	\$ 84,185
Issuance of common stock upon exercise of stock options . . . . .	104,287	—	360	—	—	—	360
Issuance of common stock related to the employee stock purchase plan . . . . .	71,533	—	875	—	—	—	875
Deferred stock-based compensation . . . . .	—	—	(402)	402	—	—	—
Amortization of deferred stock- based compensation . . . . .	—	—	—	(379)	—	—	(379)
Employee stock-based compensation under SFAS No. 123(R) . . . . .	—	—	9,291	—	—	—	9,291
Reversal of deferred stock- based compensation due to cancellations . . . . .	—	—	(1)	1	—	—	—
Nonemployee stock-based compensation . . . . .	—	—	671	—	—	—	671
Repurchase of common stock . . . . .	(360)	—	(1)	—	—	—	(1)
Components of other comprehensive loss:							
Net loss . . . . .	—	—	—	—	(86,510)	—	(86,510)
Change in unrealized gain (loss) on marketable securities . . . . .	—	—	—	—	—	492	492
Total comprehensive loss . . . . .	—	—	—	—	—	—	(86,018)
<b>Balance at December 31, 2008</b>	<u>15,304,419</u>	<u>\$15</u>	<u>\$306,828</u>	<u>\$ (4)</u>	<u>\$(298,328)</u>	<u>\$473</u>	<u>\$ 8,984</u>

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

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

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>			
Net loss	\$ (86,510)	\$ (43,069)	\$ (48,288)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	1,294	1,067	704
Amortization of discount/premium on investments	302	(453)	(181)
Stock-based compensation expense	9,583	6,828	2,022
Deferred tax benefit	2,842	(10,082)	—
Tax benefits related to employee stock-based compensation	—	2,135	—
Interest expense related to common stock warrants	—	—	56
Gain on disposal of fixed assets	(20)	(28)	(11)
Other-than-temporary impairment on investments	3,749	—	—
Realized gain on investments	(112)	(45)	46
Unrealized gain on auction rate securities rights	(2,414)	—	—
Changes in operating assets and liabilities:			
Receivable from Takeda	(6,357)	(5,140)	(10,191)
Income taxes receivable	(2,665)	—	—
Prepaid expenses and other current assets	2,676	(4,747)	(4,368)
Other assets	(2,270)	(852)	1,153
Accounts payable	(8,734)	4,090	2,778
Accrued liabilities	6,322	(889)	2,587
Accrued clinical trial expenses	25,333	495	1,105
Income taxes payable	(576)	739	—
Deferred revenue	(5,554)	(5,422)	120,821
Long-term income tax liability	(34)	9,434	—
Other long-term liabilities	514	400	(24)
Net cash provided by (used in) operating activities	<u>(62,631)</u>	<u>(45,539)</u>	<u>68,209</u>
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(3,778)	(3,525)	(1,452)
Purchases of investments	(143,154)	(243,758)	(226,999)
Sales and maturities of investments	124,280	251,388	187,721
Proceeds from sale of property and equipment	22	30	27
Change in restricted cash	—	1,040	(2,186)
Net cash provided by (used in) investing activities	<u>(22,630)</u>	<u>5,175</u>	<u>(42,889)</u>
<b>Cash flows from financing activities</b>			
Repurchases of common stock	(1)	(15)	(1)
Proceeds from issuance of common stock upon exercise of stock options, including early exercise of stock options	350	470	204
Proceeds from issuance of common stock under employee stock purchase plan	875	905	—
Proceeds from issuance of common stock upon exercise of common stock warrant	—	—	1,824
Proceeds from issuance of preferred stock, net of issuance costs	—	—	9,982
Proceeds from IPO, net of issuance costs	—	(30)	96,085
Principal payments under capital lease obligations	(132)	(292)	(272)
Net cash provided by financing activities	<u>1,092</u>	<u>1,038</u>	<u>107,822</u>
Net increase (decrease) in cash and cash equivalents	(84,169)	(39,326)	133,142
Cash and cash equivalents at beginning of the year	108,215	147,541	14,399
Cash and cash equivalents at end of the year	<u>\$ 24,046</u>	<u>\$ 108,215</u>	<u>\$ 147,541</u>
<b>Supplemental disclosures of cash flow information</b>			
Income taxes paid	\$ 1	\$ 3,131	\$ 1
Interest paid	2	14	27
<b>Noncash investing and financing activities</b>			
Accretion on mandatorily redeemable convertible preferred stock	—	—	815
Change in unrealized loss on investments	492	25	(23)
Deferred stock-based compensation, net of cancellations	(403)	(479)	(791)
Issuance of warrants to purchase common stock/(Revision of allocated fair value of warrants)	—	—	(247)
Additions to property and equipment under capital lease obligations	—	—	172
Conversion of Series A preferred stock	—	—	23,000
Conversion of Series C preferred stock	—	—	100
Conversion of preferred stock upon IPO	—	—	156,728

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

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**1. The Company**

Affymax, Inc. (the “Company”), a Delaware corporation, was incorporated on July 20, 2001. The Company is a biopharmaceutical company developing novel peptide-based drug candidates to improve the treatment of serious and often life-threatening conditions. The Company’s product candidate, Hematide™, is designed to treat anemia associated with chronic renal failure. Hematide is a synthetic peptide-based erythropoiesis stimulating agent (“ESA”) designed to stimulate production of red blood cells. The Company is conducting Phase 3 clinical trials in patients suffering from chronic renal failure, on dialysis and not on dialysis (“pre-dialysis”).

**2. Summary of Significant Accounting Policies**

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

**Cash and Cash Equivalents**

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

**Restricted Cash**

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

**Comprehensive Loss**

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on investments. At each balance sheet date presented, the Company’s other comprehensive loss consists solely of unrealized gains and losses on investments. Comprehensive loss for the years ended December 31, 2008, 2007 and 2006 are as follows (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Net loss . . . . .	\$(86,510)	\$(43,069)	\$(48,288)
Change in unrealized gain (losses) on investments . .	492	25	(23)
Comprehensive loss . . . . .	\$(86,018)	\$(43,044)	\$(48,311)

**Concentration of Risk and Uncertainties**

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The Company deposits excess cash in accounts with major financial institutions in the United States. Deposits in these banks may exceed the amount of insurance

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

provided on such deposits. The Company has not experienced any realized losses on its deposits of cash and cash equivalents. Although the Company's guidelines for investment of its excess cash are designed to maintain safety and liquidity through its policies on diversification and investment maturity, as of December 31, 2008, the Company held fair value of investments in auction rate securities ("ARS") totaling \$17.6 million that have failed in auctions.

The Company has experienced significant operating losses since inception. At December 31, 2008, the Company had an accumulated deficit of \$298.3 million. The Company has generated no revenue from product sales to date. The Company has funded its operations to date principally from its collaboration agreements with Takeda and the sale of securities. The Company expects to incur substantial additional operating losses for the next several years and will need to obtain additional financing in order to complete the development and commercialization of Hematide. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

The Company's accounts receivable balance contains receivables in connection with our two separate collaboration agreements (the "Arrangement") with Takeda Pharmaceutical Company Limited, or Takeda. The Company has not experienced any credit losses from its Arrangement with Takeda and none are expected.

The Company is currently developing its first product offering, Hematide, and has no products that have received regulatory approval. Hematide will require approval from the U.S. Food and Drug Administration ("FDA") and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that Hematide will receive the necessary approvals. If the Company is denied such approvals or such approvals are delayed, it would have a material adverse effect on the Company. To achieve profitable operations, the Company must successfully develop, test, manufacture and commercialize Hematide. There can be no assurance that Hematide can be developed successfully or manufactured at an acceptable cost and with appropriate performance characteristics, or that Hematide will be successfully commercialized. These factors could have a material adverse effect on the Company's future financial results.

**Fair Value of Financial Instruments**

For financial instruments consisting of cash and cash equivalents, receivable from Takeda, accounts payable and accrued liabilities included in the Company's 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, except the Company's investments in ARS, which are separately disclosed elsewhere, are based on quoted market prices for the same or similar instruments. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of lease obligations approximates fair value.

**Investments**

Investments are classified as available-for-sale in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and are carried at their fair market value at the balance sheet date. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification method. Unrealized gains and losses are reported as a separate component of stockholders' equity until realized.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (“SFAS No. 157”). SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. In February 2008, the FASB issued Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (“FSP No. 157-2”), which delays the effective date of SFAS No. 157 for all nonfinancial assets and liabilities except for those recognized or disclosed at least annually. In October 2008, the FASB issued Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, or FSP No. 157-3. FSP No. 157-3 clarifies the application of SFAS No. 157 in a market that is not active. The Company has adopted the provisions of SFAS No. 157 with respect to its financial assets and liabilities only.

Effective January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (“SFAS No. 159”), which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option under SFAS No. 159, except for the Series C-2 ARS Rights, as more fully described in Note 4.

**Mandatorily Redeemable Convertible Preferred Stock**

The carrying value of the previously outstanding Series A, Series B, Series C and Series D Mandatorily Redeemable Convertible Preferred Stock was increased by periodic accretion, using the effective interest method, so that the carrying amount would equal the redemption value at the redemption date. The Company recorded accretion on the mandatorily redeemable convertible preferred stock through the date of the automatic conversion of all of its outstanding preferred stock into common stock upon the closing of its initial public offering in December 2006.

**Research and Development**

All research and development costs are expensed as incurred.

**Property and Equipment**

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

**Revenue Recognition**

*Collaboration Revenue*

The Company recognizes revenue in accordance with the Securities and Exchange Commission’s Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* (“SAB 104”). When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force (“EITF”)

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (“EITF 00-21”). Application of this standard 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.

The Company has entered into two separate collaboration agreements (the “Arrangement”) with Takeda Pharmaceutical Company Limited, or Takeda, which have been combined for accounting purposes due to their proximity of negotiation. The Company evaluated the multiple elements under the combined single arrangement in accordance with the provisions of EITF 00-21. As the Company was unable to determine the stand-alone value of the delivered elements and obtain verifiable objective evidence to determine the fair value of the undelivered elements, the Company concluded that there was a single unit of accounting.

Effective January 1, 2008, the Company entered into an amendment to the Arrangement with Takeda. The amendment provides the Company’s ability to opt-out of its obligation to participate on the joint steering committee and any related subcommittees at any time beginning January 1, 2011 without any other modifications. As a result, the obligation to participate in the joint steering committee and any related subcommittee is no longer indefinite. Accordingly, the Company determined that it can separate the performance obligations that occur over the development period from the performance obligations that will occur during the commercialization period. The Company does not expect its development period obligations to extend past January 1, 2011. As a result of the change in performance period from indefinite to approximately 4.5 years (i.e., the inception of the Arrangement to January 1, 2011), beginning on January 1, 2008, the Company recognized revenue during the development period using the Contingency-Adjusted Performance Model (“CAPM”). Under the CAPM, revenue is initially recognized in the period the payment is earned under the arrangement including amounts that are either received or due from Takeda. Revenue initially recognized is based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment is earned in relation to the total projected development period. The remaining portion of the payment is then recognized on a straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period include amounts due for upfront license fees, milestone payments earned, purchases of API and reimbursement of development and commercial expenses. The cumulative effect adjustment totaling \$1.4 million for the change of estimate, which results from now being able to estimate the period of performance, was recognized as additional revenue during the three months ended March 31, 2008. Through the period of the joint steering committee obligation, the Company expects collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods. Included in the reimbursable expense is the cost of API that the Company manufactures and supplies to Takeda during the development period, which the Company will also supply during the commercialization period.

Prior to January 2008, the Company was unable to determine the period of its performance obligations under the Arrangement as the Company’s required participation on the joint steering committee extends for as long as products subject to the collaboration with Takeda are being sold by either of the parties. Accordingly, the contractual term of the Company’s joint steering committee obligations was considered indefinite. As a result, revenue for the single unit of accounting was recorded on a proportional performance basis as long as the overall Arrangement was determined to be profitable during the years ended December 31, 2007 and 2006. The Company accounted for the

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

Arrangement using a zero profit proportional performance model (i.e., revenue was recognized equal to direct costs incurred, but not in excess of cash received or receivable assuming that the overall Arrangement was expected to be profitable). The Company used an input based measure, specifically direct costs, to determine proportional performance because the Company believed that the inputs were representative of the value being conveyed to Takeda through the research and development activities and delivery of the API. The Company believed that using direct costs as the unit of measure of proportional performance also most closely reflected the level of effort related to the Company's performance under the Arrangement. Direct costs were those costs that directly resulted in the culmination of an earnings process for which Takeda received a direct benefit. The nature of these costs were third party and internal costs associated with conducting clinical trial activities for dialysis and pre-dialysis indications, costs associated with the manufacturing of API and API stability testing, allocated payroll-related costs for representatives participating on the joint steering committee and sales and marketing costs during the co-commercialization period. Direct costs specifically excluded costs of a general and administrative nature, upfront payments to manufacturers unrelated to specific product manufactured such as reservation of capacity, cost for API not yet delivered to Takeda, travel and expense related costs, sales and marketing costs during the development period, any research and development costs not associated with Hematide, interest, depreciation and amortization expense. Revenue was recognized equal to direct costs incurred, but not in excess of cash received or receivable. Amounts resulting from payments received in advance of revenue recognized were recorded as deferred revenue until the earlier of (i) when the Company could meet the criteria for separate recognition of each element under the guidance of EITF 00-21 or (ii) after the Company had fulfilled all of its contractual obligations under the Arrangement.

The Company was required to assess the profitability of the overall Arrangement on a periodic basis throughout the life of the Arrangement when events or circumstances indicated a potential change in facts. Profitability was defined as a net cash inflow resulting from the Arrangement over its life. Such assessment was based on estimates to determine the most likely outcome based on available facts and circumstances at each assessment date. The estimates included the consideration of factors such as the progress and timing of clinical trials, competitive ESAs in the market, drug related serious adverse events and other safety issues in the clinical trials, pricing reimbursement in relevant markets and historical costs incurred compared to original estimates. When the periodic assessment or other events or circumstances indicated a loss would result from performance under the Arrangement, costs would continue to be recognized as they were incurred. However, revenue would be deferred until either: (i) the Arrangement became profitable, at which point revenue would continue to be recognized, or (ii) the end of the Arrangement.

***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 the Company in the 2001 spin out from GlaxoSmithKline ("Glaxo") are recorded net of the 50% that the Company is required to remit to Glaxo.

**Clinical Trial Expense**

The Company records expense for estimated clinical study external costs, which are a significant component of research and development ("R&D") expenses. These clinical trial costs were

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

\$77.8 million, \$26.8 million and \$9.4 million for the years ended December 31, 2008, 2007 and 2006, respectively. Clinical studies are administered by third-party contract research organizations (“CROs”). CROs typically perform most of the total start-up activities for the trials, including document preparation, site identification pre-study visits, training as well as on-going program management. For the Phase 3 studies, which represent the vast majority of the clinical trial expense, the expense recorded is based on reporting received from CROs and internal analyses. The Company accrues costs for work performed by CROs based on the achievement of contracted activities during the period. Expense for investigator fees, which include patient costs, is based on internal estimates of activities using patient enrollment and contractual or estimated rates. For the Phase 2 studies, the expense is activities based such as patient monitoring as reported by the CROs and achievement of milestones. Other costs such as testing and drug materials are expensed as incurred.

For all studies, CRO reporting is reviewed by the Company for appropriateness and adjustments are made as deemed necessary to ensure that the expenses reflect the actual effort incurred by the CROs. However, if the Company does not receive complete and accurate information from the vendors or underestimates activity levels associated with a study at a given point in time, the Company may have to record adjustments, including potentially significant additional R&D expenses in subsequent periods.

Based on additional reporting by one of the CROs, the Company recorded a change in estimate to decrease clinical trial expense by \$0.7 million in the quarter ended June 30, 2008.

**Segment Information**

The Company operates in one business segment, which encompasses all the geographical regions. Management uses one measurement of profitability and does not segregate its business for internal reporting.

**Income Taxes**

The Company accounts 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.

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (“FIN 48”), which prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. The cumulative effect of adopting FIN 48 resulted in no adjustment to retained earnings as of January 1, 2007.

**Net Loss per Common Share**

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

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

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

	Year Ended December 31,		
	2008	2007	2006
	(in thousands, except per share data)		
Numerator:			
Net loss attributable to common stockholders . . .	\$(86,510)	\$(43,069)	\$(49,103)
Denominator:			
Weighted-average common shares outstanding . . .	15,223	14,957	1,529
Less: Weighted-average unvested common shares subject to repurchase . . . . .	(3)	(16)	(21)
Weighted-average number of common shares used in computing basic and diluted net loss per common share . . . . .	15,220	14,941	1,508
Basic and diluted net loss per common share . . . . .	\$ (5.68)	\$ (2.88)	\$ (32.56)

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

	Year Ended December 31,		
	2008	2007	2006
Options to purchase common stock . . . . .	2,130	2,099	1,333
Common stock subject to repurchase . . . . .	2	8	31
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan . . . . .	13	10	2
Restricted stock units . . . . .	189	31	—
Warrant to purchase common stock . . . . .	2	2	2

**Stock-Based Compensation**

Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to the Company's employees and directors after January 1, 2006. The Company's financial statements as of and for the years ended December 31, 2008, 2007 and 2006 reflect the impact of SFAS No. 123(R). In accordance with the prospective transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

The Company accounts for equity instruments issued to nonemployees in accordance with the provisions of Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ("EITF 96-18"). The equity instruments, consisting of stock options, are valued using the Black-Scholes valuation model. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Reclassifications and Adjustments**

Certain amounts in prior period financial statements have been reclassified to conform to the current period presentation. The Company separated the line item “accrued clinical trial expenses” from “accrued liabilities” in the balance sheet. This reclassification did not change previously reported net loss, total assets or stockholders’ equity.

During the quarter ended June 30, 2008, the Company identified an overstatement of clinical trial expense and collaboration revenue of \$1.3 million in the year ended December 31, 2007. As a result, clinical trial expense and collaboration revenue, which includes reimbursement for these costs, includes an out of period reduction of \$1.3 million and \$0.4 million, respectively, in the year ended December 31, 2008. The overstatement was immaterial to the financial statements for the year ended December 31, 2007 and therefore was corrected in the second quarter of 2008.

During the quarter ended December 31, 2008, the Company identified an understatement of its provision for income taxes of \$0.7 million in the year ended December 31, 2007. As a result, the Company’s provision for income taxes includes an out of period increase of \$0.7 million in the year ended December 31, 2008. The understatement was immaterial to the financial statements for the year ended December 31, 2007 and therefore were corrected in the fourth quarter of 2008.

**Recent Accounting Pronouncements**

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (“EITF No. 07-1”), which defines collaborative arrangements and establishes reporting and disclosure requirements for transactions between participants in a collaborative arrangement and between participants in the arrangements and third parties. EITF No. 07-1 is effective retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date for fiscal years beginning after December 15, 2008. The Company is currently assessing the potential impact that the adoption of EITF No. 07-1 will have on its financial statements.

Effective January 1, 2008, the Company adopted the provisions of EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (“EITF No. 07-3”). EITF No. 07-3 requires us to defer and capitalize nonrefundable advance payments for research and development activities. Such amounts will be recognized as expenses as the goods are delivered or the services are performed. If the Company does not expect the goods to be delivered or the services to be performed, the capitalized amounts should be expensed. The adoption of EITF No. 07-3 did not have a significant impact on the Company’s financial statements.

In June 2008, the EITF reached a consensus on EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity’s Own Stock* (“EITF No. 07-05”). EITF No. 07-5 provides guidance on how to determine if certain instruments (or embedded features) are considered indexed to the Company’s own stock, including instruments similar to the Company’s issued warrants to purchase its stock. EITF No. 07-5 requires companies to use a two-step approach to evaluate an instrument’s contingent exercise provisions and settlement provisions in determining whether the instrument is considered to be indexed to its own stock and exempt from the application of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Although EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008, any outstanding instrument at the date

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

of adoption will require a retrospective application of the accounting through a cumulative effect adjustment to retained earnings upon adoption. The Company is currently assessing the potential impact that the adoption of EITF No. 07-5 will have on the Company's financial statements.

**3. Balance Sheet Components**

**Property and Equipment, Net**

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

	December 31,	
	2008	2007
Leasehold improvements . . . . .	\$ 1,448	\$ 1,269
Equipment . . . . .	9,520	7,122
Software . . . . .	1,342	671
	12,310	9,062
Less: Accumulated depreciation and amortization . . . . .	(5,358)	(4,592)
	\$ 6,952	\$ 4,470

Depreciation and amortization expense for the years ended December 31, 2008, 2007 and 2006 was \$1.3 million, \$1.1 million and \$704,000, respectively.

The Company leases certain assets under capital leases having terms up to 3 years. Assets held by the Company at December 31, 2008 and 2007 under such lease arrangements are included in property and equipment on the balance sheets as follows (in thousands):

	December 31,	
	2008	2007
Equipment . . . . .	\$ 961	\$ 966
Less: Accumulated depreciation and amortization . . . . .	(954)	(832)
	\$ 7	\$ 134

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2008	2007
Payroll-related expenses . . . . .	\$5,224	\$3,004
Legal expenses . . . . .	937	355
Other . . . . .	3,670	158
	\$9,831	\$3,517

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**4. Investments**

The following is a summary of the Company's available-for-sale marketable securities (in thousands):

As of December 31, 2008					
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than- Temporary Impairment	Fair Value
Short-term investments:					
Corporate securities . . . . .	\$ 3,500	\$ —	\$ (5)	\$ —	\$ 3,495
Certificates of deposit . . . . .	1,499	3	—	—	1,502
Government securities . . . . .	65,261	418	(3)	—	65,676
Total short-term investments . . . . .	<u>\$70,260</u>	<u>\$421</u>	<u>\$ (8)</u>	<u>\$ —</u>	<u>\$70,673</u>
Long-term investments:					
Government securities . . . . .	\$ 5,273	\$ 60	\$ —	\$ —	\$ 5,333
Auction rate securities . . . . .	21,250	—	—	(3,638)	17,612
Total long-term investments . . . . .	<u>\$26,523</u>	<u>\$ 60</u>	<u>\$ —</u>	<u>\$(3,638)</u>	<u>\$22,945</u>
As of December 31, 2007					
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	
Short-term investments:					
Corporate securities . . . . .	\$31,241	\$10	\$(29)	\$31,222	
Foreign securities . . . . .	1,497	—	(3)	1,494	
Certificates of deposit . . . . .	9,703	4	(1)	9,706	
Auction rate securities . . . . .	17,700	—	—	17,700	
Total short-term investments . . . . .	<u>\$60,141</u>	<u>\$14</u>	<u>\$(33)</u>	<u>\$60,122</u>	
Long-term investments:					
Auction rate securities . . . . .	\$15,655	\$—	\$ —	\$15,655	

At December 31, 2008, the investments bear interest at rates between 0.0% and 3.6% per annum. The investments, other than ARS, mature between January 2009 and January 2010. ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days. The student loan and municipal ARS have final maturity dates from 2017 to 2046 while the closed end preferred ARS have no final maturity date.

**Fair Value Measurements**

Effective January 1, 2008, the Company adopted the provisions of SFAS No. 157 with respect to its financial assets and liabilities only. Effective January 1, 2008, the Company also adopted SFAS No. 159, which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option under SFAS No. 159, except for the Series C-2 ARS Rights, as more fully described below.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**4. Investments (Continued)**

SFAS No. 157 established a three-tier hierarchy for fair value measurements, which 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 the Company to develop its own assumptions.

The Company's cash equivalents and investments, other than ARS, are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The 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 Company's investments in ARS are classified within Level 3 of the fair value hierarchy because of the lack of observable inputs. ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days but have stated or contractual maturities that are generally greater than one year. Through mid-February 2008, every auction reset date of the ARS held by the Company was successful. In mid-February, overall market liquidity concerns resulted in the failure of a majority of the auctions in the ARS markets. In the following month, approximately one-fifth of the auctions for ARS held by the Company were successful.

Since the filing of the Company's Form 10-K for the year ended December 31, 2007, the overall ARS markets have continued to deteriorate and the ARS held by the Company have failed in all but a single successful auction. During this period through December 31, 2008, the par value of the Company's ARS holdings decreased by \$8.5 million to \$21.3 million primarily due to redemptions at par value by the issuers. The Company's sales or redemptions of ARS to date have not resulted in any loss of principal. The ARS held by the Company continue to pay interest, most recently in a range of 1 - 7%, though certain student loan issuances are temporarily at a zero coupon rate due to the particular interest provisions of the issuances. As of December 31, 2008, the Company's \$21.3 million of par value of ARS were comprised of \$17.6 million of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, \$3.1 million of closed end preferred issuances and a \$600,000 municipal issuance. The ARS held by the Company are rated AAA by a major credit rating agency, except for one ARS that is rated AA by a major credit rating agency.

As a result of the continued auction market failures, quoted prices in active markets are not available. Due to the lack of observable inputs, the Company determined the fair value of its ARS at December 31, 2008 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization and credit risk. In addition, the Company included in its analysis an illiquidity factor to estimate the discount necessary to sell a security for which there is no active market. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer's credit risk. The analysis is based on dynamic market conditions and changes in

**AFFYMAX, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**4. Investments (Continued)**

the Company's assumptions could lead to a significant change in determined value. The Company's analysis resulted in a net decrease in fair value of ARS totaling \$3.6 million as of December 31, 2008. The decrease in fair value was deemed to be other-than-temporary and recorded as an impairment charge to other income (expense), net for the year ended December 31, 2008.

The following table presents the Company's investments measured at fair value on a recurring basis as of December 31, 2008 classified by the SFAS No. 157 valuation hierarchy (in thousands):

	<u>Total</u>	<u>Fair Value Measurements Using</u>		
		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash equivalents . . . . .	\$20,643	\$20,643	\$ —	\$ —
Short-term investments:				
Corporate securities . . . . .	\$ 3,495	\$ —	\$ 3,495	\$ —
Certificates of deposit . . . . .	1,502	—	1,502	—
Government securities . . . . .	65,676	—	65,676	—
Total short-term investments . . . . .	<u>\$70,673</u>	<u>\$ —</u>	<u>\$70,673</u>	<u>\$ —</u>
Long-term investments:				
Government securities . . . . .	\$ 5,333	\$ —	\$ 5,333	\$ —
Auction rate securities . . . . .	17,612	—	—	17,612
Total long-term investments . . . . .	<u>\$22,945</u>	<u>\$ —</u>	<u>\$ 5,333</u>	<u>\$17,612</u>
ARS Rights . . . . .	<u>\$ 2,414</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,414</u>

The following table presents changes in Level 3 assets measured at fair value on a recurring basis for the year ended December 31, 2008 (in thousands):

	<u>Fair Value Measurements Using Level 3 Inputs</u>
Balance at January 1, 2008 . . . . .	\$ —
Transfers in and/or out of Level 3 . . . . .	36,405
ARS Rights . . . . .	2,414
Total unrealized losses related to ARS	
Included in net loss . . . . .	(3,749)
Total realized gains related to ARS	
Included in net loss . . . . .	111
Settlements . . . . .	(15,155)
Balance at December 31, 2008 . . . . .	<u>\$ 20,026</u>

As a result of a settlement between various regulatory agencies, including the Securities and Exchange Commission, and UBS entities relating to sales and marketing practices of ARS, in October 2008, the Company received an offer from UBS AG of Series C-2 ARS Rights in connection with the \$15.0 million of par value of ARS that were purchased through UBS and the Company continues to hold through December 31, 2008. In November 2008, the Company accepted the terms of the Series C-2 ARS Rights and delivered the required legal release of claims against the UBS entities.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**4. Investments (Continued)**

These Series C-2 ARS Rights give the Company the option to require UBS to repurchase, at par, the ARS beginning on June 30, 2010, and prior to such date, UBS has the option to buy, at par, the ARS. In connection with the ARS Rights, UBS is also making available to eligible borrowers, loans potentially up to 75% of the fair value of the ARS as determined by UBS. The Company determined that the ARS Rights do not meet the definition of a derivative security under SFAS No. 133 because the ARS Rights are non-transferable and the Company must tender the related ARS to receive the cash settlement. Therefore, the Company elected to measure the ARS Rights separately under the fair value option of SFAS No. 159 in order to partially offset the changes in the fair value of the ARS to the ARS Rights. The Company determined the value of the ARS Rights was \$2.4 million as of December 31, 2008 using a discounted cash flows analysis based on, among other things, the timing and likelihood of the recovery of the par value of the ARS from UBS. The Company recorded the fair value of the ARS Rights as a long-term other asset with a corresponding credit to other income (expense), partially offsetting the unrecognized losses incurred to date on the related ARS, during the year ended December 31, 2008. The recognition of the ARS Rights and the other-than-temporary impairment on the related ARS resulted in a net impact of \$214,000 of net other expense for the year ended December 31, 2008.

**5. Commitments and Contingencies**

The Company leases certain equipment under a capital lease arrangement expiring in February 2009 at an interest rate of 3.4%. The capital lease is collateralized by certain assets of the Company.

The Company rents its office facilities and certain equipment under noncancelable operating leases, which expire at various dates through September 2014. Under the terms of the leases, the Company is responsible for certain taxes, insurance and maintenance expenses.

In September 2006, the Company entered into an operating lease for additional office space in Palo Alto, California. The lease commenced in November 2006 and terminates in December 2010. The total square footage covered by the new lease is 30,630 square feet, of which the Company leased 15,315 square feet started in November 2006 and the remaining 15,315 square feet started in September 2007.

In December 2006, the Company entered into an extension of the operating lease for office space in Palo Alto, California. The lease extension commences in October 2007 and terminates in September 2014. The total square footage covered by the lease extension is 84,460 square feet, of which the Company leases 53,830 square feet started in October 2007 and the remaining 30,630 square feet starting in January 2011.

Rent expense for the years ended December 31, 2008, 2007 and 2006 was \$2.6 million, \$2.4 million and \$3.1 million, respectively. The Company recognizes rent expense on a straight-line basis over the lease period.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**5. Commitments and Contingencies (Continued)**

Future minimum payments under noncancelable lease obligations as of December 31, 2008 are as follows (in thousands):

	<u>Capital Leases</u>	<u>Operating Leases</u>
2009 . . . . .	\$ 7	\$ 2,583
2010 . . . . .	—	2,646
2011 . . . . .	—	2,826
2012 . . . . .	—	2,910
2013 . . . . .	—	2,997
Thereafter . . . . .	—	<u>2,304</u>
Total minimum lease payments . . . . .	<u>7</u>	<u>\$16,266</u>
Less: Interest . . . . .	—	
Present value of minimum lease payments . . . . .	7	
Less: Amount due within one year . . . . .	<u>(7)</u>	
Amount due after one year . . . . .	<u>\$—</u>	

**Legal Proceedings**

The Company has initiated binding arbitration and related litigation with Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., Ortho Pharmaceutical Corporation, The R.W. Johnson Pharmaceutical Research Institute and Johnson & Johnson Pharmaceutical Research and Development, L.L.C., or, collectively, J&J, over ownership of intellectual property related to erythropoietin receptor, or EPO-R, agonists (compounds capable of binding to and activating the EPO-R). This intellectual property is the subject of a number of U.S. and international patents and patent applications assigned to the Company and J&J, including a U.S. patent currently assigned to J&J, several U.S. patents currently assigned to the Company and a European patent application currently assigned to J&J. In this section, the Company refers to the patents and patent applications subject to the arbitration collectively as the “intellectual property in dispute”. The Company believes that it is the sole owner or co-owner of the intellectual property in dispute, including a European patent application currently naming J&J as sole owner that may issue in the near future and relates to specified ESA peptide compounds. J&J, on the other hand, alleges that they are the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which the Company is currently named as sole owner that relate to specified peptide compounds.

In June 2004, the Company filed a civil complaint in the Munich Regional Court in the Federal Republic of Germany against J&J alleging that it is an owner or co-owner of J&J’s European patent application relating to agonist peptide dimers. In October 2005, J&J filed its response to the Company’s complaint, denying its claims of inventorship and ownership. In April 2006, the Company requested the court to dismiss the complaint so that the issues it raised could be resolved pursuant to the arbitration proceeding described below. The court has done so.

In September 2004, the Company filed a civil complaint in the U.S. District Court for the Northern District of Illinois, or the Illinois case, against J&J alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J,

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**5. Commitments and Contingencies (Continued)**

for corresponding declaratory and injunctive relief, for breach of contract, and for unjust enrichment and constructive trust. The complaint alleges that the Affymax N.V. scientists are sole or co-inventors of the intellectual property in dispute, including the above-referenced J&J patents and patent applications, and that the Company is the sole or co-owner of them. The complaint also alleges that J&J breached the three-year Research and Development Agreement between Affymax N.V. and a division of Ortho Pharmaceutical Corporation, a subsidiary of J&J, or the R&D Agreement, by, among other things, engaging in a course of conduct designed to obtain patents for itself and to deny the Company patents on the Affymax scientists' inventions. The complaint further alleges that the Company has suffered damages as a result of J&J's breaches and that J&J has been unjustly enriched through its misconduct and should be subject to the imposition of a constructive trust.

J&J denied all material claims in the Company's complaint and, among other things, counterclaimed that its employees are the true inventors of the intellectual property in dispute and that it is therefore entitled to sole or co-ownership of the above-referenced patents and patent applications assigned solely or jointly to the Company. J&J also brought related claims for breach of contract, breach of fiduciary duty, unjust enrichment and constructive trust. J&J alleges, among other things, that Affymax N.V., Affymax Technologies, N.V. and Affymax Research Institute, or the Affymax Entities, filed in their own name certain patent applications allegedly claiming inventions of J&J employees without notifying or consulting with J&J, that during patent prosecution the Affymax Entities improperly removed the names of J&J employees from certain patent applications on which those employees had been identified as inventors, and that these and other alleged breaches entitle J&J to damages and waive all rights the Company may have had to the intellectual property in dispute.

J&J requested that the Illinois case be dismissed and the matter decided under the R&D Agreement's arbitration provisions. In February 2006, the Illinois court entered an order that the appropriate forum for the Company and J&J to resolve the inventorship, ownership, breach of contract and related claims was binding arbitration under the American Arbitration Association, or AAA, rules in Illinois. The Illinois court held that the claims pending in the German court were also subject to arbitration and required the Company to dismiss the German complaint, which the Company has done. The Illinois court further stated that it will retain jurisdiction over the subject matter during the arbitration in Illinois.

In April 2006, the Company filed a demand for arbitration with the AAA claiming that it is the owner or co-owner of the intellectual property in dispute and alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, for unjust enrichment and constructive trust, and for breach of fiduciary duty. In May 2006, J&J filed its answer and counterclaims, substantially restating their allegations made in the U.S. and German courts. The AAA has appointed a panel of arbitrators, and the arbitrators have established a schedule for the arbitration. The parties have commenced discovery.

In June 2007, J&J filed a motion to compel discovery of information relating to Hematide and then filed a substitute motion to compel. In July 2007, the Company filed an opposition to J&J's motion to compel and a motion for protective order. In September 2007, the arbitrators ruled that J&J can obtain limited discovery on Hematide, but that J&J cannot obtain discovery on Hematide product formulas, sequences, laboratory notebooks containing such information, experimental results, clinical trial results and strategies, or internal business planning. The arbitration hearing is scheduled to occur

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**5. Commitments and Contingencies (Continued)**

during the second half of 2009. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on the Company because of legal costs, diversion of management resources and other factors.

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

**6. Preferred Stock**

The Company's Certificate of Incorporation, as amended in February 2006, designates and authorizes 34,609,592 shares of Series A, Series B, Series C and Series D Mandatorily Redeemable Convertible Preferred Stock and 530,082 shares of Series E Redeemable Convertible Preferred Stock of which no shares are issued and outstanding as of December 31, 2008 and 2007. Series A, Series B, Series C and Series D Mandatorily Redeemable Convertible Preferred Stock and Series E Redeemable Convertible Preferred Stock hereinafter are collectively referred to as preferred stock.

In April 2006, the holders of Series A Mandatorily Redeemable Convertible Preferred Stock voluntarily elected to convert their shares of preferred stock into 848,293 shares of the Company's common stock.

In April 2006, 6,626 shares of Series C Mandatorily Redeemable Convertible Preferred Stock held by an individual automatically converted into 6,626 shares of the Company's common stock pursuant to the Company's Certificate of Incorporation which provided that such shares would automatically convert into an equal number of shares of the Company's common stock if holders do not participate in subsequent equity financings within nine months of such financing.

In connection with the closing of the Company's initial public offering in December 2006, all of the Company's shares of preferred stock outstanding at the time of the offering were automatically converted into 8,993,572 shares of the Company's common stock.

The Company's Certificate of Incorporation, as amended and restated in December 2006, designates and authorizes 10,000,000 shares of \$0.001 par value preferred stock, of which no shares are issued and outstanding as of December 31, 2008 and 2007. The rights, preferences and privileges of any preferred stock to be issued pursuant to the Company's 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, 2008.

**7. Common Stock**

The Company's Certificate of Incorporation, as amended and restated in December 2006 in connection with the closing of the Company's initial public offering, authorizes the Company to issue 100,000,000 shares of \$0.001 par value common stock.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Stock-Based Compensation**

*Equity Incentive Plans*

*2001 Stock Option/Stock Issuance Plan*

In September 2001, the Company adopted the 2001 Stock Option/Stock Issuance Plan (the “2001 Plan”). The 2001 Plan provides for both the granting of stock options and issuing shares of stock to employees and consultants of the Company. Stock options granted under the 2001 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options (“ISO”) may be granted only to Company employees. Nonqualified stock options (“NSO”) may be granted to Company employees, directors and consultants. Stock issued under the 2001 Plan may be issued to employees, directors and consultants. Stock options under the 2001 Plan may be granted for periods of up to ten years and at prices no less than the fair market value for ISOs and 85% of the fair market value for NSOs, as determined by the Board of Directors. The exercise price of an ISO or NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. To date, stock options granted generally become exercisable over four years. The Company issues new shares of common stock upon exercise of stock options.

The 2001 Plan allows for the early exercise of stock options prior to vesting. A portion of the shares sold are subject to a right of repurchase at the original issuance price by the Company, which lapses over the vesting period of the original stock option. At December 31, 2008 and 2007, a total of 1,531 and 8,233, respectively, shares were subject to repurchase by the Company.

Subsequent to the initial public offering of the Company’s common stock in December 2006, no further stock options were granted under the 2001 Plan. At the date of the initial public offering, the 7,948 shares remaining and available for future grant were cancelled.

*2006 Equity Incentive Plan*

Upon the effectiveness of the Company’s initial public offering in December 2006, the Company adopted the 2006 Equity Incentive Plan (the “2006 Plan”). Shares of common stock issuable pursuant to all then outstanding stock awards granted under the 2001 Plan remained subject to the terms of the 2001 Plan and no additional stock awards were granted pursuant to the terms of the 2001 Plan upon the effective date of the 2006 Plan.

The 2006 Plan provides for both the granting of stock awards, including stock options and restricted stock units, to employees, directors and consultants of the Company. Stock options granted under the 2006 Plan may be either ISOs or NSOs. ISOs may be granted only to Company employees. NSOs may be granted to Company employees, directors and consultants. Stock issued under the 2006 Plan may be issued to employees, directors and consultants. Stock options under the 2006 Plan may be granted for periods of up to ten years and at prices no less than the fair market value of the Company’s 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 the Company’s common stock on the date of grant. To date, stock options granted generally become exercisable over four years and do not allow for the early exercise of options prior to vesting. The terms of the restricted stock units granted by the Company to date provide for vesting and delivery of shares of common stock over three years. As of December 31, 2008 and 2007, the Company has reserved 2,600,326 and 1,919,523, respectively, shares of common stock for issuance under the 2006 Plan. The Company issues new shares of common stock upon exercise of stock options. The number of shares of common stock reserved for

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Stock-Based Compensation (Continued)**

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

*2006 Employee Stock Purchase Plan*

Upon the effectiveness of the Company's initial public offering in December 2006, the Company adopted the 2006 Employee Stock Purchase Plan (the "Purchase Plan"). As of December 31, 2008 and 2007, the Company has reserved a total of 250,035 and 174,391, respectively, shares of common stock for issuance under the Purchase Plan. The share reserve automatically increases on January 1st of each year, from January 1, 2007 through January 1, 2016, by an amount equal to the lesser of (i) 0.5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or (ii) 175,000 shares. The Company issues 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, 2008 and 2007, 71,533 and 42,228, respectively, shares of common stock were purchased under the Purchase Plan.

*Stock-Based Compensation After Adoption of SFAS No. 123(R)*

Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to the Company's employees and directors after January 1, 2006. The Company's financial statements as of and for the years ended December 31, 2008, 2007 and 2006 reflect the impact of SFAS No. 123(R). In accordance with the prospective transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

During the year ended December 31, 2008, the Company granted 222,650 and 181,625, respectively, stock options and restricted stock units to employees and directors with a weighted-average grant date fair value of \$10.61 and \$14.20 per share, respectively. During the year ended December 31, 2007, the Company granted 1,034,075 and 30,650, respectively, stock options and restricted stock units to employees and directors with a weighted-average grant date fair value of \$20.06 and \$21.74 per share, respectively. During the year ended December 31, 2006, the Company granted 842,065 stock options to employees and directors with a weighted-average grant date fair value of \$15.48 per share. As of December 31, 2008, there was unrecognized compensation cost of \$17.4 million related to these stock options and restricted stock units. The unrecognized compensation cost as of December 31, 2008 is expected to be recognized over a weighted-average amortization period of 2.04 years.

The Company estimated 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 being

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Stock-Based Compensation (Continued)**

amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee and director stock options were estimated using the following weighted-average assumptions for the years ended December 31, 2008, 2007 and 2006:

	Year Ended December 31,		
	2008	2007	2006
Expected volatility . . . . .	79%	81%	87%
Risk-free interest rate . . . . .	3.05%	4.24%	4.61%
Dividend yield . . . . .	0.00%	0.00%	0.00%
Expected term (in years) . . . . .	5.73	5.77	5.77

The expected term of stock options represents the average period the stock options are expected to remain outstanding and is based on the expected terms for industry peers as the Company 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 the Company's stock options for the years ended December 31, 2008, 2007 and 2006 was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of the Company's industry peers as the Company did not have any significant trading history for the Company's common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

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

The Company 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, 2008, 2007 and 2006 was \$7.97, \$11.82 and \$9.43 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, 2008, 2007 and 2006:

	Year Ended December 31,		
	2008	2007	2006
Expected volatility . . . . .	61% - 111%	61% - 70%	62% - 65%
Risk-free interest rate . . . . .	1.07% - 4.83%	3.73% - 4.83%	4.67% - 4.92%
Dividend yield . . . . .	0.00%	0.00%	0.00%
Expected term (in months) . . . . .	6 - 24	6 - 24	4.5 - 22.5

The Company recognized stock-based compensation expense related to employee and director stock options, restricted stock units and stock purchase rights of \$9.3 million, \$7.1 million and

**AFFYMAX, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Stock-Based Compensation (Continued)**

\$2.2 million respectively, for the years ended December 31, 2008, 2007 and 2006 under SFAS No. 123(R).

The Company recognized tax benefits related to employee stock-based compensation of \$0, \$2.1 million and \$0, respectively, for the years ended December 31, 2008, 2007 and 2006.

In addition, SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Prior to the adoption of SFAS No. 123(R), the Company accounted for forfeitures as they occurred.

**Stock Option and Restricted Stock Unit Activity**

The following table summarizes information about stock option activity for the year ended December 31, 2008:

<u>Stock Options Outstanding</u>	<u>Shares Available For Grant</u>	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price Per Share</u>	<u>Weighted-Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
<b>Balances at December 31, 2007</b> . . . . .	876,405	2,099,116	\$17.37		
Additional shares authorized . . . . .	680,803	—	—		
Options granted . . . . .	(222,650)	222,650	15.55		
Options exercised . . . . .	—	(104,287)	3.36		
Options forfeited . . . . .	72,451	(72,451)	23.72		
Options cancelled . . . . .	14,912	(14,912)	26.87		
Restricted stock units forfeited . . . . .	23,325	—	—		
Shares repurchased . . . . .	360	—	—		
<b>Balances at December 31, 2008</b> . . . . .	<u>1,445,606</u>	<u>2,130,116</u>	<u>\$17.59</u>	7.76	\$4,854,000
Options exercisable at December 31, 2008 . .		1,334,155	\$13.62	7.16	\$4,854,000

The stock options outstanding and exercisable by exercise price at December 31, 2008 are as follows:

<u>Range of Exercise Prices</u>	<u>Stock Options Outstanding</u>			<u>Stock Options Exercisable</u>	
	<u>Options Outstanding</u>	<u>Weighted-Average Remaining Contractual Life (in Years)</u>	<u>Weighted-Average Exercise Price</u>	<u>Options Exercisable</u>	<u>Weighted-Average Exercise Price</u>
\$ 0.80 - 4.36 . . . . .	688,443	6.28	\$ 2.94	688,443	\$ 2.94
10.06 - 19.92 . . . . .	459,888	8.50	17.26	260,526	18.53
21.74 - 25.91 . . . . .	547,685	8.78	23.46	169,587	23.86
30.27 - 36.43 . . . . .	434,100	8.06	33.73	215,599	33.76
	<u>2,130,116</u>			<u>1,334,155</u>	

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Stock-Based Compensation (Continued)**

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at December 31, 2008. The total intrinsic value of stock options exercised was \$1.5 million, \$5.3 million and \$4.1 million during the years ended December 31, 2008, 2007 and 2006, respectively, and was determined at the date of each stock option exercise.

The following table summarizes information about restricted stock unit activity for the year ended December 31, 2008:

<u>Restricted Stock Units Outstanding</u>	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price Per Share</u>	<u>Weighted-Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
<b>Nonvested shares at December 31, 2007</b> . . . . .	30,650	\$ 21.74		
Restricted stock units granted . . . . .	181,625	14.20		
Restricted stock units forfeited . . . . .	<u>(23,325)</u>	<u>(18.12)</u>		
<b>Nonvested shares at December 31, 2008</b> . . . . .	<u>188,950</u>	<u>\$ 14.94</u>	2.27	\$1,878,000

The aggregate intrinsic value is calculated as the difference between the grant date fair value of the restricted stock units and the fair value of the Company's common stock for restricted stock units that were in-the-money at December 31, 2008.

***Deferred Stock-Based Compensation***

In September 2003, the Company 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, 2008, the fair value of the common stock was \$9.99 per share and approximately 32,000 repriced stock options remained outstanding. During the years ended December 31, 2008, 2007 and 2006, the Company has recorded deferred stock-based compensation/(benefit) related to these stock options of \$(402,000), \$(445,000) and \$1.3 million, respectively, and recorded stock-based compensation expense/(benefit) of \$(402,000), \$(445,000) and \$1.9 million, respectively. During the year ended December 31, 2006, the Company reversed deferred stock-based compensation related to year ended December 31, 2005 of \$2.1 million and reversed amortization of deferred stock-based compensation of \$2.4 million.

During the year ended December 31, 2005 the Company issued stock options to certain employees under the Plan with exercise prices below the fair value of the Company's common stock at the date of grant. The Company estimated the fair value of its common stock based upon several factors, including progress and milestones attained in its business. In accordance with the requirements of APB No. 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock option and the fair value of the Company's stock at the date of grant. This deferred stock-based compensation is amortized to expense on a straight-line basis over the period during which the options vest, generally four years. During the year ended December 31, 2005, the Company has recorded deferred stock-based compensation related to these stock options of \$195,000, net of cancellations, and recorded amortization of such deferred stock-based compensation of \$24,000, \$32,000 and \$43,000, respectively, during the years ended December 31, 2008, 2007 and 2006.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Stock-Based Compensation (Continued)**

*Warrants*

In connection with an equipment lease agreement, the Company issued a warrant in January 2005 to purchase 1,987 shares of Series C Mandatorily Redeemable Convertible Preferred Stock at an exercise price of \$15.09 per share to the lessor. The warrant remains outstanding and expires in January 2012. Upon completion of the Company's initial public offering in December 2006, the warrant became exercisable for 1,987 shares of common stock. The fair value of the warrant of \$56,000 was recorded as interest expense during the year ended December 31, 2006.

In connection with the sale of Series D Mandatorily Redeemable Convertible Preferred Stock in July 2005, the Company issued warrants to purchase 383,097 shares of common stock at a price of \$17.00 per share to certain investors and a warrant to purchase 55,079 shares of common stock at a price of \$4.56 per share to an investment bank. The Company issued 240,561 shares of its common stock in December 2006 upon the net and cash exercise of these outstanding warrants.

*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. The Company believes 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 the Company's common stock fluctuates over the period from the grant date to the vesting date. The Company has recorded nonemployee stock-based compensation expense of \$671,000, \$159,000 and \$346,000 for the years ended December 31, 2008, 2007 and 2006.

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

The Company has entered into two separate collaboration agreements with Takeda, which have been combined for accounting purposes due to their proximity of negotiation. Consideration from these collaboration agreements includes nonrefundable upfront license fees, reimbursement for sales of active pharmaceutical ingredients, clinical and regulatory milestone payments, reimbursement of third party U.S. clinical development expenses, product profit share revenues (as co-promotion revenues) and royalties.

In February 2006, the Company issued an exclusive license to Takeda for development and commercialization of Hematide in Japan. Pursuant to this agreement, Takeda paid the Company approximately \$27 million, consisting of \$17 million in upfront licensing fees and approximately \$10 million for the purchase of 530,082 shares of the Company's Series E Redeemable Convertible Preferred Stock at a price of \$18.86 per share. In addition, the Company is eligible to receive clinical and regulatory milestone payments of up to an aggregate of \$75 million upon Takeda's successful achievement of clinical development and regulatory milestones in Japan. Takeda is responsible for all development and commercialization costs in Japan and will purchase the API for Hematide from the Company. Assuming Hematide is approved and launched in Japan, the Company will receive a royalty from Takeda on Hematide sales in Japan.

In June 2006, the parties expanded their collaboration to develop and commercialize Hematide worldwide, which includes the co-development and co-commercialization of Hematide in the U.S.

## AFFYMAX, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

#### 9. Development and Commercialization Agreements with Takeda (Continued)

Takeda received an exclusive license to develop and commercialize Hematide outside of the U.S. Beginning January 1, 2007, Takeda was responsible for the first \$50 million of third party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Of the first \$50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of \$36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda will bear 70% of the third party U.S. development expenses, while the Company will be responsible for 30% of the expenses. The Company retains responsibility for 100% of its internal development expenses. Under the June 2006 agreement, Takeda paid the Company an upfront license fee of \$105 million, and the Company is eligible to receive from Takeda up to an aggregate of \$280 million upon the successful achievement of clinical development and regulatory milestones, the majority of which relate to the renal program, including milestone payments upon completion of database lock of the Phase 3 clinical trials of \$15 million for dialysis and \$15 million for pre-dialysis, \$20 million milestone payments upon FDA acceptance of the submission of the new drug application, or NDA, and \$95 million of milestone payments upon approval by the FDA in dialysis and pre-dialysis indications. Further, the Company may receive from Takeda up to an aggregate of \$150 million upon the achievement of certain worldwide annual net sales milestones. The Company and Takeda will share equally in the net profits and losses of Hematide in the United States, which include expenses related to the marketing and launch of Hematide. Takeda will pay the Company a variable royalty based on annual net sales of Hematide outside the United States. The agreement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of Hematide.

The Company will share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of Hematide. Specifically, the Company has primary responsibility for Hematide's clinical development plan and clinical trials in the dialysis and pre-dialysis indications, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the extent any such indication is developed. The Company is responsible for United States regulatory filings in the dialysis, pre-dialysis, chemotherapy induced anemia and anemia of cancer indications, including holding the NDAs for those indications. Takeda is responsible for regulatory filings outside the United States and the creation of a global safety database.

The Company is also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of Hematide worldwide. Takeda is responsible for the fill and finish steps in the manufacture of Hematide worldwide.

The parties have agreed to jointly develop the initial commercial marketing plan for Hematide in the United States pursuant to which the Company and Takeda will divide Hematide promotional responsibilities in the U.S. The Company and Takeda will jointly decide on promotional responsibility for markets outside of these initial indications.

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

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**9. Development and Commercialization Agreements with Takeda (Continued)**

The Company has recognized \$82.2 million of revenue under the Contingency-Adjusted Performance Model during the year ended December 31, 2008, which includes a \$1.4 million cumulative adjustment resulting from an amendment to the Arrangement with Takeda that was effective on January 1, 2008. The Company has recognized \$44.3 million and \$11.7 million, respectively, of revenue under the Arrangement with Takeda using the zero profit proportional performance model during the years ended December 31, 2007 and 2006. In December 2006, Takeda completed a Phase 1 trial of Hematide in Japan resulting in the payment in January 2007 to the Company of a \$10 million milestone under the collaboration, which was recorded as a receivable from Takeda and deferred revenue at December 31, 2006. As of December 31, 2008 and 2007, the amount receivable from Takeda was \$21.7 million and \$15.3 million, respectively, which was recorded as a receivable from Takeda.

In July 2006, the Company paid Nektar Therapeutics AL Corporation a \$17.6 million milestone payment in connection with a license agreement related to Hematide. The payment was triggered by the collaboration agreements signed with Takeda in February and June 2006. The \$17.6 million payment was recorded as research and development expenses during the year ended December 31, 2006 as technological feasibility for Hematide had not been established and there was no alternative future use.

**10. Income Taxes**

The components of the provision for income taxes are as follows:

	Year Ended December 31,		
	2008	2007	2006
	(in thousands)		
Provision for income taxes:			
Current provision for income taxes:			
Federal	\$(2,950)	\$ 13,100	\$ —
State	390	2,339	—
Total current provision for income taxes	(2,560)	15,439	—
Deferred tax benefit:			
Federal	2,842	(10,082)	—
State	—	—	—
Total deferred tax benefit	2,842	(10,082)	—
Provision for income taxes	\$ 282	\$ 5,357	\$ —

The Company is subject to federal and California state income tax. The Company recorded a provision for income taxes for the years ended December 31, 2008 and 2007. The Company was in a net operating loss in 2006 and all prior periods and therefore did not record a provision for income tax for the year ended December 31, 2006.

The Company recorded a provision for income taxes for the year ended December 31, 2008 of \$282,000 consisting of \$107,000 of federal tax benefit and \$389,000 of net California state income tax expense. The \$107,000 of federal tax benefit was primarily due to a research and development credits refund available to the Company pursuant to a provision within the Housing Assistance Tax Act of 2008, which was signed into law in July 2008. The California state income tax expense of \$389,000 was

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**10. Income Taxes (Continued)**

primarily related to an out of period reduction to the Company's California research and development credits that was partially offset by additional California research and development credits that were identified.

The Company recorded a provision for income taxes for the year ended December 31, 2007 of \$5.4 million consisting of \$15.4 million of current income taxes net of a \$10.0 million of deferred tax benefit. The current income taxes of \$15.4 million resulted primarily from the inclusion in 2007 taxable income of \$120.3 million of the upfront license fees received from Takeda during 2006 that, for tax purposes, were deferred in 2006 and recognized in 2007 and resulted in U.S. federal and state taxable income for the year ended December 31, 2007. The upfront license fees from Takeda were recorded as deferred revenue for financial reporting purposes and are being recognized as revenue over a period of approximately 4.5 years, as more fully described in Note 2. The \$10.0 million net deferred tax benefit, and the related net deferred tax asset as of December 31, 2007 in the same amount, were recorded to reflect the Company's ability to carry back tax losses generated in 2008 and 2009 as a result of certain reversing tax deductible temporary differences from December 31, 2007. The Company intends to carry back its 2008 federal taxable loss to reduce its 2007 federal income tax liability to the alternative minimum income tax liability as determined under the current enacted U.S. federal income tax statutes.

The Company considered the following positive and negative factors in determining that it was more likely than not that \$10.0 million of net deferred tax asset as of December 31, 2007 would be realized:

- Net deductible temporary differences that were expected to reverse in 2008 and 2009 and that the Company would generate losses in those years that could be carried back to reduce the 2007 federal income tax liability.
- There were no relevant tax strategies available that the Company would consider feasible.
- Uncertainties, such as regulatory approval of Hematide and binding arbitration and litigation with certain subsidiaries of Johnson & Johnson, that if unfavorably resolved, would adversely affect the Company's future operations.
- The Company has incurred significant operating losses since its inception and anticipates that it will incur continued losses for the foreseeable future, and therefore the net deferred tax assets were limited to the amount available to be realized with the carry back enumerated above.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**10. Income Taxes (Continued)**

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2008	2007	2006
		(in percent)	
Federal statutory income tax rate . . . . .	(35.00)%	(35.00)%	(34.00)%
State income taxes, net of federal benefit . . . . .	0.45	4.43	(5.83)
Stock-based compensation expense . . . . .	1.40	1.72	0.61
Change in valuation allowance . . . . .	34.57	48.50	43.02
Change in federal rates and prior year true ups . .	0.51	(4.56)	0.31
Permanent differences true ups . . . . .	0.05	0.11	0.06
Tax credits . . . . .	(1.66)	(1.04)	(4.20)
Other . . . . .	—	0.05	0.03
Provision for income taxes . . . . .	<u>0.32%</u>	<u>14.21%</u>	<u>0.00%</u>

Deferred tax assets consist of the following:

	December 31,	
	2008	2007
	(in thousands)	
Net operating loss carryforwards . . . . .	\$ 40,533	\$ 8,346
Federal and State credit carryforwards . . . . .	8,691	5,093
Depreciation and amortization . . . . .	28,003	31,709
Capitalized start up costs . . . . .	5,302	7,213
Accrued liabilities and allowances . . . . .	52,144	51,179
Gross deferred tax assets . . . . .	134,673	103,540
Deferred tax liability . . . . .	(440)	(114)
Net deferred tax asset . . . . .	134,233	103,426
Less: Valuation allowance . . . . .	(126,993)	(93,344)
Net deferred tax assets . . . . .	<u>\$ 7,240</u>	<u>\$ 10,082</u>

At December 31, 2008, the Company had federal and state net operating loss carryforwards of \$80.0 million and \$116.1 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, 2008, the Company had federal and state research credit carryforwards of \$4.7 million and \$4.1 million, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2021. The California credit can be carried forward indefinitely.

The Company experienced an ownership change as defined by Sections 382 and 383 of the Internal Revenue Code which establishes an annual limit on the deductibility of pre-ownership change net operating loss and credit carryforwards that existed on December 15, 2006.

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

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**10. Income Taxes (Continued)**

recognized. The ultimate realization of deferred tax assets is dependent upon the Company's 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.

As of December 31, 2008, the Company recorded a net deferred tax asset of \$7.2 million in consideration of a FIN 48 liability recorded for the same amount. As of December 31, 2007, the Company recorded \$10.0 million of deferred tax assets to reflect the Company's ability to carry back tax losses generated in 2008 and 2009 as a result of certain reversing tax deductible temporary differences from December 31, 2007.

The valuation allowance increased \$33.6 million, \$22.6 million and \$20.8 million during the years ended December 31, 2008, 2007 and 2006.

Effective January 1, 2007, the Company adopted the provisions of FIN 48, which prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. The Company had \$11.8 million and \$10.7 million, respectively, of unrecognized tax benefits as of December 31, 2008 and 2007.

As of December 31, 2008, \$2.3 million of the unrecognized tax benefits would affect the Company's income tax provision and effective tax rate if recognized. However, as the Company would currently need to increase its valuation allowance for any additional amounts benefited, the effective tax rate would not be impacted until the valuation allowance was removed.

As of December 31, 2008 and 2007, the Company's FIN 48 liability for uncertain income tax positions was \$9.6 million and \$9.4 million, respectively, which was reflected as long-term income tax liabilities on its balance sheet. The Company adopted a policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. For the year ended December 31, 2008, the Company recognized \$596,000 of interest expense related to the \$9.6 million FIN 48 liability for uncertain income tax positions as of December 31, 2008. For the years ended December 31, 2007 and 2006, no interest expense related to uncertain income tax positions were required or recognized. For the years ended December 31, 2008, 2007 and 2006, \$81,000, \$0 and \$0, respectively, of penalties related to uncertain income tax positions were required and recognized. The Company does not anticipate that any of the unrecognized tax benefits will increase or decrease significantly over the next twelve months.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**10. Income Taxes (Continued)**

A reconciliation of the unrecognized tax benefits for the years ended December 31, 2008 and 2007 is as follows:

	December 31,	
	2008	2007
	(in thousands)	
Balance at beginning of year . . . . .	\$10,708	\$ 2,000
Additions for current year tax positions . . . . .	—	9,420
Additions for prior year tax positions . . . . .	1,438	—
Reductions for prior year tax positions . . . . .	(376)	(712)
Balance at end of year . . . . .	\$11,770	\$10,708

The Company is subject to federal and California state income tax. As of December 31, 2008, the Company's federal returns for the years ended 2005 through the current period and state returns for the years ended 2004 through the current period are still open to examination. Net operating losses and research and development credit carryforwards used in 2007 will be open for examination until 2011 and 2012 for federal and state purposes, respectively. Any remaining net operating losses and research and development carryforwards that may be used in future years are still subject to inquiry given that the statute of limitation for these items would be from the year of the utilization. There are no tax years under examination by any jurisdiction at this time.

**11. Retirement Savings Plan**

The Company has 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, the Company-paid match is 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 Company-paid match. The Company's contributions to the 401(k) plan were \$423,000, \$0 and \$0 for the years ended December 31, 2008, 2007 and 2006, respectively.

**12. Subsequent Event**

In March 2009, institutional investors purchased \$42.0 million of the Company's common stock in a private placement. Under the terms of one of two purchase agreements, the Company sold 2,844,708 newly issued shares of its common stock at a purchase price of \$11.25 per share. In the other purchase agreement, the Company sold 652,262 newly issued units at a purchase price of \$15.33 per unit, with each unit consisting of one share of common stock and one warrant to purchase 0.65 of a share of common stock. The warrants are immediately exercisable at \$16.78 per share and will expire five years from the date of issuance. The net proceeds are estimated to be approximately \$41.6 million after offering expenses.

**AFFYMAX, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**13. Quarterly Financial Data (unaudited)**

The following tables summarize the unaudited quarterly financial data for the last two fiscal years.

	<b>2008 Quarter Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
	(in thousands, except per share data)			
Collaboration revenue . . . . .	\$ 16,708	\$ 18,450	\$ 21,645	\$ 25,359
Total revenue . . . . .	16,714	19,131	21,648	25,358
Loss from operations . . . . .	(16,190)	(19,609)	(26,440)	(26,492)
Net loss attributable to common stockholders . . . . .	(15,581)	(18,915)	(26,211)	(25,803)
Basic and diluted net loss per common share . . . . .	\$ (1.03)	\$ (1.24)	\$ (1.72)	\$ (1.69)
Weighted-average number of common shares used in computing basic and diluted net loss per common share calculations . . . . .	15,148	15,197	15,235	15,299
	<b>2007 Quarter Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
	(in thousands, except per share data)			
Collaboration revenue . . . . .	\$ 7,318	\$ 9,654	\$ 10,487	\$ 16,844
Total revenue . . . . .	7,324	9,669	10,494	16,849
Loss from operations . . . . .	(9,866)	(11,256)	(13,882)	(14,133)
Net loss attributable to common stockholders . . . . .	(7,171)	(9,248)	(12,706)	(13,944)
Basic and diluted net loss per common share . . . . .	\$ (0.48)	\$ (0.62)	\$ (0.85)	\$ (0.92)
Weighted-average number of common shares used in computing basic and diluted net loss per common share calculations . . . . .	14,860	14,879	14,920	15,100

**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 (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, 2008, our disclosure controls and procedures were effective.

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’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, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control—Integrated Framework. Our management has concluded that, as of December 31, 2008, our internal control over financial reporting was effective based on these criteria.

*Remediation of Prior Material Weakness*

As of December 31, 2008, management believes that the material weakness in our internal control over financial reporting that was included in Item 4 of our Form 10-Q for the quarter ended June 30, 2008 has been effectively remediated. Prior to the quarter ended December 31, 2008, the remediation measures as described below were implemented.

We have taken appropriate actions to remediate the material weakness related to our internal controls over the completeness and accuracy of our clinical trial expense. Our remediation plan included validation and reconciliation of the clinical trial expense and accruals on a study by study basis using data provided by third parties and detailed budget versus actual expense by individual trial. In addition, we retained additional finance resource and enhanced our reporting systems and procedures to provide greater and consistent oversight in the preparation of clinical trial expense.

Ernst & Young LLP, an independent registered public accounting firm, has audited our financial statements included herein and has issued an 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  
Affymax, Inc.

We have audited Affymax Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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 appearing under Item 9A. 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, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the have audited the accompanying balance sheet as of December 31, 2008, and the related statements of operations, stockholders' equity, and cash flows for the year then ended of Affymax, Inc. and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, CA  
March 12, 2009

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control 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 because we intend to file our definitive proxy statement for our 2009 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

#### **Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item with respect to our executive officers may be found under the caption, “Executive Officers and Key Employees” appearing in our proxy statement for our 2009 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 2009 annual meeting of stockholders and is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Securities Exchange Act may be found under the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” appearing in our proxy statement for our 2009 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](http://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 is included in our proxy statement for our 2009 annual meeting of stockholders under the section entitled “Executive Compensation” 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 2009 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 2009 annual meeting of stockholders under the section entitled “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

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

The information required by this item is incorporated herein by reference to the information included in our proxy statement for our 2009 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 Accounting Fees and Services.**

The information required by this item is incorporated herein by reference to the information included in our proxy statement for our 2009 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
- Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
- Balance Sheets
- Statements of Operations
- Statements of Stockholders' Equity
- Statements of Cash Flows
- Notes to Financial Statements

(2) Financial Statement Schedules

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

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

- 3.3 Amended and Restated Certificate of Incorporation(1)
- 3.5 Amended and Restated Bylaws(2)
- 4.1 Reference is made to exhibits 3.3 and 3.5
- 4.2 Specimen Common Stock Certificate(1)
- 4.3 Warrant to purchase shares of Series C Preferred Stock(1)
- 4.4 Amended and Restated Investor Rights Agreement, dated September 7, 2006, by and between the Registrant and certain of its stockholders(1)
- 4.5 Form of Warrant to Purchase shares of Common Stock(6)
- 10.1+ Form of Indemnity Agreement for Directors and Executive Officers(1)
- 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(1)
- 10.4+ Form of Stock Issuance Agreement under 2001 Stock Option/Stock Issuance Agreement(1)
- 10.5+ 2006 Equity Incentive Plan(1)
- 10.6+ Form of Option Grant Notice and Form of Option Agreement under 2006 Equity Incentive Plan(1)
- 10.7+ 2006 Employee Stock Purchase Plan(1)
- 10.8+ Form of Offering Document under 2006 Employee Stock Purchase Plan(1)
- 10.9+ Form of Restricted Stock Unit Notice and Form of Restricted Stock Unit under 2006 Equity Incentive Plan(5)

- 10.10+ Employment Agreement, dated December 17, 2008, by and between the Registrant and Arlene M. Morris
- 10.11+ Executive Employment Agreement, dated December 17, 2008, by and between the Registrant and Paul B. Cleveland
- 10.12+ Executive Employment Agreement, dated December 17, 2008, by and between the Registrant and Steven Love
- 10.13+ Summary of Non-Employee Director Compensation Program
- 10.14 Research and Development/Office Lease, dated May 30, 1990, by and between Miranda Associates and Affymax Research Institute(1)
- 10.15 First Amendment to Lease, dated November 16, 1999, by and between Spieker Properties, L.P., successor in interest to Miranda Associates, and Affymax Research Institute(1)
- 10.16 Second Amendment to Lease, dated December 20, 1999, by and between Spieker Properties, L.P. and Affymax Research Institute(1)
- 10.17 Third Amendment, dated December 31, 2001, by and between EOP-Foothill Research Center, L.L.C., successor by merger to Spieker Properties L.P., and the Registrant(1)
- 10.18\* EPO Receptor License Agreement, dated September 5, 1996, by and between the Registrant and Genetics Institute, Inc.(1)
- 10.19 License Agreement (Therapeutic Products), dated June 28, 1996, by and between the Registrant, Dyax Corp. and Protein Engineering Corporation(1)
- 10.20 License Agreement, dated July 25, 2001, by and between the Registrant and Dyax Corp.(1)
- 10.21\* 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.(1)
- 10.22\* License Agreement, dated August 13, 2001, by and between the Registrant and XOMA Ireland Limited(1)
- 10.23\* License, Manufacturing, and Supply Agreement, dated April 8, 2004, by and between the Registrant and Nektar Therapeutics AL, Corporation(1)
- 10.24\* Collaboration and License Agreement, dated February 13, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(1)
- 10.25\* Collaboration and License Agreement, dated June 27, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(1)
- 10.26 Research and Development Agreement, dated April 2, 1992, by and between the Registrant and The R.W. Johnson Pharmaceutical Research Institute(1)
- 10.27 Sublease Agreement, dated September 1, 2006, by and between the Registrant and TIBCO Software Inc.(1)
- 10.28 First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between Registrant and Takeda Pharmaceutical Company Limited (3)
- 10.29 Fourth Amendment to Lease, dated November 30, 2006, by and between Registrant and CA-Foothill Research Center L.P. (4)

- 10.30 Second Amendment to Collaboration and License Agreements between Registrant and Takeda Pharmaceutical Company Limited effective January 1, 2008(5)
- 10.31 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(6)
- 10.32 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(6)
- 10.33+ Executive Employment Agreement, dated December 17, 2008 by and between the Registrant and Anne-Marie Duliege
- 10.34+ Executive Employment Agreement, dated December 17, 2008 by and between the Registrant and Robert Venteicher
- 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
- 23.2 Consent of PricewaterhouseCoopers 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)

- 
- (1) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, registration no. 333-136125, declared effective by the Securities and Exchange Commission on December 14, 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 Form 10-Q for the quarter ended June 30, 2007 as filed with the Securities and Exchange Commission.
  - (4) Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission.
  - (5) Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission.
  - (6) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

+ 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.



<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ /s/ R. LEE DOUGLAS R. Lee Douglas	Member of the Board of Directors	March 12, 2009
_____ /s/ KATHLEEN LAPORTE Kathleen LaPorte	Member of the Board of Directors	March 12, 2009
_____ /s/ KEITH R. LEONARD Keith R. Leonard	Member of the Board of Directors	March 12, 2009
_____ /s/ TED W. LOVE Ted W. Love	Member of the Board of Directors	March 12, 2009
_____ /s/ DAN SPIEGELMAN Dan Spiegelman	Member of the Board of Directors	March 12, 2009
_____ /s/ CHRISTI VAN HECK Christi van Heck	Member of the Board of Directors	March 12, 2009
_____ /s/ JOHN P. WALKER John P. Walker	Member of the Board of Directors	March 12, 2009

## EXHIBIT INDEX

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<hr/>	
(1)	Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, registration no. 333-136125, declared effective by the Securities and Exchange Commission on December 14, 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 Form 10-Q for the quarter ended June 30, 2007 as filed with the Securities and Exchange Commission.
(4)	Incorporated by reference to the indicated exhibit in our Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission.
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(6)	Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.
+	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.

**CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements Form S-8 (Nos. 333-139810, 333-149773) pertaining to the 2001 Stock Option/Stock Issuance Plan, 2006 Equity Incentive Plan, 2006 Employee Stock Purchase Plan of Affymax, Inc. and the Registration Statement on Form S-3 No. 333-149772 of Affymax, Inc. and in the related Prospectuses of our reports dated March 12, 2009, with respect to the financial statements of Affymax, Inc., and the effectiveness of internal control over financial reporting of Affymax, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 12, 2009

**CONSENT OF PRICEWATERHOUSECOOPERS LLP,  
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-149772) and Form S-8 (Nos. 333-139810 and 333-149773) of Affymax, Inc. of our report dated March 12, 2008 relating to the financial statements, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP  
San Jose, California  
March 12, 2009

**CERTIFICATION**

I, Arlene M. Morris, certify that:

1. I have reviewed this Annual Report on Form 10-K of Affymax, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, 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.
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ ARLENE M. MORRIS  
*President, Chief Executive Officer  
and Member of the Board of  
Directors (Principal Executive Officer)*

Date: March 12, 2009

## CERTIFICATION

I, Paul B. Cleveland, certify that:

1. I have reviewed this Annual Report on Form 10-K of Affymax, Inc. ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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.
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ PAUL B. CLEVELAND

*Executive Vice President Corporate  
Development and  
Chief Financial Officer  
(Principal Financial Officer)*

Date: March 12, 2009

**CERTIFICATION**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 Arlene M. Morris, President and Chief Executive Officer and Director, and Paul B. Cleveland, Executive Vice President, Corporate Development and Chief Financial Officer, of Affymax, Inc. (the "Company"), hereby certify that to the best of our knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and to which this certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and
2. The information contained in this Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ ARLENE M. MORRIS

*President,  
Chief Executive Officer and  
Director  
(Principal Executive Officer)*

By: /s/ PAUL B. CLEVELAND

*Executive Vice President Corporate  
Development and  
Chief Financial Officer  
(Principal Financial Officer)*

Date: March 12, 2009

This certification accompanies the Form 10-K to which it relates, 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 the Form 10-K), irrespective of any general incorporation language contained in such filing.