

Anadys Pharmaceuticals, Inc.

The background is a solid blue color. In the lower half, there are two large white circles. A double-lined white path connects the two circles, starting from the right side of the left circle and ending at the left side of the right circle. The lines are parallel and slightly curved to follow the shape of the circles.

2008 Annual Report



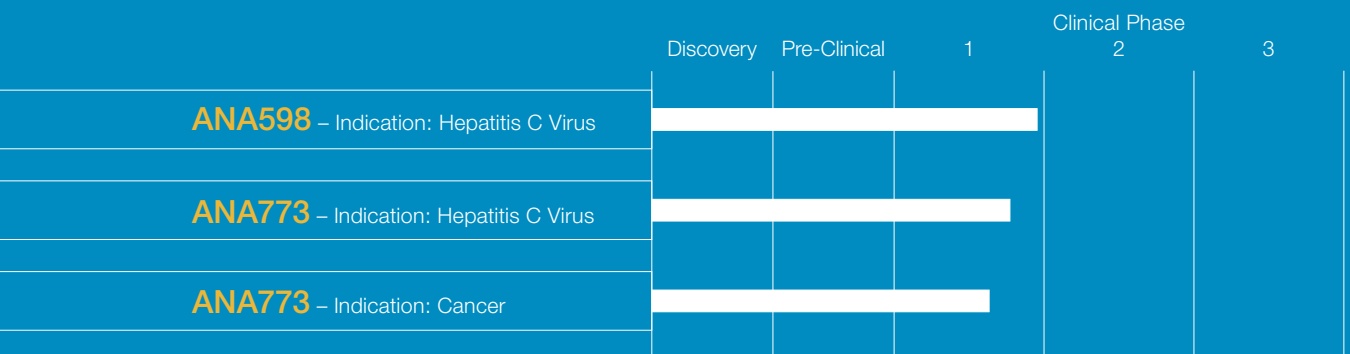
ANADYS PHARMACEUTICALS, INC.

We are a clinical-stage biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. Our objective is to develop new medicines that will improve the treatment outcomes for patients with these serious diseases.

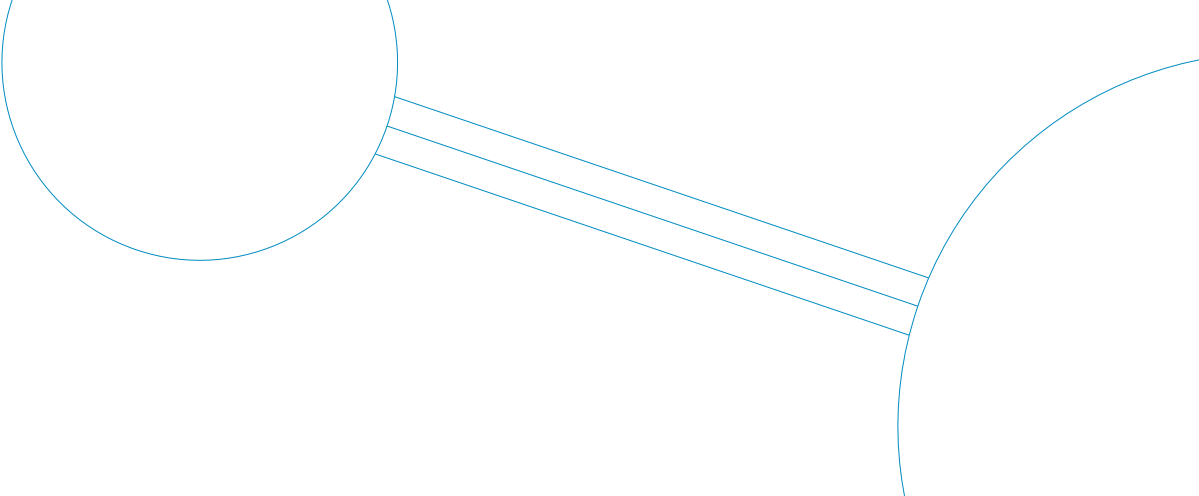
PURSUING NOVEL IDEAS DEVELOPING NOVEL MEDICINES

Our Focus: We are currently developing ANA598, a small-molecule, non-nucleoside inhibitor of the NS5B polymerase for the treatment of hepatitis C and ANA773, an oral, small-molecule inducer of endogenous interferons that acts via the Toll-like receptor 7 for the treatment of hepatitis C and cancer. We believe that both hepatitis C and cancer are two disease areas that represent large and significant unmet medical needs.

DEVELOPMENT PIPELINE



ANA598 and ANA773 are wholly owned by Anadys, were discovered at Anadys, and reflect the Company's expertise with direct antivirals and the Toll-like receptor 7 (TLR7) mechanism.



ANA598 is a direct antiviral that blocks the hepatitis C virus' (HCV) ability to multiply by inhibiting the viral RNA polymerase. **ANA598** belongs to a class of direct antivirals referred to as non-nucleosides. We believe non-nucleosides will become an important component of future combination regimens used to treat HCV infection. We believe that non-nucleoside NS5B polymerase inhibitors offer an exciting new way to potentially treat HCV infection, as part of combination regimens, which may include currently approved products or other direct antivirals currently in development.

{HCV} **ANA598** has demonstrated the preclinical properties, including potency, pharmacokinetics and early safety, that we believe are prerequisites for successful development in the HCV area and has recently demonstrated proof of viral load reduction in HCV-infected patients in our recently completed three-day Phase Ib clinical study in HCV patients.

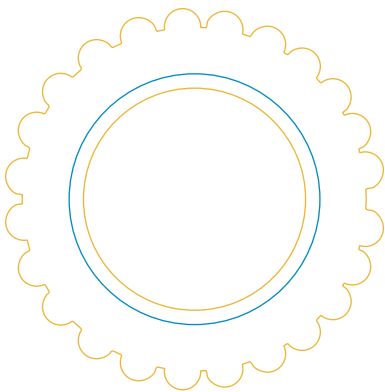
ANA773 is a novel, oral inducer of endogenous interferons that acts via the TLR7 pathway that we are developing as a treatment for both hepatitis C and cancer. With **ANA773** we are stimulating the patient's own immune system to attack either cancer cells or the hepatitis C virus by activating a key receptor on immune cells known as TLR7. With **ANA773**, we want to harness the pharmacological response triggered by TLR7 activation to treat both hepatitis C and cancer.

{HCV} We are currently conducting a Phase I clinical trial of **ANA773** which was designed to test **ANA773** in both healthy volunteers and patients with hepatitis C. The primary objectives of this study are to assess safety, tolerability and viral load decline and to explore every-other-day dosing over 28 days in HCV-infected patients.

{Cancer} We are currently conducting a Phase I clinical trial of **ANA773** in patients with advanced cancer. This trial is a safety and tolerability study designed to identify pharmacologically active doses and to establish the profile of immune stimulation, which information is intended to support the future design of clinical trials of **ANA773** (alone or in combinations) in specific tumor types.

HEPATITIS C (HCV)

Over **170,000,000 individuals**, three percent of the world's population, are chronically infected with HCV and three to four million people



become infected each year. Currently, there is no vaccine available to prevent HCV, nor an HCV-specific antiviral agent approved for treatment of chronic HCV infection.

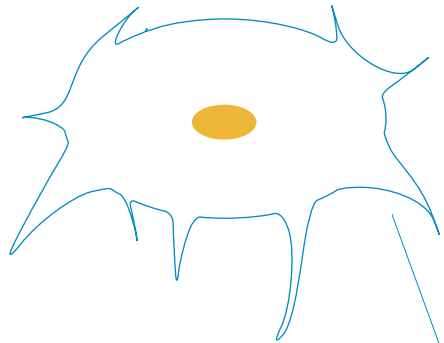
The current standard of care for treatment of chronic HCV infection is a combination of pegylated interferon-alpha and ribavirin. Interferon-alpha is administered by injection and results in abnormally high levels of this cytokine circulating systemically throughout the body. Therapy with interferon-alpha causes a number of side effects in many patients, including depression, drops in blood cell counts and flu-like symptoms, sometimes experienced during the entire year-long primary course of therapy that is standard for treatment of patients infected with genotype 1 HCV, the most difficult patient group to treat. These side effects may make patients feel worse than foregoing treatment, which reduces their motivation to initiate or continue HCV therapy. Many patients take additional drugs to treat these side effects, further increasing the cost and the risk of additional side effects to the patient. As a result, poor compliance with the HCV course of therapy may decrease the patient response rate.

It is expected that the next generation of therapies for treatment of HCV will include small-molecules, such as our product candidates ANA598 and ANA773. These new agents are expected to improve overall therapy by increasing cure rates and potentially improving tolerability and convenience of treatment if doses of currently used agents can be reduced or eliminated.

CANCER

Each year, an estimated **12,000,000 people** worldwide are diagnosed with cancer and more than half will eventually die from the disease.

According to the American Cancer Society the number of new cancer cases in the U.S. was projected at **1,400,000 for 2008.**



Several clinical observations support the importance of tumor immune surveillance in humans. The increased risk of tumor development in immunosuppressed patients, cases of spontaneous tumor regression, and the presence of tumor-reactive T cells and B cells correlating with improved prognosis all point to a role for the immune system in controlling tumor growth. Immunotherapy has had success with treating certain tumors and this approach remains of interest for improving cancer treatment options. Immunotherapy has the potential to react synergistically with other treatment modalities. New approaches to manipulate conventional cancer therapies to work in concert with the immune system will be explored. Rational combinations and sequences of therapy, coupled with treatment strategies based on emerging understanding of immunobiology, may result in therapies that control and/or eradicate established cancer. We believe that our product candidate currently in clinical development for the treatment of cancer, ANA773, has the potential to be an important component of these next-generation immunotherapies.

DEAR ANADYS SHAREHOLDERS, As I reflect back on 2008, I see a year in which Anadys achieved a remarkable transition. Having previously elected to focus our resources on two product candidates, ANA598 and ANA773, we began the year on the brink of resuming clinical development, with one active IND and one preclinical program, yet with no clinical trials actually underway. We set aggressive development goals for each program in 2008, and concluded the year with three active clinical programs: ANA598 under investigation for HCV, and ANA773 under investigation for both HCV and cancer. This exciting progress reflects our decision to focus our investments on two product candidates and could not have been achieved without the steadfast commitment of our dedicated employees.

We began clinical development of ANA598, our non-nucleoside HCV polymerase inhibitor, with a study in healthy volunteers initiated in the second quarter. We saw favorable pharmacokinetics and safety results from this single dose study, positioning us to initiate a study in HCV patients in the fourth quarter. In parallel with the healthy volunteer clinical study, we decided to accelerate certain long-term non-clinical activities, including manufacturing and chronic toxicology studies. Our investment thesis in making this decision was to position ANA598 for a rapid and efficient Phase 2 program in 2009, should we see positive results in the first HCV patient study. We announced very positive initial antiviral results for ANA598 in early January 2009, and have continued to update the status of this program during the first quarter of 2009. As we go to press, we have completed dosing at the two additional dose levels planned in this study. With 200 mg ANA598 taken twice daily we saw a median viral load decline of 2.4 log₁₀, positioning ANA598 as one of the most potent non-nucleoside HCV inhibitors described to date. We plan to report the antiviral data for all three dose levels at the European Association for the Study of the Liver (EASL) conference in Copenhagen in late April. We expect this data will further solidify ANA598 as a very attractive HCV candidate, with potential utility when added to currently approved treatments and also with promise to further improve patient outcomes when added to other direct antivirals currently in development.

ANA773 is our oral inducer of alfa interferons that acts via the TLR7 pathway. We began 2008 with an aim to study ANA773 in cancer. Mid-year, we elected to initiate investigation of ANA773 in HCV as well. The rationale for studying an oral interferon inducer in HCV is clear — alfa interferon products given by injection are the backbone of current HCV treatments, and all direct antivirals currently under development in the industry are being investigated first as add-ons to interferon-based regimens. An oral product that could replace injectable interferon in these future combination regimens would be very attractive to patients and treating physicians. We began investigation of ANA773 for HCV in healthy volunteers in the third quarter, and in this study demonstrated induction of interferon-dependent pathways starting at the 800 mg dose level. Encouragingly, the side effect profile at 800 mg was considerably better than historical reports of interferon products taken over similar timeframes. As we increased the dose in healthy volunteers, we began to see symptoms reminiscent of interferon therapy, consistent with activation of interferon-dependent pathways. We transitioned into studying ANA773 in HCV patients in the fourth quarter, starting at the 800 mg dose that was active in healthy volunteers. In early 2009, we released data showing clear dose dependent activation of interferon-dependent pathways and consequent antiviral activity, although it appears

that the doses of ANA773 required to activate these pathways in chronically infected HCV patients are higher than in healthy volunteers. We are currently taking the steps necessary to explore a higher dose of ANA773 in HCV patients.

In addition to HCV, we believe the pharmacology of TLR7 activation may have considerable benefit in cancer as well. Many of the TLR7-dependent pathways naturally activated to help clear virally infected cells offer promise to stimulate recognition and elimination of cancer cells, and we continue to explore this mechanism in an ongoing oncology study. To date we have completed escalation through five dose levels in cancer patients. ANA773 had been well tolerated to date. We look forward to reporting the pharmacologic profile of ANA773 in cancer patients at the higher doses explored thus far.

Looking ahead to the remainder of 2009, I see a number of opportunities to continue reporting on the progress of our development efforts, starting with the EASL meeting in late April. At this clinical conference we will report on the antiviral activity of ANA598 at three dose levels. We have begun a third clinical study of ANA598 over 14 days in healthy subjects and expect to have data from that study in hand during the second quarter. We also will have received results from 3-month toxicology studies of ANA598 in two species by April, and expect to receive additional longer term toxicology results throughout the second and third quarter. The clinical and non-clinical activities in the ANA598 program have been staged to position us to be ready in mid-2009 for a Phase 2 trial of ANA598 added to current standard of care treatment. By conducting substantial manufacturing activities and long-term toxicology studies early in the ANA598 development program, we expect to be able to conduct our Phase 2 program in a very efficient manner that is designed to provide evidence of ANA598's immediate antiviral benefit on top of standard of care as well as its contribution to sustainable clinical benefit, referred to as SVR in the hepatitis field. Positive results from this first Phase 2 study would help position ANA598 for a state-of-the-art late stage development program in which ANA598 can be studied in multiple patient populations, combined with several other active HCV agents. We also expect to develop a more complete picture of ANA773's activity in HCV and cancer, and to determine the appropriate path forward for the ANA773 programs based on the information to be received.

As we conduct our development activities we keep a keen focus on driving shareholder value, an outcome we can best achieve by demonstrating that our product candidates offer real promise to improve outcomes for patients suffering from HCV infection and cancer. As we have continued to refine that promise, we have engaged in discussions with other companies, especially companies with a strategic interest in the HCV field. We look forward to updating you on the outcome of these discussions if and when we have something concrete to report. We believe that the early clinical profile of ANA598, and the position we have created through the conduct of substantial non-clinical activities in parallel with the clinical program, offer the potential for an advanced development program in the hands of a larger company with complementary HCV agents under development. As we proceed with our clinical activities and our strategic business initiatives, I would like to express my appreciation for the continued support of our shareholders, an essential component of our endeavor to further the treatment of disease and recognize value from our efforts.



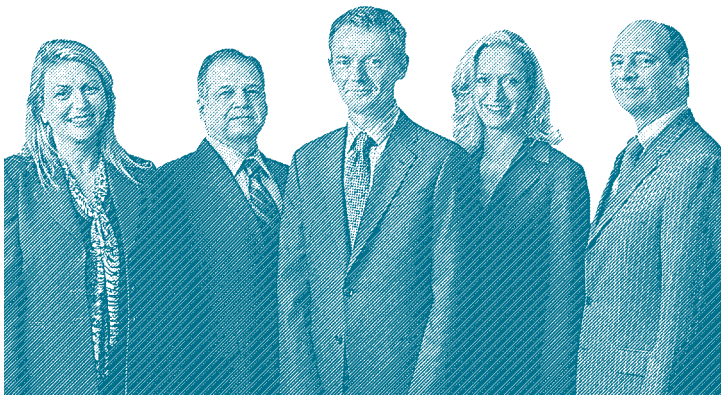
A handwritten signature in blue ink that reads "Steve Worland". The signature is written in a cursive, flowing style.

Stephen T. Worland, Ph.D.
President & Chief Executive Officer

A TEAM DEDICATED TO ACHIEVING OUR GOALS



THE ANADYS PHARMACEUTICALS, INC. TEAM: We are made up of individuals who work well together, have strong morale and spirit for their team, and define success in terms of the entire organization. Our people are at the core of our culture and our current and future successes.



PICTURED FROM LEFT TO RIGHT: Mary Yaroshevsky-Glanville, Vice President, Human Capital; James L. Freddo, M.D., Senior Vice President, Drug Development & Chief Medical Officer; Stephen T. Worland, Ph.D., President & Chief Executive Officer; Elizabeth E. Reed, J.D., Vice President, Legal Affairs & Corporate Secretary; James T. Glover, C.P.A., Senior Vice President, Operations & Chief Financial Officer.



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

Form 10-K

(MARK ONE)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008
OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission File Number 0-50632

ANADYS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

*(State or other jurisdiction of
incorporation or organization)*

22-3193172

*(I.R.S. Employer
Identification No.)*

**3115 Merryfield Row, San Diego,
California**

(Address of principal executive offices)

92121

(Zip Code)

Registrant's telephone number, including area code:

858-530-3600

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$0.001 par value

Nasdaq Global Market

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

None

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

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

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

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a
smaller reporting company)

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

The aggregate market value of the common stock held by non-affiliates of the registrant computed by reference to the closing price of the registrant's common stock reported on the Nasdaq Global Market as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$53,625,398 as of such date.

As of February 17, 2009, the Registrant had outstanding 28,830,094 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the 2009 Annual Meeting of Stockholders are incorporated herein by reference into Part III.

ANADYS PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

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INFORMATION RELATED TO FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about our development plans and programs, clinical trials, strategies and objectives, and other statements that are not historical facts, including statements which may be preceded by the words “intend,” “will,” “plan,” “expect,” “anticipate,” “estimate,” “aim,” “seek,” “believe,” “hope” or similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report on Form 10-K are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update publicly or revise any forward-looking statements. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors identified in our periodic reports filed with the Securities and Exchange Commission (SEC), including, without limitation, those discussed in “Item 1A. Risk Factors” and in “Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K.

PART I

Item 1. *Business*

Overview

Anadys Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. We are developing ANA598, a small-molecule, non-nucleoside inhibitor of the NS5B polymerase for the treatment of hepatitis C and ANA773, an oral, small molecule Toll-like receptor 7 (TLR7) agonist prodrug for the treatment of hepatitis C and cancer. Both ANA598 and ANA773 were discovered at Anadys and are wholly owned assets of Anadys.

We believe that hepatitis C and oncology are two disease areas that represent large and significant unmet medical needs. Our objective is to develop new medicines that will improve the treatment outcomes for patients with these serious diseases. We believe that meaningful improvements in patient outcomes offer the highest likelihood for commercial acceptance of our products if approved for sale.

Our expertise is based on two distinct scientific approaches to treating disease. With ANA598 we are focused on developing a direct antiviral, meaning a product candidate that acts by directly interacting with, and blocking the function of, a component of the virus. We discovered ANA598 through an extensive structure-based drug design program that focused on parameters critical for success in chronic viral diseases, including potency and sustained drug levels in blood. With ANA773, we are stimulating the patient’s own immune system to block cells infected with the hepatitis C virus from further amplifying the infection by producing more virus particles. Activation of the same pathways may also allow the patient’s immune system to attack cancer cells. ANA773 stimulates the immune system through activating a key receptor on immune cells known as TLR7. Our knowledge of TLR7 is buttressed by an extensive preclinical program exploring the pharmacology of this receptor and by previous clinical experience with other molecules that act by the TLR7 mechanism.

ANA598

ANA598 is a direct antiviral that blocks the hepatitis C virus’ (HCV) ability to multiply by inhibiting the viral RNA polymerase. ANA598 belongs to a class of direct antivirals referred to as non-nucleosides. We believe non-nucleosides will become an important component of future combination regimens used to treat HCV infection, similar to the role played by non-nucleoside inhibitors in HIV therapy. In 2007 we selected ANA598 as a development candidate. This selection represented the culmination of a comprehensive structure-based drug design program directed towards the viral RNA polymerase. ANA598 has demonstrated the preclinical properties, including potency, pharmacokinetics and early safety, that we believe are prerequisites for successful development in the HCV area.

ANA598 is currently being investigated in a Phase Ib patient study. On January 8, 2009 we announced results from the first cohort of this study which demonstrated a 2.5 log₁₀ median viral load decline after three days of dosing in the eight patients who received 200 mg of ANA598 twice-daily. This data was subsequently supplemented with data from three additional patients who also received 200 mg of ANA598 twice daily over three days. Results from all eleven patients who received the 200 mg dose level demonstrated a 2.4 log₁₀ median viral load decline. Results from these eleven patients also indicated that ANA598 was very well tolerated and no serious adverse events were reported, although conclusions regarding longer-term safety and tolerability cannot be made until the results of future clinical trials of longer duration in more patients are known. Following our announcement of the data from the patients who received the 200 mg dose level, we continued to enroll the subsequent dose cohorts, dosing patients with either placebo, or 400 mg or 800 mg twice daily over three days. We are nearing completion of dosing in the Phase Ib study and expect to receive and analyze the safety and viral load data from the 400 mg and 800 mg dose cohorts over the course of the next several weeks. We intend to release the full data from all three dose cohorts during the second quarter of 2009.

We are also currently conducting a clinical trial of ANA598 in healthy subjects to evaluate the steady-state pharmacokinetics, safety and tolerability of multiple doses of ANA598 administered orally over a 14-day period. We expect to have data from this study in the second quarter of 2009.

Preclinical evaluation of ANA598 required for initiation of clinical investigation was completed in the first quarter of 2008, leading to submission of an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA), subsequent allowance of the IND by the FDA and initiation of clinical investigation in the second quarter of 2008. In December 2008, we announced that the FDA granted fast track designation to ANA598 for the treatment of chronic HCV infection.

In the preclinical program, ANA598 was well tolerated at all doses tested in 28-day GLP toxicology studies. In September 2008, we initiated long-term, chronic toxicology studies of ANA598. Contingent on successful completion, these long-term toxicology studies are designed to support dosing up to 48 weeks in Phase II studies.

If ANA598 is successful in early stage development, we anticipate completing in mid-2009 the clinical, toxicology and manufacturing activities that should enable us to be ready to initiate longer term, Phase II, studies of ANA598 in combination with current standard of care. The actual timing for the initiation of Phase II studies will depend on a number of factors, including FDA review timelines, the timing of any potential strategic alliance or other transaction around ANA598 or ANA773, available cash resources and funding activities and the engagement of clinical sites.

ANA773

ANA773 is a novel, oral inducer of endogenous interferons that acts via the TLR7 pathway that we are developing as a treatment for both HCV and cancer. Both the prodrug and its active substance were discovered, designed and synthesized by Anadys scientists. Pharmacology studies have shown that ANA773 can elicit desired immune responses and that components of the response can be modulated by both dose and schedule of administration.

ANA773 for HCV

In July 2008, we resumed investigation of the TLR7 mechanism for HCV by taking ANA773 into a clinical trial in the Netherlands that was designed to test ANA773 in both healthy volunteers and patients with HCV. In October 2008, we completed dosing in healthy volunteers. No serious adverse events were reported. Dosing in the patient portion of the study commenced in October 2008 and has recently concluded. In this part of the study, patients received single oral doses every other day over 28 days, at doses of either 800 mg, 1200 mg or 1600 mg, with six subjects receiving ANA773 and two receiving placebo in each dose cohort. To date, we have received data from the 800 mg and 1200 mg cohorts and from seven out of the eight patients in the 1600 mg cohort. No serious adverse events have been reported and there were no discontinuations from the patient portion of the study. At the 800 mg and 1200 mg dose levels minimal immune induction and no significant viral load decrease was noted. At the 1600 mg dose level,

initial indications of immune induction and viral load decrease were seen in three of the five patients who have received ANA773 for whom we have data. We are in the process of analyzing this data and we are considering the possibility of exploring a higher dose level.

Results from preclinical pharmacology studies showed that ANA773 elicited desired immune responses influenced by both dose and schedule of administration. Results of completed toxicology studies showed that with every-other-day dosing of ANA773, immune stimulation of a magnitude believed to confer therapeutic potential could be achieved in animals without adverse toxicology findings.

ANA773 for Cancer

TLR7 agonists are of particular interest because there is precedent for their use in cancer and small molecule ligands for this receptor have been identified. Topical imiquimod (Aldara®) is approved for the treatment of basal cell carcinoma in the United States (U.S.), and has demonstrated activity against other tumor types including melanoma and chronic lymphocytic leukemia. Immunotherapy is potentially synergistic with other treatment modalities and new approaches to manipulate conventional cancer therapies to work in concert with the immune system are being explored.

We are currently conducting a Phase I clinical trial in the United States in cancer patients under a U.S. IND. This trial is a safety and tolerability study designed to identify pharmacologically active doses and establish the profile of immune stimulation, which information is intended to support the future design of clinical trials of ANA773 (alone or in combinations) in specific tumor types.

We are in the early stages of drug development with both ANA598 and ANA773. Substantial further investment by us will be necessary in order to progress our product candidates beyond the events referenced above and through additional clinical testing before we will be able to seek regulatory approval.

Industry Background

Based on available market data, we estimate that the global HCV market in 2008 was between \$2 and 3 billion. Due to significant global prevalence and substantial unmet medical need, improving the treatment of chronic HCV virus infection remains an important priority for the medical community and the pharmaceutical industry. Many patients with chronic HCV infection do not receive the current standard of care due to concerns about adverse events or have incomplete response to the current standard of care. If untreated or inadequately treated, chronic HCV infection can result in significant liver damage (cirrhosis), liver transplantation and liver cancer.

The World Health Organization (WHO) estimates that 170 million persons globally are chronically infected with HCV and 3 to 4 million persons are newly infected each year. Cirrhosis develops in about 10% to 20% of persons with chronic infection, and liver cancer develops in 1% to 5% of persons with chronic infection over a period of 20 to 30 years. It is estimated that more than 3 million people are chronically infected with HCV in the U.S. and that only about 100,000 of these patients are currently under treatment. The National Institutes of Health estimates that HCV results in 10,000 to 12,000 deaths in the U.S. annually and the Center for Disease Control and Prevention estimates that the number of deaths could increase to nearly 40,000 by 2010. HCV also exacerbates the severity of underlying liver disease when it coexists with other hepatic conditions. In particular, liver disease progresses more rapidly among persons with alcoholic liver disease and HCV infection.

There is currently no vaccine available to prevent infection with HCV. The current standard of care for treatment of chronic HCV infection is a combination of pegylated interferon-alpha and ribavirin. Interferon-alpha is administered by injection and results in abnormally high levels of this cytokine circulating systemically throughout the body. Therapy with interferon-alpha causes a number of side effects in many patients, including depression, drops in blood cell count and flu-like symptoms, sometimes experienced during the entire year-long primary course of therapy that is standard for treatment of patients infected with genotype 1 HCV, the most difficult patient group to treat. These side effects may make patients feel worse than foregoing treatment, which reduces their motivation to initiate or continue HCV therapy. Many patients take additional drugs to treat these side effects, further increasing the cost and the risk of additional

side effects to the patient. As a result, poor compliance with the HCV course of therapy may decrease the patient response rate.

In addition to the side effects, current therapies do not provide sustained elimination of the virus, called “sustained virologic response” (SVR), for a large proportion of chronically infected patients. For example, in clinical trials, approximately 50 percent of the genotype 1 patients, which represent the largest portion of HCV patients in the U.S., Europe and Japan, do not achieve sustained virologic response six months after the end of the treatment. Due to the lack of alternative treatments, patients without a sustained virologic response have no other treatment option but to undergo a second 48-week course of interferon-alpha-based therapy with a different brand of interferon-alpha. This second course of therapy subjects the relapsed patient to a similar risk of side effects as the previous course of therapy and offers the benefit of SVR in only a small fraction of patients who complete the 48 week treatment.

In response to the limitations of existing treatments for HCV infection, direct antiviral therapies (both protease and polymerase inhibitors) have emerged as a potential addition to or alternative to the current standard of care. Unlike interferons, which work by stimulating the immune system’s response to viral infection, HCV direct antivirals directly target the virus by inhibiting the protease or polymerase. Accordingly, direct antivirals have the potential to significantly improve treatment outcomes, when added to the standard of care in difficult-to-treat patients, including patients infected with HCV genotype 1. The addition of direct antivirals to the standard of care could also lead to shorter treatment duration, which could increase patient compliance. While direct antivirals will likely initially be used in combination with pegylated interferon-alpha and ribavirin, it may be possible eventually to replace one or both components of the current treatment regimen with a combination of oral therapies directed at HCV, including both protease and polymerase inhibitors.

Quantification of viral concentration (viral load) in the blood is an accepted surrogate of clinical effect in viral diseases. New treatments are evaluated on the ability to decrease or eliminate detectable viral particles in blood. With viral load as an accepted surrogate, proof of concept in the treatment of viral diseases can be obtained in Phase I human clinical trials. We believe this early proof of concept results in a higher probability of success post Phase I than the probability of success associated with drug development in many other therapeutic areas.

Cancer

Cancer remains a disease with significant unmet medical need. Each year, an estimated 12 million people worldwide are diagnosed with cancer and more than half will eventually die from their disease. According to the American Cancer Society, the number of new cancer cases in the United States is projected at 1.4 million for 2008, and approximately one out of every two men, and one out of every three women, will develop cancer during his or her lifetime. Cancer accounts for nearly one-quarter of all deaths in the United States, exceeded only by heart disease.

Cancer Treatment Today

Current treatments for cancer include surgery, chemotherapy, and radiation, as well as small molecules, antibodies, hormone therapy, and other targeted agents. Surgical and radiation treatments are limited in their effectiveness because they treat the tumor at a specific site, may not remove all the cancer cells, and are not effective if the cancer has spread beyond its initial site. Chemotherapy can treat the cancer at multiple sites, but causes severe side effects because it destroys healthy cells and tissues as well as cancer cells. In many cases, chemotherapy can only reduce tumors in size and not eliminate them completely, resulting in disease recurrence. Targeted molecular therapies, including antibody and small molecule therapies, have shown promise, but typically are most effective for only subsets of the patient population. Furthermore, all drug therapies, both new and old, have been vulnerable to the emergence of tumor resistance and disease recurrence.

Several clinical observations support the importance of tumor immune surveillance in humans. The increased risk of tumor development in immunosuppressed patients, cases of spontaneous tumor regression and the presence of tumor-reactive T cells and B cells correlating with improved prognosis all point to a role

for the immune system in controlling tumor growth. Immunotherapy has had success in treating certain tumors and this approach remains of interest for improving cancer treatment options. Immunotherapy is potentially synergistic with other treatment modalities and new approaches to manipulate conventional cancer therapies to work in concert with the immune system will be explored. Rational combinations and sequences of therapy, coupled with treatment strategies based on emerging understanding of immunobiology, may result in therapies that control and/or eradicate established cancer.

Toll-Like Receptors

Toll-Like Receptors — or TLRs — are a relatively new scientific discovery, though their origins date back hundreds of millions of years. TLRs evolved as a way to protect organisms against pathogens such as viruses and bacteria. This defense mechanism has proven so effective that it is an integral part of the human immune system today and a promising target for innovative new medicines.

In 1997, the first human TLR was cloned. To date, scientists have discovered 10 TLRs in humans, each recognizing generic molecular patterns associated with a variety of invading pathogens.

TLR Agonists in Viral Diseases

Certain TLRs are responsible for fighting bacterial and fungal infections; others respond specifically to viral infections.

Unlike adaptive immunity, which enables the immune system to remember and fight specific infections that it has encountered before, innate immunity is the ability to recognize foreign invaders upon their very first meeting. This function is regulated in part by TLRs, a family of proteins that serve as a first line of defense in the body.

Once a TLR recognizes a particular pathogen, it launches a dual assault. First, it triggers the body's innate immunity, initiating an inflammatory response to fight the invader that includes induction of interferon, a natural disease fighter that is the basis for many approved products. It then alerts and educates the body's adaptive immune system so that it will recognize the pathogen in the future. If TLRs fail, the body is left vulnerable to infection.

TLR Agonists in Cancer

As key regulators of both innate and adaptive immune responses, TLRs have been shown in research studies to affect several diseases, including cancer. Clinical studies have demonstrated that activation of TLR7 is effective in treating certain cancers that appear on the skin. Specifically, topical imiquimod (Aldara®) is approved for the treatment of superficial basal cell carcinoma. Unfortunately, however, imiquimod is poorly tolerated when administered orally, limiting its utility for broader indications requiring systemic exposure.

Additional justification for the investigation of TLR7 agonists for the treatment of cancer comes from the many studies conducted with TLR9 agonists. TLR7 and TLR9 agonists share common signaling pathways, partially overlap in cell-type expression, and have comparable direct and indirect activities as immunostimulants. A large body of data exists from animal models and human studies suggesting the potential utility of appropriately modified natural agonists of TLR9 either in monotherapy or combination therapy for the treatment of cancer. TLR7 and TLR9 agonists are, however, administered differently to patients: TLR7 agonists can be administered orally, while TLR9 agonists are thus far only injectable.

Our Strategy

The key elements of our strategy include the following:

- *Advance the Development of ANA598 in HCV.* We are developing ANA598, a non-nucleoside inhibitor of the HCV NS5B polymerase. During 2009 we intend to:
 - Complete the Phase Ib clinical trial in HCV infected patients, and announce the full data set from all dose cohorts during the second quarter of 2009;

- Complete a 14 day trial in healthy subjects and receive data from that trial in the second quarter of 2009;
- Complete the manufacturing of drug substance and drug product necessary to initiate Phase II studies of ANA598 by the middle of 2009;
- Complete six and nine month toxicology studies of ANA598, which are designed to enable dosing up to 48 weeks in Phase II studies; and
- Contingent on the receipt of additional funding, conduct Phase II studies of ANA598 in combination with the current standard of care (pegylated interferon-alpha and ribavirin).
- *Advance the Development of ANA773 in HCV.* We have recently completed dosing in a Phase I clinical trial of ANA773 in HCV patients. During 2009 we intend to:
 - Analyze the data from the 1600 mg dose level in HCV infected patients;
 - Assess the possibility of exploring a higher dose in HCV infected patients; and
 - Pending completion of the analysis of the 1600 mg dose level and potentially the results of a higher dose level, determine the business case for proceeding into Phase II and further non-clinical activities necessary to support Phase II trials with ANA773 as a therapy for HCV infection.
- *Advance the Development of ANA773 in Cancer.* We are currently conducting a Phase I clinical trial of ANA773 in cancer patients. During 2009 we intend to:
 - Explore the pharmacodynamic response in cancer patients;
 - Select the tumor types for potential Phase II evaluation; and
 - Select the dose and schedule for potential Phase II clinical trials.
- *Pursue the development of novel, high quality product candidates in major disease areas.* We select our product candidates based on demonstrated properties that suggest the potential to change treatment paradigms and become important products in time. Our strategy is to couple high quality candidates with a disciplined investment approach, pursuing time- and cost-efficient paths to obtaining clinical data.
- *Opportunistically Explore Strategic Alliances around our product candidates.* We intend to explore potential strategic alliances and other transactions around ANA598 and ANA773.

We currently have no ongoing collaborations.

Our Development Programs

ANA598 for HCV

ANA598 is a direct antiviral that blocks the hepatitis C virus' ability to multiply by inhibiting the viral RNA polymerase. ANA598 belongs to a class of direct antivirals referred to as non-nucleosides. We believe non-nucleosides will become an important component of future combination regimens used to treat HCV infection, similar to the role played by non-nucleoside inhibitors in HIV therapy. In 2007 we selected ANA598 as a development candidate. This selection represented the culmination of a comprehensive structure-based drug design program directed towards the viral RNA polymerase. ANA598 has demonstrated the preclinical properties, including potency, pharmacokinetics and early safety, that we believe are prerequisites for successful development in the HCV area and has recently demonstrated proof of viral load reduction in HCV-infected patients in our Phase Ib study described below.

We believe that non-nucleoside NS5B polymerase inhibitors offer an exciting potential new way to target treating HCV infection, as part of combination regimens which may include other direct antivirals (such as protease inhibitors and/or nucleosides polymerase inhibitors) and/or immunomodulators (such as pegylated interferon). We believe that polymerase inhibitors have the potential to be equally important components of future regimens as protease inhibitors, which is another class of HCV direct antivirals

currently in clinical development by a number of companies, including Vertex (with Mitsubishi and Johnson & Johnson) and Schering Plough. Historically, it has been challenging to identify non-nucleoside polymerase inhibitors that display both potency and sustained drug levels in blood. With ANA598, we believe we have created a product candidate that has the potential to overcome this challenge. We believe that we have the opportunity to be competitive in the effort to develop non-nucleoside polymerase inhibitors for the treatment of HCV, since, to our knowledge the number of non-nucleosides in development is smaller than the number of potentially attractive combinations that can be formed with attractive protease inhibitors and nucleoside polymerase inhibitors in development. We believe that the future evolution of HCV therapy will likely include protease inhibitors, nucleosides and non-nucleosides used in various combinations. Therefore, we view ANA598 as complementary to, rather than competitive with, protease inhibitors and nucleosides that are currently in development as HCV therapies.

Preclinical evaluation of ANA598 required for initiation of clinical investigation was completed in the first quarter of 2008, leading to submission of an IND to the FDA, subsequent allowance of the IND by the FDA and initiation of clinical investigation in the second quarter of 2008. In December 2008, we announced that the FDA granted fast track designation to ANA598 for the treatment of chronic HCV infection.

ANA598 is currently being investigated in a Phase Ib patient study in which patients are to receive ANA598 twice daily over three days at dose levels of either 200 mg, 400 mg or 800 mg. In January 2009 we announced results from the first cohort of this study which demonstrated a 2.5 log₁₀ median viral load decline after three days of dosing in the eight patients who received 200 mg of ANA598 twice-daily. Subsequent to this announcement, we determined that, due to drug dispensing errors in the clinic, a small number of patients intended to receive the next dose level inadvertently received ANA598 200 mg or matching placebo, including two additional genotype 1a patients and one additional genotype 1b patient who received active ANA598. Taking into account these additional patients, the median viral load decline at the end of treatment was 2.4 log₁₀ (with a range of 0.4-3.4 log₁₀) for the eleven patients who received ANA598 at 200 mg twice-daily. The five genotype 1a patients who received ANA598 demonstrated a median viral load decline of 1.5 log₁₀, while the six genotype 1b patients who received ANA598 demonstrated a median viral load decline of 2.6 log₁₀. The results further indicated that ANA598 was very well tolerated at the 200 mg twice-daily dose level and no serious adverse events were reported, although conclusions regarding longer-term safety and tolerability cannot be made until the results of future clinical trials of longer duration in more patients are known. Following our announcement of the data from the patients who received the 200 mg dose level, we continued to enroll the subsequent dose cohorts, dosing patients with either placebo, or 400 mg or 800 mg twice daily over three days. We are nearing completion of dosing in the Phase Ib study and expect to receive and analyze the safety and viral load data from the 400 mg and 800 mg dose cohorts over the course of the next several weeks. We intend to release the full data from all three dose cohorts during the second quarter of 2009.

We are also currently conducting a clinical trial of ANA598 in healthy subjects to evaluate the steady-state pharmacokinetics, safety and tolerability of multiple doses of ANA598 administered orally over a 14-day period. Approximately forty subjects are to participate in the trial and will receive doses of ANA598 ranging from 400 mg to 1200 mg once daily or 600 mg twice daily. We expect to have data from this study in the second quarter of 2009.

In a Phase I study in healthy volunteers conducted in 2008, ANA598 was administered as capsules at single oral doses of 400 mg, 800 mg, 1400 mg, 2000 mg (fed and fasted) and 3000 mg. In addition, a separate cohort received two 800 mg doses 12 hours apart. ANA598 was well tolerated at all doses and there were no serious adverse events or withdrawals from the study. All reported adverse events were classified as mild or moderate, with no apparent dose relationship. The pharmacokinetic profile demonstrated sustained plasma levels of ANA598 consistent with the potential for once-daily or twice-daily oral dosing.

In the preclinical program, ANA598 was well tolerated at all doses tested in 28-day GLP toxicology studies. In September 2008, we initiated six and nine month chronic toxicology studies of ANA598. Contingent on successful completion these long-term toxicology studies are designed to support dosing up to 48 weeks in Phase II studies.

We have conducted in vitro laboratory studies that showed ANA598 has the potential to be synergistic with interferon-alpha, and additive-to-synergistic with the protease inhibitor telaprevir (VX-950), and the nucleoside polymerase inhibitor PSI-6130 (the active agent of R7128). Synergistic means that the actual combined effect of the two agents is greater than would be predicted from simply adding the effects of each agent alone. Additive-to-synergistic means that at a minimum the combined actual effect of the two agents together equals what would be predicted by adding their individual effects (additive), and that upon reaching certain threshold concentrations the two agents begin to act in a synergistic fashion. These studies also showed that ANA598 retained activity against HCV mutants known to confer resistance to other classes of direct antivirals, including protease inhibitors, nucleoside inhibitors and non-nucleosides that bind at a specific structural site (the “thumb” site) in the HCV NS5B polymerase enzyme. HCV mutants resistant to ANA598 have been shown to be fully susceptible to interferon-alpha, telaprevir (VX-950) and PSI-6130. We have also presented data demonstrating synergy between ANA598 and immunoregulatory proteins termed “cytokines” induced by ANA773, Anadys’ TLR7 agonist oral prodrug, also in development for hepatitis C.

If ANA598 is successful in early stage development, we anticipate completing in mid-2009 the clinical, toxicology and manufacturing activities required to initiate longer term, Phase II, studies of ANA598 in combination with current standard of care.

ANA773 for HCV

In July 2008, we resumed investigation of the TLR7 mechanism for HCV by taking ANA773 into a clinical trial designed to test ANA773 in both healthy volunteers and patients with HCV. This trial is being conducted in the Netherlands. In the healthy volunteer portion of the study, which concluded in October 2008, subjects received a single dose followed by four doses taken every other day, at levels from 200 mg to 1600 mg, with six subjects receiving ANA773 and two receiving placebo in each dose cohort. No serious adverse events were reported. Biomarker induction indicative of immune activation was seen in a majority of healthy volunteers beginning at 800 mg. Some side effects commonly seen with interferon treatment, including fever and chills, were observed at higher doses. The frequency and intensity of interferon-like side effects increased with dose, and one healthy volunteer at the 1200 mg dose and two healthy volunteers at the 1600 mg dose discontinued from the trial before completion of dosing.

Dosing in the patient portion of the study commenced in October 2008 and recently concluded. In this part of the study, patients received single oral doses every other day over 28 days, at doses of either 800 mg, 1200 mg or 1600 mg, with six subjects receiving ANA773 and two receiving placebo in each dose cohort. To date, we have received data from the 800 mg and 1200 mg cohorts and seven out of the eight patients in the 1600 mg cohort. No serious adverse events have been reported and there were no discontinuations from the patient portion of the study. At the 800 mg and 1200 mg dose levels minimal immune induction and no significant viral load decrease was noted. At the 1600 mg dose level, initial indications of immune induction and viral load decrease were seen in three of the five patients for whom we have data. We are in the process of analyzing this data and we are considering the possibility of exploring a higher dose level.

Results from pre-clinical pharmacology studies showed that ANA773 elicited desired immune responses and that the profile of response could be modulated by both dose and schedule of administration. Results of 13-week GLP toxicology studies showed that with every-other-day dosing of ANA773, immune stimulation of a magnitude believed to confer therapeutic potential could be achieved without adverse toxicology findings. The immune stimulation observed with every-other-day dosing of ANA773 in monkeys included induction of interferon-alpha and interferon dependent responses at levels that were sustained over 13 weeks of dosing.

The toxicology results from every-other-day dosing of ANA773 over 13 weeks contrast with results from prior 13-week animal toxicology studies that utilized daily dosing of ANA975, a TLR7 agonist prodrug previously in development by us for the treatment of chronic hepatitis C. In initial 13-week animal toxicology studies of ANA975 dosed daily, unexpected findings associated with intense immune stimulation were observed. When lower daily doses of ANA975 were then explored in a subsequent 13-week animal toxicology study, adverse findings were noted even at dose levels where desired immunostimulatory

effects were not measurable, following which the decision was made in 2007 to discontinue development of ANA975.

ANA773 for Cancer

We are also developing ANA773 as a potential treatment for cancer. ANA773 stimulates the body's immune system through activation of the TLR7 receptor. The pharmacologic consequences of TLR7 activation are broad and include induction of cytokines such as interferon-alpha as well as activation of immune effector cell populations known as natural killer (NK) cells and cytotoxic T lymphocytes (CTLs). The cytokine induction and cellular activation mechanisms both offer the potential for direct control of tumor cell growth. Furthermore, there is evidence to support the concept that activation of NK and CTL cells may be beneficial in enhancing the effect of existing cancer therapies, including monoclonal antibodies and certain chemotherapies. We are developing ANA773 with this broad potential in mind. In our first clinical study we plan to identify a safe and well-tolerated dose of ANA773, as well as assess pharmacodynamic activity reflected by induction of cytokines and activation of NK cells and CTLs at various doses and schedules. We expect to have a portion of this information in hand during the first half of 2009, which will position ANA773 for subsequent clinical investigations in specific tumor types, alone and in combination with other agents.

Clinical observations provide direct evidence of the importance of the immune system in controlling cancer in humans, including the increased risk of cancer in patients with an immune system that is not functioning normally and the correlation between cancer survival and the degree to which tumors are recognized as abnormal by lymphocytes. The host immune system plays an essential role in controlling the ability of cancer cells to multiply, invade and metastasize. Immune system surveillance identifies cells within the body that have been transformed by DNA damage and targets them for destruction before they multiply and metastasize. It is believed that every human would rapidly develop cancer were it not for this immune surveillance. Although not widely recognized, many currently approved cancer therapies actually rely on some aspect of the host immune system as an integral aspect of their mechanism of action. For example, many therapeutic monoclonal antibodies work by tagging tumor cells for recognition and removal by NK cells. In light of the successes with these classes of therapy, there remains considerable interest among many oncologists, or cancer doctors, to more broadly utilize immune activation as a therapeutic approach, alone and in combination with other therapies.

The potential benefits of the TLR7 mechanism in cancer therapy arise from the fundamental role of this receptor in immune activation. TLR7 plays a gatekeeper function during infection, recognizing that a pathogen (the microscopic organisms that cause infection) is present and triggering responses that lead to control and elimination of the pathogen. We are seeking to harness these same immunological responses as a way to potentially control and eliminate cancer cells from the body.

The TLR7 receptor is expressed in certain cell types that play key roles in the immune system. The potential benefit of a TLR7 agonist in treating cancer may arise from direct action in immunological cells that express TLR7. For example, certain B cell malignancies such as chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphoma (NHL) may respond because the B cells that lie at the heart of these malignancies can self-destruct upon TLR7 activation. Alternatively, the benefit in cancer may arise from action against cells that do not express the TLR7 receptor but respond to immune system components that become stimulated upon TLR7 activation. Immune system components that become activated include NK cells and CTLs and circulating cytokines. These stimulated components of the immune system can directly eliminate tumor cells and may also enhance the activity of certain existing cancer therapies, including some monoclonal antibodies and certain chemotherapies. Over time in our ANA773 development program, we may explore several of these avenues for potential utility of a TLR7 agonist in cancer.

There is a degree of precedent to support the use of the TLR7 mechanism in cancer. One marketed product that works by stimulating the immune system via the TLR7 mechanism is imiquimod (Aldara®). While the FDA-approved indications for imiquimod are limited to topical treatment of skin diseases, such as superficial basal cell carcinoma, actinic keratosis and warts induced by the human papillomavirus, there are several reports of imiquimod demonstrating activity against skin metastases from solid tumors, such as breast cancer. However, to date no one has successfully developed an oral TLR7 agonist for cancer. We

believe the combination of our prodrug approach, described below, and our understanding of TLR7 pharmacology provides us an opportunity to utilize the TLR7 mechanism to systemically treat a broad spectrum of cancers, including solid tumors and B cell diseases, with oral administration of ANA773.

ANA773 is a prodrug of an active TLR7 agonist we believe may confer benefit in cancer treatment. As a prodrug, ANA773 itself does not activate the TLR7 receptor. Rather, the body's metabolic processes transform ANA773 to an active form after absorption from the digestive tract, resulting in the active TLR7 agonist circulating in the blood. Both ANA773 and the active agent it delivers were designed and synthesized by our scientists. The use of a prodrug provides for efficient delivery of the active agent to the bloodstream and avoids undesirable effects of an active TLR7 agent in the digestive tract prior to absorption. We have shown in multiple preclinical studies that oral delivery of ANA773 produced the desired blood concentrations of the active agent and provided immune stimulation. In our clinical investigations, we are administering ANA773 orally.

We have reported the activity of ANA773 and its active form at multiple scientific conferences. In October 2007, we presented data showing that activation of TLR7 in vivo by the active form of ANA773 leads to the expected cellular responses, including activation of NK cells and CTLs. Earlier in 2007, we presented data from an in vitro study demonstrating that ANA773 and its active metabolite stimulate secretion of interferon alpha and enhance direct tumor cell killing by NK cells. In addition to enhancing direct NK cell killing, the active metabolite of ANA773 also enhanced the ability of rituximab, an antibody against CD20, to trigger immune-mediated cell killing of transformed B cells. We have also presented data from in vivo preclinical studies showing that the schedule of administration had a significant effect on the profile of immune stimulation induced by ANA773. Alternating dosing with periods of no dosing led to more robust NK cell activation and more stable levels of interferon-alpha induction, compared to chronic daily administration. We anticipate that different dosing schedules may be required in different tumor settings.

In the fourth quarter of 2007 the FDA accepted our IND application to commence clinical investigation of ANA773 in advanced cancer patients and we are currently conducting a Phase I clinical trial in the United States. The Phase I clinical trial of ANA773 is a multiple, ascending dose study conducted in patients with advanced solid tumors. In addition to safety and tolerability, patients are to be monitored for pharmacodynamic responses indicative of immunological stimulation. During 2009, we intend to select the tumor types for Phase II exploration and identify the dose and schedule for potential future Phase II clinical trials.

Manufacturing and Supply

All of our manufacturing is out-sourced to third parties, with control by our internal managers. We rely on third-party manufacturers to produce sufficient quantities of ANA598 and ANA773 for use in clinical trials. We intend to continue this practice for any future clinical trials and large-scale commercialization of ANA598 and ANA773. Both of our current product candidates are small-molecule drugs. Historically, these drugs have been simpler and less expensive to manufacture than biologic drugs.

Intellectual Property

Our policy is to pursue patents and to otherwise endeavor to protect our technology, inventions and improvements that are commercially important to the development of our business. We also rely upon trade secrets that may be important to the development of our business.

Our success will depend in large part on our ability to:

- Obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business;
- Defend and enforce our patents;
- Preserve the confidentiality of our trade secrets; and
- Operate without infringing the patents and proprietary rights of third parties.

We hold issued patents and pending patent applications in the United States, and in foreign countries we deem appropriate, covering intellectual property developed as part of our research and development programs. Our intellectual property holdings include, but are not limited to, United States and/or foreign patents and patent applications covering ANA598 and/or other non-nucleoside polymerase inhibitors, United States and/or foreign patents and patent applications covering ANA773 and/or other TLR7 agonists, as well as United States and foreign patent applications covering the manufacture, pharmaceutical compositions and methods of use of these compounds.

We intend to continue using our scientific expertise to pursue and file patent applications on new developments with respect to uses, methods and compositions of matter in order to enhance our intellectual property position in our areas of therapeutic focus.

We intend to aggressively prosecute our patent applications and enforce and defend our patents and otherwise protect our proprietary technology. Although we believe our rights under patents and patent applications provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Any patents or patent rights that we obtain may be circumvented, challenged or invalidated by our competitors.

We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. Our practice is to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or other relationships with us. These agreements generally provide that all confidential information developed by or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties. In the case of employees, the agreements generally provide that all discoveries, developments, inventions and other intellectual property conceived or reduced to practice by the individual while employed by us will be our exclusive property. In the case of advisors and consultants, the agreements generally provide that all discoveries, developments, inventions, and other intellectual property conceived or reduced to practice by the individual as a result of performance of services for us and not resulting from research related to work supported by another entity with which the individual is party to a confidentiality agreement, shall be our exclusive property. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy to us in the event of unauthorized disclosure of confidential information or other breaches of the agreements.

Competition

The biotechnology and pharmaceutical industries are very competitive and subject to rapid and significant technological change. Our product candidates, if approved for sale, will compete with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and medical conditions that we are targeting. We believe that a significant number of drugs are currently under development and may become available in the future for the treatment of HCV and cancer. Due to the level of focus on developing treatments for these indications, ongoing research efforts are intense and new treatments are being sought out and developed by our competitors. Some of these products use therapeutic approaches that may compete directly or indirectly with ANA598 or ANA773. In addition, less expensive generic forms of currently marketed drugs could lead to additional competition upon patent expiration or invalidations.

HCV

Treating HCV with Interferon-based Therapies

Current standard treatments for HCV include an interferon-based product combined with ribavirin. Although interferons result in antiviral effects, they are injectable products and cause numerous side effects.

Next generation interferon-based products, so-called pegylated interferons, were developed to provide an improved dosing regimen and are approved as once-per-week injected products. Currently approved therapies for the treatment of HCV infection include Peg-Intron (pegylated interferon-alpha-2b) and Intron-A (interferon-alpha-2b), which are marketed by Schering-Plough, Pegasys (pegylated interferon-alpha-2a) and Roferon-A (interferon-alpha-2a), which are marketed by Roche and several branded and generic versions of ribavirin.

Many patients experience unpleasant side effects when receiving interferon-based products, including flu-like symptoms such as fatigue, pyrexia, myalgia, cough, headache, and rigors, psychiatric reactions, such as depression, irritability and anxiety, as well as neutropenia and thyroid dysfunction. Due to the nature of HCV infection, patients may not show any symptoms from the HCV itself when they initiate therapy. Ironically, harsh side effects often make patients feel sicker than the disease itself. As a result, physicians often delay treatment of HCV-infected patients until tests of liver function demonstrate initial liver degeneration due to the infection. In clinical studies, harsh side effects have caused discontinuation of treatment in approximately 10 to 20 percent of patients. These side effects also require additional drug therapies, which increase the cost to the patient. Further, the optimal dose, treatment length and response rates to interferon and ribavirin therapy vary considerably based on HCV genotype and mode of therapy, i.e., monotherapy or combination therapy.

Direct Antivirals in Development for Treating HCV

In response to the limitations of existing treatments for HCV infection, the development of direct antiviral therapies (both protease and polymerase inhibitors) has emerged as a potential addition to or alternative to the standard treatment. Unlike interferons, which work by stimulating the immune system's response to viral infection, HCV direct antivirals directly target the virus by inhibiting the protease or polymerase. Accordingly, direct antivirals may significantly improve treatment outcomes, when added to the standard of care in difficult-to-treat patients, including patients infected with HCV genotype 1, relative to treatment with the standard of care alone. The addition of direct antivirals to the standard of care could also lead to shorter treatment duration, which could increase patient compliance. While direct antivirals will likely initially be used in combination with pegylated interferon-alpha and ribavirin, it may be possible eventually to replace one or both components of the current treatment regimen with a combination of oral therapies directed at HCV, including both protease and polymerase inhibitors.

ANA598 belongs to a class of direct antivirals known as non-nucleoside polymerase inhibitors. If approved, ANA598 would likely be used in combination with the current standard of care and/or other direct antiviral agents such as protease inhibitors and other polymerase inhibitors. Although any product currently approved or approved in the future for the treatment of HCV infection could potentially decrease or eliminate the commercial opportunity of ANA598, we expect that in a combination setting a non-nucleoside polymerase inhibitor would be complementary with a protease inhibitor and a nucleoside polymerase inhibitor. We believe that other non-nucleoside polymerase inhibitors would likely be the most direct competitors of ANA598, but depending on the resistance profiles of the compounds, it is possible that even two non-nucleoside polymerase inhibitors could be complementary. To our knowledge, other non-nucleoside polymerase inhibitor programs are currently under clinical evaluation by Pfizer, Gilead, Merck, Abbott, Boehringer Ingelheim and ViroChem. Further, a number of companies have non-nucleoside polymerase inhibitor research programs.

Additional compounds in late stage clinical trials for HCV that may be complementary to or competitive with ANA598 include Albuferon, in development by Human Genome Sciences and Novartis, telaprevir, in development by Vertex Pharmaceuticals, Janssen Pharmaceutica and Mitsubishi Tanabe Pharma, boceprevir and SCH-900518, in development by Schering-Plough, ITMN-191, in development by Intermune and Roche, TMC-435350, in development by Tibotec and Medivir, MK-7009, in development by Merck, BI-201335, in development by Boehringer Ingelheim, and R-7128 in development by Pharmasset and Roche.

Immunological Agents in Development for the Treating HCV

Due to the side effects and poor treatment response to interferon therapy discussed above, there are currently a number of agents in development that could potentially replace today's pegylated interferons. ANA773 is an oral prodrug of a TLR7 agonist under evaluation for the treatment of HCV. There are a number of agents in clinical development that could potentially compete with ANA773 as new agents for the treatment of HCV, including, Albuferon, in development by Novartis and Human Genome Sciences, and Locteron, in development by Biolex Therapeutics, both of which are longer-acting versions of interferon alfa. Also, in development as potential improvements to existing interferons are PEG-interferon lambda, in development by Zymogenetics and Bristol Myers-Squibb, and omega interferon in development by Intarcia Therapeutics. IMO-2055, a TLR9 agonist in development by Idera, is also being studied in early stage clinical trials in HCV patients and PF-04878691, an oral TLR7 agonist is in development by Pfizer for HCV.

Cancer

Current treatments for cancer include surgery, chemotherapy, and radiation, as well as small molecules, antibodies, hormone therapy, and other targeted agents. Surgical and radiation treatments are limited in their effectiveness because they treat the tumor at a specific site, may not remove all the cancer cells, and are not effective if the cancer has spread beyond its initial site. Chemotherapy can treat the cancer at multiple sites, but causes severe side effects because it destroys healthy cells and tissues as well as cancer cells. In many cases, chemotherapy can only reduce tumors in size and not eliminate them completely, resulting in disease recurrence. Targeted molecular therapies, including antibody and small molecule therapies, have shown promise, but typically are most effective for only subsets of the patient population. Furthermore, all drug therapies, both new and old, have been vulnerable to the emergence of tumor resistance and disease recurrence.

ANA773 is a prodrug of a TLR7 agonist under evaluation for oncology indications. Any product currently approved or approved in the future for the treatment of cancer could decrease or eliminate the commercial opportunity of ANA773. Programs that most directly compete with ANA773 at this time are several TLR9 agonists under evaluation for oncology indications, including IMO-2055, in development by Idera and Merck KGaA, and a cancer program in development by Dynavax.

Competitive Risks

To date, we have only conducted short term Phase I clinical trials of ANA598 and ANA773. Therefore, it is difficult to predict the efficacy, safety and tolerability that these product candidates will demonstrate in longer term trials, alone or in combination with other agents. It is also difficult to predict how these product candidates will interact with other product candidates in development or on the market, until we perform combination studies. Further, it is difficult to predict whether our product candidates will cause any toxicity issues, potential side effects, or other negative consequences associated with their long-term use. During the course of future clinical trials, we may discover that these product candidates are less effective, require unacceptable dosing regimens, or have a similar side effect profile as the profile associated with current therapies or future competitors. This may result in our product candidates being less advantageous or less desirable from a patient and treating physician perspective as compared to current therapies for HCV or cancer.

We face competition from pharmaceutical and biotechnology companies both in the U.S. and abroad. Our competitors may utilize discovery technologies and techniques or partner with collaborators in order to develop products more rapidly or successfully than we or our future collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources than we do and far more experience in the discovery and development of product candidates and the commercialization of potential products. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

We believe that our ability to compete depends, in part, upon our ability to create, maintain and license scientifically advanced technology. Further, we need to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary technology or processes and secure sufficient capital resources for the substantial time period between technological conception and commercial sales of products based upon our technology.

We expect that competition among HCV and cancer therapies approved for sale will be based on various factors, including improved product efficacy, safety and tolerability, ease of administration (*e.g.*, oral vs. intravenous administration), availability, price, reimbursement status and patent position. Potential competitors may develop treatments for HCV or cancer that are more effective and/or safer or more convenient than our product candidates or that would make our technology and product candidates obsolete or non-competitive.

Government Regulations

We are subject to regulation by the FDA and comparable regulatory agencies in foreign countries with respect to the development and commercialization of products and services resulting from our drug discovery activities. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, efficacy, labeling, storage, record keeping, advertising and promotion of these products and services.

As an initial step in the drug approval process of pharmaceuticals, an applicant typically conducts preclinical laboratory and animal studies of the product candidate. Following these studies, the applicant will submit an Investigational New Drug (or equivalent) (IND) application to the FDA (or comparable foreign regulatory agency). Once the IND becomes effective, the applicant can commence clinical studies of the product candidate in humans to determine safety, tolerability and efficacy. Following clinical studies, the marketing of a new drug requires the filing of a New Drug Application (NDA) with the FDA and its subsequent approval (similar requirements exist within foreign agencies). The process required by the FDA and comparable agencies before a pharmaceutical or biologic device may be marketed in the U.S. or in any other country generally requires many years and substantial effort and financial resources, and approval from the FDA may not be received in a timely manner, if at all. The time required to satisfy FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based upon the type, complexity and novelty of the product or the targeted disease. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Under the FDA's regulations, the clinical testing program required for marketing approval of a new drug typically involves three sequential phases, which may overlap.

- *Phase I:* Studies are conducted on normal, healthy human volunteers or patients to determine safety, dosage tolerance, absorption, metabolism, distribution and excretion. If possible, Phase I studies may also be designed to gain early evidence of effectiveness.
- *Phase II:* Studies are conducted on small groups of patients afflicted with a specific disease to gain preliminary evidence of efficacy, to determine the common short-term side effects and risks associated with the substance being tested and to determine dosage tolerance and optimal dosage.
- *Phase III:* Involves large-scale studies conducted on disease-afflicted patients to provide statistical evidence of efficacy and safety and to provide an adequate basis for physician labeling.

Frequent reports are required in each phase, and, if unwarranted hazards to subjects are found, the FDA may request modification or discontinuance of clinical testing until further preclinical testing is conducted. Additional testing (Phase IV) may be conducted after FDA approval for marketing is granted and could be designed to evaluate alternative utilizations of drug products prior to their being marketed for such additional utilizations as well as to test for complications resulting from long-term exposure not revealed in earlier clinical testing.

Environmental and Safety Matters

Certain of our development activities involve the controlled use of biological, hazardous and radioactive materials and waste. We are also subject to numerous federal, state and local environmental and safety laws and regulations, including those governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. The cost of compliance with and any violation of these regulations could have a material adverse effect on our business and results of operations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we cannot assure investors that accidental contamination or injury from these materials will not occur.

To date, compliance with laws and regulations relating to the protection of the environment has not had a material effect on our capital expenditures or our competitive position. However, we are not able to predict the extent of government regulation, and the cost and effect thereof on our results of operations, which might result from any legislative or administrative action pertaining to environmental or safety matters. In the event of contamination or injury, we could be held liable for substantial damages or penalized with fines in an amount exceeding our resources, and our clinical trials could be suspended. In addition, we may have to incur significant costs to comply with future environmental laws and regulations.

Research and Development Expenses

Research and development expenses consist primarily of costs associated with the discovery, pre-clinical and clinical development of our product candidates. Research and development expenses are the primary source of our expenses and totaled \$26.0 million, \$28.2 million and \$25.4 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Employees

As of March 1, 2009, we had 47 full-time employees, including 34 in research and development, and the balance in general and administrative positions, with 23 of our employees holding Ph.D., M.D. or other advanced degrees. None of our employees is represented by a labor union, and we consider our employee relations to be good.

Executive Officers of the Registrant

The following table sets forth information regarding our executive officers as of March 1, 2009:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steve Worland, Ph.D.	51	President and Chief Executive Officer
James T. Glover	59	Senior Vice President, Operations and Chief Financial Officer
James L. Freddo, M.D.	54	Senior Vice President, Drug Development and Chief Medical Officer
Mary Yaroshevsky-Glanville	44	Vice President, Human Capital
Elizabeth E. Reed, J.D.	38	Vice President, Legal Affairs and Corporate Secretary

Steve Worland, Ph.D. joined us in 2001 and has served as our President and Chief Executive Officer and a member of the Board of Directors since August 2007. Dr. Worland served as our Chief Scientific Officer beginning in 2001 and was promoted to Executive Vice President, Head of Research and Development in October 2004. In December 2005 he was named Executive Vice President, Pharmaceuticals, assuming additional responsibilities, including strategic planning and corporate development, while continuing to lead Anadys' research and development efforts. In June 2006 he was named President, Pharmaceuticals. From 1999 to 2001 he was Vice President, Head of Antiviral Research, at Agouron Pharmaceuticals, a Pfizer Company. Dr. Worland was at Agouron from 1988 through the acquisition of Agouron by Warner-Lambert in 1999. Dr. Worland was a National Institutes of Health Postdoctoral Fellow in Molecular Biology at Harvard University from 1985 to 1988. He received his B.S. in Biological

Chemistry from the University of Michigan and his Ph.D. in Chemistry from the University of California, Berkeley.

James T. Glover joined us in September 2006 as Senior Vice President, Operations and Chief Financial Officer. Mr. Glover joined us from Beckman Coulter, Inc., a multi-billion dollar global clinical diagnostics and biomedical research company, where he served as Senior Vice President and Chief Financial Officer since 2003. During his 17-year tenure at Beckman Coulter, he held a variety of significant management positions, including: Vice President, Controller and Chief Accounting Officer (2003); Vice President and Treasurer (1999 to 2003); Vice President and Controller (1993-1999); Vice President-Strategic Planning & Program Management, Diagnostic Division (1993); Vice President-Controller/Divisional CFO (1989-1993). Prior to that, Mr. Glover worked for six years with several divisions of SmithKline Beckman, Inc., including Allergan, Inc. Mr. Glover was appointed as a member of the Board of Directors of Varian, Inc. in May 2008 and was elected Chairman of their Audit Committee in February 2009. Mr. Glover, a certified public accountant, holds a Master of Business Administration from Pepperdine University and a B.S. in Accounting from California State Polytechnic University.

James L. Freddo, M.D. joined us in July 2006 as Chief Medical Officer and was named Senior Vice President, Drug Development and Chief Medical Officer in July 2008. Prior to joining Anadys, Dr. Freddo was Vice President, Clinical Site Head and Development Site Head, Pfizer Global Research and Development, La Jolla. Previously at Pfizer, he was Executive Director, Site Therapeutic Area Leader, Clinical Development, Oncology. While at Pfizer, Dr. Freddo led the team responsible for the registration of Sutent® (sunitinib malate), a drug approved by the FDA in January 2006 for treating advanced kidney cancer and gastrointestinal stromal tumors. Prior to Pfizer, Dr. Freddo held a variety of senior management positions at Wyeth-Ayerst Research from December 1996 until June 2002, including Senior Director, Oncology, Senior Director, Infectious Diseases, and Senior Director, Transplantation Immunology. Dr. Freddo was appointed as a member of the Board of Directors of InfuSystem Holdings, Inc. in April 2008. He holds a B.S. degree in Medical Technology from the State University of New York at Stony Brook, and a M.D. degree from the University of North Carolina, where he also completed his fellowship training.

Mary Yaroshevsky-Glanville joined us in April 2001 and has served as our Vice President, Human Capital since December 2005. Ms. Yaroshevsky-Glanville served as our Senior Director, Human Capital from August 2002 to December 2005 and Director of Human Capital from April 2001 to August 2002 (initially as Computer Systems Analyst — Human Resources Information Systems). She served as Director of Human Resources at Inflazyme Inc. from 2000 to 2001. Prior to that time, Ms. Yaroshevsky-Glanville served as Director of Human Resources at Inex Pharmaceuticals Corp. from 1995 to 2000 and as Manager, Human Resources and Office Administration at Inex from 1994 through 1995. Ms. Yaroshevsky-Glanville has a Human Resources Management Certificate from the British Columbia Institute of Technology, has received a Certified Human Resources Professional designation from the Human Resources Management Association, and holds a B.Sc. in Computer Information System Management from the DeVry Institute of Technology.

Elizabeth E. Reed, J.D. joined us in October 2001 and has served as our Vice President, Legal Affairs and Corporate Secretary since December 2006. Ms. Reed served as our Senior Director, Legal Affairs and Corporate Secretary from December 2002 to December 2006, as our Director of Legal Affairs and Corporate Secretary from January 2002 through December 2002 and as our Director of Legal Affairs from October 2001 through January 2002. Prior to joining us, Ms. Reed was associated with the law firms of Cooley Godward LLP and Brobeck, Phleger & Harrison LLP. Ms. Reed is a member of the State Bar of California and received her B.S. in Business Administration with an emphasis in finance from the Haas School of Business at the University of California, Berkeley and holds a J.D., *cum laude*, from Harvard Law School.

Company Website

We file annual, quarterly, current reports, proxy statements and other information with the Securities and Exchange Commission. Our primary website can be found at <http://www.anadyspharma.com>. We make available free of charge at this website (under the “Investors — SEC Filings” caption) all of our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934,

including our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and amendments to those reports. These reports are made available on the website as soon as reasonably practicable after their filing with, or furnishing to, the Securities and Exchange Commission. Furthermore, we also make available on our website free of charge, and in print to any shareholder who requests it, the Committee Charters for our Audit, Compensation, and Corporate Governance and Nominating Committees, as well as the Code of Business Conduct and Ethics that applies to all directors, officers and employees of the Company. Amendments to these documents or waivers related to the Code of Business Conduct and Ethics will be made available on our website as soon as reasonably practicable after their execution.

The Company was incorporated in Delaware in September 1992 as ScripTech Pharmaceuticals, Inc., and in 1994 we changed our name to Scriptgen Pharmaceuticals, Inc. In May 2000, following the addition of a substantially new management team and the infusion of new capital, product candidates and technologies, we changed our name to Anadys Pharmaceuticals, Inc.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings before making any investment decisions regarding our stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline, and you may lose all or part of the money you paid to buy our common stock.

Risks Related to Our Business

Our business is heavily centered around our ANA598 program. Any unexpected data or other challenges we may encounter in the ANA598 program could delay or preclude our ability to transition to Phase II trials of ANA598, which could cause our stock price to decline significantly.

Our planned clinical development timelines for ANA598 are structured with the objective that if ANA598 is successful in early stage development, we expect to be ready to initiate longer term clinical trials, known as Phase II studies, of ANA598 with current standard of care treatments in mid-2009. We are currently conducting a Phase Ib clinical trial of ANA598 in HCV infected patients, in which patients are dosed twice daily for three days, and a Phase I clinical trial in healthy volunteers in which subjects are dosed once or twice-daily over a fourteen day period. If we see adverse toxicity or other unexpected results, or experience any other challenges, in our early clinical trials or any concurrently-run animal toxicology studies, or with the manufacturing of our clinical trial materials, our desired timelines for the program could be detrimentally impacted. If the ANA598 program is not ready to transition to Phase II studies consistent with our stated timelines, our ability to enter into a strategic alliance around ANA598 or raise additional capital could be adversely affected, and our stock price could decline significantly.

Any set-back or failure of ANA598 or ANA773 could have a large negative impact on our business and stock price.

Our development portfolio currently consists of only ANA598 and ANA773 and thus entails highly concentrated risk of failure. If one or both of these compounds fail or have set-backs, our business and stock price may suffer.

We will need additional funds to conduct Phase II trials of ANA598 and/or ANA773, and we may not be able to obtain such funds.

Prior to conducting a full Phase II program of ANA598 and/or ANA773 for the treatment of HCV or a Phase II program of ANA773 for the treatment of cancer, we will need to obtain additional funds. However, we may not be successful in obtaining such funds. Potential sources of additional funds include a new strategic alliance or other transaction, the sale of equity securities, project financing or debt financing. We cannot be sure that additional financing will be available when we need it, especially in this current tumultuous economic environment, or that, if available, financing will be obtained on terms favorable to us or our stockholders. If we are unable to raise additional funds on our desired timelines, we may need to postpone the initiation of Phase II trials until we obtain such funds, which may cause our stock price to decline significantly.

Our strategy to engage in a strategic alliance could fail.

We are currently in discussions with a number of biotechnology and pharmaceutical companies regarding potential strategic alliances and other transactions around ANA598 and ANA773. However, completing transactions of this nature is difficult and time-consuming and there is no guarantee that we will be able to complete a transaction on our desired time-line or on terms acceptable to us. Potentially interested parties may terminate discussions based upon their assessment of our competitive, financial, regulatory or intellectual property position or any other reason. Furthermore, depending on the outcome of our ongoing discussions, we may delay further activity in this area until 2010, when we expect to have 28 day viral load data from our ANA598 program. If we make such a determination and choose to suspend further activity in

this area during 2009, or if we are unable for any reason to enter into a transaction this year, we will need to obtain funding through alternative means, most likely through the sale of additional equity securities, in order to proceed with Phase II studies of ANA598. However, there is no guarantee that we will be able to sell equity securities on favorable terms, or at all. Furthermore, the sale of equity securities by us could potentially result in a perception by the investment community that we were unable to enter into a strategic alliance or other transaction around ANA598 and/or ANA773 on favorable terms, or at all, which could significantly reduce the price at which we can sell equity securities. In addition, if we choose to defer a potential strategic alliance or other transactions around ANA598 and ANA773 until we have longer term viral load data, we and our stockholders will bear the risk that ANA598 or ANA773 will fail prior to any future alliance. Even if we successfully establish new strategic alliances, these relationships may never result in the successful development or commercialization of any product candidates or the generation of sales or royalty revenue.

Raising additional funds by issuing securities or through debt or project financing or strategic alliances and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings, project financings strategic alliances and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders' ownership will be diluted. Other financing activities may also have an equity component which may lead to dilution. Any debt or project financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem capital stocks or make investments. In addition, if we raise additional funds through strategic alliances and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. For example, we might be forced to relinquish all or a portion of our sales and marketing rights with respect to potential products or license intellectual property that enables licensees to develop competing products.

We are at an early stage of development, and we may never attain product sales.

Our existing organizational structure was formed in May 2000. Since then, most of our resources have been dedicated to the development of our proprietary drug discovery technologies, research and development and preclinical and early-stage clinical testing of compounds. Our current product candidates are at only the very early stages of clinical trials. ANA598, ANA773 and any other compounds that we may develop, may never be approved for commercial sales. These compounds will require extensive and costly development, preclinical testing and clinical trials prior to seeking regulatory approval for commercial sales. The time required to attain product sales and profitability is lengthy and highly uncertain, and we cannot assure you that we will be able to achieve or maintain product sales.

We expect our net operating losses to continue for at least several years, and we are unable to predict the extent of future losses and when we will become profitable in our business operations, if ever.

We have incurred net operating losses since our incorporation in 1992, and through December 31, 2008 we have an accumulated deficit of \$256.1 million. Our operating losses are attributable in large part to the significant research and development costs required to identify and validate potential product candidates and conduct preclinical studies and clinical trials. To date, we have generated limited revenues, consisting of one-time or limited payments associated with past collaborations or grants, and we do not anticipate generating product revenues for at least several years, if ever. We expect to increase our operating expenses over at least the next several years in order to fund the development costs of our product candidates and further our development activities. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our research and product development efforts, we are unable to predict the extent of any future losses or when we will become profitable in our business operations, if ever. Even if we do achieve

profitability in our business operations, we may not be able to sustain or increase such profitability on an ongoing basis.

The technologies on which we rely are unproven and may not result in the development of commercially viable products.

Our current product candidates, ANA598 and ANA773, were selected based on the presumption that intervention at their respective targets, HCV polymerase and TLR7, offers a therapeutic benefit. There can be no assurance that intervention at either target will offer sufficient benefit and acceptable toxicity to warrant continued development and approval. ANA773 relies on the biology of a specific receptor, or protein, named Toll-Like Receptor-7, or TLR7. However, the interaction between small molecules and TLR7 represents a relatively new mechanism of action for the treatment of disease, including HCV and cancer, and there is no guarantee that an acceptable balance between therapeutic benefit and risk will be achieved with TLR7 agonists in HCV infected patients or in cancer patients. For example, in June 2006 we suspended dosing of ANA975, a TLR7 agonist prodrug, in our then on-going ANA975 clinical trial due to information from 13-week toxicology studies in animals which showed intense immune stimulation. We subsequently conducted additional pre-clinical studies and were unable to identify an acceptable balance between therapeutic benefit and risk using a daily dosing schedule over 13-weeks. Accordingly, we subsequently discontinued the development of ANA975 as a therapy for HCV infection. The science underlying ANA598 is also new and unproven, as no products acting at the HCV polymerase have been approved for marketing. ANA598 and ANA773 are at only the very beginning stage of clinical investigation. The process of successfully discovering product candidates is expensive, time-consuming and unpredictable, and the historical rate of failure for drug candidates is extremely high. If our approaches to drug discovery and development are not successful, we will not be able to establish or maintain a clinical development portfolio or generate product revenue.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, we can provide no assurances that ANA598 or ANA773 will have favorable results in future clinical trials, or receive regulatory approval.

Positive results from preclinical studies or early clinical trials should not be relied upon as evidence that later or larger-scale clinical trials will succeed. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. There is no guarantee that viral load declines seen in early patient trials will be replicated in future trials of longer duration and/or larger patient populations. For example, short-term viral load data from our ANA598 Phase Ib study may not translate into long-term benefit due to the potential emergence of resistant variants or other factors. Furthermore, if concurrent toxicology studies have unexpected results, the clinical development of the compound at issue could be suspended, delayed and/or terminated. If ANA598, ANA773, or any other product candidate, fails to demonstrate sufficient safety and efficacy in any clinical trial or shows unexpected findings in concurrent toxicology studies, we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts related to ANA598 or ANA773, we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

We intend to develop ANA598 and ANA773 as components of combination treatments, which presents additional challenges to the drug development process.

We are developing ANA598 and ANA773 as potential components of future combination treatments. We may face additional challenges with this approach, as opposed to developing product candidates for monotherapy. For example, any negative properties of our product candidates may be exacerbated when combined with other agents and/or have unexpected effects in humans. Furthermore, the optimal development of our product candidates may entail explorations of combinations with other agents, which could require us to establish agreements or alliances with other companies or third parties. There is no guarantee that we will be able to enter into such alliances or agreements on terms that we view as favorable, or at all. If

we are unable to optimize the development of our product candidates, our business prospects could be harmed, causing our stock price to suffer.

Fast track designation does not guarantee approval, or expedited approval, of ANA598 and there is no guarantee that ANA598 will maintain fast track designation.

In December 2008, we announced that the FDA granted fast track designation to ANA598 for the treatment of chronic HCV infection. Under the FDA Modernization Act of 1997, fast track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address an unmet medical need for such a condition. Mechanisms intended to facilitate development include opportunities for frequent dialogue with FDA reviewers and for timely review of submitted protocols. However, the designation does not guarantee approval or expedited approval of any application for the product. Furthermore, the FDA may revoke fast track designation from a product candidate at any time if it determines that the criteria are no longer met.

We are currently investigating ANA773 in both HCV and cancer. Any setback with the compound in one program could adversely affect our ability to develop it for the other indication, which would cause our business and stock price to suffer.

In July 2008, we announced our plans to investigate ANA773, our oral TLR7 agonist prodrug that we have been developing for cancer, as a potential treatment for hepatitis C. We have recently conducted a Phase I clinical trial of ANA773 for HCV and continue to conduct a separate Phase I clinical trial in oncology. Although the trials are being conducted separately, any setback with the compound in one program could have an adverse effect on our ability to develop it for the other indication, which would cause our business and stock price to suffer.

In 2007 we terminated our ANA975 development program due to challenges seen in animal toxicology studies. To the extent that the ANA975 toxicology observations are mechanism related, our ANA773 programs for cancer and hepatitis C could be negatively impacted, causing our stock price to decline.

ANA975 is an oral prodrug of isatoribine, a TLR7 agonist. In 2007 we discontinued the development of ANA975 as a treatment for HCV infection due to intense immune stimulation in animals. To the extent that any of the ANA975 toxicology observations are mechanism related, rather than compound specific, we will need to determine whether the level of immune stimulation induced by TLR7 agonists can be modulated to achieve a potential therapeutic benefit with an acceptable safety profile. Although results from our recently concluded ANA773 13-week animal toxicology study indicated that with every-other-day dosing of ANA773, immune stimulation of a magnitude believed to confer therapeutic potential can be achieved without adverse toxicology findings, there is no guarantee that this favorable toxicology profile will persist in future toxicology studies of longer duration, or that we will not see adverse safety findings in humans. If we are unable to modulate the immunomodulatory effect with a dose and schedule that provides therapeutic benefit without causing unacceptable adverse events, then the future development of ANA773 may be terminated, which would materially and adversely affect our business and cause our stock price to decline significantly.

We are currently conducting a Phase I clinical trial of ANA773 in oncology and are continuing to recruit patients. If patient enrollment does not move as quickly as we would like, our future development activities for ANA773 in oncology could be delayed, which could cause our stock price to decline.

We began dosing patients in a Phase I clinical trial of ANA773 in February 2008 and the investigators at our clinical sites continue to recruit cancer patients to participate in the trial. Our future development activities for ANA773 in oncology depend upon us enrolling a sufficient number of patients in this Phase I clinical trial. Development activities could be delayed if there is insufficient patient enrollment in this Phase I trial, which is a function of many factors, including the size and nature of the patient population, the nature

of the protocol, the proximity of patients to clinical sites, the number of other products under development competing for the same patients in trials and the eligibility criteria for the clinical trial. The eligibility criteria for clinical trials in patients with advanced solid tumors is somewhat limiting. Furthermore, there is no guarantee that the institutions and investigators conducting the clinical trials will devote adequate time and resources to our trials, perform as contractually required or meet our desired timeline.

We have recently completed dosing in a Phase 1 clinical trial of ANA773 for HCV in the Netherlands and are in the process of determining the next steps for the program. There is no guarantee that we will be able to efficiently pursue the development of ANA773 as a treatment for HCV.

We have recently completed dosing in a Phase 1 clinical trial of ANA773 for HCV that was designed to test ANA773 first in healthy volunteers and subsequently in HCV infected patients. In the patient portion of this study we did not see evidence of immune stimulation or viral load reduction until the highest dose tested to date, the 1600 mg dose. At the 1600 mg dose level, initial indications of immune induction and viral load decrease were seen in three of the five patients who received ANA773 for whom we have data. We are in the process of analyzing this data and are considering the possibility of exploring a higher dose level; however, there is no guarantee that we will choose to continue our development of ANA773 for HCV. If we decide to continue the study we will need to seek regulatory and ethics committee approval to amend the protocol for the study. There is no guarantee that we will be able to do so or that the clinical investigators who are conducting the study will desire to participate in an extension of the study. If we decide to and are able to continue the study, there is no guarantee that the dose levels required to induce the level of immune stimulation required to have an antiviral effect will be tolerable over time. Also, there is no guarantee that the magnitude of immune stimulation that we believe will confer therapeutic benefit will sufficiently reduce viral load. If the HCV trial is stopped due to safety or tolerability issues, or if the tested doses fail to sufficiently reduce viral load, our business and stock price could suffer. Also, if we are unable to achieve viral load reduction at levels comparable to injectable interferon but with a cleaner side effect profile, the prospects for developing ANA773 as a competitive HCV product will be diminished. Furthermore, the Phase I clinical trial is being conducted in the Netherlands and not under a U.S. IND. If, in the future, we want to proceed with the development of ANA773 for HCV in the United States, we will need to obtain the approval of the FDA under a U.S. IND. There is no guarantee that the FDA will agree that ANA773 should be tested as an investigational treatment for HCV. Currently there is no evidence that a TLR7 agonist can confer long-term benefit as a therapy for HCV at an acceptable safety risk, and there is no guarantee that the FDA will view the data from our Phase I study in the Netherlands as sufficiently compelling to allow clinical investigation, even if we view the data positively. If the FDA does not view the data from our Phase I study in the Netherlands as sufficiently compelling, it may not allow studies under a U.S. IND, in which case we would be precluded from pursuing the development and commercialization of ANA773 for HCV in the United States. Even if the FDA allows the investigation of ANA773 as a treatment for HCV in the United States, there is no guarantee that the FDA will agree with our proposed clinical development plan, which could result in a delay of future clinical development in the United States and harm the value of the program.

Our securities available-for-sale held in the form of marketable securities are subject to market, interest and credit risk that may reduce their value

A portion of our securities available-for-sale is invested in marketable securities. Our cash position may be adversely affected by changes in the value of these securities. In particular, the value of these holdings may be adversely affected by increases in interest rates, downgrades by rating agencies on the issuers of corporate bonds included in the portfolio and by other factors which may result in other than temporary declines in value of the investments. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio and may adversely affect our cash position.

Delays in the commencement of clinical testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.

Our potential drug products will require additional nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. Previously, we have conducted only early-stage clinical trials on our own. As a result, we have very limited experience conducting clinical trials.

In part because of this limited experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. Delays in the commencement of clinical testing could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites;
- manufacturing sufficient quantities or producing drug meeting our quality standards of a product candidate;
- obtaining approval of an IND application or proposed trial design from the FDA; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size and nature of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, the number of other products under development competing for the same patients in trials and the eligibility criteria for the clinical trial.

Delays in the completion of, or the termination of, clinical testing of our current and potential product candidates could result in increased costs to us and delay or prevent us from generating revenues.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us, potential future collaborators, the FDA, or other regulatory authorities due to a number of factors, including:

- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated enrollment or retention rate of patients in clinical trials;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials;
- negative results of clinical trials;
- negative or potentially problematic results of ongoing and concurrent non-clinical toxicology studies;
- requests by the FDA for supplemental information on, or clarification of, the results of clinical trials conducted in other countries;
- insufficient supply or deficient quality of drug candidates or other materials necessary for the conduct of our clinical trials; or
- serious adverse events or other undesirable drug-related side effects experienced by participants.

Many of the factors that may lead to a delay, suspension or termination of clinical testing of a current or potential product candidate may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays in the completion of, or termination of, clinical testing, our financial results and the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed.

We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs.

Our December 31, 2008 cash, cash equivalents and marketable securities balance was \$27.9 million. We believe that this balance will be sufficient to satisfy our anticipated operational cash needs for at least the next 12 months. However, we will need to seek additional funding within this period of time in order to initiate Phase II studies. There is no guarantee that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs.

In addition, we will need to raise additional capital to, among other things:

- fund our development programs;
- acquire rights to products or product candidates, technologies or businesses;
- establish and maintain manufacturing, sales and marketing operations; and
- commercialize our product candidates, if any, that receive regulatory approval.

Our future funding requirements will depend on, and could increase significantly as a result of many factors, including:

- the progress of our clinical trials;
- the progress of our nonclinical development activities;
- our ability to establish and maintain strategic alliances;
- the costs involved in enforcing or defending patent claims and other intellectual property rights;
- the pace and timing of development activities conducted under joint development arrangements we may establish;
- the cost and timing of regulatory approvals;
- the costs of establishing or expanding manufacturing, sales and distribution capabilities;
- the costs related to development and manufacture of pre-clinical, clinical and validation lots for regulatory and commercialization of drug supply;
- the success of the commercialization of ANA598, ANA773 and any additional products; and
- the extent to which we acquire or invest in other products technologies and businesses.

We do not anticipate that we will generate significant continuing revenues for at least several years, if ever. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings, strategic alliances and licensing arrangements, project financing and grant funding, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.

If our efforts to obtain rights to new products or product candidates from third parties do not yield product candidates for clinical development or are not otherwise successful, we may not generate product revenues or achieve profitability.

Our long-term ability to earn product revenue depends in part on our ability to identify and obtain new products or product candidates through licenses from third parties. If our internal development programs that are focused on the development of small-molecule therapeutics for the treatment of HCV and cancer fail, we will need to obtain rights to new products or product candidates from third parties. We may be

unable to obtain suitable product candidates or products from third parties for a number of reasons, including:

- we may be unable to purchase or license products or product candidates on terms that would allow us to make an appropriate return from resulting products;
- competitors may be unwilling to assign or license product or product candidate rights to us; or
- we may be unable to identify suitable products or product candidates.

If we are unable to obtain rights to new products or product candidates from third parties, our ability to generate product revenues and achieve profitability may suffer.

Even if we successfully complete clinical trials of ANA598, ANA773 or any future product candidate, there are no assurances that we will be able to submit, or obtain FDA approval of, a new drug application.

There can be no assurance that if our clinical trials of ANA598, ANA773 or any other potential product candidate are successfully completed, we will be able to submit a new drug application, or NDA, to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. If we are unable to submit a NDA with respect to ANA598, ANA773 or any future product candidate, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product in the U.S. The FDA can and does reject NDAs and may require additional clinical trials, even when drug candidates performed well or achieved favorable results in large-scale Phase III clinical trials. If we fail to commercialize ANA598, ANA773 or any future product candidate, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

If we successfully develop products but those products do not achieve and maintain market acceptance, our business will not be profitable.

Even if ANA598, ANA773 or any future product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;
- effectiveness of our or our collaborators' sales and marketing strategy;
- our ability to obtain sufficient third-party insurance coverage or reimbursement; and
- our ability to establish or maintain an attractive price for ANA598 when used in combination with other agents.

If ANA598 does not provide additional clinical benefit when included within a treatment regimen, that product likely will not be accepted favorably by the market. Similarly, if ANA773 does not provide additional clinical benefit when included within a treatment regimen, that product will likewise not be accepted favorably by the market. If any products we or our collaborators may develop do not achieve market acceptance, then we will not generate sufficient revenue to achieve or maintain profitability.

In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete; or
- complications, such as long-term toxicities and viral resistance, arise with respect to use of our products.

We depend on outside parties to conduct our clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing product candidates.

We engage clinical investigators and medical institutions to enroll patients in planned clinical trials and contract research organizations to perform data collection and analysis and other aspects of our preclinical studies and clinical trials. As a result, we depend on these clinical investigators, medical institutions and contract research organizations to properly perform the studies and trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by third-parties, our drug development costs will increase and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. In addition, we may not be able to maintain any of these existing relationships, or establish new ones on acceptable terms, if at all.

We do not have internal manufacturing capabilities, and if we fail to develop and maintain supply relationships with future collaborators or other outside manufacturers, we may be unable to develop or commercialize any of our products.

Our ability to develop and commercialize products will depend in part on our ability to manufacture, or arrange for collaborators or other parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements and in sufficient quantities for clinical testing and eventual commercialization. Our current manufacturing agreements reflect a much smaller scale than would be required for commercialization. If we are unable to enter into or maintain commercial-scale manufacturing agreements with future collaborators or capable contract manufacturers on acceptable terms the development and commercialization of our products could be delayed, which would adversely affect our ability to generate revenues and would increase our expenses.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.

We do not currently have the capabilities for the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. The establishment and development of our own sales force to market any products we may develop in the U.S. will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other non-technical capabilities necessary to commercialize any product we may develop, we will need to contract with third parties to market and sell any products we may develop in the U.S. We will also need to develop a plan to market and sell any products we may develop outside the U.S. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If we are unable to attract and retain key management and scientific staff, we may be unable to successfully develop or commercialize our product candidates.

We are a small company, with approximately 50 employees, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, our programs depend on our ability to retain highly skilled chemists, biologists, and preclinical and clinical personnel in the fields of HCV and oncology. We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical businesses, particularly in the San Diego, California area. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our development objectives. In addition, all of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. Currently we do not have employment agreements with any employees or members of senior management that provide any guarantee of continued employment by us. We do not currently carry “key person” insurance covering members of senior management other than Steve Worland, Ph.D., our President and Chief Executive Officer. The insurance covering Dr. Worland is in the amount of \$1.5 million. If we lose the services of Dr. Worland, James T. Glover, our Senior Vice President, Operations and Chief Financial Officer, James L. Freddo, M.D., our Senior Vice President, Drug Development and Chief Medical Officer, or other members of our senior management team or key personnel, we may not be able to find suitable replacements, and our business may be harmed as a result.

Our quarterly results and stock price may fluctuate significantly.

We expect our results of operations to be subject to quarterly fluctuations. The level of our revenues, if any, and results of operations at any given time, will be based primarily on the following factors:

- the status of development of ANA598, ANA773 and our other product candidates, including results of preclinical studies and clinical trials and changes in regulatory status;
- our execution of collaborative, licensing or other arrangements, and the timing and accounting treatment of payments we make or receive under these arrangements;
- whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by commercial collaborators of any amounts payable to us;
- variations in the level of expenses related to our product candidates or potential product candidates during any given period; and
- the effect of competing technological and market developments.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. In particular, if our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. In addition, fluctuations in the stock prices of other companies in the biotechnology and pharmaceuticals industries and in the financial markets generally may affect our stock price. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we engage in any acquisition, we will incur a variety of costs, and we may never realize the anticipated benefits of the acquisition.

We may attempt to acquire businesses, technologies, services or products or in-license technologies that we believe are a strategic fit with our business, at the appropriate time and as resources permit. We believe that strategic acquisitions of complementary businesses, technologies, services or products are a material component of our business strategy to provide us with access to new compounds that are potentially synergistic with our existing product candidate portfolio. If we undertake any acquisition, the process of integrating the acquired business, technology, service or product may result in unforeseen

operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. These operational and financial risks include:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to acquiring and developing acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- negative effect on our earnings (or loss) per share;
- difficulty and cost in combining and integrating the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, contractors or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited experience in identifying acquisition targets, successfully completing potential acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. Moreover, we may fail to realize the anticipated benefits of any acquisition or devote resources to potential acquisitions that are never completed. If we fail to successfully identify strategic opportunities, complete strategic transactions or integrate acquired businesses, technologies, services or products, we may not be able to successfully expand our product candidate portfolio to provide adequate revenue to attain and maintain profitability.

Earthquake or wildfire damage to our facilities could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego, California, are located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts. In addition, San Diego has experienced several severe wildfires during the past several years which have destroyed or damaged many businesses and residences in the San Diego area. In the event of an earthquake or a severe wildfire, if our facilities or the equipment in our facilities are significantly damaged or destroyed for any reason, or we are otherwise required to shut down our operations, we may not be able to rebuild or relocate our facility or replace any damaged equipment, or otherwise recommence our business operations, in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Our Industry

Because our product candidates and development and collaboration efforts depend on our intellectual property rights, adverse events affecting our intellectual property rights will harm our ability to commercialize products.

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or effectively-protected trade secrets cover them.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for ANA598 or ANA773 or provide

sufficient protection to afford us a commercial advantage against competitive products or processes. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even with respect to patents that have issued or will issue, we cannot guarantee that the claims of these patents are, or will be valid, enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. For example:

- we might not have been the first to make, conceive, or reduce to practice the inventions covered by all or any of our pending patent applications and issued patents;
- we 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;
- it is possible that none of our pending patent applications will result in issued patents;
- our issued or acquired patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties;
- our issued patents may not be valid or enforceable;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Patent applications in the U.S. are maintained in confidence for up to 18 months or longer after their filing. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on our product candidates. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our drug candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us. We may be particularly affected by this because we expect that ANA598, if approved, will be marketed in foreign countries with high incidences of HCV infection.

Other companies may obtain patents and/or regulatory approvals to use the same drugs to treat diseases other than HCV or cancer. As a result, we may not be able to enforce our patents effectively because we may not be able to prevent healthcare providers from prescribing, administering or using another company's product that contains the same active substance as our products when treating patients infected with HCV or who have cancer.

If we fail to obtain and maintain patent protection and trade secret protection of ANA598 or ANA773, proprietary technologies and their uses, the competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

If we are sued for infringing intellectual property rights of others, it will be costly and time-consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success also depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Numerous U.S. and foreign

issued patents and pending patent applications owned by others exist in HCV and cancer. These could materially affect our ability to develop our drug candidates or sell our 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 technologies may infringe. There also may be existing patents, of which we are not aware, that our product candidates or technologies may inadvertently infringe. Further, there may be issued patents and pending patent applications in fields relevant to our business, of which we may become aware from time to time, that we believe we do not infringe or that we believe are invalid or relate to immaterial portions of our overall drug discovery and development efforts. We cannot assure you that third parties holding any of these patents or patent applications will not assert infringement claims against us for damages or seeking to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. Any litigation or claims against us, with or without merit, may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. In addition, intellectual property litigation or claims could result in substantial damages and force us to do one or more of the following if a court decides that we infringe on another party's patent or other intellectual property rights:

- cease selling, incorporating or using any of our product candidates or technologies that incorporate the challenged intellectual property;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, it at all; or
- redesign our processes or technologies so that they do not infringe, which could be costly and time-consuming and may not be possible.

If we find during clinical evaluation that our drug candidates for the treatment of HCV or cancer should be used in combination with a product covered by a patent held by another company or institution, and that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, inducing infringement of the third-party patents covering the product recommended for co-administration with our product. In that case, we may be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on reasonable terms, or at all.

If we fail to obtain any required licenses or make any necessary changes to our technologies, we may be unable to develop or commercialize some or all of our product candidates.

We may be involved in lawsuits or proceedings to protect or enforce our patent rights, trade secrets or know-how, which could be expensive and time-consuming.

The defense and prosecution of intellectual property suits and related legal and administrative proceedings can be both costly and time-consuming. Litigation and interference proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. Further, the outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree and which may be difficult to comprehend by a judge or jury. An adverse determination in an interference proceeding or litigation with respect to ANA598 or ANA773, to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. If required, the necessary licenses may not be available on acceptable terms, or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from commercializing ANA598 or ANA773, which could have a material and adverse effect on our results of operations.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is risk that some of our confidential information

could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We also 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. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Many competitors have significantly more resources and experience, which may harm our commercial opportunity.

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug and chemical companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources, experience and expertise in:

- research and development;
- preclinical testing;
- clinical trials;
- regulatory approvals;
- manufacturing; and
- sales and marketing of approved products.

Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical or other companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

If our competitors develop treatments for HCV or cancer that are approved faster, marketed better or demonstrated to be more effective than ANA598, ANA773, or any other products that we may develop, our commercial opportunity will be reduced or eliminated.

We believe that a significant number of drugs are currently under development and may become available in the future for the treatment of HCV and certain cancers. Potential competitors may develop treatments for HCV or certain cancers that are more effective or less costly than our product candidates or that would make our product candidates obsolete or non-competitive. Some of these products may use therapeutic approaches that compete directly with ANA598 or ANA773. In addition, less expensive generic forms of currently marketed drugs could lead to additional competition upon patent expiration or invalidations.

ANA598, a non-nucleoside polymerase inhibitor, was selected as a development candidate in June 2007. If approved, ANA598 would likely be used in combination with the current standard of care and/or other direct antiviral agents such as protease inhibitors and polymerase inhibitors. Any product currently approved or approved in the future for the treatment of HCV infection could decrease or eliminate the commercial opportunity of ANA598. Other non nucleoside inhibitors would likely be the most direct competitors for ANA598. To our knowledge, non-nucleoside polymerase inhibitor programs are currently under clinical evaluation by Pfizer, Gilead, Merck, Abbott, Boeringer Ingleheim and ViroChem. Further, a number of companies have non-nucleoside polymerase inhibitor research and pre-clinical development programs.

Other potential competitors are products currently approved for the treatment of HCV infection: Peg-Intron (pegylated interferon-alpha-2b), Rebetol (ribavirin), and Intron-A (interferon-alpha-2b), which are marketed by Schering-Plough, Pegasys (pegylated interferon-alpha-2a), Copegus (ribavirin USP), and Roferon-A (interferon-alpha-2a), which are marketed by Roche. Additional compounds in late state clinical trials for HCV include Albuferon, in development by Human Genome Sciences and Novartis, telaprevir, in development by Vertex Pharmaceuticals and Janssen Pharmaceutica, boceprevir and SCH-900518, in development by Schering-Plough, ITMN-191, in development by Intermune and Roche, TMC-435350, in development by Tibotec and Medivir, MK-7009 in development by Merck, BI-201335 in development by Boehringer Ingelheim, and R-7128 in development by Pharmasset and Roche.

ANA773 is a prodrug of a TLR7 agonist under evaluation for oncology and hepatitis C indications. Any product currently approved or approved in the future for the treatment of cancer could decrease or eliminate the commercial opportunity of ANA773 in the oncology markets. Programs that most directly compete with the ANA773 oncology program at this time are other TLR agonists under evaluation for oncology indications, IMO-2055, in development by Idera and Merck KGaA and a cancer program in development by Dynavax.

ANA773 is also subject to competition in the treatment of HCV from all of the HCV products and compounds in development listed above as potential competitors of ANA598 and most specifically from the products and development candidates that act as an immunomodulator or have an immunomodulatory component, including Peg-Intron (pegylated interferon-alpha-2b), Rebetol (ribavirin), Intron-A (interferon-alpha-2b), Pegasys (pegylated interferon-alpha-2a), Copegus (ribavirin USP), and Roferon-A (interferon-alpha-2a), each of which are products currently approved for the treatment of HCV. IMO-2055, a TLR9 agonist in development by Idera, is also being studied in early stage clinical trials in HCV patients. Other agents in development as potential replacements to pegylated interferon-alfa include Albuferon, in development by Human Genome Sciences and Novartis and Locteron, in development by Biolex Therapeutics, both of which are longer-acting versions of interferon alfa. Also, in development as potential improvements to existing interferons are PEG-interferon lambda, in development by Zymogenetics and Bristol Myers-Squibb, and omega interferon in development by Intarcia Therapeutics.

If we cannot establish pricing of our product candidates acceptable to the government, insurance companies, managed care organizations and other payors, any product sales will be severely hindered.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for any products we or our collaborators may develop;
- our ability to generate adequate revenues and gross margins; and
- the availability of capital.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the U.S., which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care, control pharmaceutical prices or reduce government insurance programs, may result in lower prices for our product candidates. While we cannot predict whether any legislative or regulatory proposals affecting our business will be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

If we cannot arrange for reimbursement policies favorable to our product candidates, their sales will be severely hindered.

Our ability to commercialize ANA598, ANA773 or any other product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of ANA598, ANA773 or any other products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services, including treatments for HCV and cancer. Also, the trend toward managed health care in the U.S. as well as legislative proposals to reform health care, control pharmaceutical prices or reduce government insurance programs, may also result in exclusion of our product candidates from reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our ability to earn product revenue and generate significant profits and could impact our ability to raise capital.

Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our results of operations.

We face an inherent risk of product liability exposure for claimed injuries related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we or our collaborators sell our product candidates commercially. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- the inability to establish new collaborations with potential collaborators;
- substantial costs of related litigation;
- substantial monetary awards to patients; and
- the inability to commercialize our product candidates.

We currently have product liability insurance that covers our clinical trials and plan to increase and expand this coverage as we commence larger scale trials. We also intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time-consuming and costly.

Our research and development involves the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, including ethylacetate and acetonitrile, radioactive materials and biological materials including plasma from patients infected with HCV or other infectious diseases that have the potential to transmit disease. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. If we fail to comply with these laws and regulations or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial liability or required to suspend or modify our operations. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials could be suspended. In addition, we may have to incur significant costs to comply with future environmental laws and regulations. We do not currently have a pollution and remediation insurance policy.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug discovery programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

Risks Related to Our Common Stock

Future sales of our common stock may cause our stock price to decline.

Our current stockholders hold a substantial number of shares of our common stock that they are able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares or the expectation that such sale may occur, could significantly reduce the market price of our common stock.

Our stock price may be volatile.

The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- changes in the regulatory status of our product candidates, including the status and results of our clinical trials of ANA598 and ANA773;
- significant contracts, new technologies, acquisitions, commercial relationships, joint ventures or capital commitments;

- disputes or other developments relating to proprietary rights, including patents, trade secrets, litigation matters, and our ability to patent or otherwise protect our product candidates and technologies;
- conditions or trends in the pharmaceutical and biotechnology industries;
- fluctuations in stock market prices and trading volumes of similar companies or of the markets generally;
- variations in our quarterly operating results;
- changes in securities analysts' estimates of our financial performance;
- failure to meet or exceed securities analysts' or investors' expectations of our quarterly financial results, clinical results or our achievement of milestones;
- sales of large blocks of our common stock, or the expectation that such sales may occur, including sales by our executive officers, directors and significant stockholders;
- additions or departures of key personnel;
- discussion of our business, products, financial performance, prospects or our stock price by the financial and scientific press and online investor communities such as chat rooms;
- regulatory developments in the U.S. and foreign countries;
- economic and political factors, including wars, terrorism and political unrest; and
- technological advances by our competitors.

Our largest stockholders may take actions that are contrary to your interests, including selling their stock.

A small number of our stockholders hold a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. In addition, the average number of shares of our stock that trade each day is generally low. As a result, sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions include:

- dividing our board of directors into three classes serving staggered three-year terms;
- prohibiting our stockholders from calling a special meeting of stockholders;
- permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;
- prohibiting our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66⅔% stockholder approval; and
- requiring advance notice for raising matters of business or making nominations at stockholders' meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the

holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never paid cash dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our headquarters and research and development facility is located in approximately 40,000 square feet of office and laboratory space in San Diego, California. We occupy this facility under a lease, which expires on August 1, 2009. We are actively engaged in the search for a new facility upon the expiration of our current lease. We believe that suitable space will be available on commercially reasonable terms.

Item 3. *Legal Proceedings*

We are currently not a party to any material legal proceedings.

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

No matters were submitted to a vote of security holders during the fourth quarter ended December 31, 2008.

Part II

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

Market Information

Our common stock is traded on the Nasdaq Global Market under the symbol ANDS. The following table sets forth the high and low sales prices for our common stock for the periods indicated, as reported on the Nasdaq Global Market.

<u>2008</u>	<u>High</u>	<u>Low</u>
First Quarter	\$1.77	\$1.36
Second Quarter	3.13	1.50
Third Quarter	2.98	2.10
Fourth Quarter	2.68	1.50

<u>2007</u>	<u>High</u>	<u>Low</u>
First Quarter	\$5.30	\$3.15
Second Quarter	4.90	3.68
Third Quarter	3.88	1.90
Fourth Quarter	2.27	1.58

Holders

As of February 17, 2009, there were approximately 2,200 holders of our common stock.

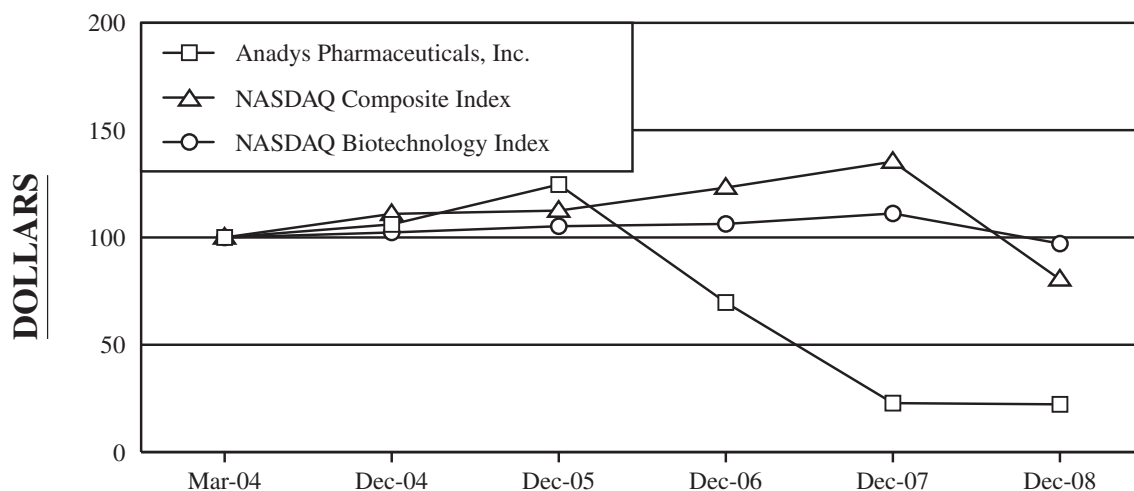
Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, for development of our business and therefore do not anticipate that we will declare or pay cash dividends on our capital stock in the foreseeable future.

Performance Measurement Comparison(1)

The following graph shows a comparison of the fifty-seven month total cumulative returns of an investment of \$100 in cash on March 26, 2004 in (i) our common stock the first trading date following our initial public offering, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. All values assume reinvestment of the full amount of all dividends (to date, we have not declared any dividends).

Comparison of cumulative total return on investment since our initial public offering on March 26, 2004:



	March 26, 2004	December 31, 2004	December 31, 2005	December 31, 2006	December 31, 2007	December 31, 2008
Anadys Pharmaceuticals, Inc.	\$100.00	\$106.09	\$124.65	\$ 69.69	\$ 22.80	\$22.24
NASDAQ Composite Index	100.00	110.99	112.52	123.23	135.32	80.46
NASDAQ Biotechnology Index	100.00	102.33	105.23	106.31	111.18	97.14

(1) This section is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference in any filing of the Company under the 1933 Act or the 1934 Act 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 selected financial data set forth below with respect to our consolidated statements of operations for each of the three years in the period ended December 31, 2008 and, with respect to our consolidated balance sheets, at December 31, 2008 and 2007 are derived from our consolidated financial statements that have been audited by Ernst & Young LLP, independent registered public accounting firm, which are included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2005 and 2004 and the balance sheet data as of December 31, 2006, 2005, and 2004 are derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

	For the Years Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except net loss per share)				
Consolidated Statements of Operations Data:					
Revenues	\$ —	\$ 24,118	\$ 5,420	\$ 4,887	\$ 1,762
Operating expenses:					
Research and development(1)	25,993	28,192	25,419	20,901	26,711
General and administrative(1)	8,109	8,692	11,308	7,705	8,260
Total operating expenses(1)	<u>34,102</u>	<u>36,884</u>	<u>36,727</u>	<u>28,606</u>	<u>34,971</u>
Loss from operations	<u>(34,102)</u>	<u>(12,766)</u>	<u>(31,307)</u>	<u>(23,719)</u>	<u>(33,209)</u>
Other income (expense):					
Interest income	1,482	3,611	4,727	2,103	525
Interest expense	—	—	(69)	(189)	(228)
Other, net.	218	(17)	(111)	(118)	(67)
Total other income, (expense) net	<u>1,700</u>	<u>3,594</u>	<u>4,547</u>	<u>1,796</u>	<u>230</u>
Net loss	<u>(32,402)</u>	<u>(9,172)</u>	<u>(26,760)</u>	<u>(21,923)</u>	<u>(32,979)</u>
Accretion to redemption value of redeemable convertible preferred stock	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(175)</u>
Net loss applicable to common stockholders	<u><u>\$(32,402)</u></u>	<u><u>\$(9,172)</u></u>	<u><u>\$(26,760)</u></u>	<u><u>\$(21,923)</u></u>	<u><u>\$(33,154)</u></u>
Net loss per share, basic and diluted:	<u><u>\$ (1.13)</u></u>	<u><u>\$ (0.32)</u></u>	<u><u>\$ (0.94)</u></u>	<u><u>\$ (0.89)</u></u>	<u><u>\$ (1.92)</u></u>
Shares used in calculating net loss per share, basic and diluted:	<u><u>28,750</u></u>	<u><u>28,646</u></u>	<u><u>28,512</u></u>	<u><u>24,756</u></u>	<u><u>17,233</u></u>

(1) As a result of the adoption of Statement of Accounting Standards No. 123R, *Share-Based Payment*, (SFAS No. 123R) on January 1, 2006, there is a lack of comparability in our research and development expense and our general and administrative expense for the periods presented prior to January 1, 2006. Please reference Note 8 in our consolidated financial statements for additional information related to the impact of SFAS No. 123R on our research and development expenses and our general and administrative expenses.

	As of December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and securities available-for-sale . . .	\$ 27,936	\$ 56,495	\$ 82,149	\$ 104,851	\$ 33,674
Working capital	24,325	52,084	75,054	98,682	28,001
Total assets	31,674	61,526	89,401	116,976	40,949
Long-term debt, net of current portion	—	—	—	682	1,193
Accumulated deficit	(256,054)	(223,652)	(214,480)	(187,720)	(165,797)
Total stockholders' equity	25,825	55,679	60,325	78,936	31,285

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this Annual Report on Form 10-K (this Annual Report). Operating results are not necessarily indicative of results that may occur in future periods.

This Annual Report contains forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about our development plans and programs, clinical trials, strategies, objectives, and other statements that are not historical facts, including statements which may be preceded by the words "intend," "will," "plan," "expect," "anticipate," "estimate," "aim," "seek," "believe," "hope" or similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update publicly or revise any forward-looking statements. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors identified in our periodic reports filed with the Securities and Exchange Commission (SEC), including those set forth in "Item 1A. Risk Factors" in this Annual Report.

Overview

Anadys Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. For the treatment of chronic hepatitis C virus (HCV), we are developing ANA598, a small-molecule, non-nucleoside inhibitor of the NS5B polymerase, and ANA773, an oral, small-molecule toll-like receptor 7 (TLR7) agonist prodrug. We are also developing ANA773 for the treatment of cancer.

In the second quarter of 2008, we commenced dosing in a Phase I single, ascending dose clinical trial of ANA598 in healthy volunteers to assess the safety and pharmacokinetics of the agent. In late September 2008, we announced preliminary results of the Phase I clinical trial of ANA598 in healthy volunteers and the finalization of the protocol for a Phase Ib trial of ANA598 in HCV infected patients. Dosing began in the Phase Ib clinical trial during the fourth quarter of 2008. During the first quarter of 2009 we announced results from the first dose level of the Phase Ib clinical trial. Eleven patients at the first dose level received 200 mg twice daily for three days. At the end of the treatment period the median viral load decline in the eleven patients who received 200 mg of ANA598 twice daily was 2.4 log₁₀. We expect to report the full set of data from this study during the second quarter of 2009.

In July 2008, we announced the expansion of our development efforts in HCV to include clinical investigation of ANA773. As an approach to treating hepatitis C, the TLR7 mechanism is independent from, and potentially complementary to ANA598. In July 2008, we initiated dosing in the healthy volunteer portion of a Phase I clinical trial of ANA773 for the treatment of HCV. This portion of the trial was designed to assess the safety, pharmacokinetics and immunological activity of ANA773. In October 2008, we completed dosing in healthy volunteers. Dosing began in HCV-infected patients during the fourth quarter of 2008. The primary objectives of the patient portion of the study are to assess safety, tolerability and viral load decline in HCV patients. To date, we have received data from the 800 mg and 1200 mg cohorts and from seven out of the eight patients in the 1600 mg cohort. At the 800 mg and 1200 mg dose levels minimal immune induction and no significant viral load decrease was noted. At the 1600 mg dose level, initial indications of immune induction and viral load decrease were seen in three of the five patients who have received ANA773 for whom we have data. We are in the process of analyzing this data and are considering the possibility of exploring a higher dose level. This Phase I trial is being conducted in the Netherlands.

In February 2008, patient dosing commenced in a Phase I clinical trial of ANA773 in cancer patients in the United States. This first-in-human trial is a safety and tolerability study designed to identify pharmacologically active doses and preliminary anti-tumor activity as well as to select the dose and schedule for potential Phase II trials. We continue to enroll patients and explore the safety and tolerability profile of ANA773 in the ongoing Phase I trial, and expect to identify a pharmacologically active dose and establish the profile of immune stimulation in the first half of 2009, which information is intended to support the future design of clinical trials of ANA773 (alone or in combinations) in specific tumor types.

We have incurred significant operating losses since our inception and, as of December 31, 2008, our accumulated deficit was \$256.1 million. We expect to incur substantial losses for at least the next several years as we:

- continue the development of ANA598 for the treatment of HCV;
- continue the development of ANA773 for the treatment of HCV;
- continue the development of ANA773 for the treatment of cancer;
- develop methods for and scale-up manufacturing of ANA598 and ANA773 for clinical trials and potential commercialization;
- commercialize any product candidates that receive regulatory approval; and
- potentially in-license technology and acquire or invest in businesses, products or technologies that are synergistic with our own.

Research and Development

Research and development expenses consist primarily of costs associated with the discovery, pre-clinical and clinical development of our product candidates. In addition, research and development expenses may include external costs such as fees paid to clinical research organizations, clinical trial investigators, contract research organizations, drug substance and drug product manufacturers and consultants. Research and development expenses may also include internal costs such as compensation, supplies, materials, an allocated portion of facilities costs, an allocated portion of information systems support personnel and depreciation.

Under our former License and Co-Development Agreement with Novartis International Pharmaceutical Ltd. (Novartis), reimbursements of development costs for ANA975 from Novartis were recorded as an offset to research and development expense. For the years ended December 31, 2008, 2007 and 2006, we have recorded as offsets to research and development expense \$0.05 million, \$0.5 million and \$3.7 million, respectively.

At this time, due to the risks inherent in the clinical trial process and given the early-stage of development of our product candidates, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for commercialization. Clinical development timelines, likelihood of success and total costs vary widely. However, we expect our research and

development costs to be substantial and to increase as we advance our product candidates through clinical development.

The following summarizes our research and development expenses for the years ended December 31, 2008, 2007 and 2006 (in thousands):

	For the Years Ended December 31,		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
ANA598	\$11,044	\$ 8,390	\$ 4,328
ANA773	8,177	6,136	3,944
ANA380	—	700	935
ANA975, net of reimbursement	117	560	818
Discovery stage programs	—	1,936	5,041
Infrastructure and support personnel	5,384	7,194	7,464
Severance related to reduction in force	—	813	—
Non-cash employee and non-employee share-based compensation	<u>1,271</u>	<u>2,463</u>	<u>2,889</u>
Total research and development expense	<u>\$25,993</u>	<u>\$28,192</u>	<u>\$25,419</u>

Effective July 1, 2008, we began allocating costs for ANA773 between our HCV and oncology programs. For the six months ended December 31, 2008, ANA773 HCV related costs were \$3.1 million and ANA773 oncology related costs were \$0.9 million.

General and Administrative

General and administrative expenses consist primarily of salaries and benefits for executive, finance, investor relations, business development, human resources and legal personnel. In addition, general and administrative expenses include insurance costs, professional services and an allocated portion of facilities costs and information systems support personnel.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis and make adjustments to the consolidated financial statements as considered necessary. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. While all of our significant accounting policies are described in Note 1 to our consolidated financial statements included in this Annual Report, we believe the following accounting policies involve the judgments and estimates used in the preparation of our consolidated financial statements:

Drug Development Costs. Drug development costs include costs associated with the development of our product candidates including non-clinical activities, toxicology studies, manufacturing of non-clinical and clinical materials and clinical trials. We review and accrue drug development costs based on work performed. We estimate work performed utilizing factors such as subject enrollment, estimated timeline for completion of studies and other factors. These costs and estimates vary based on the type, scope and length of non-clinical and clinical studies as well as other factors. Drug development cost accruals are subject to revisions as studies, projects and trials progress to completion. Expense is adjusted for revisions in the period in which the facts that give rise to the revision become known.

Share-Based Compensation. We account for share-based compensation in accordance with Statement of Financial Accounting Standards No. 123R, *Share-Based Payment* (SFAS No. 123R). Under the

provisions of SFAS No. 123R, share-based compensation cost is estimated at the grant date based on the award's fair-value as calculated by a Black-Scholes option-pricing model and is recognized as expense evenly over the requisite service period. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, the risk-free interest rate and the expected term of the awards. If any of the assumptions used in the model change significantly, share-based compensation expense may differ materially in the future from that recorded in the current period.

Revenue Recognition. We may receive payments from collaborators for compound licenses, technology access fees, option fees, research services, milestones and royalty obligations. These payments are recognized as revenue or reported as deferred revenue until they meet the criteria for revenue recognition as outlined in Staff Accounting Bulletin, No. 104, *Revenue Recognition*, which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the SEC, and Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. We recognize revenue when (1) persuasive evidence of the arrangement exists; (2) delivery has occurred or services were rendered; (3) the price is fixed or determinable and (4) the collectability is reasonably assured. Specifically, we have applied the following policies in recognizing revenue:

- Revenue from milestones is recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) our performance obligations after the milestone achievement will continue to be funded by the collaborator at the comparable level and (iii) the milestone is not refundable or creditable. If all of these criteria are not met, the milestone payment is recognized over the remaining minimum period of our performance obligations under the agreement. Upfront fees under our collaborations, such as technology access fees, are recognized over the period the related services are provided. Non-refundable upfront fees not associated with our future performance are recognized when received.
- Fees that we receive for research services are generally recognized as the services are provided, as long as the amounts received are not refundable regardless of the results of the research project.

Pending Adoption of Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF No. 07-1). EITF No. 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable U.S. GAAP or, in the absence of other applicable U.S. GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF No. Issue 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF No. 07-1 will be effective for us beginning on January 1, 2009. The adoption of EITF No. 07-1 is not expected to have a material effect on our consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with GAAP in the United States (the GAAP hierarchy). SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of SFAS No. 162 to have a material impact on our consolidated financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2008, 2007 and 2006

Revenue. During 2008, we did not recognize any revenue. We recorded revenues of \$24.1 million and \$5.4 million for the years ended December 31, 2007 and 2006, respectively. The \$18.7 million increase from 2006 to 2007 was primarily attributed to the recognition of previously deferred revenue upon the termination of our License and Co-Development Agreement with Novartis.

Research and Development Expenses. Research and development expenses were \$26.0 million, \$28.2 million and \$25.4 million for the years ended December 31, 2008, 2007 and 2006, respectively. The \$2.2 million decrease from 2007 to 2008 was primarily due to cost savings derived from our completed strategic restructuring which included the halting of early stage discovery efforts and the termination of our collaborations with both Novartis and LG Life Sciences. These decreases were partially offset by an increase in development costs for ANA598 and ANA773. We incurred development costs associated with our ANA598 program related to our completed Phase Ia clinical trial in healthy volunteers, our on-going Phase Ib clinical trial in patients, the initiation of long-term chronic toxicology studies of ANA598 and the manufacturing of clinical and non-clinical materials. Development costs for ANA773 include costs associated with the manufacturing of non-clinical and clinical materials, our completed 13-week GLP toxicology studies, our on-going Phase I clinical trial for HCV and our on-going Phase I clinical trial for oncology. Our non-cash share-based compensation expense associated with share-based payments granted to our research and development employees was \$1.3 million and \$2.5 million for the years ended December 31, 2008 and 2007, respectively. The decrease in our non-cash share-based compensation expense was primarily associated with the cancellation of outstanding stock options for personnel involved in our completed strategic restructuring as well as a reduction in the weighted average fair value assigned to stock options granted in 2008 compared to both 2007 and 2006.

The \$2.8 million increase from 2006 to 2007 was primarily due to an increase in external preclinical development costs for ANA598 and ANA773. The increase was partially offset by a decrease in development costs associated with ANA975 and cost savings associated with our restructuring effected during 2007, including the halting of early stage discovery efforts. Included in research and development expense for the year ended December 31, 2007, is \$0.8 million of severance related costs associated with our restructuring. Our non-cash share-based compensation expense associated with share-based payments granted to our research and development employees was \$2.9 million for the year ended December 31, 2006.

General and Administrative Expenses. General and administrative expenses were \$8.1 million, \$8.7 million and \$11.3 million for the years ended December 31, 2008, 2007 and 2006, respectively. The \$0.6 million decrease from 2007 to 2008 was primarily the result of cost savings derived from our completed strategic restructuring. Non-cash share-based compensation expense associated with share-based payments granted to our general and administrative employees and non-employee directors for the years ended December 31, 2008 and 2007 was \$1.5 million and \$1.7 million, respectively.

The \$2.6 million decrease from 2006 to 2007 was primarily attributable to a decrease in share-based compensation from 2006 to 2007, partially offset by an increase in costs associated with our restructuring and other severance related costs. The higher share-based compensation expense during 2006 was largely driven by the acceleration of the unvested stock options held by Kleanthis G. Xanthopoulos, Ph.D. our former President and Chief Executive Officer and current member of our Board of Directors upon his resignation as President and Chief Executive Officer. Non-cash share-based compensation expense associated with share-based payments granted to our general and administrative employees and non-employee directors for the year ended December 31, 2006 was \$4.2 million, which included \$3.0 million of stock-based compensation associated with the acceleration of Dr. Xanthopoulos' stock unvested stock options.

Interest Income. Interest income was \$1.5 million, \$3.6 million and \$4.7 million for the years ended December 31, 2008, 2007 and 2006, respectively. The \$2.1 million decrease in our interest income from 2007 to 2008 was the result of a lower average cash, cash equivalents and securities available-for-sale balance and lower interest rates during 2008 compared to 2007. Our average balance of cash, cash

equivalents and securities available-for-sale, which were invested in interest bearing securities, was \$40.6 million in 2008 compared to \$67.7 million in 2007. The decrease in our average cash balance from 2007 to 2008 was driven by our use of cash, cash equivalents and securities to fund our on-going operations. The \$1.1 million decrease in our interest income from 2006 to 2007 was the result of a lower average cash, cash equivalents and securities available-for-sale balance during 2007 compared to 2006. Our average balance of cash, cash equivalents and securities available-for-sale, which were invested in interest bearing securities, was \$67.7 million in 2007 compared to \$93.0 million in 2006. The decrease in our average cash balance from 2006 to 2007 was driven by our use of cash, cash equivalents and securities to fund our on-going operations.

Liquidity and Capital Resources

Overview

Our December 31, 2008 cash, cash equivalents and marketable securities balance was \$27.9 million. Our cash, cash equivalents and available-for sale securities decreased by \$28.6 million from December 31, 2007 to December 31, 2008 which represents the use of our cash, cash equivalents and securities available-for-sale to fund our operations during the year ended December 31, 2008.

In order to conduct Phase II clinical trials of ANA598 and/or ANA773 for the treatment of HCV or a Phase II clinical trial of ANA773 for the treatment of cancer, we will need to seek additional financing which could be completed through a number of financing vehicles including the sale of equity securities, new strategic alliance agreements or other transactions, project financing or debt financing. However, we may not be successful in obtaining strategic alliance or other agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that additional debt or equity financing will be available when needed or that, if available, such financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds through debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. As a result, if we are not able to obtain additional financing during the second half of 2009, we will postpone, reduce the scope of or eliminate some or all of our development programs. With these reductions in expenditures, we believe that our existing cash, cash equivalents and securities available-for-sale will be sufficient to meet our working capital requirements through December 31, 2009.

Future Cash Requirements

We expect our development expenses to be substantial and to increase as we continue the advancement of our development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

- the progress of our nonclinical development activities;
- the progress of our clinical trials;
- our ability to establish and maintain strategic alliances
- the costs involved in enforcing or defending patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs of establishing or expanding manufacturing, sales and distribution capabilities;
- the costs related to development and manufacture of pre-clinical, clinical and validation lots for regulatory and commercialization of drug supply;

- the success of the commercialization of ANA598, ANA773 or any other product candidates we may develop; and
- the extent to which we acquire or invest in other products, technologies and businesses.

Investment Portfolio

As of December 31, 2008, we have \$27.7 million of marketable securities consisting of money market funds, commercial paper, U.S. government sponsored enterprise securities and corporate debt securities with maturities that range from 1 day to 21 months with an overall average months to maturity of 6.9 months. We have the ability to liquidate these marketable securities without restriction.

Included in our portfolio of securities available-for-sale as of December 31, 2008, is an American General Finance Corporation, a subsidiary of American International Group, Inc. (AIG), corporate bond that matures on August 15, 2009. As of December 31, 2008, the face value of the security is \$2.2 million and the current market value is \$1.6 million, which resulted in a \$0.6 million unrealized loss that is recorded as a component of accumulated other comprehensive loss.

As of December 31, 2008, we performed a review of all of the securities in our portfolio with an unrealized loss position, including the American General Finance Corporation corporate bond, to determine if any other-than-temporary impairments were required to be recorded. Factors considered in our assessment included but were not limited to the following: our ability and intent to hold the security until maturity; the number of months until the security's maturity, the number of quarters that each security was in an unrealized loss position, ratings assigned to each security by independent rating agencies, the magnitude of the unrealized loss compared to the face value of the security and other market conditions. No other-than-temporary impairments were identified as of December 31, 2008 related to securities currently in our portfolio. We also noted that none of the securities as of December 31, 2008 have been in an unrealized loss position for greater than one year. As of December 31, 2008 we do not own any marketable securities which are classified as asset-backed securities or auction rate securities.

Cash Flows from Operating Activities and Investing Activities

Our consolidated statements of cash flows are summarized as follows (in thousands):

	For the Years Ended December 31,		
	2008	2007	2006
Net cash used in operating activities	<u>\$(28,288)</u>	<u>\$(25,658)</u>	<u>\$(20,585)</u>
Cash provided by (used in) investing activities			
Purchase of securities available-for-sale	(8,806)	\$(15,131)	\$(14,310)
Proceeds from sale of securities available-for-sale	12,463	13,170	5,750
Purchase of property and equipment	(213)	(356)	(1,522)
Proceeds from disposal of property and equipment. . . .	<u>392</u>	<u>—</u>	<u>—</u>
Net cash provided by (used in) investing activities.	<u>\$ 3,836</u>	<u>\$ (2,317)</u>	<u>\$(10,082)</u>

Cash flows used in operating activities increased by \$2.6 million from the year ended December 31, 2007 to the year ended December 31, 2008. We expect to continue to utilize cash and marketable securities to fund our operating activities as we continue to advance our wholly owned product candidates ANA598 and ANA773. We are not currently party to any development collaborations and therefore cash to fund future operations will most likely have to be obtained from one of the following sources: our current investment portfolio, the sale of other equity securities, new strategic alliance agreements or other transactions project financing or debt financing.

Cash flows provided by (used in) investing activities increased by \$6.2 million from the year ended December 31, 2007 to December 31, 2008. The overall increase in the cash flows provided by investing activities is primarily related to the timing of the purchases and maturities of our marketable securities. In addition, proceeds from the disposal of property and equipment increased \$0.4 million from 2007 to 2008. Cash flows used in investing activities decreased by \$7.8 million from the year ended December 31, 2006 to

the year ended December 31, 2007. The overall reduction in the cash flows used in investing activities from 2007 to 2006 is primarily related to the use of the proceeds from the sale of securities available-for-sale used to fund our operations during 2007.

Cash Flows from Financing Activities

Our consolidated statements of cash flows are summarized as follows (in thousands):

	For the Years Ended December 31,		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Cash provided by (used in) financing activities			
Proceeds from exercise of stock options and employee stock purchase plan	\$259	\$257	\$ 954
Principal payments on long-term debt	<u>—</u>	<u>—</u>	<u>(1,559)</u>
Net cash provided by (used in) financing activities	<u>\$259</u>	<u>\$257</u>	<u>\$ (605)</u>

Cash flows provided by financing activities were fairly consistent from the year ended December 31, 2007 to the year ended December 31, 2008.

Cash flows provided by financing activities increased by \$0.9 million from the year ended December 31, 2006 to the year ended December 31, 2007. The increase was primarily a result of the outstanding principal due under the loan and security agreements being paid in full during February 2006.

Aggregate Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2008 (in thousands):

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less than 1 Year</u>	<u>2010 to 2011</u>	<u>2012 to 2013</u>	<u>Thereafter</u>
Operating leases	\$1,241	\$1,241	\$ —	\$ —	\$ —
Minimum royalty commitment	<u>800</u>	<u>100</u>	<u>200</u>	<u>200</u>	<u>300</u>
	<u>\$2,041</u>	<u>\$1,341</u>	<u>\$200</u>	<u>\$200</u>	<u>\$300</u>

We also enter into agreements with clinical sites and contract research organizations that conduct our clinical trials. We generally make payments to these entities based upon the number of subjects enrolled and the length of their participation in the trials. To date, the majority of our clinical costs have been related to the costs of subjects entering our clinical trials as well as the manufacturing of compounds to be used in our clinical trials. Costs associated with clinical trials will continue to vary as the trials go through their natural phases of enrollment and follow-up. The costs will also be influenced by the pace of the development activities, timing of the development activities and regulatory requirements associated with the conduct of our clinical trials. At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product development programs, we are unable to estimate with any certainty the total costs we will incur in the continued development of our product candidates for potential commercialization. Due to these same factors, we are unable to determine the anticipated completion dates for our current product development programs. Clinical development timelines, probability of success and development costs vary widely. As we continue our development programs, we anticipate that we will make determinations as to 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 an ongoing assessment of the product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty whether any of our product candidates will be subject to future partnering, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when, or if, and to what extent we will receive cash inflows from the commercialization of our product candidates.

Fair Value Inputs

We adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157) as of January 1, 2008. See Note 2 and Note 3 to the audited Consolidated Financial Statements. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset.

We value our marketable securities by using quoted market prices, broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The types of securities valued based on quoted market prices in active markets include money market securities. We do not adjust the quoted price for such securities. The types of instruments valued based on quoted prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency include commercial paper, U.S. government sponsored enterprise securities and corporate debt securities. The price for each security at the measurement date is sourced from an independent pricing vendor. Periodically, management assesses the reasonableness of these sourced prices by comparing them to the prices provided by our portfolio managers to derive the fair value of these financial instruments. Historically, we did not experience significant deviation between the prices from the independent pricing vendor and our portfolio managers. Management assesses the inputs of the pricing in order to categorize the financial instruments into the appropriate hierarchy levels.

Off-Balance Sheet Arrangements

As of December 31, 2008, 2007 and 2006, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements and related financial information required to be filed are indexed on page F-1 of this Annual Report on Form 10-K and are incorporated herein.

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

Not Applicable.

Item 9A. Controls and Procedures

Management's Report on Internal Control Over Financial Reporting

Evaluation of Disclosure Controls and Procedures: Our President and Chief Executive Officer and Senior Vice President, Operations and Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of the end of the period covered by this Annual Report. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Operations and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2008 in providing them with

material information related to the Company in a timely manner, as required to be disclosed in the reports the Company files under the Exchange Act.

Management's Annual Report on Internal Control over Financial Reporting: Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f).

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and Senior Vice President, Operations and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control — Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is set forth below.

Changes in Internal Control Over Financial Reporting: There was no significant change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Anadys Pharmaceuticals, Inc.

We have audited Anadys Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Anadys Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Anadys Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Anadys Pharmaceuticals, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2008 of Anadys Pharmaceuticals, Inc. and our report dated February 26, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 26, 2009

Item 9B. Other Information

Not applicable.

Part III

Certain information required by Part III of Form 10-K is omitted from this report because we expect to file a definitive proxy statement for our 2009 Annual Meeting of Stockholders (the Proxy Statement) within 120 days after the end of our fiscal year pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended, and the information included in the Proxy Statement is incorporated herein by reference to the extent provided below.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Item 10 of Form 10-K is incorporated by reference to the information under the headings “Election of Directors,” “Section 16(a) Beneficial Ownership Reporting Compliance,” “Audit Committee” and “Shareholder Communications with the Board of Directors” in our Proxy Statement.

Certain information required by Item 10 of Form 10-K regarding our executive officers is set forth in Item 1 of Part I of this Annual Report under the caption “Executive Officers of the Registrant.”

We have adopted a Code of Business Conduct and Ethics, which applies to all our directors, officers and employees, including our President and Chief Executive Officer and Senior Vice President, Operations and Chief Financial Officer and all of our finance team. The Code of Business Conduct and Ethics is posted on our website, <http://www.anadyspharma.com> (under the “Investors — Corporate Governance” caption). In addition, we will provide to any person without charge, upon request, addressed to the Corporate Secretary at Anadys Pharmaceuticals, Inc., 3115 Merryfield Row, San Diego, CA 92121, a copy of our Code of Business Conduct and Ethics. We intend to satisfy the disclosure requirement regarding any amendment to, or waiver of, a provision of the Code of Business Conduct and Ethics for our President and Chief Executive Officer and Senior Vice President, Operations and Chief Financial Officer or persons performing similar functions, by posting such information on our website.

Item 11. Executive Compensation

The information required by Item 11 of Form 10-K is incorporated by reference to the information under the heading “Compensation of Executive Officers” and “Compensation of Directors” in our Proxy Statement.

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

The following table summarizes our outstanding securities and securities available for future issuance under our equity compensation plans. Security holders of the Company have approved the 2002 Equity Incentive Plan, 2004 Equity Incentive Plan (2004 Plan), 2004 Non-Employee Directors’ Stock Option Plan and 2004 Employee Stock Purchase Plan.

In connection with the hiring of certain executive officers during 2006, the Compensation Committee of our Board of Directors approved inducement grants of non-qualified stock options. These option awards were granted without security holder approval pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv). Although these options were granted outside the 2004 Plan, they are subject to substantially identical terms and conditions as those contained in the 2004 Plan.

<u>Plan Category</u>	<u>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options</u>	<u>(b) Weighted-Average Exercise Price of Outstanding Options</u>	<u>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</u>
Equity compensation plans approved by security holders	6,170,366	\$3.88	1,723,783
Equity compensation plans not approved by security holders	<u>375,000</u>	\$3.00	<u>—</u>
Total	<u>6,545,366</u>		<u>1,723,783</u>

The additional information required by Item 12 of Form 10-K related to security ownership of certain beneficial owners and management is incorporated herein by reference to the information under the heading “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

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

The information required by Item 13 of Form 10-K related to transactions with related persons, promoters and certain control persons, if any, is incorporated herein by reference to the information under the heading “Certain Transactions” in our Proxy Statement. The information required by Item 13 of Form 10-K relating to director independence is incorporated herein by reference to the information under the heading “Election of Directors” in our Proxy Statement.

Item 14. *Principal Accounting Fees and Services*

The information required by Item 14 of Form 10-K is incorporated herein by reference to the information under the heading “Ratification of Selection of Independent Registered Accounting Firm” in our Proxy Statement.

Part IV

Item 15. *Exhibits and Financial Statement Schedules*

(a) The following financial statements, financial statements schedules and exhibits are filed as part of this report or incorporated herein by reference:

(1) *Financial Statements.* See index to consolidated financial statements on page F-1.

(2) *Financial Statement Schedules.* All financial statements schedules for which provision is made in Regulation S-X are omitted because they are not required under the related instructions, are inapplicable, or the required information is given in the financial statements, including the notes thereto.

(3) *Exhibits.*

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
3.1	Form of Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q (SEC File No. 000-50632) filed on May 14, 2004.
3.2	Amended and Restated Bylaws of the Registrant	Incorporated by reference to the Registrant’s Current Report on Form 8-K (SEC File No. 000-50632) filed on December 5, 2007.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
4.1	Form of Specimen Common Stock Certificate	Incorporated by reference to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.1 #	2002 Equity Incentive Plan	Incorporated by reference to Exhibit 10.3 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on November 14, 2003.
10.2 #	Form of Stock Option Agreement under 2002 Equity Incentive Plan	Incorporated by reference to Exhibit 10.4 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on November 14, 2003.
10.3#	2004 Equity Incentive Plan	Incorporated by reference to Exhibit 10.5 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.4 #	Form of Stock Option Agreement under 2004 Equity Incentive Plan	Incorporated by reference to Exhibit 10.6 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.5#	Form of Amendment to Stock Option Agreement Under 2004 Equity Incentive Plan, applicable to Non-Employee Director grants	Attached Hereto
10.6#	2004 Employee Stock Purchase Plan	Incorporated by reference to Exhibit 10.7 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.7#	Form of Offering Document under the 2004 Employee Stock Purchase Plan	Incorporated by reference to Exhibit 10.8 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.8#	Form of Indemnification Agreement by and between the Registrant and each of its directors and officers	Incorporated by reference to Exhibit 10.11 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on November 14, 2003.
10.9#	Form of Stock Option Agreement Under 2004 Non-Employee Directors' Stock Option Plan	Incorporated by reference to Exhibit 10.10 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.10#	Terms of Employment dated February 1, 2001 by and between the Registrant and Steve Worland, Ph.D.	Incorporated by reference to Exhibit 10.27 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on November 14, 2003.
10.11 #	Terms of Employment dated October 2, 2001 by and between the Registrant and Elizabeth E. Reed	Incorporated by reference to Exhibit 10.30 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.12	Sub-lease agreement dated February 23, 2004 by and between the Registrant and Torrey Mesa Research Institute.	Incorporated by reference to Exhibit 10.33 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
10.13#	Consulting Agreement dated May 25, 2005 by and between Marios Fotiadis and Anadys Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.37 in the Registrant's Quarterly Report on Form 10-Q (SEC File No. 000-50632) filed on August 12, 2005.
10.14 #	Form of Inducement Stock Option Agreement	Incorporated by reference to Exhibit 10.42 in the Registrant's Current Report on Form 8-K (SEC File No. 000-50632) filed on September 25, 2006.
10.15#	Terms of Employment dated September 11, 2006 by and between the registrant and James T. Glover.	Incorporated by reference to Exhibit 10.43 in the Registrant's Current Report on Form 8-K (SEC File No. 000-50632) filed on September 25, 2006.
10.16#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and Stephen T. Worland, Ph.D.	Incorporated by reference to Exhibit 10.16 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.17#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and James T. Glover, CPA.	Incorporated by reference to Exhibit 10.17 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.18#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and James L. Freddo, M.D.	Incorporated by reference to Exhibit 10.18 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.19#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and Elizabeth E. Reed.	Incorporated by reference to Exhibit 10.19 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.20#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and Mary Yaroshevsky-Glanville.	Incorporated by reference to Exhibit 10.20 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.21#	Terms of Employment dated June 21, 2006 by and between the registrant and James L. Freddo, M.D.	Incorporated by reference to Exhibit 10.21 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.22#	Terms of Employment dated March 6, 2001 by and between the registrant and Mary-Yaroshevsky-Glanville.	Incorporated by reference to Exhibit 10.22 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.23#	Executive Officer Bonus Plan	Incorporated by reference to Exhibit 10.23 in the Registrant's Annual Report on Form 10-K (SEC File No. 000-50632) filed on March 5, 2008.
10.24#	Amended and Restated 2004 Non-Employee Directors' Stock Option Plan.	Incorporated by reference to Exhibit 10.24 in the Registrant's Quarterly Report on Form 10-Q (SEC File No. 000-50632) filed on May 1, 2008.
21.1	List of Subsidiaries of the Registrant	Incorporated by reference to Exhibit 21.1 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on November 14, 2003.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
23.1	Consent of Independent Registered Public Accounting Firm	Attached Hereto.
31.1	Certification of President and Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Act of 1934, as amended	Attached Hereto.
31.2	Certification of Senior Vice President, Operations and Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Act of 1934, as amended	Attached Hereto.
32.1	Certifications of President and Chief Executive Officer and Senior Vice President, Operations and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Attached Hereto.

Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on the 2nd day of March, 2009.

ANADYS PHARMACEUTICALS, INC.

By: /s/ STEPHEN T. WORLAND, PH.D. _____

Stephen T. Worland, Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen T. Worland, Ph.D. and James T. Glover, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and any other documents in connection therewith, and to file the same, with all exhibits thereto, 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 in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, as amended, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ STEPHEN T. WORLAND, PH.D.</u> Stephen T. Worland, Ph.D.	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 2, 2009
<u>/s/ JAMES T. GLOVER</u> James T. Glover	Senior Vice President, Operations and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 2, 2009
<u>/s/ GEORGE A. SCANGOS, PH.D.</u> George A. Scangos, Ph.D.	Chairman of the Board	March 2, 2009
<u>/s/ MARK G. FOLETTA</u> Mark G. Foletta	Director	March 2, 2009
<u>/s/ MARIOS FOTIADIS</u> Marios Fotiadis	Director	March 2, 2009
<u>/s/ STEVEN H. HOLTZMAN</u> Steven H. Holtzman	Director	March 2, 2009

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ STELIOS PAPADOPOULOS, PH.D.</u> Stelios Papadopoulos, Ph.D.	Director	March 2, 2009
<u>/s/ DOUGLAS E. WILLIAMS, PH.D.</u> Douglas E. Williams, Ph.D.	Director	March 2, 2009
<u>/s/ KLEANTHIS G. XANTHOPOULOS, PH.D.</u> Kleanthis G. Xanthopoulos, Ph.D.	Director	March 2, 2009

ANADYS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Anadys Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Anadys Pharmaceuticals, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Anadys Pharmaceuticals, Inc. at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Anadys Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 26, 2009

ANADYS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
(In thousands, except share data)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,476	\$ 34,669
Securities available-for-sale	17,460	21,826
Prepaid expenses and other current assets	<u>2,202</u>	<u>1,004</u>
Total current assets	30,138	57,499
Property and equipment, net	1,476	2,647
Other assets	<u>60</u>	<u>1,380</u>
Total assets	<u>\$ 31,674</u>	<u>\$ 61,526</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 558	\$ 1,084
Accrued expenses	4,823	3,766
Current portion of deferred rent	348	565
Other current liabilities	<u>84</u>	<u>—</u>
Total current liabilities	5,813	5,415
Long-term portion of deferred rent	—	367
Other long-term liabilities	36	65
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2008 and December 31, 2007; no shares issued and outstanding at December 31, 2008 and December 31, 2007	—	—
Common stock, \$0.001 par value; 90,000,000 shares authorized at December 31, 2008 and December 31, 2007; 28,816,763 and 28,696,948 shares issued and outstanding at December 31, 2008 and December 31, 2007, respectively	29	29
Additional paid-in capital	282,297	279,221
Accumulated other comprehensive (loss) gain	(447)	81
Accumulated deficit	<u>(256,054)</u>	<u>(223,652)</u>
Total stockholders' equity	<u>25,825</u>	<u>55,679</u>
Total liabilities and stockholders' equity	<u>\$ 31,674</u>	<u>\$ 61,526</u>

See accompanying notes to consolidated financial statements.

ANADYS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		
	2008	2007	2006
	(In thousands, except net loss per share)		
Revenues:			
Collaborative agreements	\$ —	\$ 24,118	\$ 5,354
Grants	—	—	66
Total revenues	—	24,118	5,420
Operating Expenses:			
Research and development	25,993	28,192	25,419
General and administrative	8,109	8,692	11,308
Total operating expenses	34,102	36,884	36,727
Loss from operations	(34,102)	(12,766)	(31,307)
Other income (expense):			
Interest income	1,482	3,611	4,727
Interest expense	—	—	(69)
Other, net	218	(17)	(111)
Total other income (expense)	1,700	3,594	4,547
Net loss	\$(32,402)	\$ (9,172)	\$(26,760)
Net loss per share, basic and diluted	\$ (1.13)	\$ (0.32)	\$ (0.94)
Shares used in calculating net loss per share, basic and diluted . . .	28,750	28,646	28,512

See accompanying notes to consolidated financial statements.

ANADYS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
(In thousands, except share data)									
Balance at December 31, 2005 . . .	—	\$—	28,374,136	\$28	\$267,499	\$(839)	\$ (32)	\$(187,720)	\$ 78,936
Issuance of common stock pursuant to the exercise of stock options and warrants . . .	—	—	143,335	1	562	—	—	—	563
Issuance of common stock pursuant to the employee stock purchase plan	—	—	78,727	—	391	—	—	—	391
Compensation related to stock options and warrants issued to non-employees	—	—	—	—	326	—	—	—	326
SFAS 123R stock-based compensation expense including forfeitures	—	—	—	—	6,859	—	—	—	6,859
Reversal of deferred compensation upon the adoption of SFAS 123R	—	—	—	—	(839)	839	—	—	—
Comprehensive loss:									
Unrealized gain on short-term investments	—	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	—	(26,760)	(26,760)
Comprehensive loss	—	—	—	—	—	—	—	—	(26,750)
Balance at December 31, 2006 . . .	—	\$—	28,596,198	\$29	\$274,798	\$ —	\$ (22)	\$(214,480)	\$ 60,325
Issuance of common stock pursuant to the exercise of stock options and warrants . . .	—	—	30,192	—	89	—	—	—	89
Issuance of common stock pursuant to the employee stock purchase plan	—	—	70,558	—	168	—	—	—	168
Compensation related to stock options and warrants issued to non-employees	—	—	—	—	101	—	—	—	101
SFAS 123R stock-based compensation expense including forfeitures	—	—	—	—	4,065	—	—	—	4,065
Comprehensive loss:									
Unrealized gain on short-term investments	—	—	—	—	—	—	103	—	103
Net loss	—	—	—	—	—	—	—	(9,172)	(9,172)
Comprehensive loss	—	—	—	—	—	—	—	—	(9,069)
Balance at December 31, 2007 . . .	—	\$—	28,696,948	\$29	\$279,221	\$ —	\$ 81	\$(223,652)	\$ 55,679
Issuance of common stock pursuant to the exercise of stock options and warrants . . .	—	—	36,567	—	106	—	—	—	106
Issuance of common stock pursuant to the employee stock purchase plan	—	—	83,248	—	153	—	—	—	153
Compensation related to stock options and warrants issued to non-employees	—	—	—	—	66	—	—	—	66
SFAS 123R stock-based compensation expense including forfeitures	—	—	—	—	2,751	—	—	—	2,751
Comprehensive loss:									
Unrealized loss on short-term investments	—	—	—	—	—	—	(528)	—	(528)
Net loss	—	—	—	—	—	—	—	(32,402)	(32,402)
Comprehensive loss	—	—	—	—	—	—	—	—	(32,930)
Balance at December 31, 2008 . . .	—	\$—	28,816,763	\$29	\$282,297	\$ —	\$(447)	\$(256,054)	\$ 25,825

See accompanying notes to consolidated financial statements.

ANADYS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		
	2008	2007	2006
	(In thousands)		
Cash Flows from Operating Activities:			
Net loss	\$(32,402)	\$ (9,172)	\$(26,760)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,141	1,431	1,509
Stock-based compensation	2,751	4,065	6,859
Amortization of premium/discount on securities available-for-sale	157	—	—
Loss on the sale of available-for-sale securities	24	—	—
Compensation related to stock option issuances to non-employees	16	52	276
Interest expense related to warrants issued in connection with debt	—	—	23
Rent expense related to warrants issued in connection with lease	50	49	50
(Gain) loss from disposal of property and equipment	(149)	27	73
Changes in operating assets and liabilities:			
Accounts receivable	—	1,175	4,850
Prepaid expenses and other current assets	(1,198)	(63)	(290)
Other assets	1,320	7	253
Accounts payable	(526)	290	(222)
Accrued expenses	1,057	449	(546)
Deferred rent	(584)	(466)	(405)
Deferred revenue	—	(23,567)	(6,255)
Other liabilities	55	65	—
Net cash used in operating activities	(28,288)	(25,658)	(20,585)
Cash Flows from Investing Activities:			
Purchase of securities available-for-sale	(8,806)	(15,131)	(14,310)
Proceeds from sale and maturity of securities available-for-sale	12,463	13,170	5,750
Purchase of property and equipment	(213)	(356)	(1,522)
Proceeds from the sale of property and equipment	392	—	—
Net cash provided by (used in) investing activities	3,836	(2,317)	(10,082)
Cash Flows from Financing Activities:			
Proceeds from exercise of stock options and employee stock purchase plan	259	257	954
Principal payments on long-term debt	—	—	(1,559)
Net cash provided by (used in) financing activities	259	257	(605)
Net decrease in cash and cash equivalents	(24,193)	(27,718)	(31,272)
Cash and cash equivalents at beginning of year	34,669	62,387	93,659
Cash and cash equivalents at end of year	\$ 10,476	\$ 34,669	\$ 62,387
Supplemental Disclosure of Cash Flow Information:			
Cash paid during the year for interest	\$ —	\$ —	\$ 69
Supplemental Disclosure of Non-Cash Investing and Financing Activities:			
Reversal of deferred compensation upon the adoption of SFAS 123R	\$ —	\$ —	\$ 839
Unrealized (loss) gain on securities available-for-sale	\$ (528)	\$ 103	\$ 10

See accompanying notes to consolidated financial statements.

ANADYS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Anadys Pharmaceuticals, Inc. (Anadys or the Company) is a clinical-stage biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. For the treatment of chronic hepatitis C, the Company is developing ANA598, a small — molecule, non-nucleoside inhibitor of the NS5B polymerase, and ANA773, an oral, small - molecule, toll-like receptor 7 (TLR7) agonist prodrug. The Company is also developing ANA773 for the treatment of cancer.

Basis of Financial Statement Presentation

In order to conduct Phase II clinical trials of ANA598 and/or ANA773 for the treatment of HCV or a Phase II clinical trial of ANA773 for the treatment of cancer, the Company will need to seek additional financing which could be completed through a number of financing vehicles including the sale of equity securities, new strategic alliance agreements or other transactions, project financing or debt financing. However, the Company may not be successful in obtaining strategic alliance or other agreements, or in receiving milestone or royalty payments under those agreements. In addition, the Company cannot be sure that additional debt or equity financing will be available when needed or that, if available, such financing will be obtained on terms favorable to the Company or the Company's stockholders. If the Company raises additional funds through debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict the Company's ability to operate the Company's business. As a result, if the Company is not able to obtain additional financing during the second half of 2009, the Company will postpone, reduce the scope of or eliminate some or all of its development programs. With these reductions in expenditures, the Company believes that its existing cash, cash equivalents and securities available-for-sale will be sufficient to meet the Company's working capital requirements through December 31, 2009.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Anadys Pharmaceuticals Europe GmbH and Anadys Development Limited. All significant intercompany accounts and transactions have been eliminated. In 2003, the Company discontinued its Anadys Pharmaceuticals Europe GmbH operations and intends to dissolve that entity. Anadys Development Limited was established in 2005 to serve as a legal representative of the Company for conducting clinical trials in Europe. As of and for the year ended December 31, 2008, neither Anadys Pharmaceuticals Europe GmbH nor Anadys Development Limited had active operations.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual amounts could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of highly liquid investments with an original maturity of less than three months when purchased and are readily convertible to known amounts of cash.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Securities Available-for-Sale

Investments with an original maturity of more than three months when purchased have been classified by management as securities available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary (of which there have been none to date) on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific-identification method. The Company views its available-for-sale securities as available for use in current operations. Accordingly, the Company has classified all investments as short-term, even though the stated maturity date may be one year or more beyond the current balance sheet date.

Fair Value of Financial Instruments

The carrying amount of cash, cash equivalents, securities available-for-sale, accounts payable and accrued expenses are considered to be representative of their respective fair value because of the short-term nature of those items.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash, cash equivalents and securities available-for-sale. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management, however, believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain safety and liquidity.

During 2007 and 2006, the Company derived a majority of its revenues from a License and Co-Development Agreement with Novartis International Pharmaceutical Ltd. (Novartis) which was terminated during 2007.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (ranging from three to five years) using the straight-line method. Leasehold improvements are amortized over the estimated useful life of the asset or the lease term, whichever is shorter.

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standard (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value of the asset to the carrying value of the asset and records the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Although the Company's current and historical operating and cash flow losses are indicators of impairment, the Company believes expected undiscounted future operating cash flows will exceed the carrying value of the long-lived assets, and accordingly the Company has not recognized an impairment loss through December 31, 2008.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Research and Development

Research and development expenses consist primarily of costs associated with the discovery, pre-clinical and clinical development of the Company's product candidates. In addition, research and development expenses may include external costs such as fees paid to clinical research organizations, clinical trial investigators, contract research organizations, drug substance and drug product manufacturers, consultants, and internal costs of compensation and other expenses for research and development personnel, supplies and materials, facility costs, and depreciation.

Under the Company's former License and Co-Development Agreement with Novartis, which was terminated during 2007, reimbursements of development costs for ANA975 from Novartis were recorded as an offset to research and development expense.

Accumulated Other Comprehensive Income (Loss)

In accordance with SFAS No. 130, *Reporting Comprehensive Income*, all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments and foreign currency translation adjustments, are reported, net of their related tax effect, to arrive at comprehensive income (loss).

Deferred Rent

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense recorded and amounts paid under the lease agreement is recorded as deferred rent in the accompanying consolidated balance sheet. During 2004, the Company entered into a sub-lease agreement to lease the Company's corporate headquarters and research and development facility located in San Diego, California. In accordance with the sub-lease agreement, the Company was allocated a \$1.6 million tenant improvement allowance as an incentive to move into the facility. The Company recorded this incentive as an increase to both property and equipment and deferred rent and these amounts are being amortized on a straight-line basis over the life of the lease of 62 months. As of December 31, 2008 and 2007, the Company has \$0.2 million and \$0.5 million, respectively, of unamortized deferred rent associated with the lease incentive.

Stock-Based Compensation

The Company accounts for compensation expense for options granted to employees and directors in accordance with SFAS No. 123R, *Share-Based Payment*, (SFAS No. 123R).

The Company accounts for compensation expense for options granted to non-employees other than directors in accordance with SFAS No. 123R, and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. Such expense is based on the fair value of the options issued using the Black-Scholes method and is periodically remeasured as the underlying options vest in accordance with EITF Issue No. 96-18.

In accordance with SFAS No. 123R and the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 107, the Company records share-based compensation as components of either research and development expense or general and administrative expense. Share-based compensation is recognized on a straight-line basis.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Net Loss Per Share

The Company calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic loss per share (EPS) is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net loss by the weighted-average number of common shares equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

Common stock equivalents from stock options and warrants of approximately 6.6 million, 5.6 million and 5.3 million were excluded from the calculation of net loss per share for the years ended December 31, 2008, 2007 and 2006, respectively, because the effect would be antidilutive.

Revenue Recognition

The Company may receive payments from collaborators for compound licenses, technology access fees, option fees, research services, milestones and royalty obligations. These payments are recognized as revenue or reported as deferred revenue until they meet the criteria for revenue recognition as outlined in Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the SEC and Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The Company recognizes revenue when (1) persuasive evidence of the arrangement exists; (2) delivery has occurred or services were rendered; (3) the price is fixed or determinable and (4) the collectability is reasonably assured. In addition, the Company has applied the following principles in recognizing revenue:

- Revenue from milestones is recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) the Company's performance obligations after the milestone achievement will continue to be funded by the collaborator at the comparable level and (iii) the milestone is not refundable or creditable. If all of these criteria are not met, the milestone payment is recognized over the remaining minimum period of the Company's performance obligations under the agreement. Upfront fees under collaborations, such as technology access fees, are recognized over the period the related services are provided. Non-refundable upfront fees not associated with the Company's future performance are recognized when received.
- Fees that the Company receives for research services are generally recognized as the services are provided, as long as the amounts received are not refundable regardless of the results of the research project.

Pending Adoption of Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF No. 07-1). EITF No. 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable U.S. GAAP or, in the absence of other applicable U.S. GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF No. Issue 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF No. 07-1

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

will be effective for the Company beginning on January 1, 2009. The adoption of EITF No. 07-1 is not expected to have a material effect on the Company's consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with GAAP in the United States (the GAAP hierarchy). SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not expect the adoption of SFAS No. 162 to have a material impact on the Company's consolidated financial statements.

Adoption of New Accounting Pronouncements

In June 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF No. 07-3). EITF No. 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF No. 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF No. 07-3 was effective for the Company beginning on January 1, 2008. The adoption of EITF No. 07-3 did not have a material effect on the Company's consolidated financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS No. 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 was effective for the Company beginning on January 1, 2008. The adoption of SFAS No. 159 did not have a material effect on the Company's consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS No. 157 applies whenever other standards required (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS No. 157 was effective for the Company beginning on January 1, 2008. The adoption of SFAS No. 157 did not have a material effect on the Company's consolidated financial statements.

2. Investments

Securities available-for-sale consisted of the following as of December 31, 2008 and 2007, respectively (in thousands):

	December 31, 2008			Market Value
	Amortized Cost	Unrealized		
		Gain	Loss	
U.S. Government sponsored enterprise securities . . .	\$ 6,604	\$ 72	\$ —	\$ 6,676
Corporate debt securities	11,304	64	(584)	10,784
	\$17,908	\$136	\$(584)	\$17,460

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	December 31, 2007			
	Amortized Cost	Unrealized		Market Value
		Gain	Loss	
U.S. Government sponsored enterprise securities	\$ 3,492	\$ 5	\$ —	\$ 3,497
Corporate debt securities	18,253	96	(20)	18,329
	\$21,745	\$101	\$(20)	\$21,826

The amortized cost and estimated fair value of the Company securities available-for-sale by contractual maturity as of December 31, 2008 and 2007 are shown below (in thousands):

	December 31, 2008			
	Amortized Cost	Unrealized		Market Value
		Gain	Loss	
Within one year	\$15,641	\$106	\$(580)	\$15,167
After one year through two years	2,267	30	(4)	2,293
	\$17,908	\$136	\$(584)	\$17,460

	December 31, 2007			
	Amortized Cost	Unrealized		Market Value
		Gain	Loss	
Within one year	\$12,487	\$ 27	\$ (6)	\$12,508
After one year through two years	9,258	74	(14)	9,318
	\$21,745	\$101	\$(20)	\$21,826

Included in the Company's portfolio of securities available-for-sale as of December 31, 2008, is a corporate bond issued by American General Finance Corporation, a subsidiary of American International Group, Inc. (AIG), that matures on August 15, 2009. As of December 31, 2008, the face value of the security is \$2.2 million and the current market value is \$1.6 million, which resulted in a \$0.6 million unrealized loss that the Company has recorded as a component of accumulated other comprehensive loss.

As of December 31, 2008, the Company performed a review of all of the securities in its portfolio with an unrealized loss position, including the American General Finance Corporation corporate bond discussed above, to determine if any other-than-temporary impairments were required to be recorded. Factors considered in the Company's assessment included, but were not limited to the following: the Company's ability and intent to hold the security until maturity; the number of months until the security's maturity, the number of quarters that each security has been in an unrealized loss position, ratings assigned to each security by independent rating agencies, the magnitude of the unrealized loss compared to the face value of the security and other market conditions. No other-than-temporary impairments were identified as of December 31, 2008 related to securities currently in the Company's portfolio. The Company also noted that none of the securities as of December 31, 2008 have been in an unrealized loss position for greater than one year.

3. Fair Value Measurements

Effective January 1, 2008, the Company adopted SFAS No. 157 which defines fair value, provides a consistent framework for measuring fair value under U.S. GAAP and expands fair value financial statement disclosure requirements. SFAS No. 157 does not require any new fair value measurements. It only applies to accounting pronouncements that already require or permit fair value measures, except for standards that relate to share-based payments (SFAS No. 123R).

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

SFAS No. 157's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. SFAS No. 157 classifies these inputs into the following hierarchy;

Level 1 Inputs — Quoted prices for identical instruments in active markets.

Level 2 Inputs — Quoted prices for similar instruments in active markets; and quoted prices for identical or similar instruments in markets that are not active.

Level 3 Inputs — Instruments with primarily unobservable value drivers.

As of December 31, 2008, the Company has \$27.7 million of marketable securities consisting of money market funds, commercial paper, U.S. government sponsored enterprise securities and corporate debt securities with maturities that range from 1 day to 21 months with an overall average time to maturity of 6.9 months. The Company has the ability to liquidate these investments without restriction. The Company determines fair value for marketable securities with Level 1 inputs through quoted market prices. The Company determines fair value for marketable securities with Level 2 inputs through broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The Company adopted SFAS No. 157 effective January 1, 2008.

The following table presents the Company's assets that are measured at fair value on a recurring basis as of December 31, 2008 (in thousands):

Description	December 31, 2008	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 3,202	\$3,202	\$ —	\$—
Commercial paper	8,196	—	8,196	—
U.S. government sponsored enterprise securities	6,675	—	6,675	—
Corporate debt securities	<u>9,585</u>	<u>—</u>	<u>9,585</u>	<u>—</u>
	<u>\$27,658</u>	<u>\$3,202</u>	<u>\$24,456</u>	<u>\$—</u>

4. Property and Equipment

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

	As of December 31,	
	2008	2007
Furniture and fixtures	\$ 69	\$ 72
Equipment	5,412	6,406
Computers and software	1,798	2,220
Leasehold improvements	<u>1,833</u>	<u>1,833</u>
	9,112	10,531
Less accumulated depreciation and amortization	<u>(7,636)</u>	<u>(7,884)</u>
	<u>\$ 1,476</u>	<u>\$ 2,647</u>

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Depreciation and amortization expense relating to property and equipment for the years ended December 31, 2008, 2007 and 2006 was \$1.1 million, \$1.4 million and \$1.5 million, respectively.

5. Other Balance Sheet Captions

	As of December 31,	
	2008	2007
Prepaid expenses and other current assets consist of the following (in thousands):		
Prepaid tenant deposit	\$1,260	\$ —
Prepaid insurance	193	227
Interest receivable	278	341
Other prepaid expenses	471	436
	\$2,202	\$1,004
Other assets consist of the following (in thousands):		
Note receivable	\$ 60	\$ 120
Tenant deposit	—	1,260
	\$ 60	\$1,380
Accrued expenses consist of the following (in thousands):		
Accrued personnel costs	\$ 344	\$ 345
Accrued employee bonus	1,347	907
Accrued drug development	2,110	1,523
Accrued legal and patent costs	198	150
Accrued facility costs	124	191
Accrued severance costs	—	205
Other accrued expenses	700	445
	\$4,823	\$3,766

6. Commitments and Contingencies

As of December 31, 2008, the Company leases its corporate headquarters and research and development facility under a non-cancelable lease, which expires on August 1, 2009. The lease requires the Company to pay a share of real estate taxes and building operating expenses if such expenses exceed a base level stipulated in the lease. Gross rent expense for the years ended December 31, 2008, 2007 and 2006 was approximately \$2.1 million, \$2.0 million and \$1.9 million, respectively.

Future minimum lease payments under equipment and facility leases are as follows as of December 31, 2008 (in thousands):

2009	\$1,241
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Total future minimum lease payments for the year ended December 31, 2009 have not been reduced by \$0.6 million of sublease rentals to be received in the future under a non-cancelable sublease.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. Collaboration and License Agreements

Novartis International Pharmaceutical Ltd.

During 2007, the Company and Novartis decided to discontinue the development of ANA975. As a result, during 2007 the Company recognized \$21.0 million of previously deferred revenue. No revenue was recognized under the Novartis collaboration in 2008.

During the years ended December 31, 2008, 2007 and 2006, the Company recorded \$0.05 million, \$0.5 million, and \$3.7 million as offsets to research and development expense, which represent Novartis' share of ANA975 expenses incurred by the Company.

8. Stockholders' Equity

Warrants

As of December 31, 2008, the Company had outstanding warrants to purchase 71,366 shares of common stock outstanding with exercise prices ranging from \$6.87 to \$28.22. These warrants expire at various times between February 23, 2009 and December 17, 2012.

Stock Options

In 2002, the Company adopted the 2002 Equity Incentive Plan (the 2002 Plan). In connection with the adoption of the 2002 Plan, the Company's 1994 Stock Option Plan and 1998 Equity Incentive Plan (collectively, the "Prior Plans") were amended and restated into the 2002 Plan. All options that were previously granted under the Prior Plans became governed by the 2002 Plan and the Prior Plans no longer existed as individual plans. The 2002 Plan provided for the issuance of incentive stock options to officers and other employees of the Company and non-qualified stock options, awards of stock and direct stock purchase opportunities to directors, officers, employees and consultants of the Company.

During March 2004 upon the effectiveness of the Company's initial public offering (IPO), the 2004 Equity Incentive Plan (the 2004 Plan) was adopted. The initial share reserve under the 2004 Plan was equal to the number of shares of common stock reserved under the 2002 Plan that remained available for future stock awards upon the effectiveness of the IPO. Options granted under the 2002 Plan continue to be governed by the provisions of the 2002 Plan. On October 24, 2008, the Company registered an additional 1,000,000 shares for issuance under the 2004 Plan in accordance with the provisions of the 2004 Plan. The total number of shares which remain available for grant under the 2004 Plan is 247,504 shares at December 31, 2008. The options are exercisable at various dates and will expire no more than ten years from their date of grant, or in the case of certain non-qualified options, ten years from the date of grant. The exercise price of each option shall be determined by the Board of Directors although generally options have an exercise price equal to the fair market value of the Company's stock on the date of the option grant. In the case of incentive stock options, the exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. For holders of more than 10% of the Company's total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company's common stock at the date of grant and for a term not to exceed five years.

Upon the effectiveness of the initial public offering, the 2004 Non-Employee Directors' Stock Option Plan (the NEDSOP Plan) was adopted. On October 24, 2008, the Company registered an additional 143,880 shares for issuance under the NEDSOP Plan in accordance with the provisions of the NEDSOP Plan. The total number of shares which remain available for grant under the NEDSOP Plan is 228,963 shares at December 31, 2008. The options are exercisable at various dates and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the Board of Directors although generally options have an exercise price equal to the fair market value of the Company's stock on the date of the option grant.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In connection with the hiring of certain executives during 2006, the Compensation Committee of the Company's Board of Directors approved inducement grants of non-qualified stock options to purchase shares of Anadys' Common Stock. The total number of shares which remain outstanding under the inducement grants is 375,000 shares at December 31, 2008. These option awards were granted without stockholder approval pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv). Although these options were granted outside the 2004 Plan, they are subject to substantially identical terms and conditions as those contained in the 2004 Plan.

The following table summarizes information about stock options outstanding under the 2002 Plan, 2004 Plan, the NEDSOP Plan and inducement grants as of December 31, 2008:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.48-\$2.00	1,691,750	9.5	\$1.94	128,437	\$1.98
\$2.11-\$2.80	1,355,314	8.6	\$2.41	587,574	\$2.37
\$2.95-\$3.57	1,317,784	5.3	\$2.99	1,135,211	\$2.98
\$3.58-\$7.00	1,336,903	6.4	\$5.06	1,009,898	\$5.29
\$7.10-\$15.61	<u>843,615</u>	6.6	\$9.22	<u>743,377</u>	\$9.18
	<u>6,545,366</u>			<u>3,604,497</u>	

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2005	3,089,271	\$6.06		
Granted	2,220,900	5.37		
Exercised	(140,225)	4.01		
Cancelled	<u>(122,766)</u>	8.14		
Balance at December 31, 2006	5,047,180	\$5.77		
Granted	2,005,875	2.59		
Exercised	(30,192)	2.95		
Cancelled	<u>(1,475,036)</u>	6.52		
Balance at December 31, 2007	5,547,827	\$4.44		
Granted	1,508,493	2.07		
Exercised	(36,567)	2.90		
Cancelled	<u>(474,387)</u>	5.47		
Balance at December 31, 2008	<u>6,545,366</u>	<u>\$3.83</u>	<u>7.49</u>	<u>\$56</u>
Exercisable at December 31, 2008	<u>3,604,497</u>	<u>\$4.77</u>	<u>6.26</u>	<u>\$ 1</u>

The total intrinsic value of options exercised during the year ended December 31, 2007 was \$0.05 million determined as of the date of exercise. There was no material intrinsic value for options exercised during the year ended December 31, 2008. The Company settles employee stock option exercises with newly issued common shares.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company did not grant any stock options to non-employees for the years ended December 31, 2008 and 2007. The Company granted 15,000 shares to non-employees for the year ended December 31, 2006. Compensation expense related to non-employee stock option grants was \$0.01 million, \$0.05 million and \$0.3 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Share-Based Compensation

SFAS No. 123R and SAB No. 107 require the Company to record share-based compensation as components of either research and development expense or general and administrative expense. In accordance with SFAS No. 123R and SAB No. 107, the Company has reported the following amounts of stock-based compensation expense in the consolidated Statements of Operations (in thousands, except per share data):

	For the Years Ended December 31,		
	2008	2007	2006
Research and development expense	\$1,271	\$2,463	\$2,889
General and administrative expense	1,492	1,650	4,241
Total share-based compensation expense	<u>\$2,763</u>	<u>\$4,113</u>	<u>\$7,130</u>
Net share-based compensation expense, per common share basic and diluted	<u>\$ 0.10</u>	<u>\$ 0.14</u>	<u>\$ 0.25</u>

As of December 31, 2008, there was an additional \$3.9 million of total unrecognized compensation cost related to unvested share-based awards granted under the Company's stock option plans. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.68 years.

The fair value of options granted to employees and directors was estimated at the date of grant using a Black-Scholes option-valuation model with the weighted-average assumptions stated below.

	For the Years Ended December 31,		
	2008	2007	2006
Risk-free interest rate	2.45%	4.20%	4.66%
Dividend yield	0%	0%	0%
Volatility factors of the expected market price of the Company's common stock	71%	70%	67%
Weighted-average expected life of option (years)	6	6	6

The estimated weighted-average fair value of stock options granted during 2008, 2007 and 2006 was \$1.31, \$1.67 and \$3.43, respectively.

Dividend Yield — The Company has never declared or paid dividends on common stock and has no plans to do so in the foreseeable future.

Expected Volatility — Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated or is expected to fluctuate during a period. The Company considered the historical volatility from its IPO through the dates of grants, in combination with the historical volatility of peer companies and business and economic considerations in order to estimate the expected volatility, due to the Company's short history as a public company.

Risk-Free Interest Rate — This is the U.S. Treasury rate for the week of each option grant during the quarter having a term that most closely resembles the expected life of the option.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Expected Life of the Option Term — This is the period of time that the options granted are expected to remain unexercised. Options granted during the year have a maximum contractual term of ten years. The Company estimates the expected life of the option term based on actual past behavior for similar options with further consideration given to the class of employees to whom the options were granted.

SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company assesses the forfeiture rate on an annual basis and revises the rate when deemed necessary.

Employee Stock Purchase Plan

Under the Company's 2004 Employee Stock Purchase Plan (Purchase Plan), employees may purchase common stock every six months (up to but not exceeding 12% of each employee's earnings) over the offering period at 85% of the fair market value of the common stock at certain specified dates. The offering period may not exceed 24 months. This purchase discount is significant enough to be considered compensatory under SFAS No. 123R. As a result, the Company recorded \$0.2 million in stock-based compensation for the year ended December 31, 2008 related to the Purchase Plan.

For the years ended December 31, 2008, 2007 and 2006, 83,248 shares, 70,558 shares and 78,727 shares of common stock were issued under the Purchase Plan, respectively. On October 24, 2008, the Company registered an additional 431,641 shares for issuance under the Purchase Plan in accordance with the provisions of the Purchase Plan. The weighted-average fair value of employee stock Purchase Plan purchases was \$1.84, \$2.38 and \$4.97 per share for 2008, 2007 and 2006, respectively.

Shares Reserved for Issuance

Shares of common stock reserved for future issuance as of December 31, 2008 are as follows:

	<u>December 31, 2008</u>
Warrants	71,366
Employee Stock Purchase Plan	1,123,783
Stock options under the Company's Plans:	
Granted and outstanding	6,545,366
Reserved for future issuance	<u>599,712</u>
	<u>7,145,078</u>

9. Income Taxes

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. The Company adopted the provisions of FIN 48 effective January 1, 2007. The adoption of FIN 48 did not impact the Company's consolidated financial condition, results of operations or cash flows. As of December 31, 2008 and 2007, the Company has not recorded any uncertain tax benefits.

Significant components of the Company's deferred tax assets are shown below. A valuation allowance of \$80.5 million and \$67.6 million has been established to offset the deferred tax assets, as realization of such assets has not met the more likely than not threshold under SFAS No. 109, *Accounting for Income Taxes*, as of December 31, 2008 and 2007, respectively.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	As of December 31,	
	2008	2007
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 46,681	\$ 38,784
Research and development credits	4,663	3,430
Non-qualified stock options	3,844	3,474
Capitalized research and development expense	25,058	21,396
Accruals	248	475
Other	30	24
Total deferred tax assets	80,524	67,583
Valuation allowance for deferred tax assets	(80,524)	(67,583)
Net deferred taxes	\$ —	\$ —

As of December 31, 2008 the Company had federal and state tax net operating loss (NOL) carryforwards of approximately \$118.5 million and \$90.7 million, respectively. Approximately \$4.0 million of the federal loss carryforwards will begin expiring in 2009 and approximately \$5.8 million of the state loss carryforwards will begin expiring in 2011, unless previously utilized. The Company also has federal and state research tax credit (R&D credit) carryforwards of approximately \$1.6 million and \$4.6 million respectively. The federal research credits will begin expiring in 2027 unless previously utilized. The state research credits do not expire.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing ownership of certain shareholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. The Company has initiated an analysis of Section 382 and, based on this analysis, the Company believes that multiple changes of ownership have occurred and therefore its NOL and R&D credit carryforwards and other deferred tax assets will be subject to annual limitations in future periods. The Company has completed its analysis and has determined that, as of December 31, 2008 and 2007, approximately \$16.0 million of the deferred tax assets related to NOL and credit carryforwards will expire unused and, accordingly, the Company has removed such assets from its deferred tax assets with a corresponding reduction to its valuation allowance. There may be additional limitations imposed on the Company's ability to fully utilize its remaining deferred tax assets due to future ownership changes. Any amounts that are determined by the Company to expire prior to their utilization due to such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. In addition, future changes in the unrecognized tax benefit will have no impact on the effective tax rate due to the existence of the valuation allowance.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2008, the Company did not record any interest or penalties.

The tax years 1993 to 2008 remain open to examination by the major taxing jurisdictions to which the Company is subject, as tax authorities may have the right to examine prior periods where net operating losses or tax credits were generated and carried forward.

ANADYS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

10. Savings Plan

The Company has a retirement savings plan for all employees, subject to certain age requirements, pursuant to Section 401(k) of the Internal Revenue Code. The Company matches 25% of employee contributions up to 6% of eligible compensation. Employer contributions were \$0.1 million for each of the years ended December 31, 2008, 2007 and 2006.

11. Unaudited Quarterly Results of Operations

The following quarterly financial data, in the opinion of management, reflects all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of results for the periods presented.

<u>Fiscal Year 2008</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
	(In thousands, except net loss per share)			
Revenues	\$ —	\$ —	\$ —	\$ —
Net loss	(7,444)	(7,092)	(9,349)	(8,517)
Net loss per share, basic and diluted	(0.26)	(0.25)	(0.32)	(0.30)
<u>Fiscal Year 2007</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
	(In thousands, except net loss per share)			
Revenues	\$ 1,102	\$ 1,302	\$21,489	\$ 225
Net (loss) income	(6,683)	(6,996)	12,307	(7,800)
Net (loss) income per share, basic and diluted	(0.23)	(0.24)	0.43	(0.27)

During quarter ended September 30, 2007, the Company and Novartis decided to discontinue the development of ANA975 and as a result the Company recognized \$21.0 million of previously deferred revenue.

EXECUTIVE MANAGEMENT & CORPORATE OFFICERS

Stephen T. Worland, Ph.D.
President & Chief Executive Officer

James T. Glover, C.P.A.
Senior Vice President, Operations &
Chief Financial Officer

James L. Freddo, M.D.
Senior Vice President, Drug Development &
Chief Medical Officer

Elizabeth E. Reed, J.D.
Vice President, Legal Affairs &
Corporate Secretary

Mary Yaroshevsky-Glanville
Vice President, Human Capital

BOARD OF DIRECTORS

George A. Scangos, Ph.D. (Chairman)
President & Chief Executive Officer
Exelixis, Inc.

Mark G. Foletta
Senior Vice President, Finance &
Chief Financial Officer
Amylin Pharmaceuticals, Inc.

Marios Fotiadis
Global Director
TVM Capital, Inc.

Steven H. Holtzman
Chair & Chief Executive Officer
Infinity Pharmaceuticals, Inc.

Stelios Papadopoulos, Ph.D.
Former Vice-Chairman
Cowen & Co., LLC

Douglas E. Williams, Ph.D.
Chief Executive Officer
ZymoGenetics, Inc.

Stephen T. Worland, Ph.D.
President & Chief Executive Officer
Anadys Pharmaceuticals, Inc.

Kleanthis G. Xanthopoulos, Ph.D.
President & Chief Executive Officer
Regulus Therapeutics, Inc.

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COMMON STOCK

Anadys Pharmaceuticals, Inc. common stock trades on the NASDAQ Global Market under the symbol ANDS.

ANNUAL MEETING

Friday, May 29, 2009
9:00 a.m. Pacific Daylight Time
Anadys Pharmaceuticals, Inc.
3115 Merryfield Row
San Diego, CA 92121

Important Note About Forward-Looking Statements. Except for historical information, this Annual Report contains forward-looking statements that involve risks and uncertainties which may cause actual results to differ materially from the statements made. These forward-looking statements represent the judgment of Anadys as of the date of the printing of this Annual Report. Forward-looking statements include, but are not limited to, plans and expected timing for our development programs, expectations regarding future HCV treatment possibilities, the anticipated future clinical benefits of ANA598 and ANA773, as well as the ability to engage in a transaction with another company interested in HCV. For more detailed information on the risks and uncertainties associated with these forward-looking statements and the Company's other activities, see the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 that accompanies this Annual Report. Anadys does not undertake any obligations to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.



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