AFFYMAX INC
Form 10-K
April 02, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006

or

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

Commission File Number 001-33213

AFFYMAX, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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 x No o

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

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer x

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

The initial public offering of Affymax, Inc. s Common Stock, par value $0.001 per share, commenced on December 15, 2006. There was no public market for the Company s Common Stock prior to that date.

As of February 28, 2007, the registrant had outstanding 14,878,740 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Proxy Statement for the 2007 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, 2006, 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
TABLE OF CONTENTS

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 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. 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 lead product candidate, Hematide , is designed to treat anemia associated with chronic kidney disease and cancer. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic kidney disease, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may increase the risk of other diseases or death. A major cause of anemia is insufficient production of, or insufficient response to, erythropoietin, or EPO, a naturally occurring hormone that stimulates the production of red blood cells. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Hematide is designed to be less frequently dosed than currently marketed ESAs, and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers. We are currently conducting Phase 2 clinical trials in patients suffering from end-stage renal disease who are on dialysis, as well as in earlier stage chronic kidney disease patients, or predialysis patients. We have had preliminary discussions with the Food and Drug Administration, or FDA, regarding Phase 3 clinical trials in both dialysis and predialysis patients. Based on those discussions, we believe that our clinical, preclinical and manufacturing work is sufficient to proceed to Phase 3 clinical trials and we are continuing discussions with the FDA relating to the design of these trials. Assuming timely conclusion of the discussions with the FDA, we would expect to commence separate Phase 3 trials in both dialysis and predialysis patients during the second half of 2007**.** In oncology supportive care, we have initiated a Phase 2 clinical trial evaluating Hematide in cancer patients who suffer from anemia as a consequence of their chemotherapy treatment. We are also building a proprietary pipeline of other novel drug candidates which are designed to offer advantages over first generation recombinant protein therapeutics currently addressing large markets.

According to IMS Health Incorporated, recombinant EPO, or rEPO, generated $13 billion in worldwide revenues for 12 months ended June 2006, of which we believe approximately $9 billion was generated in the U.S. Of this $9 billion, we estimate that approximately $3 billion is attributable to use of rEPO in patients on dialysis, and the remaining $6 billion is attributable to other indications, including

oncology and use in predialysis patients. Despite the success of rEPO, we believe that worldwide markets for predialysis and cancer are underserved. Currently marketed rEPO is typically given up to three times per week to dialysis patients, and every one to three weeks to oncology patients. We believe the requirement for relatively frequent dosing has historically limited the use of these ESAs in predialysis and oncology treatment settings and that Hematide, with less frequent dosing, has the potential to expand these markets. While the dialysis market is currently well penetrated, we believe Hematide has the potential to offer reduced operational cost and complexity for healthcare providers compared to currently marketed ESAs.

In February and June 2006, we entered into two separate agreements with Takeda Pharmaceutical Company Limited, or 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 bears the first $50 million of third party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Thereafter, Takeda will bear 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. We are eligible to receive additional payments from Takeda of up to a total of $345 million upon the successful achievement of clinical development and regulatory milestones. 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.

In addition to our lead program, we are using our discovery platform to develop a pipeline of peptide based drug candidates. We are currently advancing research on Adeptide , a peptide based, non-injectable ESA. Our Innotide program is evaluating a family of peptide based drug candidates that show early positive results in the area of tissue protection in preclinical models of stroke, myocardial infarct, and renal injury. In addition, we have a preclinical research collaboration with EntreMed, Inc. on Angiotide , a novel synthetic peptide that may be useful in treating cancer by blocking angiogenesis, or blood vessel formation in tumors.

Our Lead Product Candidate: Hematide

Hematide is a synthetic peptide-based ESA designed for less frequent dosing. It is currently in Phase 2 clinical trials and is being developed for treatment of anemia associated with end-stage renal disease, predialysis chronic kidney disease and cancer. In clinical trials in both healthy volunteers and patients, Hematide has demonstrated the ability to stimulate the production of red blood cells. In vivo studies have also demonstrated that Hematide dosing can be less frequent compared to rEPOs currently on the market. The primary toxicology observed to date has been associated with the exaggerated red blood cell production seen at high and frequent doses, a result similar to that observed with the rEPO class of drugs. To date, over 400 patients have received Hematide in ongoing clinical studies. The type and frequency of adverse events including serious adverse events associated with Hematide in these clinical trials are similar to those events that have been reported for currently marketed ESAs in studies targeting similar hemoglobin levels. 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 progenitor cells, known as stem cells, and 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 kidney disease, or treatments such as chemotherapy, that result in underproduction of EPO or a muted response to EPO.

Anemia generally exists in men when the hemoglobin level in blood, which is a measure of red blood cells, is less than 12 g/dL, or the hematocrit, which is a ratio of the volume packed red blood cells to the volume of whole blood, is less than 37%, and in women when hemoglobin is less than 11 g/dL or hematocrit is less than 33%. The FDA, the medical community and others have 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 a hemoglobin of greater than 12 g/dL.

Anemia associated with Chronic Kidney Disease. One of the most common forms of chronic anemia is that which occurs in patients with chronic kidney disease. According to the American Journal of Kidney Disease, chronic kidney disease affects as many as 19 million Americans. As kidney function deteriorates due to the underlying disease, the ability of the kidney to produce adequate EPO is impaired, resulting in decreased production of new red blood cells and anemia.

Over time, chronic kidney disease usually progresses to irreversible end-stage renal disease, the most severe stage of the disease. End-stage renal disease patients require either lifetime dependence on renal dialysis, a medical procedure in which blood is cleansed of impurities, or a kidney transplant. Patients with end-stage renal disease are nearly always moderately to severely anemic unless treated with an ESA like rEPO. According to the Centers for Medicare and Medicaid Services, or CMS, there are approximately 320,000 end-stage renal disease patients on dialysis in the U.S. served by approximately 4,700 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. IMS Health estimates that the U.S. sales of EPOGEN, the dominant therapy for anemia in dialysis patients, totaled $2.9 billion for the 12 months ended June 2006.

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 predialysis, 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 predialysis patient office visits, we believe that the predialysis 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. 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. Severe fatigue associated with anemia affects approximately three-fourths of all cancer patients undergoing chemotherapy. In some cancer patients, such as those with multiple myeloma and acute leukemia, the underlying cancer itself causes anemia. In these patients, the production of and responsiveness to EPO is believed to be reduced by molecules known as cytokines that are produced by or in response to tumors. An oncologist s ability to treat a patient s cancer is often limited by the patient s ability to tolerate the side effects, including anemia, of highly toxic courses of chemotherapy. Better management of chemotherapy induced anemia could lead to better dose optimization of chemotherapy in cancer patients.

The FDA has recently issued a public health advisory re-evaluating the safe use of the ESA class and is scheduled to convene its Oncology Drugs Advisory Committee (ODAC) in May 2007 to consider the mechanism of action of ESAs and to review the effects of ESAs on survival and tumor progression in cancer patients. Use of ESAs has been associated with shortened time to tumor progression in certain patients with advanced head and neck cancer. Increased risk of death has been reported when ESAs are administered to target a hemoglobin of 12 g/dL in patients with active malignant disease receiving neither chemotherapy nor radiation therapy, a population for which ESAs are not approved or indicated.

Based on our marketing research, there are approximately 3 million actively treated cancer patients in the U.S. Of those patients, roughly 1.2 million undergo chemotherapy to treat their cancer. About 65% of chemotherapy patients become anemic, with 47% of those receiving ESA therapy. Further, based on the January to June 2005 Tandem cancer audit, over 90% of chemotherapy patients receive chemotherapy treatment in three or four week cycles or less frequently, yet the most prevalent dosing intervals of current ESAs for cancer patients are every one to two weeks. We believe that a less frequent, more convenient dosing regimen, every three to four weeks to coincide with chemotherapy, may increase market penetration and expand use of ESAs for oncology patients.

Anemia associated with Other Conditions. 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 kidney disease and cancer, but are not currently testing Hematide s effectiveness in treating anemia in other conditions.

Current Therapy and Limitations

According to IMS Health, rEPO generated $13 billion in worldwide revenue for the 12 months ended June 2006, of which approximately $9 billion was generated in the U.S. Of the $9 billion in U.S. revenue, we estimate that $3 billion is attributable to use for dialysis patients, and the remaining $6 billion is attributable to other indications, including use in oncology and predialysis patients. ESAs, in the form of rEPO variants, have been used successfully to manage the anemia of dialysis, predialysis 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. To date, the therapeutic options have not progressed significantly beyond the relatively short-acting and inconvenient recombinant protein products currently on the market. Further, the majority of products in development are variations of the existing products on the market.

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. 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 predialysis, 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 predialysis chronic kidney disease 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 predialysis and oncology treatment settings and that, with its longer acting profile, Hematide has the potential to expand these markets. In the oncology setting, anemia management often involves administration of ESAs more frequently than typical chemotherapy regimens, which usually require treatment every three to four weeks. Although existing ESAs are sometimes given in larger doses in an effort to achieve extended dosing, and despite studies by the manufacturers of these ESAs aimed at extending the dose interval of these products, medical record audit data and oncologist survey response indicate that existing ESAs are still administered to chemotherapy patients once a week to once every two weeks on average. In addition, recent studies by manufacturers of ESAs indicate that the higher levels of hemoglobin associated with larger and more frequent doses result in a statistically significant increase in cardiovascular events. For these reasons, we believe that an ESA designed for every four weeks administration could expand the market opportunity for anemia management therapies in the oncology setting.

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 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 in dialysis, predialysis, PRCA and cancer patients. 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, we have designed Hematide to require less frequent dosing than currently marketed ESAs. We believe that Hematide s properties are superior to the properties of rEPO drugs currently on the market, particularly in terms of required frequency of administration. As a long-acting ESA, we believe that Hematide may overcome many of the patient care limitations of currently marketed rEPOs. We believe that flexibility of dosing based on duration of effect will 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 animal models 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 have any apparent effect on clinical response to the drug.

Hematide Development Program

We are currently conducting multiple Phase 2 clinical trials of Hematide in patients with chronic anemia due to chronic kidney disease and cancer. We believe the pharmacokinetics and pharmacodynamics of Hematide have been shown 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 kidney disease patients, and every two, three or four weeks in cancer patients, coincident with the patient s chemotherapy regimen. Data from our ongoing open-label human clinical trials indicate that Hematide induces a consistent, appropriately rapid, prolonged, dose-dependent increase in reticulocytes and hemoglobin. To date, over 400 patients have received Hematide in ongoing clinical studies. 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.

Current Phase 2 Clinical Trials

We are currently conducting multiple Phase 2 clinical trials of Hematide at sites in the U.S. and Europe in dialysis patients, predialysis patients, cancer patients on chemotherapy 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 Phase 2 clinical trials are to evaluate the safety of Hematide and determine the dosing regimen that produces the appropriate hemoglobin values in the patient populations addressed. 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 predialysis and chemotherapy induced anemia patients, we are seeking to correct their anemia by raising hemoglobin values. Secondary endpoints of our clinical trials include frequency of red blood cell transfusions.

To date, over 400 patients have received Hematide in ongoing clinical studies. 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. Additionally, we have observed that treatment of predialysis patients and cancer patients on chemotherapy with Hematide leads to corrections of anemia at rates and within timeframes that are appropriate for effective ESA treatment, given the current standard of care and regulatory guidelines. Dialysis patients also appear to respond to Hematide therapy as expected.

Most of our ongoing trials are dose-ranging trials in which we enroll cohorts of patients until we discover the correct dose to achieve an appropriate therapeutic response. In each of our dose-ranging trials, we will not know exactly how many patients will eventually be enrolled until the conclusion of the trial. Pre-dialysis and dialysis patients participating in our dose-ranging trials have the option to continue treatment and remain in long-term follow up studies being conducted in Europe and the U.S. These studies are intended to support the long term safety and efficacy of Hematide.

Phase 3 Development Plans

In dialysis and predialysis patients with chronic kidney disease, we are planning to pursue global regulatory approval for Hematide by conducting several registration studies to confirm the safety and efficacy of Hematide, and to compare the safety and efficacy of Hematide to currently marketed ESAs. We have had preliminary discussions with the FDA regarding Phase 3 clinical trials in both dialysis and pre-dialysis patients. Based on those discussions, we believe that our clinical, preclinical and manufacturing work is sufficient to proceed to Phase 3 clinical trials and we are continuing discussions with the FDA relating to the design of these trials. Assuming timely conclusion of the discussions with the FDA, we would expect to commence separate Phase 3 trials in both dialysis and predialysis patients during the

second half of 2007. The trials are expected to address both correction of anemia and maintenance of correction in ESA-naïve patients, and maintenance of correction of anemia in patients switching from rEPOs to Hematide in the dialysis setting. This program will seek to adequately describe the effective dose and safety profile of Hematide via both intravenous and subcutaneous routes of administration.

In oncology, we anticipate that multiple Phase 3 pivotal trials will be conducted in various cancer patient populations. In one of these trials, the efficacy of Hematide in reducing the requirement for red blood cell transfusions in patients undergoing chemotherapy will be assessed in a randomized, placebo-controlled, blinded, multi-national study.

Research Pipeline

We have leveraged our drug discovery platform to produce multiple peptide-based therapeutic product candidates. The following are some of our research stage programs in which we have found, through use of our proprietary technologies, novel peptides which compete with the natural ligand for binding to target receptors and/or which have agonistic or antagonistic activities. The activities of these peptides are being further characterized and optimized in our research labs.

Adeptide Non-Injectable Peptide-based ESA

The small size, potency and stability of our proprietary peptides that can effectively stimulate the production of red blood cells suggests that such peptide-based ESAs could be delivered by routes, such as intranasal or pulmonary, that do not require injections. Recently we have observed, for example, the ability to generate significant hemoglobin responses in rats after just two intranasal doses of peptide-based ESAs. We believe that such alternative delivery forms of our peptide-based Hematide and Innotide related peptides may expand the market potential for such products.

Innotide Tissue Protective Peptides

In addition to a role in erythropoiesis, EPO has been reported to have tissue protective properties that may protect tissues from damage in response to localized insufficiency of blood and oxygen, known as ischemia, or in response to toxic chemotherapy. Some of these reported activities include protection of neural tissues from ischemic stroke and protection of renal tissues from chemotherapeutic drugs. Innotide represents a series of synthetic peptides discovered and developed by us which act through the EPO receptor, and which are being evaluated in preclinical models of stroke, heart attack and chemotherapy induced organ damage. Innotide peptides bind to and appear to differentially activate the EPO receptor. We believe Innotide may have tissue protective properties characteristic of EPO, but potentially without significant erythropoiesis stimulating activity. Other potential properties of Innotide, including its specificity, potency, relatively small size, stability and ability to be modified to modulate its activity, may also constitute advantages.

Angiotide Anti-Angiogenesis Factor

In September 2004, we entered into a collaboration with EntreMed, Inc. to develop peptides with anti-angiogenic activites for cancer therapy and the prevention of metastases. Angiogenesis, or the formation of blood vessels, plays an essential role in embryonic development, normal growth of tissues, wound healing and the female reproductive cycle. Angiogenesis, however, is also necessary for tumors to grow beyond a few millimeters in size and for the spread and growth of tumor cell metastases. Under our collaboration, we have identified several related peptides with significant activity in vitro and in animal models in vivo.

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.

Specifically for Hematide, active pharmaceutical ingredient, or API, has been manufactured by multiple contract manufacturers or CMOs. We intend to establish long term commercial supply agreements with at least two CMOs for manufacture of drug substance. 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. We currently have responsibility for production of final Hematide drug product. Over time, responsibility for final drug product manufacture and control will be transferred to Takeda, our worldwide collaboration partner 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. 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

Since our inception, 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 $54.3 million, $24.1 million and $17.3 million for the years ended December 31, 2006, 2005 and 2004, 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. This agreement contemplates that the February 2006 agreement that we have also entered into with Takeda will be 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. Beginning January 1, 2007, Takeda will bear the first $50 million of third-party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Thereafter, Takeda will bear 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 we are eligible to receive from Takeda up to an aggregate of $280 million upon the successful achievement of clinical development and regulatory milestones. 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. Takeda will own and have responsibility for regulatory filings outside the United States. Takeda will also be responsible for creating 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 was the sole responsibility of Affymax. 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 effective after the second anniversary 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 kidney disease 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 will 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. We may receive from Takeda up to an additional total of $65 million upon Takeda s successful achievement of clinical development and regulatory milestones 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 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 after the second anniversary of the effective date of the agreement. 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 manufacturing 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.

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. We also intend to enter into other licensing agreements with companies in strategically relevant therapeutic areas to further leverage our capabilities.

Competition

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. These companies also have significantly greater research capabilities than us. Many universities and private and public research institutes are active in chronic kidney disease 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, the worldwide rEPO market totaled $13 billion in revenue for the 12 months ended June 2006 of which the global leaders, PROCRIT, marketed by J&J, and Aranesp, marketed by Amgen, represented the majority of the market. Aranesp, introduced in 2001, is rapidly gaining market share, particularly in the oncology market. In late 2005, U.S. quarterly sales of Aranesp surpassed those of PROCRIT. Aranesp is approved for once-monthly dosing for treatment of anemia in prediaysis 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 predialysis patients. In 2005, Amgen submitted a biologics license supplement to include a once-monthly dosing regimen for predialysis 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.

In addition to marketed ESAs, there are several ESA product candidates in various stages of active development. Roche has filed for U.S. and European marketing approval of a PEGylated ESA, called Mircera, which reportedly has greater serum stability than any of the currently marketed products. PEG is a polymer that increases the time rEPO remains in the circulation. Roche and Amgen are currently engaged in patent infringement litigation with respect to this product candidate. Another potential competitor, FibroGen, Inc., or FibroGen, is developing a small molecule which is designed to inhibit enzymes that promote the degradation of Hypoxia-Inducible Factor, or HIF, which plays a key role in activating genes that protect the body against low levels of oxygen, or hypoxia. By increasing the level of HIF in a patient s circulation, FibroGen s molecule may promote the production of greater levels of naturally-occurring EPO. In addition, generic versions of short-acting rEPO are being developed in Europe following the expiration of Amgen s key European EPO patent in 2004. Generic EPOGEN products are not expected to enter the U.S. market until after 2015, 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. 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, 2006, we had 105 employees, including 32 who hold Ph.D. or M.D. degrees. We had 78 employees engaged in research and development, and our remaining employees are management or administrative staff. 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*. 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, Avixis, Gematide, Hematide, Innotide, and Affymax and logo. We have applied in certain other countries to register the trademarks: Avixi 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, 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*.

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 or be successfully commercialized.

Hematide, which is our only product candidate in clinical development, is an ESA in multiple Phase 2 clinical trials for the treatment of anemia associated with chronic kidney disease and cancer. All of our other compounds or potential product candidates are in the research stage. In order to commercialize Hematide, a new chemical entity, we will be required to conduct additional 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 have had preliminary discussions with the FDA regarding Phase 3 clinical trials in both dialysis and pre-dialysis patients. Based on those discussions, we believe that our clinical, preclinical and manufacturing work is sufficient to proceed to Phase 3 clinical trials and we are continuing discussions with the FDA relating to the design of those trials. We do not know, and are unable to predict, what type and how many clinical trials the Food and Drug Administration, or FDA, will require us to conduct or the cost, timing or risks associated with conducting such trials in order to obtain approval to market Hematide.

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. 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. The FDA also issued a public health advisory re-evaluating the safe use of the ESA class and is scheduled to convene its Oncology Drugs Advisory Committee (ODAC) in May 2007 to consider the mechanism of action of ESAs and to review the effects of ESAs on survival and tumor progression in cancer patients. The FDA concerns may negatively affect the scope, size, risk or timing of completion of our clinical trials and significantly delay commercialization 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 this product candidate 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 our other product candidates to market.

Some of the recent safety concerns surrounding commercially available ESAs relate to clinical trials conducted in patients with anemia of cancer that suggests higher mortality and serious side effects associated with ESA treatment. Restrictions on labeling or use of ESAs as a result of these concerns may limit the potential market opportunity such that even if the Company is ultimately successful in obtaining regulatory approval, the commercial market and potential for Hematide may also be negatively impacted.

We are at an early stage of development as a company and have limited sources of revenue. Our current revenue recognition policy may limit our ability to report any profits, and we may never become profitable.

We are a development stage biopharmaceutical company with a limited operating history. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. Our ability to generate revenue depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our lead product candidate, Hematide, and our other product candidates. If we are unable to commercialize Hematide, it will be a long time before we will be able to commercialize our other product candidates, if ever. Further, under our current revenue recognition policy, we will not recognize profits, if any, from our performance under the Takeda collaboration agreements until we can objectively determine the fair value of all our undelivered obligations under our Takeda collaboration agreements or when we have performed all of our obligations under those agreements. Since the duration of some of those obligations is indefinite, even if we successfully commercialize Hematide we may not be able to report any profits under generally accepted accounting principles until a number of years after our receipt of payments under the Takeda collaboration agreements.

Our existing product candidates 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 one or more of our product candidates or if sales revenue from any product candidate that receives marketing approval is insufficient, we may not achieve profitability, and we may be unable to continue our operations.

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.

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.

None of our product candidates has been commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Hematide or any of our other product candidates, in which case we would not generate revenue or become profitable. In particular, the therapeutic indications targeted by our lead product candidate 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 ESA s within the dialysis market may pose a risk to our ability to obtain 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., 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, the Centers for Medicare and Medicaid Services, or 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%. We cannot be certain what reimbursement policies will be in effect at the time we seek to enter the dialysis market in the U.S., or the effect these policies may have on our ability to compete effectively.

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 of the broader market for ESAs and reduce the potential revenues for Hematide.

In the predialysis 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 predialysis 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 predialysis patients may be comparatively difficult, as these patients are spread more thinly across a variety of treatment settings than end stage renal disease patients receiving treatment at dialysis centers.

In addition, market acceptance of ESAs as well as our lead product candidate, Hematide, and any future product candidates by physicians, healthcare payors and patients will depend on a number of additional factors, including:

- the clinical indications for which the product candidate is approved;
- acceptance by physicians and patients of each product candidate 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 at levels above those currently accepted
- as industry guidance;
- 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 any future products that we may develop, 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 our product candidates could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. 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), and NeoRecormon, currently marketed outside the U.S. by Roche. Aranesp is approved for once-monthly dosing for treatment of anemia in prediaysis 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 predialysis patients. In addition, in April 2006 Roche filed for U.S. and European marketing approval for Mircera, which reportedly has greater serum stability and is longer acting than any rEPO product that is currently on the market. Roche and Amgen are currently engaged in patent litigation. Amgen alleges that Mircera infringes six U.S. patents owned by Amgen. If Amgen does not seek or obtain a preliminary injunction, Mircera would likely enter the market before Hematide. Because of its ability to be longer acting, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide. Another potential competitor, FibroGen, Inc., or FibroGen, is developing a small molecule which is designed to inhibit enzymes that promote the degradation of Hypoxia-Inducible Factor, or HIF, which plays a key role in activating genes that protect the body against low levels of oxygen, or hypoxia. By increasing the level of HIF in a patient s circulation, FibroGen s molecule may promote the production of greater levels of naturally-occurring EPO. The introduction of generics 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.

All 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 our product candidates 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 existing rEPO patents expire in the U.S. in 2015.

The last significant U.S. patent for epoetin alfa, a version of short-acting rEPO, expires in 2015. Patents related to epoetin alfa expired in the E.U. in 2004. Generic versions of short-acting rEPO are currently being developed in and for various markets outside the U.S., including the E.U. Generic shortacting rEPO is already being sold in various territories outside the U.S. and the E.U. We expect that biogenerics, 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 generics into the ESA market could prove to be a significant threat to Hematide if they are able to demonstrate bioequivalence to existing ESAs. Generics will constitute additional competition for Hematide and could drive its price down, which may adversely affect our revenues.

Any failure or delay in completing clinical trials for our product candidates could severely harm our business.

Each of our product candidates must undergo extensive preclinical studies and clinical trials as a condition to regulatory approval. Preclinical studies and clinical trials are expensive and take many years to complete. We estimate that clinical trials and related regulatory review in initial indications for our most advanced product candidate, Hematide, will continue for at least four years, but could take significantly longer to complete. The completion of clinical trials for our product candidates may be delayed or halted for many reasons, including:

- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- our inability, or the inability of our collaborators or licensees, to manufacture or obtain from third parties materials sufficient to complete our preclinical studies and clinical trials;
- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- 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;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, including serious adverse events associated with Hematide;
- the failure of patients to complete clinical trials due to side effects, dissatisfaction with the product candidate 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.

Clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial and competing clinical trials. Patients participating in the trials may not live through completion of the trial or may suffer adverse medical effects unrelated to treatment with our product candidate. The results from preclinical testing and prior clinical trials may not be predictive of results obtained in 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 any of our product candidates will prevent us from receiving regulatory approval and negatively impact our business.

It is possible that none of our product candidates will complete clinical trials in any of the markets in which we intend to sell those product candidates. We also do not know and are unable to predict what clinical trials the FDA will require us to conduct or the scope, size or design of such trials, which could result in additional delays in bringing our product candidates to market. Accordingly, we may not receive the regulatory approvals needed to market our product candidates. Any failure or delay in completing clinical trials for our product candidates would delay commercialization of our product candidates and severely harm our business and financial condition.

All of our product candidates other than Hematide are in early stage research. If we are unable to develop, test and commercialize our other product candidates, our business will be adversely affected.

A key element of our strategy is to discover, develop and commercialize a portfolio of new products in addition to Hematide. We are seeking to do so through our internal research programs and intend to explore 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 the following:

- 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 is not 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.

Our strategy also includes in-licensing or acquiring product candidates that leverage our product development strengths. We may not be able to license or acquire promising product candidates on reasonable terms, if at all.

If we fail to maintain our existing, or enter into new, strategic collaborations, we may have to reduce or delay our product candidate development efforts or increase our expenditures.

Our business model is based in part upon entering into strategic collaborations for development of our product candidates. If we are not able to maintain our existing collaboration with Takeda to develop and commercialize Hematide, our business could be severely adversely affected. In addition, if we fail to establish and maintain additional strategic collaborations for our other potential product candidates:

- the development of our current 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.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have experienced significant operating losses since our inception in 2001. At December 31, 2006, we had a deficit accumulated during the development stage of approximately $168.7 million. We have generated no revenue from product sales to date. We have funded our operations to date principally from the sale of our securities and from payments by Takeda under our collaboration agreements. We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials, prepare for commercialization of our initial products, begin new development programs and add the necessary infrastructure to support operating as a public company. Even if we receive regulatory approval for one or more products, we must successfully commercialize our products before we can become profitable. We anticipate that it will be at least several years before we can commercialize our lead product candidate, Hematide, and even longer for our current product candidates, if at all. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve or sustain profitability.

Reimbursement may not be available for our product candidates, which could diminish our sales or affect our ability to sell our products profitably.

Market acceptance and sales of our product candidates 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 any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates 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 our products.

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 our products 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, President Bush signed into law new Medicare prescription drug coverage legislation that changes the methodology used to calculate reimbursement for certain drugs such as Hematide. In addition, the legislation directs the Secretary of Health and Human Services to contract with procurement organizations to purchase physician-administered drugs from the manufacturers and provides physicians with the option to obtain drugs through these organizations as an alternative to purchasing from the manufacturers, which some physicians may find advantageous.

As a result of 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. 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 fact, the National Institute for Health and Clinical Excellence, the body that provides guidance to the U.K. s National Health Service on what healthcare technologies to reimburse and at what levels, currently recommends against the wide use of ESAs in the treatment of chemotherapy induced anemia. In addition, further, as a result of the recent safety concerns relating to ESAs, the Centers for Medicare & Medicaid policies has recently announced that it is reviewing policies relating to the use of ESAs. Further, 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. CMS currently reimburses healthcare providers for use of ESAs at ASP plus 6%. In the future, CMS may reimburse ESAs under methods other than ASP plus 6%, including capitation, a method that reimburses providers a fixed, per capita amount per patient regardless of the level of service provided. We cannot guarantee that Hematide, or any of our other product candidates, will be reimbursed by CMS to incent physician adoption.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of Hematide and our other product candidates, or to continue our research and development programs.

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

- complete the clinical development of Hematide and our other product candidates;
- launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organization and sales force to address certain markets;
- continue our research and development programs; and
- license or acquire additional product candidates.

We believe that existing cash, cash equivalents and short-term investments and the interest thereon, will enable us to maintain our currently planned operations through at least 18 months. However, we may be required to raise additional capital to complete the development and commercialization of Hematide. We may be required to raise additional capital to complete the development and commercialization of our current product candidates**.**

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 may experience significant 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 capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and

- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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

We design the clinical trials for our product candidates, but we rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these 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 on acceptable terms. These third-party collaborators generally may terminate their engagements with us at any time and having to enter into alternative collaboration arrangements would delay introduction of our product candidates to market. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to conduct research on our product candidates and develop them.

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 our product candidates.

Our dependence upon third parties for the manufacture and supply of our products may cause delays in, or prevent us from, successfully developing and commercializing products.

We do not currently have the infrastructure or capability internally to manufacture the drug products that we need to conduct our clinical trials. We have entered into agreements with contract manufacturers to produce our supplies of Hematide; however, we have no long term contracts for supply of Hematide or any of our other product candidates. Hematide is a new chemical entity that has never been produced at commercial scale, and as such, there are underlying risks associated with the manufacture of the substance, which could include: cost overruns, process scale-up, process reproducibility, stability issues and timely availability of raw materials, as well as regulatory issues associated with the manufacture of our product

candidates. Any of these risks may prevent or delay us from successfully developing Hematide or other product candidates.

For the foreseeable future, we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates.

We, our third-party manufacturers and our partners are required to comply with applicable FDA manufacturing practice regulations. If one of our third-party manufacturers fails to maintain compliance with these regulations, the production of our product candidates 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 any of our product candidates. 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 give greater priority to the production of other products over our product candidates. Any inability to acquire sufficient quantities of our product candidates 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 our product candidates in a cost-effective manner or on a timely basis.

The commercial success of our collaborations depends in part on the development and marketing efforts of our collaboration partners, 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 collaboration arrangements subjects our company 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 our product candidates, obtain and maintain regulatory approvals and achieve market acceptance of a product once commercialized. Our collaboration partners may elect to delay or terminate development of one or more product candidates, independently develop products that compete with ours, or fail to commit sufficient resources to the marketing and distribution of products developed through their collaboration with us. Competing products, either developed by our collaboration partners or to which our collaboration partners have rights or acquire in the future, may result in our partners withdrawal of support for our product candidates.

In the event that one or more of our collaboration partners fails to diligently develop or commercialize a product candidate covered by one of our collaboration agreements, we may have the right to terminate our partner s rights to such product candidate but we will not receive any future revenue from that product candidate unless we are either able to find another partner or to commercialize the product candidate on our own, which is likely to result in significant additional expense. Business combinations, significant changes in business strategy, litigation and/or financial difficulties may also adversely affect the willingness or ability of one or more of our collaboration partners to complete their obligations under our collaboration agreements. If our collaboration partners fail to perform in the manner we expect, our potential to develop and commercialize products through our collaborations and to generate future revenue from the sale of these products, would be significantly reduced. If a conflict of interest arises between us and one or more of our collaboration partners, they may act in their own self-interest and not in the interest of our company or our stockholders. If one or more of our collaboration partners were to breach or terminate their collaboration agreements with us or otherwise fail to perform their obligations

thereunder in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates or research programs 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 our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates 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 to product candidates 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. Because we may acquire rights to late-stage products, the remaining patent terms of licensed patents relating to those products 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 patents on our product candidates, 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 compounds that are similar to our product candidates 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 product candidates 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 products 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 bringing our product candidates to market.

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 our product candidates successfully.

We currently have no sales, marketing or distribution capabilities. To commercialize our product candidates, 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 any of our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to 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 are not able to collaborate with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition. If we do collaborate with and rely on pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms. 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 our product candidates, conduct our clinical trials and commercialize our 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 Robert Naso, our Executive Vice President, Research and Development. The loss of services of either Ms. Morris or Dr. Naso 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 our product candidates.

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. We do not carry key person insurance covering any members of our senior management. Each of our officers and key employees may terminate his 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 our product candidates 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 our product candidates 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.

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 some or all of our product candidates.

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulation by FDA and other regulatory authorities in the U.S. and other countries, and regulations may differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates 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 any of our product candidates. 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. 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 a product candidate, 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 our future products.

Any regulatory approvals that we or our collaboration partners receive for our product candidates 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 any of our product candidates, 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 our product candidates. 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.

We intend to market our future products in international markets. In order to market our future products 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. We may not obtain foreign regulatory approvals on a timely basis, if at all. We 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 our future products in both the U.S. and 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 our future product to other available therapies. If reimbursement of our future products 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 our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any products. 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 our product candidates. 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 our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

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 may be 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 is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- new products or services introduced or announced by us or our commercialization 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 our litigation with J&J, including both substantive and procedural rulings by the arbitration panel;
- actual or anticipated results from, and any delays in, our clinical trials;
- actual or anticipated regulatory approvals or our product candidates or competing products;
- actions taken by regulatory agencies with respect to our product candidates, or ESAs generally, clinical trials, manufacturing process or sales and marketing activities;
- changes in laws or regulations applicable to our products, 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 February 28, 2007, our executive officers, directors and principal stockholders, together with their respective affiliates, currently own approximately 65% 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.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission and the Nasdaq Global Market, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, commencing in 2007, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. As a result of our compliance with Section 404, we will incur substantial accounting expense and expend significant management efforts and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to ensure such compliance.

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 after this offering, 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.

As of February 28, 2007, the holders of approximately 14,878,740 shares of common stock outstanding, plus an additional 1,744,609 shares issuable upon the exercise of outstanding options and 1,987 shares issuable upon the exercise of outstanding warrants are subject to lock-up agreements with the underwriters of our initial public offering that restrict the stockholders ability to transfer shares of our common stock for at least 180 days from the date of the final prospectus. Morgan Stanley could release all or some portion of the shares subject to lock-up agreements prior to expiration of the lock-up period.

As of February 28, 2007, the holders of approximately 10,309,784 shares of common stock based on shares outstanding including 1,987 shares underlying outstanding warrants, will be entitled to rights with respect to registration of such shares under the Securities Act of 1933, as amended. If such holders, by exercising their registration rights, cause a large number of securities to be registered and sold in the public market, these sales could have an adverse effect on the market price for our common stock. If we were to initiate a registration and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital.

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; and
- 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.

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We currently lease approximately 69,145 square feet, which will increase to 84,460 square feet starting in October 2007, 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 clamed 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. The AAA has appointed a panel of arbitrators, and the arbitrators have established a schedule for the arbitration. The parties have commenced discovery. The arbitration hearing is scheduled to occur during the second half of 2008.

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

In November 2006, we submitted certain matters to our stockholders for their approval by written consent in connection with our initial public offering. On November 22, 2006, our stockholders approved each of these matters, as set forth below. We did not receive written consents from every stockholder. On November 22, 2006, there were 41,527,386 shares of common stock outstanding (on an as-if converted basis and without giving effect to the one-for-four reverse split of our common stock and preferred stock effected on November 30, 2006). The results of the voting (on an as-if-converted basis and without giving effect to the one-for-four reverse split of our common stock and preferred stock effected on November 30, 2006) from the stockholders that returned written consents to us is as follows:

1. The amendment and restatement of our Amended and Restated Certificate of Incorporation to effect a one-for-four reverse split of our common stock and preferred stock, and in connection therewith, to reduce the number of outstanding shares of our capital stock;

For: 31,717,134
Against: 0

2. The amendment and restatement of our Amended and Restated Certificate of Incorporation following our initial public offering;

For: 31,717,134
Against: 0

3. The amendment and restatement of our Bylaws following our initial public offering;

For: 31,717,134
Against: 0

4. The adoption of the 2006 Equity Incentive Plan;

For: 31,717,134
Against: 0

5. The adoption of the 2006 Employee Stock Purchase Plan;

For: 31,717,134
Against: 0

7. The approval of our form of Indemnity Agreement; and

For: 31,717,134
Against: 0

8. The amendment of our 2001 Stock Option/Stock Issuance Plan to increase the number of shares available for issuance thereunder by 1,122,500 (280,625 shares on a post-reverse split basis).

For: 31,717,134
Against: 0

PART II.

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

Market For Our Common Stock

Our common stock has been traded on the NASDAQ Global Market under the symbol AFFY since December 15, 2006. As of February 28, 2007, there were approximately 190 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 for the period since our initial public offering on December 15, 2006.

	High	Low
2006		
4th Quarter (from December 15, 2006)	$ 37.20	$ 33.80

The closing price for our common stock as reported by the NASDAQ Global Market on February 28, 2007 was $35.61 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

The following sets forth information regarding all unregistered securities sold by us during 2006 (with share amounts adjusted to give effect to a one-for-four reverse stock split effected in connection with our initial public offering):

(1) On February 16, 2006, we issued and sold an aggregate of 530,082 shares of Series E preferred stock to Takeda for approximately $10,000,000 in cash. The shares of our Series E preferred stock converted into shares of our common stock at the rate of one share of common stock for each share of Series E preferred stock in connection with the closing of our initial public offering.

(2) From January 1, 2006 to December 31, 2006, we granted options under our 2001 Stock Option/Stock Issuance Plan, or 2001 Plan, to purchase 810,815 shares of common stock at exercise prices ranging from $4.36 to $18.84 per share. During the period, options to purchase 202,401 shares of common stock were exercised for aggregate consideration of $203,655 at exercise prices ranging from $0.80 to $4.36 per share. Also, of the options granted, options to purchase 13,510 shares of common stock were canceled without being exercised.

(3) In December 2006, we issued 133,293 shares of common stock to 10 accredited investors upon the net exercise of outstanding warrants. Also, in December 2006, we issued 107,268 shares of common stock to one accredited investor for cash consideration in the aggregate amount of $1,823,556 upon the exercise of outstanding warrants.

The offers, sales and issuances of the securities described in paragraphs (1) and (3) were exempt from registration under the Securities Act under Section 4(2) of the Securities Act and/or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. All of the purchasers of securities for which we relied on Rule 506 of Regulation D and/or Section 4(2) represented that they were accredited investors as defined under the Securities Act or a person described under Rule 506(b)(2)(ii) under the Securities Act. We believe that the issuances are exempt from the registration

requirements of the Securities Act on the basis that (a) the purchasers in each case represented to us that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about us or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

The offers, sales and issuances of the securities described in paragraph (2) were deemed to be exempt from registration under the Securities Act pursuant to either (1) Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (2) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering.

Use of Proceeds from the Sale of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1, as amended (File No. 333-136125) and a Registration Statement on Form S-1 filed pursuant to Rule 462(b) (File No. 333-139363) that were declared effective by the Securities and Exchange Commission on December 14, 2006. We registered 4,255,000 shares of our common stock for an aggregate offering price of $106,375,000, all of which were sold. The offering was completed after the sale of all 4,255,000 shares. Morgan Stanley & Co. Incorporated acted as the sole book running and lead manager for the offering, Cowen and Company, LLC, Thomas Weisel Partners LLC and RBC Capital Markets acted as co-managers for the offering. Of this amount, $7.4 million was paid in underwriting discount and commissions, and an additional $2.9 million of other expenses were incurred, all of which was incurred during the fiscal year ended December 31, 2006. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10% or more of our common stock, or to our affiliates. As of December 31, 2006, we had applied the aggregate net proceeds of $96 million from our initial public offering in short-term and long-term investment accounts.

The foregoing represents our best estimate of our use of proceeds for the period indicated. No payments were made to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

Issuer Purchases of Equity Securities

The following table provides information relating to repurchases of our common stock in the three months ended December 31, 2006:

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, 2006 - October 31, 2006	0	$	N/A	N/A
November 1, 2006 - November 30, 2006	875	$ 0.80	N/A	N/A
December 1, 2006 - December 31, 2006	0	$	N/A	N/A
Total	875	$ 0.80	N/A	N/A

(1) The 875 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, for (i) our common stock, (ii) the Nasdaq Composite Index (U.S.) and (iii) the Nasdaq Biotechnology Index as of December 31, 2006. 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 CUMULATIVE TOTAL RETURN*
Among Affymax Inc., The NASDAQ Composite Index
And The NASDAQ Biotechnology Index

* $100 invested on 12/15/06 in Affymax, Inc. stock or on 11/30/06 in Index-including reinvestment of dividends.

(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,					Cumulative Period From July 20, 2001 (Date of Inception) to
	2006	2005	2004	2003	2002	December 31, 2006
	(in thousands, except per share data)					
Statements of Operations Data:						
Collaboration revenue	$ 11,688	$	$	$	$	$ 11,688
License and royalty revenue	38	74	151	225	103	591
Total revenue	11,726	74	151	225	103	12,279
Operating expenses:						
Research and development	54,347	24,051	17,338	13,660	16,834	132,170
General and administrative	11,089	10,032	4,931	4,953	5,529	39,060
Amortization of intangible assets				6,107	6,085	14,471
Impairment of assets				4,224		4,224
Total operating expenses	65,436	34,083	22,269	28,944	28,448	189,925
Loss from operations	(53,710)	(34,009)	(22,118)	(28,719)	(28,345)	(177,646)
Interest income	5,549	1,413	439	357	645	8,924
Interest expense	(84)	(29)		(7)	(26)	(170)
Other income (expense), net	(43)	49	281	172	(320)	143
Net loss(2)	(48,288)	(32,576)	(21,398)	(28,197)	(28,046)	(168,749)
Accretion of mandatorily redeemable preferred stock	(815)	(597)	(105)	(164)	(154)	(1,899)
Net loss attributable to common stockholders	$ (49,103)	$ (33,173)	$ (21,503)	$ (28,361)	$ (28,200)	$ (170,648)
Net loss per common share:						
Basic and diluted(1)(2)	$ (32.56)	$ (101.65)	$ (70.39)	$ (103.10)	$ (105.69)	
Weighted-average number of common shares used in per share calculations:	1,508	326	305	275	267	

	December 31,				
	2006	2005	2004	2003	2002
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 224,292	$ 57,893	$ 24,720	$ 24,654	$ 21,507
Related party receivable	10,191				
Long-term investments	6,133				
Total assets	249,988	60,960	27,728	28,353	36,907
Mandatorily redeemable convertible preferred stock		168,784	112,396	92,361	72,292
Deficit accumulated during the development stage	(168,749)	(120,461)	(87,885)	(66,487)	(38,290)
Total stockholders equity (deficit)	116,899	(113,691)	(87,162)	(65,677)	(37,281)

(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 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 lead product candidate, Hematide, is designed to treat anemia associated with chronic kidney disease and cancer. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic kidney disease, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may 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, and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers. We are currently conducting Phase 2 clinical trials in patients suffering from end-stage renal disease who are on dialysis, as well as in earlier stage chronic kidney disease patients, or predialysis patients. We have had preliminary discussions with the FDA regarding Phase 3 clinical trials in both dialysis and predialysis patients. Based on those discussions, we believe our clinical, preclinical and manufacturing work is sufficient to proceed to Phase 3 clinical trials and we are continuing discussions with the FDA relating to the design of these trials. Assuming timely conclusion of the discussions with the FDA, we would expect to commence separate Phase 3 trials in both dialysis and predialysis patients during the second half 2007. In oncology supportive care, we have initiated a Phase 2 clinical trial evaluating Hematide in cancer patients who suffer from anemia as a consequence of their chemotherapy treatment. We are also building a proprietary pipeline of other novel drug candidates which are designed to offer advantages over first generation recombinant protein therapeutics currently addressing large markets.

To date, we have not generated any product revenue. We have funded our operations primarily through the sale of equity securities, license fees from collaborative partners, operating and capital lease financings 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 as we expand our research and development activities and move our product candidates into later stages of development. As of December 31, 2006, we had an accumulated deficit of approximately $168.7 million.

In December 2006, we issued 4,255,000 shares of our common stock in connection with our initial public offering, including the issuance of 555,000 shares upon the full exercise of the underwriters option to cover over-allotments. The aggregate net proceeds from the offering, including the shares issued upon exercise of the over-allotment option, were approximately $96 million, after deducting underwriting discounts and commissions and other offering expenses.

Collaboration with Takeda Pharmaceutical Company Limited, or Takeda

We have entered into two collaboration agreements, or the Arrangement, 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, or API, clinical and regulatory milestone payments, reimbursement of third party U.S. clinical development expenses, product profit share revenues (as co-promotion revenues) and royalties.

In February 2006, we issued an exclusive license to Takeda for the development and commercialization of Hematide in Japan. Pursuant to this agreement, Takeda has paid us approximately $37 million to date, consisting of $17 million in upfront license fees, $10 million in milestone payments, and approximately $10 million for the purchase of 530,082 shares of our Series E Redeemable Convertible Preferred Stock at a price of $18.86 per share, which we determined was at fair value. In addition, we are eligible to receive additional clinical and regulatory milestone payments of up to an aggregate of $65 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 API for Hematide from us. Assuming Hematide is approved and launched in Japan, we will receive a royalty from Takeda on Hematide sales in Japan.

In June 2006, we expanded our collaboration to develop and commercialize Hematide worldwide, which includes the co-development and co-commercialization of 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 will bear the first $50 million of third-party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Thereafter, Takeda will bear 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 June 2006 agreement, Takeda paid us an upfront license fee of $105 million, and we are eligible to receive from Takeda up to an aggregate of $280 million upon the successful achievement of clinical development and regulatory milestones. 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 a variable royalty based on annual net sales of Hematide outside the U.S. The agreement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of Hematide.

We will share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of Hematide. Specifically, we have 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. We are responsible for U.S. 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 U.S. and the creation of a global safety database.

We are 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.

We have agreed to jointly develop the initial commercial marketing plan for Hematide in the U.S. pursuant to which we and Takeda will divide Hematide promotional responsibilities in the U.S. We 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 us or our third-party partners. Specifically, during the first ten years of the agreement, if we or our third-party partners develop 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.

We have recognized $11.7 million of revenue under our Arrangement with Takeda during the year ended December 31, 2006. In December 2006, Takeda completed a Phase 1 trial of Hematide in Japan resulting in the payment in January 2007 to us of a $10 million milestone under the collaboration.

Research and Development Expenses

Research and development expenses consist of: (i) license fees paid to third parties for use of their intellectual property; (ii) 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; (iii) payments to contract manufacturing organizations, which produce our active pharmaceutical ingredient; (iv) payments to consultants; (v) employee-related expenses, which include salaries and benefits; 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.

We expect to incur increasing research and development expenses in future periods as we conduct more research and perform preclinical studies and clinical trials for our product candidate pipeline. Our strategy includes entering into collaborations with third parties to participate in the development and commercialization of some of our product candidates. As a result, we cannot predict our future research and development expenses with any degree of certainty.

The table below sets out our research and development expenses excluding stock-based compensation by project since 2004 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.

	Hematide	Gematide	Other Research Programs	Total
2004	74 %	18 %	8 %	100 %
2005	78 %	6 %	16 %	100 %
2006	90 %	0 %	10 %	100 %

Under the worldwide agreement with Takeda, we will share responsibility for clinical development activities required for U.S. regulatory approval of Hematide. We will have primary responsibility for Hematide s clinical development plan and clinical trials in the dialysis and predialysis indications, while Takeda will have primary responsibility in the chemotherapy induced anemia and anemia of cancer indications. Beginning January 1, 2007, Takeda will bear the first $50 million of third-party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Thereafter, Takeda will bear 70% of the U.S. third-party development expenses, while we are responsible for 30% of the expenses. The Company retains responsibility for 100% of its 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 United States. Except for Hematide, we can not forecast with any degree of certainty which of our product candidates, if any, will be subject to future partnerships or how such arrangements would affect our development plans or capital requirements.

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 our lead product candidate, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as ongoing assessment as to the product candidate s commercial potential. We anticipate developing additional product candidates internally and intend to consider in-licensing product candidates, which will increase our research and development expenses in future periods. We believe that the cash received from Takeda, existing cash, cash equivalents and short-term investments and the interest thereon, will enable us to maintain our currently planned operations through at least 18 months**.** However, we may be required to raise additional capital to complete the development and commercialization of Hematide and we will need to raise additional capital to support continued development of our product candidates thereafter. We cannot be certain that that additional funding will be available on acceptable terms, or at all.

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 prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

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 accounting principles generally accepted in the United States. 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

We recognize revenue in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*. 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.

Takeda Agreements

We have entered into two separate collaboration agreements, or the Arrangement, with Takeda, 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.

We are unable to determine the period of our 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 is currently indefinite. As a result, revenue for the single unit of accounting is recorded on a proportional performance basis as long as the overall Arrangement is determined to be profitable.

We account for the Arrangement using a zero profit proportional performance model (i.e., revenue will be recognized equal to direct costs incurred, but not in excess of cash received or receivable assuming that the overall Arrangement is expected to be profitable). We use an input based measure, specifically direct costs, to determine proportional performance because we believe that the inputs are representative of the value being conveyed to Takeda through the research and development activities and delivery of the API. We believe that using direct costs as the unit of measure of proportional performance also most closely reflects the level of effort related to our performance under the Arrangement. Direct costs are those costs that directly result in the culmination of an earnings process for which Takeda receives a direct benefit. The nature of these costs are 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 exclude 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.

Amounts resulting from payments received in advance of revenue recognized are recorded as deferred revenue in accordance with the zero profit proportional performance model described above until the earlier of (i) when we can meet the criteria for separate recognition of each element under the guidance of EITF 00-21; or (ii) after we have fulfilled all of our contractual obligations under the Arrangement.

We are required to assess the profitability of the overall Arrangement on a periodic basis throughout the life of the Arrangement when events or circumstances indicate a potential change in facts. Profitability is defined as a net cash inflow resulting from the Arrangement over its life. Such assessment is based on estimates to determine the most likely outcome based on available facts and circumstances at each assessment date. The estimates include the consideration of factors such as the progress and timing of clinical trials, competitive ESAs in the market, the development progress of other potential ESAs, 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 indicate a loss will result from performance under the Arrangement, we will continue to recognize costs as they are incurred. However, revenue will be deferred until either (i) the Arrangement becomes profitable, at which point we will continue to recognize revenue under the zero profit proportional performance model, or (ii) the end of the Arrangement.

Preclinical Study and Clinical Trial Accruals

We estimate our preclinical study and clinical trial expenses based on our estimates of the services received pursuant to contracts with several research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include the following:

- fees paid to contract research organizations in connection with preclinical studies;
- fees paid to contract research organizations and clinical research organizations in connection with clinical trials; and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for preclinical studies and clinical trials.

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Stock-Based Compensation

Through December 31, 2005, we have accounted for stock-based employee compensation arrangements using the intrinsic value method in accordance with the recognition and measurement provisions of Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, including the Financial Accounting Standards Board, or FASB, Interpretation, or FIN, No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*. Under APB No. 25, compensation expense is based on the difference, if any, on the date of grant between the fair value of our common stock and the exercise price of the stock option. For periods prior to December 31, 2005, we have complied with the disclosure-only provisions required by Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123*.

Under APB No. 25, we recognized stock-based compensation expense, which is a non-cash charge, for employee stock options granted in 2005 at exercise prices that, for financial reporting purposes, were determined to be below the fair value of the underlying common stock on the date of grant.

The fair value of the common stock underlying stock options granted during this period was estimated by the board of directors with input from management based upon several factors, including progress and milestones attained in our business. In the absence of a public trading market for our common stock, our board of directors was required to estimate the fair value of our common stock.

In connection with the preparation of the financial statements necessary for the filing of our initial public offering, we reassessed the fair value of our common stock at option grant dates from January 2005 through September 2006. In July 2006, we engaged an independent valuation firm to perform a retrospective analysis to determine the fair value of our common stock for accounting purposes as of February 13, 2006, which report was prepared using an income approach. Subsequently, we reassessed the valuations of common stock related to our other grants of stock options from January 1, 2005 through September 30, 2006 using a market-based approach.

We recorded deferred stock-based compensation relative to employee stock options granted in 2005 of approximately $195,000, net of a cancellation due to an employee termination, during the year ended December 31, 2005 in accordance with the requirements of APB No. 25. We amortized $28,000 and $43,000 of deferred stock-based compensation expense during the years ended December 31, 2005 and 2006, respectively.

In addition, during September 2003, we approved the repricing of existing employee stock options from $4.00 to $0.80 per share, which was deemed to be the fair market value. The repriced stock options are subject to variable accounting. We measure the additional compensation expense for each period based on the difference between the reassessed fair value of the shares and the exercise price of the stock options of $0.80 per share and incur compensation expense on a graded vesting basis in accordance with FIN No. 28, *Accounting for Stock Appreciation Rights and other Variable Stock Option or Award Plans*. We incurred stock-based compensation expense related to the repriced stock options of approximately $0, $4.0 million and $1.9 million during the years ended December 31, 2004, 2005 and 2006, respectively. As of December 31, 2006, stock options to purchase approximately 40,000 shares were subject to variable accounting. In addition, in 2006 there was a reversal of stock-based compensation expense of $2.4 million (see Note 12 to our audited financial statements).

While our financial statements through December 31, 2005 account for stock option grants pursuant to APB No. 25, in accordance with SFAS No. 123, we disclosed in the notes to our financial statements the pro forma impact on our net loss had we accounted for stock option grants using the minimum value method of accounting. We did not utilize the minimum value method subsequent to our adoption of SFAS No. 123(R) on January 1, 2006 for options granted subsequent to December 31, 2005, and the fair value of our stock options will be higher as a result.

We account for stock-based compensation arrangements with nonemployees in accordance with SFAS No. 123, as amended by SFAS No. 148, and Emerging Issues Task Force, or 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 expected 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 of volatility and expected term of the option could materially change the value of an option and the resulting expense. As of December 31, 2006, stock options to nonemployees to purchase approximately 31,000 shares were outstanding.

Adoption of SFAS No. 123(R)

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards 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, as amended, and supersedes APB No. 25. 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). As of December 31, 2006, we had unrecognized stock-based compensation costs of $9.0 million related to stock options granted during the year ended December 31, 2006. The cost is expected to be amortized over a weighted average amortization period of 3.14 years.

We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants. The fair value of these stock option grants is estimated as of the date of grant using the

Black-Scholes valuation model with the following weighted-average assumptions for stock options granted during the year ended December 31, 2006: expected term of 5.77 years, expected stock price volatility of 87%, weighted-average risk-free interest rate of 4.61% and dividend yield of 0%. The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the expected terms for industry peers as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock options. The expected stock price volatility for our common stock for the year ended December 31, 2006 was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers as we did not have any significant trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. We will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available. The risk-free interest rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of our stock options. The expected dividend assumption was based on our history and expectation of dividend payouts.

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), we accounted for forfeitures as they occurred.

We had a choice of two attribution methods for allocating compensation costs under SFAS No. 123(R): the straight-line method, which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the graded vesting attribution method, which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. We chose the former method and amortized the fair value of each option on a straight-line basis over the requisite period of the last separately vesting portion of each award.

Net Operating Losses and Tax Credit Carryforwards

At December 31, 2006, we had federal and state net operating loss carryforwards of approximately $83.1 million and $81.6 million, respectively. The federal net operating loss carryforwards begin to expire in 2021 and state net operating loss carryforwards begin to expire in 2013, if not utilized. Under the provisions of Section 382 of the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized annually in the future to offset taxable income. A valuation allowance has been established to reserve the potential benefits of these carryforwards in our financial statements to reflect the uncertainty of future taxable income required to utilize available tax loss carryforwards and other deferred tax assets. If a change in our ownership is deemed to have occurred or occurs in the future, our ability to use our net operating loss carryforwards in any fiscal year may be significantly limited.

At December 31, 2006, we had federal and state research credit carryforwards of approximately $3.5 million and $3.8 million, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2021. The California credit can be carried forward indefinitely. We also had $42.5 million of capitalized research and development costs, in excess of book basis, under Internal Revenue Code §59e. These costs will be amortized over a ten year period beginning with the month of the expenditure. In 2006, we expensed our research and development costs for tax purposes. Additionally, we had $22.4 million of capitalized start-up costs, in excess of book basis, under Internal Revenue Code §195. Such costs capitalized on or before October 22, 2004, will be amortized over a period of 60 months beginning with the month we have an active trade or business. Start-up costs capitalized after October 22, 2004, will be amortized over a 180 month period beginning with the month we have an active trade or

business. In 2006, the requirements to cease capitalization of start-up expenses were met and amortization expense of $4.7 million will be reported for tax purposes related to the capitalization of start-up costs in prior years. We also had $11.5 million of capitalized intangible assets acquired as part of the net assets acquired from GlaxoSmithKline plc., in excess of book basis, under Internal Revenue Code §197. These costs will be amortized over a fifteen year period beginning with the month the intangible asset was acquired.

As discussed above, we received advance royalties under the Arrangement with Takeda and have deferred the recognition of these payments to future years for book purposes. For tax purposes, we expect to defer the recognition of taxable income generated by the receipt of these payments until 2007. While we expect that we will likely recognize some of the deferred tax asset related to our net operating loss carryforwards as a result of the taxable income generated by these royalty payments, a full valuation allowance of $70.8 million has been established for net operating loss and credit carryovers and for the future tax benefit for the deferred tax assets related to the other temporary deductible differences as we believe, based on available objective evidence, that it is more likely than not that the deferred tax assets are not realizable. The net change in the valuation allowance in 2006 was an increase of $20.8 million.

Results of Operations

Comparison of Years Ended December 31, 2006 and 2005

	Years Ended December 31,		Increase/	% Increase/
	2006	2005	(Decrease)	(Decrease)
	(in thousands, except percentages)			
Revenue	$ 11,726	$ 74	$ 11,652	15,746 %
Research and development expenses(1)	54,347	24,051	30,296	126
General and administrative expenses(1)	11,089	10,032	1,057	11
Interest income (expense), net	5,465	1,384	4,081	295
Other income (expense), net	(43)	49	(92)	(188)
Accretion of redeemable convertible preferred stock to redemption value	815	597	218	37
(1) Includes the following stock-based compensation charges:				
Research and development expenses	$ 1,746	$ 1,343	$ 403	30 %
General and administrative expenses	276	2,958	(2,682)	(91)

Revenue. We recognized $11.7 million of revenue under our Arrangement with Takeda for the year ended December 31, 2006. We recognized immaterial revenues for the year ended December 31, 2005 from royalty payments.

Research and Development Expenses. The increase in research and development expenses was primarily due to an increase of approximately $17 million in milestone payments in connection with the Nektar license, an increase of approximately $7 million in clinical trial costs resulting from three additional clinical trials and enrollment of higher number of patients, an increase of approximately $4 million in personnel costs resulting from increased headcount and stock-based compensation expense and an increase in costs associated with the manufacturing and testing of Hematide.

General and Administrative Expenses. The increase in general and administrative expenses was primarily due to an increase of approximately $2 million in personnel costs resulting from higher headcount, net of lower stock-based compensation expenses, and increased legal and audit fees.

General and administrative expenses for 2006 are reduced by an out-of-period adjustment. The Company identified an overstatement of stock-based compensation charges of $2.4 million for the year ending December 31, 2005. It was determined that the 2005 overstatement of stock-based compensation expense was immaterial to the annual financial statements for the years ending December 31, 2006 and 2005 and to the quarterly financial information for the same periods and therefore was corrected in the first quarter of 2006.

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

Other Income (Expense), Net. Other income (expense), net, was immaterial for the years ended December 31, 2005 and 2006.

Accretion of Redeemable Convertible Preferred Stock to Redemption Value. 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. Pursuant to our previous amended and restated certificate of incorporation, all outstanding shares of preferred stock would have been converted into common stock upon the closing of an offering where the price per share is greater than $15.09, the gross proceeds to us are at least $40 million and we have a pre-offering market capitalization of at least $200 million. We recorded a non-cash charge of $597,000 and $815,000 in the year ended December 31, 2005 and 2006, respectively.

Comparison of Years Ended December 31, 2005 and 2004

	Years Ended December 31, 2005	2004	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)			
Revenue	$ 74	$ 151	$ (77)	(51)%
Research and development expenses(1)	24,051	17,338	6,713	39
General and administrative expenses(1)	10,032	4,931	5,101	103
Interest income (expense), net	1,384	439	945	215
Other income (expense), net	49	281	(232)	(83)
Accretion of redeemable convertible preferred stock to redemption value	597	105	492	469
(1) Includes the following stock-based compensation charges:				
Research and development expenses	$ 1,343	$ 13	$ 1,330	10,231 %
General and administrative expenses	2,958		2,958	100

Revenue. We recognized immaterial revenues for the years ended December 31, 2004 and 2005 from license and royalty payments.

Research and Development Expenses. The increase in research and development expenses was primarily due to an increase of approximately $4 million in personnel costs resulting from increased headcount and an increase in stock-based compensation expense, an increase of approximately $2 million in clinical trial costs resulting from commencement of three Phase 2 clinical trials, an increase of approximately $1 million in costs associated with manufacturing and stability testing of Hematide.

General and Administrative Expenses. The increase in general and administrative expenses resulted primarily from an increase of approximately $3 million in charges associated with stock-based compensation, increased legal fees of approximately $1 million resulting from the payment of international patent maintenance fees, various corporate transactions and litigation-related expenses, an increase of approximately $1 million in personnel costs and increased professional and consulting expenses.

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

Other Income (Expense), Net. Other income (expense), net, decreased due to lower level of profit on sales of excess fixed assets.

Accretion of Redeemable Convertible Preferred Stock to Redemption Value. We recorded a non-cash charge of $105,000 and $597,000 for the accretion on our redeemable convertible preferred stock in 2004 and 2005, respectively.

Liquidity and Capital Resources

Since our inception, we have financed our operations through sale of capital stock, license fees from collaborative partners, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. Through December 31, 2006, we have received net proceeds of $256.2 million from the issuance of common stock and convertible preferred stock and $122 million of upfront license fees from our collaboration agreements with Takeda. As of December 31, 2006, we had $230.4 million in unrestricted cash, cash equivalents, short-term investments 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 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.

	Years Ended December 31,	
	2006	2005
	(in thousands)	
Cash, cash equivalents, short-term investments and long-term investments	$ 230,425	$ 57,893
Working capital	$ 228,652	$ 53,238

	Years Ended December 31,		
	2006	2005	2004
	(in thousands)		
Cash provided by (used in):			
Operating activities	$ 68,298	$ (24,765)	$ (19,949)
Investing activities	$ (42,978)	$ (20,502)	$ 64
Financing activities	$ 107,822	$ 58,009	$ 19,934
Capital expenditures (included in investing activities above)	$ (1,452)	$ (127)	$ (134)

Net cash used in operating activities primarily reflects the net loss for those periods, which was reduced in part by depreciation and amortization, non-cash stock-based compensation and non-cash changes in operating assets and liabilities. Net cash provided by operating activities for the year ended December 31, 2006 includes upfront license fees received from Takeda. Net cash used in investing activities was primarily related to purchase of investments and, to a lesser extent, purchase of property and equipment. Net cash provided by financing activities was primarily attributable to net proceeds of the Company s initial public offering of $96.1 million and issuance of Series E preferred stock in the year

ended December 31, 2006, issuance of Series D preferred stock in the year ended December 31, 2005 and issuance of Series C preferred stock in a second closing in the year ended December 31, 2004.

Our future contractual obligations, including financing costs, at December 31, 2006 were as follows:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
	(in thousands)				
Capitalized lease obligations	$ 448	$ 306	$ 142	$	$
Operating lease obligations	$ 22,142	$ 3,389	$ 5,077	$ 5,464	$ 8,212
Total fixed contractual obligations	$ 22,590	$ 3,695	$ 5,219	$ 5,464	$ 8,212

In April 2004, we entered into a License, Manufacturing and Supply Agreement with Nektar Therapeutics AL, Corporation, or Nektar, under which we obtained from Nektar a worldwide, non-exclusive license, with limited rights to grant sublicenses, under certain intellectual property covering pegylation technology to manufacture, develop and commercialize 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 our drug candidates and potential drug candidates;
- our ability to 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 our product candidates; 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.

We believe that the existing cash, cash equivalents, short-term investments and long-term investments together with the interest thereon, will enable us to maintain our currently planned operations through at least 18 months. However, we may be required to raise additional capital to complete the development and commercialization of Hematide. Our capital requirements are likely to increase. As a result, we may need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed we may not be able to continue development of our product candidates or we could be required to 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. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates 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 June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*, or FIN No. 48, which clarifies the accounting for uncertainty in tax positions. FIN No. 48 requires that we recognize the impact of a tax position in our financial statements, if that position is more likely than not to be sustained on audit, based on the technical merits of the position. The provisions of FIN No. 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the potential impact that the adoption of FIN No. 48 may have on our financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. Traditionally, there have been two widely-recognized methods for quantifying the effects of financial statement misstatements: the roll-over method and the iron curtain method. The roll-over metho focuses primarily on the impact of a misstatement on the income statement including the reversing effect of prior year misstatements but its use can lead to the accumulation of misstatements in the balance sheet. The iron-curtain method, on the other hand, focuses primarily on the effect of correcting the period-end balance sheet with less emphasis on the reversing effects of prior year errors on the income statement. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company s financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the iron curtain and the roll-over methods. We adopted SAB 108 during the third quarter of 2006.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which 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. SFAS No. 157 is effective commencing with our fiscal year 2009 annual financial statements. We are currently assessing the potential impact that the adoption of SFAS No. 157 will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115,* or SFAS No. 159, which is effective January 1, 2008. SFAS No. 159 permits us to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is expected to expand the use of fair value measurement, with is consistent with the Board s long-term measurement objectives for accounting for financial instruments. We are currently evaluating the impact, if any, that the adoption of SFAS No. 159 will have on our financial statements on the adoption date of January 1, 2008.

Off-Balance Sheet Arrangements

There were no significant off-balance sheet arrangements at December 31, 2006.

Item 7A. Quantitative and Qualitative Disclosure of Market Risks

Our exposure to market risk is confined to our cash, cash equivalents, short-term investments and long-term investments which have maturities of less than thirteen months. 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, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in interest rates would have a material negative impact on the value of our investment portfolio.

Item 8. Financial Statements and Supplementary Data.

Our financial statements and notes thereto appear on pages 63 to 96 of this Annual Report on Form 10-K.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Affymax, Inc.
(a development stage company)

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders equity and of cash flows present fairly, in all material respects, the financial position of Affymax, Inc. (a development stage company) at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 and cumulatively, for the period from July 20, 2001 (date of inception) to December 31, 2006 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, the Company changed the manner in which it accounts for stock-based compensation for the year ended December 31, 2006.

/s/ *PRICEWATERHOUSECOOPERS LLP*

San Jose, California
March 30, 2007

AFFYMAX, INC.
(A development stage company)

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31,	
	2006	**2005**
Assets		
Current assets		
Cash and cash equivalents	$ 147,541	$ 14,399
Restricted cash	1,051	
Short-term investments	76,751	43,494
Related party receivable	10,191	
Prepaid expenses and other current assets	5,090	722
Total current assets	240,624	58,615
Property and equipment, net	2,014	1,110
Restricted cash	1,135	
Long-term investments	6,133	
Other assets	82	1,235
Total assets	$ 249,988	$ 60,960
Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)		
Current liabilities		
Accounts payable	$ 9,113	$ 3,336
Accrued liabilities	2,566	1,818
Capitalized lease obligations, current	293	223
Total current liabilities	11,972	5,377
Deferred revenue	120,821	
Other long term liabilities	156	180
Capitalized lease obligations, net of current	140	310
Total liabilities	133,089	5,867
Commitments and contingencies (Note 5)		
Mandatorily redeemable convertible preferred stock: no shares authorized and no shares issued and outstanding at December 31, 2006; $0.0001 par value, 34,609,592 shares authorized at December 31, 2005 and 8,451,004 shares issued and outstanding at December 31, 2005		168,784
Stockholders equity (deficit)		
Common stock: $0.001 par value, 100,000,000 shares authorized at December 31, 2006 and 14,878,304 shares issued and outstanding at December 31, 2006; $0.0001 par value, 50,500,000 shares authorized at December 31, 2005 and 332,731 shares issued and outstanding at December 31, 2005	15	
Additional paid-in capital	285,771	7,200
Deferred stock-based compensation	(94)	(409)
Deficit accumulated during the development stage	(168,749)	(120,461)
Other comprehensive loss	(44)	(21)
Total stockholders equity (deficit)	116,899	(113,691)
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders equity (deficit)	$ 249,988	$ 60,960

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

AFFYMAX, INC.
(A development stage company)

STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,			Cumulative Period From July 20, 2001 (Date of Inception) to December 31,
	2006	2005	2004	2006
Collaboration revenue	$ 11,688	$	$	$ 11,688
License and royalty revenue	38	74	151	591
Total revenue	11,726	74	151	12,279
Operating expenses				
Research and development	54,347	24,051	17,338	132,170
General and administrative	11,089	10,032	4,931	39,060
Amortization of intangible assets				14,471
Impairment of assets				4,224
Total operating expenses	65,436	34,083	22,269	189,925
Loss from operations	(53,710)	(34,009)	(22,118)	(177,646)
Interest income	5,549	1,413	439	8,924
Interest expense	(84)	(29)		(170)
Other income (expense), net	(43)	49	281	143
Net loss	(48,288)	(32,576)	(21,398)	(168,749)
Accretion of mandatorily redeemable convertible preferred stock	(815)	(597)	(105)	(1,899)
Net loss attributable to common stockholders	$ (49,103)	$ (33,173)	$ (21,503)	$ (170,648)
Net loss per common share:				
Basic and diluted	$ (32.56)	$ (101.65)	$ (70.39)	
Weighted-average number of common shares used in computing basic and diluted net loss per common share calculations	1,508	326	305	

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

AFFYMAX, INC.

(A development stage company)

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)
Cumulative Period from July 20, 2001 (Date of Inception) to December 31, 2006
(in thousands, except share and per share data)

	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Other Comprehensive (Loss) Income	Total Stockholders Equity (Deficit)
Issuance of common stock in August 2001 at $4.00 per share for cash	249,995	$	$ 1,000	$	$	$	$ 1,000
Issuance of common stock upon exercise of stock options at $4.00 per share for cash	3,342		13				13
Value of common stock issued in September 2001 through November 2001 in exchange for services rendered	4,210		76				76
Accretion on mandatorily redeemable convertible preferred stock			(64)				(64)
Components of other comprehensive loss:							
Net loss					(10,244)		(10,244)
Change in unrealized gain (loss) on marketable securities						47	47
Total comprehensive loss							(10,197)
Balance at December 31, 2001	257,547		1,025		(10,244)	47	(9,172)
Issuance of common stock upon exercise of stock options at $4.00 per share for cash	122,604		490				490
Value of common stock issued to employees in February 2002 in exchange for services rendered	2,294		9				9
Value of common stock issued to nonemployees in exchange for services rendered	9,037		42				42
Repurchase of common stock in December 2002	(112,500)		(450)				(450)
Accretion on mandatorily redeemable convertible preferred stock			(154)				(154)
Components of other comprehensive loss:							
Net loss					(28,046)		(28,046)
Change in unrealized gain (loss) on marketable securities							
Total comprehensive loss							(28,046)
Balance at December 31, 2002	278,982		962		(38,290)	47	(37,281)

AFFYMAX, INC.
(A development stage company)
STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)
Cumulative Period from July 20, 2001 (Date of Inception) to December 31, 2006
(in thousands, except share and per share data)

	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Other Comprehensive (Loss) Income	Total Stockholders Equity (Deficit)
Issuance of common stock upon exercise of stock options at $4.00 per share for cash	2,168		9				9
Issuance of common stock upon exercise of stock options at $0.80 per share for cash	1,150						
Value of common stock issued to nonemployees in exchange for services rendered	2,187		3				3
Accretion on mandatorily redeemable convertible preferred stock			(164)				(164)
Components of other comprehensive loss:							
Net loss					(28,197)		(28,197)
Change in unrealized gain (loss) on marketable securities						(47)	(47)
Total comprehensive loss							(28,244)
Balance at December 31, 2003	284,487		810		(66,487)		(65,677)
Issuance of common stock upon exercise of stock options at $0.80 per share for cash	22,629		18				18
Repurchase of common stock	(3,281)		(13)				(13)
Accretion on mandatorily redeemable convertible preferred stock			(105)				(105)
Value of common stock issued to nonemployees in exchange for services rendered	15,646		13				13
Components of other comprehensive loss:							
Net loss					(21,398)		(21,398)
Change in unrealized gain (loss) on marketable securities							
Total comprehensive loss							(21,398)
Balance at December 31, 2004	319,481		723		(87,885)		(87,162)

AFFYMAX, INC.
(A development stage company)
STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)
Cumulative Period from July 20, 2001 (Date of Inception) to December 31, 2006
(in thousands, except share and per share data)

	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Other Comprehensive (Loss) Income	Total Stockholders Equity (Deficit)
Issuance of common stock upon exercise of stock options at $0.80 per share for cash	13,250		11				11
Accretion on mandatorily redeemable convertible preferred stock			(597)				(597)
Deferred stock-based compensation			4,710	(4,710)			
Amortization of deferred stock-based compensation				4,001			4,001
Reversal of deferred stock-based compensation due to cancellation			(300)	300			
Issuance of stock options to nonemployees for services			300				300
Issuance of warrants to purchase common stock			2,353				2,353
Components of other comprehensive loss:							
Net loss					(32,576)		(32,576)
Change in unrealized gain (loss) on marketable securities						(21)	(21)
Total comprehensive loss							(32,597)
Balance at December 31, 2005	332,731		7,200	(409)	(120,461)	(21)	(113,691)

AFFYMAX, INC.
(A development stage company)
STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)
Cumulative Period from July 20, 2001 (Date of Inception) to December 31, 2006
(in thousands, except share and per share data)

	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Other Comprehensive (Loss) Income	Total Stockholders Equity (Deficit)
Issuance of common stock upon exercise of stock options at $0.80 to $4.36 per share for cash	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)			
Issuance of stock options to nonemployees for services			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)
Balance at December 31, 2006	14,878,304	$ 15	$ 285,771	$ (94)	$ (168,749)	$ (44)	$ 116,899

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

AFFYMAX, INC.
(A development stage company)

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31, 2006	2005	2004	Cumulative Period From July 20, 2001 (Date of Inception) to December 31, 2006
Cash flows from operating activities				
Net loss	$ (48,288)	$ (32,576)	$ (21,398)	$ (168,749)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities				
Depreciation and amortization	704	729	860	21,030
Stock-based compensation expense	2,022	4,301	13	6,466
Interest expense related to common stock warrants	56			56
Loss on termination of capital lease				156
(Gain) loss on disposal of fixed assets	(11)	(57)	(201)	175
Impairment of assets				4,224
Realized (gain) loss on investments	(46)			(93)
Lease deposit write off				23
Changes in operating assets and liabilities :				
Related party receivable	(10,191)			(10,191)
Prepaid expenses and other current assets	(4,368)	(102)	(148)	(4,818)
Other assets	1,153	100	100	1,353
Accounts payable	5,777	2,530	253	8,507
Accrued liabilities	693	478	702	1,968
Deferred revenue	120,821			120,821
Other long term liabilities	(24)	(168)	(130)	156
Net cash provided by (used in) operating activities	68,298	(24,765)	(19,949)	(18,916)
Cash flows from investing activities				
Purchases of property and equipment	(1,452)	(127)	(134)	(3,261)
Purchases of marketable securities	(226,999)	(141,031)	(41,118)	(524,145)
Maturities of marketable securities	187,632	120,579	41,101	441,310
Proceeds from sale of property and equipment	27	77	215	533
Acquisition of net assets, net of cash acquired				(1,086)
Change in restricted cash	(2,186)			(2,186)
Net cash provided by (used in) investing activities	(42,978)	(20,502)	64	(88,835)
Cash flows from financing activities				
Repurchases of common stock	(1)		(13)	(464)
Proceeds from issuance of common stock upon exercise of stock options, including early exercise of stock options	204	11	18	744
Proceeds from issuance of common stock upon exercise of common stock warrant	1,824			1,824
Proceeds from issuance of common stock				1,000
Proceeds from issuance of preferred stock, net of issuance costs	9,982	58,144	19,929	157,035
Proceeds from IPO, net of issuance costs	96,085			96,085
Principal payments under capital lease obligations	(272)	(146)		(932)
Net cash provided by financing activities	107,822	58,009	19,934	255,292
Net increase in cash and cash equivalents	133,142	12,742	49	147,541
Cash and cash equivalents at beginning of the period	14,399	1,657	1,608	
Cash and cash equivalents at end of the period	$ 147,541	$ 14,399	$ 1,657	$ 147,541

AFFYMAX, INC.
(A development stage company) (Continued)

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31, 2006	2005	2004	Cumulative Period From July 20, 2001 (Date of Inception) to December 31, 2006
Supplemental disclosures for cash flow information				
Interest paid	$ 27	$ 26	$	$ 110
Noncash investing and financing activities				
Accretion on mandatorily redeemable convertible preferred stock	815	597	105	1,899
Change in unrealized loss on marketable securities	(23)	(21)		(44)
Deferred stock-based compensation, net of cancellations	(791)	4,410		3,619
Issuance of warrants to purchase common stock/(Revision of allocated fair value of warrants)	(247)	2,353		2,106
Additions to property and equipment under capital lease obligations	172	679		1,426
Conversion of Series A preferred stock	23,000			23,000
Conversion of Series C preferred stock	100			100
Conversion of preferred stock upon IPO	156,728			156,728

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

AFFYMAX, INC.
(A development stage company)

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 lead product candidate, Hematide, is designed to treat anemia associated with chronic kidney disease and cancer. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Hematide is currently in Phase 2 clinical trials in patients suffering from end-stage renal disease who are on dialysis, as well as in earlier stage chronic kidney disease patients, or predialysis patients.

In July 2001, the Company entered into an Asset Purchase Agreement (the Agreement) with Affymax Research Institute, its parent company, GlaxoSmithKline plc and certain other subsidiaries of GlaxoSmithKline plc (collectively, GSK). Pursuant to the Agreement, the Company acquired from GSK certain assets, technology and intellectual property, while assuming certain liabilities. In exchange for the assets and liabilities, the Company issued shares of Series A Mandatorily Redeemable Convertible Preferred Stock which were converted into 848,293 shares of common stock in April 2006 (Note 6).

In December 2006, the Company completed its initial public offering of 4,255,000 shares of its common stock at a public offering price of $25.00 per share, including the underwriters exercise of their option to purchase an additional 555,000 shares to cover over-allotments. The aggregate net cash proceeds from the offering, including the shares issued upon exercise of the over-allotment option, were approximately $96.1 million, after deducting the underwriting discount and commissions and other offering expenses. In connection with the closing of the initial public offering, all of the Company s shares of convertible preferred stock outstanding at the time of the offering were automatically converted into 8,993,572 shares of common stock. In addition, the Company issued 240,561 shares of its common stock in December 2006 upon the net and cash exercise of outstanding warrants that would have terminated if not exercised prior to the closing of the Company s initial public offering.

The Company is in the development stage and since inception has devoted substantially all of its efforts to research and development, raising capital and recruiting personnel.

2. Summary of Significant Accounting Policies

Reverse Stock Split

In October 2006, the Company s board of directors approved a one-for-four reverse stock split of the Company s common stock and redeemable convertible preferred stock, which was approved by the Company s stockholders in November 2006. The split became effective in November 2006 upon the filing of an amendment to the restated certificate of incorporation. All share and per share amounts included in the Company s financial statements have been adjusted to reflect this stock split for all periods presented.

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.

Concentration of Risk and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company deposits excess cash in accounts with three major financial institutions in the United States. Deposits in these banks may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company believes that its guidelines for investment of its excess cash maintains safety and liquidity through its policies on diversification and investment maturity.

The Company has experienced significant operating losses since inception. At December 31, 2006, the Company had a deficit accumulated during the development stage of approximately $168.7 million. The Company has generated no revenue from product sales to date. The Company has funded its operations to date principally from the sale of securities and collaboration agreements. The Company expects to incur substantial additional operating losses for the next several years and may need to obtain additional financing in order to complete the clinical development of Hematide and other product candidates, launch and commercialize and product candidates for which it receives regulatory approval, continue research and development programs and license or acquire additional product candidates. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

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

Marketable Securities

Marketable securities are classified as available-for-sale in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and are carried at their 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 (deficit) until realized.

Marketable securities include auction rate securities that are structured as short-term, highly liquid investments that can be readily converted into cash every 30 to 90 days. However, since the stated or contractual maturities of these securities is greater than 90 days, these securities were classified as short-term investments.

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.

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

The Company recognizes revenue in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*. 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) 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, 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.

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 is currently indefinite. As a result, revenue for the single unit of accounting is recorded on a proportional performance basis as long as the overall Arrangement is determined to be profitable.

The Company accounts for the Arrangement using a zero profit proportional performance model (i.e., revenue will be recognized equal to direct costs incurred, but not in excess of cash received or receivable assuming that the overall Arrangement is expected to be profitable). The Company uses an input based measure, specifically direct costs, to determine proportional performance because the Company believes that the inputs are representative of the value being conveyed to Takeda through the research and development

activities and delivery of the active pharmaceutical ingredients (API). The Company believes that using direct costs as the unit of measure of proportional performance also most closely reflects the level of effort related to the Company s performance under the Arrangement. Direct costs are those costs that directly result in the culmination of an earnings process for which Takeda receives a direct benefit. The nature of these costs are 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 exclude 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 will be 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 are recorded as deferred revenue until the earlier of (i) when the Company can meet the criteria for separate recognition of each element under the guidance of EITF 00-21 or (ii) after the Company has fulfilled all of its contractual obligations under the Arrangement.

The Company is required to assess the profitability of the overall Arrangement on a periodic basis throughout the life of the Arrangement when events or circumstances indicate a potential change in facts. Profitability is defined as a net cash inflow resulting from the Arrangement over its life. Such assessment is based on estimates to determine the most likely outcome based on available facts and circumstances at each assessment date. The estimates include the consideration of factors such as the progress and timing of clinical trials, competitive ESAs (erythropoiesis stimulating agents) 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 indicate a loss will result from performance under the Arrangement, costs will continue to be recognized as they are incurred. However, revenue will be deferred until either: i) the Arrangement becomes profitable, at which point revenue will continue to be recognized under the zero profit proportional performance model, or (ii) the end of the Arrangement.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for indicators of possible impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset s fair value or discounted estimates of future cash flows.

Intangible Assets

Intangible assets resulting from the acquisition of assets and liabilities from GSK were being amortized on a straight-line basis over their estimated useful lives of three years. Amortization expense for the years ended December 31, 2004, 2005, 2006 and for the cumulative period from July 20, 2001 (date of inception) through December 31, 2006 was $0, $0, $0 and $14.5 million, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. The Company s unrealized gains (losses) on

available-for-sale securities represent the components of comprehensive loss that are excluded from the net loss.

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 bases 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.

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 period. Stock options, common stock subject to repurchase, warrants, mandatorily redeemable convertible preferred stock and redeemable convertible preferred stock were not included in the diluted net loss per common share calculation for all periods presented because the inclusion of such shares would have had an antidilutive effect.

	Year Ended December 31,		
	2006	2005	2004
	(in thousands, except per share data)		
Numerator:			
Net loss attributable to common stockholders	$ (49,103)	$ (33,173)	$ (21,503)
Denominator:			
Weighted-average number of common shares outstanding used in computing basic and diluted net loss per common share	1,508	326	305
Basic and diluted net loss per common share	$ (32.56)	$ (101.65)	$ (70.39)

The following mandatorily redeemable convertible preferred stock, redeemable convertible preferred stock, stock options, common stock subject to repurchase and warrants were excluded from the computation of diluted net loss per common share for the periods presented because including them would have an antidilutive effect (in thousands):

	Year Ended December 31,		
	2006	2005	2004
Mandatorily redeemable convertible preferred stock (as if converted)		9,280	5,305
Options to purchase common stock	1,333	700	677
Common stock subject to repurchase	31	2	
Warrants to purchase common stock	2	438	
Warrants to purchase mandatorily redeemable convertible preferred stock		2	

Stock-Based Compensation

Prior to January 1, 2006 the Company accounted for stock-based employee compensation arrangements using the intrinsic value method in accordance with the recognition and measurement provisions of Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, including the Financial Accounting Standards Board (FASB)

Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*. Under APB No. 25, compensation expense is based on the difference, if any, on the date of grant between the fair value of the Company s common stock and the exercise price of the stock option.

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 year ended December 31, 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 had a choice of two attribution methods for allocating compensation costs under SFAS No. 123(R): the straight-line method, which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the graded vesting attribution method, which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. The Company chose the former method and amortized the fair value of each option on a straight-line basis over the requisite period of the last separately vesting portion of each award.

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.

Revisions to Previously Reported Financial Information

Stock-based compensation

The Company identified an overstatement of stock-based compensation charges of $2.4 million for the year ending December 31, 2005. It was determined that the 2005 overstatement of stock based compensation was immaterial to the annual financial statements for the years ending December 31, 2006 and 2005 and to the quarterly financial information for the same periods and therefore was corrected in the first quarter of 2006.

Other items

The Company concluded that it was appropriate to revise certain balances in the statement of cash flows for the year ended December 31, 2005. The revision resulted from the inclusion of cash equivalents in the purchases and maturities of marketable securities. Accordingly, the Company revised the statement of cash flows for the year ended December 31, 2005 to reduce the purchases and maturities of marketable securities by $47 million. This revision had no impact on the balance sheets or statement of operations. Furthermore, this revision does not affect previously reported cash flows from operations, investing activities or from financing activities in the previously reported statements of cash flows.

Recent Accounting Pronouncements

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN No. 48), which clarifies the accounting for uncertainty in tax positions. FIN No. 48 requires that the Company recognize the impact of a tax position in the financial statements, if that position is more likely than not to be sustained on audit, based on the

technical merits of the position. The provisions of FIN No. 48 are effective as of the beginning of the Company s 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the potential impact that the adoption of FIN No. 48 will have on its financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. Traditionally, there have been two widely-recognized methods for quantifying the effects of financial statement misstatements: the roll-over method and the iron curtain method. The roll-over method focuses primarily on the impact of a misstatement on the income statement including the reversing effect of prior year misstatements but its use can lead to the accumulation of misstatements in the balance sheet. The iron-curtain method, on the other hand, focuses primarily on the effect of correcting the period-end balance sheet with less emphasis on the reversing effects of prior year errors on the income statement. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company s financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the iron curtain and the roll-over methods. The Company adopted SAB 108 during the third quarter of 2006.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which 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. SFAS No. 157 is effective commencing with the Company s fiscal year 2009 annual financial statements. The Company is currently assessing the potential impact that the adoption of SFAS No. 157 will have on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 115* (SFAS No. 159), which is effective January 1, 2008. SFAS No. 159 permits the Company to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is expected to expand the use of fair value measurement, with is consistent with the Board s long-term measurement objectives for accounting for financial instruments. The Company is currently evaluating the impact, if any, that the adoption of SFAS No. 159 will have on its financial statements on the adoption date of January 1, 2008.

3. Balance Sheet Components

Property and Equipment, Net

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

	December 31, 2006	2005
Leasehold improvements	$ 486	$ 303
Equipment	5,757	4,864
Software	489	449
	6,732	5,616
Less: Accumulated depreciation and amortization	(4,718)	(4,506)
	$ 2,014	$ 1,110

Depreciation and amortization expense for the years ended December 31, 2004, 2005 and 2006 was $860,000, $729,000 and $704,000, respectively. Depreciation and amortization expense for the cumulative period from July 20, 2001 (date of inception) through December 31, 2006 was $6.6 million.

The Company leases certain assets under capital leases having terms up to 3 years. Assets held by the Company at December 31, 2005 and 2006 under such lease arrangements are included in property and equipment on the balance sheets as follows (in thousands):

	December 31, 2006	2005
Equipment	$ 966	$ 924
Less: Accumulated depreciation and amortization	(549)	(401)
	$ 417	$ 523

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2006	2005
Payroll and related expenses	$ 1,923	$ 1,199
Legal expenses	299	264
Deferred rent	177	171
Sales and use tax	19	103
Other	148	81
	$ 2,566	$ 1,818

4. Investments

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

	As of December 31, 2006		
	Cost	Unrealized Gain (Loss)	Fair Value
Short-term investments:			
Corporate securities	$ 12,342	$ (7)	$ 12,335
Foreign securities	3,196	(1)	3,195
Certificates of deposit	5,507	2	5,509
Government securities	13,000	(28)	12,972
Auction rate securities	42,740		42,740
Total short-term investments	$ 76,785	$ (34)	$ 76,751
Long-term investments:			
Government securities	$ 6,143	$ (10)	$ 6,133

	As of December 31, 2005		
	Cost	Unrealized Gain (Loss)	Fair Value
Short-term investments:			
Corporate securities	$ 1,805	$ (4)	$ 1,801
Foreign securities	950	(2)	948
Government securities	18,160	(16)	18,144
Auction rate securities	22,600	1	22,601
Total short-term investments	$ 43,515	$ (21)	$ 43,494

77

At December 31, 2006, the securities bear interest at rates between 4.0% and 5.4% per annum and mature between January 2007 and January 2008. Since inception there have been no material realized gains and losses.

5. Commitments and Contingencies

The Company leases certain equipment under capital lease arrangements expiring at various dates through November 2008 at interest rates of 2.2% to 7.2%. The capital leases are 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 we leased 15,315 square feet starting in November 2006 and the remaining 15,315 square feet starting 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 we lease 53,830 square feet starting in October 2007 and the remaining 30,630 square feet starting in January 2011.

Rent expense for the years ended December 31, 2004, 2005, 2006 and, cumulatively, for the period from July 20, 2001 (date of inception) through December 31, 2006 was $3.0 million, $3.0 million, $3.1 million and $16.4 million, respectively. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid.

Future minimum payments under noncancelable lease obligations as of December 31, 2006 are as follows (in thousands):

	Capital Leases	Operating Leases
2007	$ 306	$ 3,389
2008	134	2,505
2009	8	2,572
2010		2,638
2011		2,826
Thereafter		8,212
Total minimum lease payments	448	$ 22,142
Less: Interest	(15)	
Present value of minimum lease payments	433	
Less: Amount due within one year	(293)	
Amount due after one year	$ 140	

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, 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 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 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. In February 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 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. The arbitration hearing is scheduled to occur during the second half of 2008. 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, 2006. 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 at a conversion ratio of approximately 1.4753 shares of common stock for each share of preferred stock, for an aggregate number of 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. Prior to the completion of the Company s initial public offering, each share of Series B Mandatorily Redeemable Convertible Preferred Stock was convertible into approximately 1.4753 shares of common stock and each share of Series C and Series D Mandatorily Redeemable Convertible Preferred Stock and Series E Redeemable Convertible Preferred Stock was convertible into one share of 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, 2006. 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.

As of December 31, 2005, the preferred stock comprised of (in thousands, except share and per share data):

Series	Original Issue Price Per Share	Shares Authorized	Shares Issued and Outstanding	Carrying Amount	Liquidation Value Per Share	Liquidation Amount
A	$ 40.00	2,300,000	575,000	$ 23,000	$ 40.00	$ 23,000
B	40.00	5,000,000	1,249,998	49,711	40.00	50,000
C	15.09	10,609,592	2,650,399	39,897	15.09	40,000
D	15.09	16,700,000	3,975,607	56,176	22.64	90,000
		34,609,592	8,451,004	$ 168,784		$ 203,000

No dividends on preferred stock have been declared since inception through December 31, 2006.

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.

The Company s Certificate of Incorporation, as amended on July 8, 2005, authorized the Company to issue 50,500,000 shares of $0.0001 par value common stock.

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 ISO s 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. As of December 31, 2005 and 2006, the Company has reserved 1,306,655 and 1,587,280, respectively, shares of common stock for issuance under the 2001 Plan. The Company issues new shares of common stock upon exercise of stock options.

The 2001 Plan allows for the early exercise of 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, 2005 and 2006, the Company had a total of 1,755 and 31,427 shares subject to repurchase by the Company, respectively.

Subsequent to the initial public offering of the Company s common stock in December 2006, no further options will be 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 will be 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 to employees and consultants of the Company. Stock options granted under the 2006 Plan may be either ISO s or NSO s. ISO s may be granted only to Company employees. NSO s 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. The 2006 Plan does not allow for the early exercise of options prior to vesting. As of December 31, 2006, the Company has reserved 1,250,000 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 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 31st 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 incentive 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). The Company has reserved a total of 100,000 shares of common stock for issuance under the Purchase Plan. The share reserve automatically increases on January 1 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 upon exercise of stock options. 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, 2006, no shares of common stock were purchased under the Purchase Plan.

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

Prior to January 1, 2006 the Company accounted for stock-based employee compensation arrangements using the intrinsic value method in accordance with the recognition and measurement provisions of Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, including the Financial Accounting Standards Board (FASB) Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*. Under APB No. 25, compensation expense is based on the difference, if any, on the date of grant between the fair value of the Company s common stock and the exercise price of the stock option.

Had compensation cost for the Company s employee stock-based compensation arrangements been determined based upon the fair value of each stock option on the date of grant consistent with the methodology prescribed under SFAS No. 123, the Company s pro forma net loss attributable to common stockholders and pro forma net loss per common share under SFAS No. 123 would have been as follows (in thousands, except per share data):

	Years Ended December 31, 2005	2004	Cumulative Period From July 20, 2001 (Date of Inception) to December 31, 2005
Net loss attributable to common stockholders, as reported	$ (33,173)	$ (21,503)	$ (121,545)
Add: Employee stock-based compensation based on intrinsic value method included in reported net loss	4,001		4,001
Deduct: Employee stock-based compensation determined under fair value based method	(115)	(98)	(527)
Pro forma net loss attributable to common stockholders	$ (29,287)	$ (21,601)	$ (118,071)
Net loss per common share, basic and diluted:			
As reported	$ (101.65)	$ (70.39)	
Pro forma	$ (89.74)	$ (70.71)	

The above pro forma effects on net loss may not be representative of the effects on net loss for future years as stock option grants typically vest over several years and additional stock options are generally granted each year.

The Company estimated the fair value of the stock options using the minimum value method in accordance with the provisions of SFAS No. 123. The fair value of the stock options was estimated at the grant date with the following assumptions:

	Years Ended December 31, 2005	2004	Cumulative Period From July 20, 2001 (Date of Inception) to December 31, 2005
Expected term (in years)	6	4	4.12
Dividend yield	0%	0%	0%
Risk-free interest rate	3.92% - 4.34%	2.83% - 3.72%	2.29% - 4.55%

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2004, 2005 and, cumulatively, for the period from July 10, 2001 (date of inception) through December 31, 2005 was $0.10, $7.33 and $0.70, respectively.

Pro forma disclosures for the year ended December 31, 2006 are not presented because stock-based employee compensation was accounted for under SFAS No. 123(R) s fair-value method during this period.

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 year ended

December 31, 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). Stock-based compensation expense recognized during the year ended December 31, 2006 includes:

- compensation expense for stock-based awards granted to employees subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R) of $2.2 million;

- amortization of deferred stock-based compensation based on the intrinsic value method for stock options granted to employees during the year ended December 31, 2005 of $43,000;

- stock-based compensation expense in connection with the repricing of employee stock options in September 2003 of $1.9 million;

- reversal of stock-based compensation expense of $2.4 million (see Note 12); and

- compensation expense for stock-based awards granted to non-employees prior and subsequent to January 1, 2006 that were earned during the year ended December 31, 2006 of $346,000.

The effect of the change of recording stock-based compensation expense from the original provisions of SFAS No. 123 to the provisions of SFAS No. 123(R) for the year ended December 31, 2006 is as follows:

	Impact from SFAS No. 123(R) Provisions for Year Ended December 31, 2006 (in thousands of dollars, except per share data)
Operating expenses	
Research and development	$ 493
General and administrative	1,659
Total stock-based compensation expense	$ 2,152
Effect on basic and diluted net loss per common share	$ 1.43

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options. The implementation of SFAS No. 123(R) did not have an impact on cash flows from financing activities during the year ended December 31, 2006.

During the year ended December 31, 2006, the Company granted 842,065 stock options to employees with a weighted-average grant date fair value of $15.48 per share. As of December 31, 2006, there was unrecognized compensation costs of $9.0 million related to these stock options. The cost is expected to be recognized over a weighted-average amortization period of 3.14 years.

The Company estimated the fair value of employee stock options using the Black-Scholes valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options were estimated using the following weighted-average assumptions for the year ended December 31, 2006:

	Year Ended December 31, 2006	
Expected volatility	87	%
Risk-free interest rate	4.61	%
Dividend yield	0.00	%
Expected term (in years)	5.77	

84

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 year ended December 31, 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 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 year ended December 31, 2006 was $9.43 per share. 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 year ended December 31, 2006:

	Year Ended December 31, 2006
Expected volatility	62% - 65%
Risk-free interest rate	4.67% - 4.92%
Dividend yield	0.00%
Expected term (in months)	4.5 - 22.5

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 Activity

The following tables summarize information about stock options granted and stock issued from July 20, 2001 (date of inception) through December 31, 2006 and stock options outstanding and exercisable and options vested at December 31, 2006:

	Shares	Options Outstanding	
	Available for Grant	Number of Shares	Weighted-Average Exercise Price
Shares authorized	425,000		
Options granted	(214,410)	214,410	$ 4.00
Options exercised		(3,342)	4.00
Options forfeited	11,120	(11,120)	4.00
Options cancelled	243	(243)	4.00
Stock issuance	(4,210)		
Balances at December 31, 2001	217,743	199,705	4.00
Additional shares authorized	156,250		
Options granted	(367,750)	367,750	4.00
Options exercised		(122,604)	4.00
Options forfeited	40,883	(40,883)	4.00
Options cancelled	8,130	(8,130)	4.00
Stock issuance	(11,331)		
Stock repurchased	112,500		
Balances at December 31, 2002	156,425	395,838	4.00
Options granted	(245,211)	245,211	1.03
Options exercised		(3,318)	2.89
Options forfeited	186,746	(186,746)	4.00
Options cancelled	76,784	(76,784)	4.00
Stock issuance	(2,187)		
Balances at December 31, 2003	172,557	374,201	2.07
Additional shares authorized	343,500		
Options granted	(330,895)	330,895	0.80
Options exercised		(22,629)	0.80
Options forfeited	4,189	(4,189)	0.86
Options cancelled	832	(832)	0.80
Stock issuance	(15,646)		
Stock repurchased	3,281		
Balances at December 31, 2004	177,818	677,446	0.80
Additional shares authorized	381,905		
Options granted	(70,975)	70,975	0.80
Options exercised		(13,250)	0.80
Options forfeited	35,000	(35,000)	0.80
Balances at December 31, 2005	523,748	700,171	0.80
Additional shares authorized	1,530,625		
Shares cancelled	(7,948)		
Options granted	(848,315)	848,315	10.22
Options exercised		(202,401)	1.01
Options forfeited	12,260	(12,260)	10.81
Options cancelled	1,250	(1,250)	4.36
Stock repurchased	880		
Balances at December 31, 2006	1,212,500	1,332,575	$ 6.67

The options outstanding and vested by exercise price at December 31, 2005 are as follows:

Options Outstanding and Exercisable			Options Vested	
Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life (in Years)	Number Vested	Weighted-Average Exercise Price
$0.80	700,171	7.83	363,981	$ 0.80

The options outstanding and vested by exercise price at December 31, 2006 are as follows:

Options Outstanding and Exercisable				Options Vested			
Exercise Price	Number Outstanding	Number Outstanding and Exercisable	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value	Number Vested	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
$ 0.80	505,267	505,267	7.04		356,320	$ 0.80	6.85	
4.36	506,211	506,211	9.11		88,395	4.36	9.11	
18.84	283,597	283,597	9.62		2,589	18.84	9.63	
25.00	37,500		9.95					
	1,332,575	1,295,075	8.46	$ 36,130,000	447,304	$ 1.61	7.31	$ 14,507,000

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, 2006. The total intrinsic value of stock options exercised during the year ended December 31, 2006 was $4.1 million determined at the date of each stock option exercise.

Deferred Stock-Based Compensation

In July 2003, the Company determined the fair value of common stock to be $0.80 per share. During 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. Accordingly, subsequent increases in the value of the common stock will result in additional compensation expense. At December 31, 2006, the fair value of the common stock was $34.04 per share and approximately 40,000 repriced stock options remain outstanding. During the year ended December 31, 2005 and 2006, the Company has recorded deferred stock-based compensation related to these stock options of $4.2 million and $1.3 million, respectively, and recorded amortization of such deferred stock-based compensation of $4.0 million and $1.9 million, respectively. During 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 (see Note 12).

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 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 $28,000 and $43,000, respectively, during the year ended December 31, 2005 and 2006.

The Company granted stock options to employees with exercise prices below the fair value on the date of grant as follows:

Grant Date	Number of Options Granted	Exercise Price Per Share	Reassessed Fair Value Per Share	Intrinsic Value Per Share
January 19, 2005	16,275	$ 0.80	$ 4.16	$ 3.36
April 20, 2005	9,750	$ 0.80	$ 7.80	$ 7.00
July 26, 2005	35,000	$ 0.80	$ 8.24	$ 7.44
October 12, 2005	8,200	$ 0.80	$ 8.56	$ 7.76
February 7, 2006	160,721	$ 4.36	$ 15.20	$ 10.84
February 10, 2006	346,247	$ 4.36	$ 15.20	$ 10.84
July 28, 2006	210,645	$ 18.84	$ 24.00	$ 5.16
September 27, 2006	54,952	$ 18.84	$ 25.44	$ 6.60
October 25, 2006(1)	9,500	$ 18.84	$ 25.44	$ 6.60

(1) The Company did not grant any stock options to employees between October 26, 2006 and December 31, 2006.

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 a price of $15.09 per share to the lessor. The warrant expires in January 2012 or five years from the effective date of the Company s initial public offering, whichever is longer. In December 2006, the warrant to purchase Series C Mandatorily Redeemable Convertible Preferred Stock was automatically converted into a warrant to purchase 1,987 shares of common stock in connection with the completion of the Company s initial public offering. The fair value of the warrant of $56,000 was recorded as interest expense. The warrant remains outstanding at December 31, 2006.

In connection with the sale of Series D Mandatorily Redeemable Convertible Preferred Stock, the Company issued warrants in July 2005 to purchase 383,097 shares of common stock at a price of $17.00 per share to certain investors. The warrants expire upon the earlier of July 2010, on the effective date of the Company s initial public offering, a sale of all or substantially all of the assets or a change of control. The allocated fair value of the warrants of $1.9 million was recorded as a reduction to the carrying value of the Series D Mandatorily Redeemable Convertible Preferred Stock. The fair value of the warrants was determined using the Black-Scholes valuation model with the following assumptions: volatility of 87%, risk-free interest rate of 3.79%, dividend yield of 0%, exercise price of $17.00, and an expected term of 5 years.

In connection with the sale of Series D Mandatorily Redeemable Convertible Preferred Stock, the Company issued a warrant in July 2005 to purchase 55,079 shares of common stock at a price of $4.56 per share to an investment bank. The warrant expires upon the earlier of 2012, on the effective date of the Company s initial public offering, a sale of all or substantially all of the assets or a change of control. The allocated fair value of the warrant of $412,000 was recorded as a reduction to the carrying value of the Series D Mandatorily Redeemable Convertible Preferred Stock. The fair value of the warrant was determined using the Black-Scholes valuation model with the following assumptions: volatility of 94%, risk-free interest rate of 4.02%, dividend yield of 0%, exercise price of $4.56, and an expected term of 7 years

The Company issued 240,561 shares of its common stock in December 2006 upon the net and cash exercise of outstanding warrants that would have terminated if not exercised prior to the closing of the

Company s initial public offering. As of December 31, 2006, a warrant to purchase 1,987 shares of common stock remains outstanding.

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 stock-based compensation expense of $13,000, $300,000, $346,000 and $780,000 for the years ended December 31, 2004, 2005, 2006 and for the cumulative period from July 20, 2001 (date of inception) through December 31, 2006.

9. Related Party Transactions

Employee Loans

The Company had two notes receivable from employees in the amount of $100,000 each. Each note was collateralized by the deed to the respective home. Interest accrued at the rate of 5.5% and 8.0% per annum for the two notes. Accrued interest was forgiven on each note s anniversary date, if the employee remained in good standing with the Company. The two notes were due in June 2007 unless forgiven on the date, if ever, the Company became subject to the reporting requirements of the Securities Exchange Commission in connection with the Company s initial public offering of its common stock. Accordingly, the two notes were forgiven upon the effectiveness of the initial public offering of the Company s common stock in December 2006.

10. Development and Commercialization Agreements with Takeda

The Company has entered into two separate collaboration agreements (Arrangement) 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 (API), clinical and regulatory milestone payments, reimbursement of third party U.S. clinical development expenses, product profit share revenues (as co-promotion revenues) and royalties.

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 active pharmaceutical ingredient (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. Takeda received an exclusive license to develop and commercialize Hematide outside of the U.S. Beginning January 1, 2007, Takeda will bear the first $50 million of third-party expenses related to development in pursuit of U.S. regulatory approval of Hematide. 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. 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. 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.

The Company has recognized $11.7 million of revenue under the Arrangement with Takeda during the year ended December 31, 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. The amount was included as a related party receivable at December 31, 2006. As of December 31, 2006, the amount receivable from Takeda was $10.2 million, which was recorded as a related party receivable.

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 agreement 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 has not been established and there is no alternative future use.

11. Income Taxes

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

	December 31,	
	2006	2005
Net operating loss carryforwards	$ 33,014	$ 9,898
Federal and State credit carryforwards	6,055	4,025
Depreciation and amortization	21,631	24,592
Capitalized start up costs	8,919	11,242
Accrued liabilities and allowances	1,131	222
Gross deferred tax assets	70,750	49,979
Deferred tax liability		
Net deferred tax asset	70,750	49,979
Less: Valuation allowance	(70,750)	(49,979)
Net deferred tax assets	$	$

At December 31, 2006, the Company had federal and state net operating loss carryforwards of $83.1 million and $81.6 million, respectively. The federal net operating loss carryforwards begin to expire in 2021 and state net operating loss carryforwards begin to expire in 2013, if not utilized.

At December 31, 2006, the Company had federal and state research credit carryforwards of $3.5 million and $3.8 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 also had $42.5 million of capitalized research and development costs, in excess of book basis, under Internal Revenue Code §59e. The decision to make the election to capitalize the Company s research and development costs is made on a year by year basis in order to preserve the Company s net operating loss carryforwards into future years. These costs are amortized over a ten year period beginning with the month of the expenditure. The Company expensed its research and development costs for tax purposes.

Under the provisions of Section 382 of the Internal Revenue Code, substantial changes in the Company s ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income. The Company has completed its analysis of this issue and determined that it experienced a change in ownership during December 2006. Notwithstanding such ownership change, the Company believes that it will be able to utilize a portion of its net operating loss carryforwards in 2007 against the income recognized for tax purposes with respect to the Takeda royalty payments.

Management establishes a valuation allowance for those deductible temporary differences when it is more likely than not that the benefit of such deferred tax assets will not be 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 become deductible. Management considers the historical level of taxable income, projections for future taxable income, 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 reduced.

The valuation allowance increased $9.3 million, $12.7 million and $20.8 million during the years ended December 31, 2004, 2005 and 2006.

The Company received advance royalties related to its collaboration agreement with Takeda and has deferred the recognition of these payments to future years for book purposes. For tax purposes, the Company expects to defer the recognition of taxable income generated by the receipt of these payments until 2007. While management expects that the Company will likely recognize some of the deferred tax asset related to its net operating loss carryforwards as a result of the taxable income generated by these royalty payments, a full valuation allowance of $70.8 million has been established for net operating loss and

credit carryovers and for the future tax benefit for the deferred tax assets related to the other temporary deductible differences.

Additionally, the Company had $22.4 million of capitalized start-up costs, in excess of book basis, under Internal Revenue Code §195. In 2006, the requirements to cease capitalization of start up expenses were met and amortization expense of $4.7 million will be reported for tax purposes related to the capitalization of start up costs in prior years.

The Company also had $11.5 million of capitalized intangible assets acquired as part of the net assets acquired from GlaxoSmithKline plc., in excess of book basis, under Internal Revenue Code §197. These costs are amortized over a fifteen year period beginning with the month the intangible asset was acquired.

12. Quarterly Financial Data (unaudited)

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

	Fiscal 2006 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
Collaboration revenue	$	$ 127	$ 4,124	$ 7,437
Total revenue	8	141	4,134	7,443
Loss from operations	(7,332)	(28,698)	(8,108)	(9,572)
Net loss attributable to common stockholders	(6,865)	(28,053)	(6,389)	(7,796)
Basic and diluted net loss per common share	$ (20.34)	$ (23.49)	$ (4.76)	$ (2.49)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	338	1,194	1,343	3,126

	Fiscal 2005 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
Collaboration revenue	$	$	$	$
Total revenue	37	16	14	7
Loss from operations	(7,521)	(7,356)	(8,068)	(11,064)
Net loss attributable to common stockholders	(7,414)	(7,286)	(7,626)	(10,847)
Basic and diluted net loss per common share	$ (22.95)	$ (22.43)	$ (23.39)	$ (32.80)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	323	325	326	331

Stock-based compensation

In connection with the preparation of the financial statements necessary for the filing of the Company s initial public offering, the Company reassessed the fair value of its common stock at stock option grant dates from January 2005 through September 30, 2006.

The revised values of the common stock resulted in an overstatement of stock-based compensation related charges of $0.4 million and $1.3 million for the three month periods ended March 31, 2006 and June 30, 2006, respectively. The quarterly financial data presented above includes adjustments to correct the overstatement of stock-based compensation expense in the respective quarters.

The Company identified an overstatement of stock-based compensation charges of $0.7 million, $0.8 million and $0.6 million for the three month periods ended March 31, 2006, June 30, 2006 and September 30, 2006, respectively, related to the accounting for stock options. The quarterly financial data presented above includes adjustments to correct the overstatement of stock based compensation in each of the respective quarters. In addition, the quarter ending March 31, 2006 includes an out of period adjustment of $2.4 million related to 2005. It was determined that the 2005 overstatement of stock based compensation was immaterial to the annual financial statements for the years ending December 31, 2006 and 2005 and to the quarterly financial information for the same periods and therefore was corrected in the first quarter of 2006.

Revenue recognition

The Company identified an overstatement of collaboration revenue of $0.7 million for the three month period ended September 30, 2006. There is no impact on the amount of revenue recorded during the year ended December 31, 2006, as the financial statements for the three month period ended December 31, 2006 include a $0.7 million adjustment to correct the overstatement of revenue**.** The quarterly financial data presented above includes adjustments to correct the overstatement of revenue in the three month period ended September 30, 2006.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term disclosure controls and procedures as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to the company s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation as of December 31, 2006, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective.

There have been no changes in our internal controls over financial reporting during the fourth quarter of the year ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Exemption from Management s Report on Internal Control Over Financial Reporting for 2006

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly-public companies.

Item 9B. Other Information.

None.

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 2007 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 2007 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 2007 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 2007 annual meeting of stockholders and is incorporated herein by reference.

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

Item 11. Executive Compensation.

The information required by this item is included in our proxy statement for our 2007 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 2007 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 2007 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, 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 2007 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 2007 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 Independent Registered Public Accounting Firm
- Balance Sheets
- Statements of Operations
- Statements of Stockholders Equity (Deficit)
- 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.

(3) Management Contract or Compensatory Plan or Arrangement

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(1)
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)
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+	Employment Agreement, dated June 10, 2003, by and between the Registrant and Arlene M. Morris(1)
10.10+	Executive Employment Agreement, dated November 17, 2005, by and between the Registrant and Paul B. Cleveland(1)

10.11+	Executive Employment Agreement, dated March 4, 2004, by and between the Registrant and Robert B. Naso(1)
10.12+	Executive Employment Agreement, dated August 9, 2005, by and between the Registrant and Ali Mahdavi(1)
10.13+	Summary of Non-Employee Director Compensation Program(1)
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*	Letter Agreement, dated September 20, 2004, by and between the Registrant and EntreMed, Inc.(1)
10.25	Extension of Letter Agreement for TFPI Product Candidates, dated August 23, 2005, by and between the Registrant and EntreMed, Inc.(1)
10.26	Second Extension of Letter Agreement for TFPI Product Candidates, dated December 19, 2005, by and between the Registrant and EntreMed, Inc.(1)
10.27	Third Extension of Letter Agreement for TFPI Product Candidates, dated February 28, 2006, by and between the Registrant and EntreMed, Inc. (previously filed as Exhibit No. 10.30)(1)
10.28	Fourth Extension of Letter Agreement for TFPI Product Candidates, dated May 24, 2006, by and between the Registrant and EntreMed, Inc. (previously filed as Exhibit No. 10.31)(1)
10.29*	Collaboration and License Agreement, dated February 13, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(1)
10.30*	Collaboration and License Agreement, dated June 27, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(1)
10.31	Research and Development Agreement, dated April 2, 1992, by and between the Registrant and The R.W. Johnson Pharmaceutical Research Institute(1)
10.32	Sublease Agreement, dated September 1, 2006, by and between the Registrant and TIBCO Software Inc.(1)
10.33	Fifth Extension Letter Agreement for TFPI Product Candidates, dated August 23, 2006, by and between the Registrant and EntreMed, Inc.(1)
10.34	Sixth Extension Letter Agreement for TFPI Product Candidates, dated November 27, 2006, by and between the Registrant and EntreMed, Inc.(1)

10.35	Fourth Amendment to Lease dated November 30, 2006, by and between Registrant and CA-Foothill Research Center L.P.
10.36	Seventh Extension Letter Agreement for TFPI Product Candidates, dated February 23, 2007, by and between the Registrant and Entremed, Inc.
23.1	Consent of 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.

+ 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.

99

SIGNATURES

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

AFFYMAX, INC.
By: /s/ ARLENE M. MORRIS
Arlene M. Morris
President, Chief Executive Officer and Member of the Board of Directors

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ ARLENE M. MORRIS Arlene M. Morris	President, Chief Executive Officer and Member of the Board of Directors (*Principal Executive Officer*)	March 30, 2007
/s/ PAUL B. CLEVELAND Paul B. Cleveland	Executive Vice President, Corporate Development and Chief Financial Officer (*Principal Financial Officer*)	March 30 , 2007
/s/ A. MAHDAVI Ali Mahdavi	Vice President, Finance and Administration (*Principal Accounting Officer*)	March 30, 2007
/s/ JOHN P. WALKER John P. Walker	Member of the Board of Directors	March 30, 2007
/s/ NICHOLAS G. GALAKATOS Nicholas G. Galakatos, Ph.D.	Member of the Board of Directors	March 30, 2007
/s/ KATHLEEN LAPORTE Kathleen LaPorte	Member of the Board of Directors	March 30, 2007
/s/ ELIZABETH CZEREPAK Elizabeth Czerepak	Member of the Board of Directors	March 30, 2007
/s/ R. LEE DOUGLAS R. Lee Douglas	Member of the Board of Directors	March 30, 2007
/s/ TED W. LOVE Ted W. Love	Member of the Board of Directors	March 30, 2007
/s/ DAN SPIEGELMAN Daniel K. Spiegelman	Member of the Board of Directors	March 30, 2007

EXHIBIT INDEX

Exhibit Number	Description
3.3	Amended and Restated Certificate of Incorporation(1)
3.5	Amended and Restated Bylaws(1)
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)
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+	Employment Agreement, dated June 10, 2003, by and between the Registrant and Arlene M. Morris(1)
10.10+	Executive Employment Agreement, dated November 17, 2005, by and between the Registrant and Paul B. Cleveland(1)
10.11+	Executive Employment Agreement, dated March 4, 2004, by and between the Registrant and Robert B. Naso(1)
10.12+	Executive Employment Agreement, dated August 9, 2005, by and between the Registrant and Ali Mahdavi(1)
10.13+	Summary of Non-Employee Director Compensation Program(1)
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*	Letter Agreement, dated September 20, 2004, by and between the Registrant and EntreMed, Inc.(1)
10.25	Extension of Letter Agreement for TFPI Product Candidates, dated August 23, 2005, by and between the Registrant and EntreMed, Inc.(1)
10.26	Second Extension of Letter Agreement for TFPI Product Candidates, dated December 19, 2005, by and between the Registrant and EntreMed, Inc.(1)
10.27	Third Extension of Letter Agreement for TFPI Product Candidates, dated February 28, 2006, by and between the Registrant and EntreMed, Inc. (previously filed as Exhibit No. 10.30)(1)
10.28	Fourth Extension of Letter Agreement for TFPI Product Candidates, dated May 24, 2006, by and between the Registrant and EntreMed, Inc. (previously filed as Exhibit No. 10.31)(1)
10.29*	Collaboration and License Agreement, dated February 13, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(1)
10.30*	Collaboration and License Agreement, dated June 27, 2006, by and between the Registrant and Takeda Pharmaceutical Company Limited(1)
10.31	Research and Development Agreement, dated April 2, 1992, by and between the Registrant and The R.W. Johnson Pharmaceutical Research Institute(1)
10.32	Sublease Agreement, dated September 1, 2006, by and between the Registrant and TIBCO Software Inc.(1)
10.33	Fifth Extension Letter Agreement for TFPI Product Candidates, dated August 23, 2006, by and between the Registrant and EntreMed, Inc.(1)
10.34	Sixth Extension Letter Agreement for TFPI Product Candidates, dated November 27, 2006, by and between the Registrant and EntreMed, Inc.(1)
10.35	Fourth Amendment to Lease dated November 30, 2006, by and between Registrant and CA-Foothill Research Center L.P.
10.36	Seventh Extension Letter Agreement for TFPI Product Candidates, dated February 23, 2007, by and between the Registrant and Entremed, Inc.
23.1	Consent of 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.

+ 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.