

The background of the entire page is a blurred, microscopic image showing various green and blue cellular structures. A white, rounded rectangular box is positioned in the upper third of the page, containing the company name and report title.

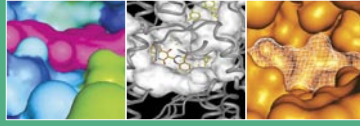
ANADYS PHARMACEUTICALS, INC.

ANNUAL REPORT '07

COMMITTED TO MAKING A DIFFERENCE



**ANADYS PHARMACEUTICALS, INC.** is a biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. The Company is developing ANA598, a small-molecule, non-nucleoside inhibitor of the NS5B polymerase for the treatment of hepatitis C and ANA773, an oral TLR7 agonist prodrug for cancer.



## HCV

Hepatitis C virus (HCV) is a major cause of acute hepatitis and chronic liver disease, including cirrhosis and liver cancer. Globally, an estimated 170 million individuals, 3% of the world's population, are chronically infected with HCV and 3 to 4 million people become infected each year. Currently, there is no vaccine available to prevent HCV, nor a HCV-specific antiviral agent approved for treatment of chronic infection. The number of people facing death or serious liver disease from HCV is rising steadily because people often live for decades with the virus before symptoms emerge.

The current standard of care is a combination of pegylated interferon (IFN) with ribavirin. Inadequate response rates, in particular for patients infected with genotype 1 HCV, along with significant side-effects of approved therapy, support the medical need for improved treatment options. It is estimated that less than 5% of people with chronic HCV infection living in the US are under treatment today. The majority do not know they are infected and others have failed interferon-based therapy or avoid treatment altogether.

It is expected that the next generation of therapies for treatment of HCV will include small molecules, such as our clinical candidate ANA598, that directly act upon specific viral enzymes to inhibit viral replication. These new agents are expected to improve overall therapy by increasing cure rates and improving tolerability and convenience of treatment.

## CANCER

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 2007, and approximately one out of every two men, and one out of every three women, will develop cancer during their lifetime. Cancer accounts for nearly one-quarter of all deaths in the United States, exceeded only by heart disease.

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. We believe that ANA773, our product candidate currently in clinical development for the treatment of cancer, has the potential to be an important component of these next-generation immunotherapies.



## To OUR SHAREHOLDERS,

Anadys is committed to improving patient care in the areas of hepatitis C and oncology. We approach this challenging mission

with the mindset that only superior product candidates offer the potential to meaningfully improve treatment outcomes. We selected our two product candidates, ANA598 in hepatitis C and ANA773 in oncology, based on demonstrated properties that suggest just such potential—the potential to change treatment paradigms and become important products in time. We couple high quality candidates with a disciplined investment approach, pursuing time- and cost-efficient paths to obtaining clinical data. We believe this strategy will provide the most effective way to demonstrate the potential of our product candidates and accelerate external recognition of that potential.

2007 was a year of significant change for Anadys, but also a year of significant continuity. In July we undertook a strategic restructuring of the company that enabled us to focus on our two most attractive product opportunities, ANA598 and ANA773. As part of the increased focus, we discontinued development of ANA975 and ANA380 and halted our early discovery efforts. Accompanying the remodeling of our portfolio we changed the profile and size of our workforce, and I became President and CEO. But throughout these changes, we continued to adhere to our philosophy that only the best product candidates warrant continued development and that we must prioritize our development activities to maximize return on our investments.

It is important to note that ANA598 and ANA773 were discovered at Anadys. The profiles of both product candidates reflect our years of disciplined science applied to understanding the requirements for success in their respective therapeutic areas. We believe this legacy positions both candidates favorably for future development.

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 the second quarter of 2007 we selected ANA598 as a development candidate. We believe ANA598 represents a scientific breakthrough in achieving a balance between potency and preclinical pharmacokinetics in this class of non-nucleoside HCV inhibitors, a breakthrough made possible as a result of the comprehensive structure-based drug design program we directed towards the HCV 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. We look forward to initiating clinical investigation of ANA598 in the second quarter of 2008.

We are developing ANA773 for use in certain oncology treatment settings. ANA773 activates the body's immune system through Toll-like Receptor 7 (TLR7), a component of the innate immune system. TLR7 plays a gatekeeper function during infection, recognizing that a pathogen is present and initiating a response to control and eliminate the pathogen. We are harnessing the same immunological response, triggered by TLR7 activation, as a way to control and eliminate cancer cells from the body. Our development plans for ANA773 in cancer benefit from our years of prior experience with TLR7 agonists, including the lessons learned from the ANA975 program. In the fourth quarter of 2007, the FDA accepted our IND application to commence clinical investigation of ANA773. We are currently conducting a Phase I clinical trial in patients with advanced cancer.

Looking ahead, we anticipate several important milestones in 2008. In the second quarter we anticipate filing the IND for ANA598 and commencing our clinical investigation in healthy volunteers. In the third quarter we anticipate moving into a trial of ANA598 in HCV-infected patients, paving the way for clinical proof of concept, as reflected by viral load reduction data, in the first quarter of next year. With ANA773, this year we intend to explore the safety and tolerability profile of the agent. In addition, we expect to identify pharmacologically active doses and establish the profile of immune stimulation as reflected by cellular activation and circulating cytokines. The information regarding immune activation and safety will support the future design of clinical trials of ANA773 (alone or in combinations) in specific tumor types. As we advance our programs in 2008 we will remain vigilant with regard to our spending levels, seeking those investments that provide the greatest increase in confidence in our product candidates.

Beyond 2008, we hope to use our two current product candidates as a sound basis for building Anadys into an important biopharmaceutical company. We intend to continue our focus on finding and developing new product candidates that offer the potential to make a genuine difference in how patients with serious disease are treated. By focusing only on the best product candidates and by being judicious in how we invest in these candidates, we hope to simultaneously create new medicines and increase shareholder value. As we carry out this exciting mission, we thank you, our shareholders, for your continued support.

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 and Chief Executive Officer

# ANA598

a non-nucleoside HCV polymerase inhibitor

In 2007 we selected ANA598 as a candidate for the treatment of chronic hepatitis C virus (HCV) infection. This directly acting antiviral agent is a non-nucleoside inhibitor of the NS5B polymerase, a virally encoded enzyme essential for replication of the hepatitis C virus. ANA598 was chosen from a number of competing candidates based on a balance of preclinical properties, including intrinsic potency as a NS5B inhibitor, activity in cellular models, ability to administer the compound orally, a favorable pharmacokinetic profile, and promising findings in early indicators of safety and tolerability.

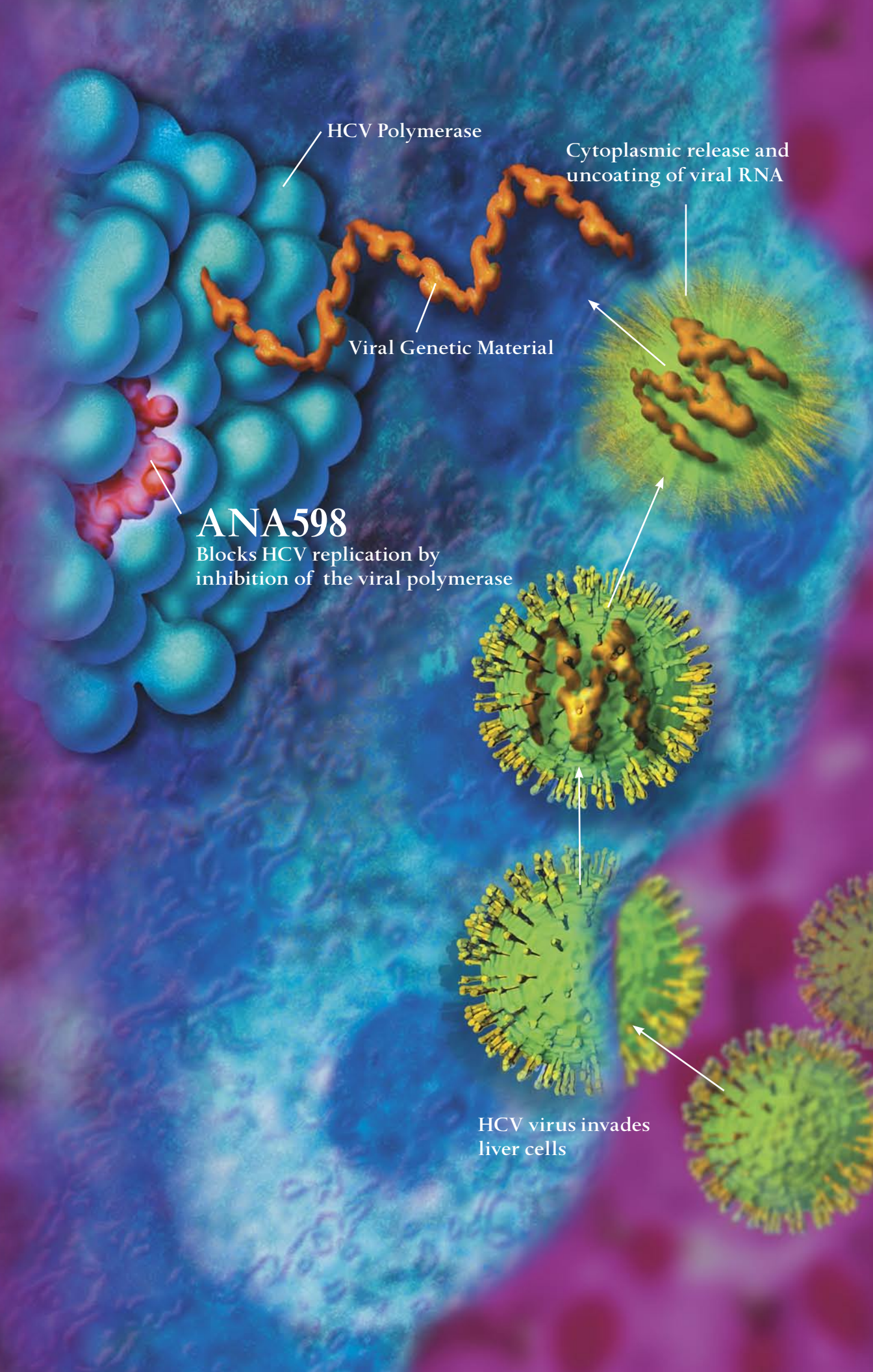
Since nomination of ANA598 as a clinical candidate in June of 2007, further preclinical testing has been very encouraging. In particular, we have demonstrated that ANA598:

- Is well-tolerated in animal studies at clinically relevant doses in 14- and 28-day studies, and
- Produces significant and rapid reduction in viral load in a primate model of HCV infection.

Two animals chronically infected with HCV genotype 1b each received once-daily oral doses of ANA598 at 30 mg/kg for four days. A rapid viral load decline was seen in both animals. At 48 hours (24 hours after the second dose), viral load declines were 2.2 and 2.6  $\log_{10}$  in the individual animals. In a preceding study conducted to assess the pharmacokinetics (PK), safety, tolerability and preliminary antiviral activity of ANA598, activity was also demonstrated in animals infected with HCV genotype 1a.

Taken together, our findings are highly encouraging that ANA598 will have clinical activity in patients infected with HCV genotype 1. This is particularly relevant since genotype 1 patients, the most prominent patients in the US, western Europe and Asia, show the lowest response rate to current treatments.

We plan to file an IND for ANA598 in the second quarter of 2008. Following preliminary testing in healthy volunteers, we look forward to exploring the clinical utility of this exciting new direct antiviral agent in the treatment of patients with HCV infection during 2008.



HCV Polymerase

Cytoplasmic release and uncoating of viral RNA

Viral Genetic Material

**ANA598**  
Blocks HCV replication by inhibition of the viral polymerase

HCV virus invades liver cells

# ANA773

a TLR7 agonist prodrug for oncology indications

During the last decade, significant advances have been made in the use of immunotherapeutic agents for the treatment of cancer. This success is in part due to the scientific community's increased understanding of how the immune system responds to extrinsic and intrinsic biological threats and in part due to a greater facility in selectively enhancing immune response in a controlled and beneficial way. The immune system consists of two complex and interrelated components, the innate and adaptive systems. Activation of toll-like receptors (TLRs) triggers the innate system which is typically the first line of defense against bacterial and viral infections. Furthermore, the innate system primes the adaptive system to subsequently respond to such threats. With ANA773, we are seeking to harness the pharmacological response triggered by TLR7 activation to control cancer.

Supported by encouraging preclinical results, we are currently developing ANA773 for the treatment of cancer. In the fourth quarter of 2007 our IND was accepted by the FDA and we are currently conducting a Phase 1 clinical trial in the United States. The Phase 1 clinical trial of ANA773 is a multiple, ascending dose study conducted in patients with advanced solid tumors. In addition to safety and tolerability, patients will be monitored for pharmacodynamic responses indicative of immunological stimulation. Initially, patients will be dosed every other day. We expect to investigate additional schedules during this first clinical trial and estimate that up to 60 patients will be enrolled in the study.

In 2007 we also completed a significant pharmacology program demonstrating that the fundamental characteristics of immune response elicited by ANA773 were dependent not only upon the dose level but also upon the schedule of administration. In our clinical program we also plan to investigate whether we can match particular profiles of immune activation, triggered by particular schedules, to desired effects in different cancer populations.

Immune Stimulation

TLR7 Agonist  
TLR7 Receptor

Dendritic cell

Cytokines and Chemokines

Cytotoxic T Lymphocytes

Enhanced Tumor Lysis by Cytotoxic T Cells

Lysis of Target Tumor Cells by Natural Killer Cells

Natural killer cells

Therapeutic Mab

Enhanced Antibody Dependent Cellular Cytotoxicity with Therapeutic Mab

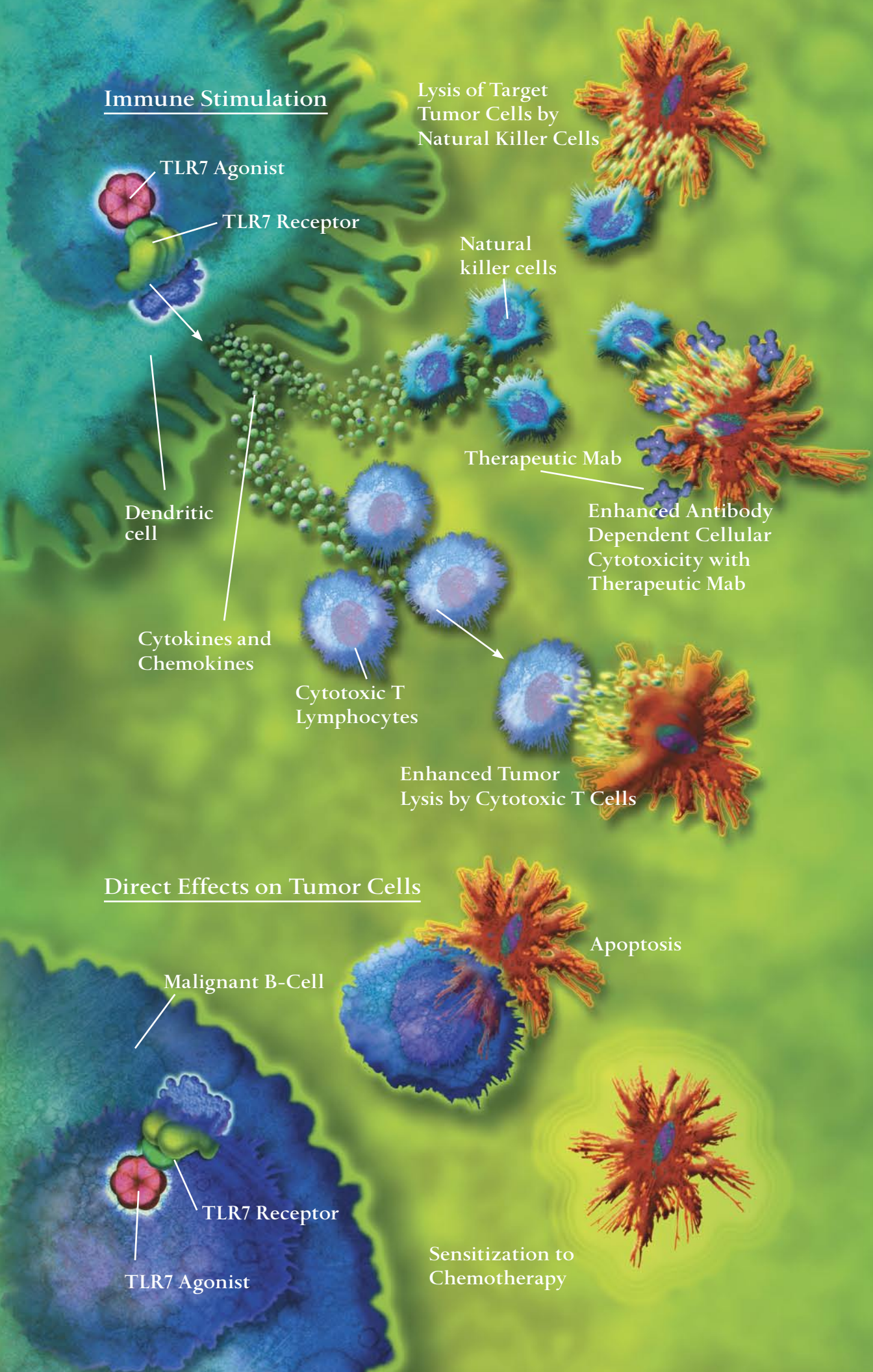
Direct Effects on Tumor Cells

Malignant B-Cell

TLR7 Receptor  
TLR7 Agonist

Apoptosis

Sensitization to Chemotherapy



# The People Behind Anadys

It is our commitment to make a difference.



Our people are the heart and soul of Anadys. Their focus is the patient and their passion is creating novel medicines to improve the quality of human life.



PICTURED FROM LEFT TO RIGHT: Mary Yaroshevsky-Glanville, Vice President, Human Capital; James L. Freddo, M.D., 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.



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**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, 2007
- 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** **22-3193172**  
*(State or other jurisdiction of* *(I.R.S. Employer*  
*incorporation or organization)* *Identification No.)*

**3115 Merryfield Row, San Diego, California** **92121**  
*(Address of principal executive offices)* *(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 \$90,001,036 as of such date.

As of February 19, 2008, the Registrant had outstanding 28,696,948 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 2008 Annual Meeting of Stockholders are incorporated herein by reference into Part III.

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**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 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. The Company is developing ANA598, a small-molecule, non-nucleoside inhibitor of the NS5B polymerase for the treatment of hepatitis C and ANA773, an oral Toll-like receptor 7 (TLR7) agonist prodrug for cancer. Both ANA598 and ANA773 were discovered at Anadys and are wholly owned assets of Anadys.

We believe that the areas of 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 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. We are leveraging this experience in an effort to more efficiently develop ANA773.

#### *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.

We are currently completing the pre-clinical and toxicology studies with ANA598 that are necessary for submitting an Investigational New Drug Application (IND) to the Food and Drug

Administration (FDA) and we plan to file an IND during the second quarter of 2008. Pending FDA allowance, we plan to initiate clinical trials of ANA598 in the second quarter of 2008. Our planned clinical development timelines are structured with the objective that if ANA598 is successful in early stage clinical trials, we expect to be in a position to establish clinical proof of concept (viral load reduction in patients) during the first quarter of 2009.

### ***ANA773***

ANA773 is a novel, oral prodrug of a proprietary TLR7 agonist. 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.

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.

The FDA has accepted our IND application to study ANA773 in cancer patients and we are currently conducting a Phase I clinical trial in the United States. In the first trial we intend to explore the pharmacodynamic response in cancer patients. In the third quarter of 2008 we intend to select the tumor types for Phase II evaluation and in the fourth quarter of 2008 we intend to determine the dose and schedule for potential Phase II studies. As we advance the development of ANA773, we continue to conduct toxicology studies to support clinical trials of longer duration.

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**

### ***HCV***

Based on available market data, we estimate that the global HCV market in 2007 was approximately \$3 billion. Due to significant global prevalence and substantial unmet medical need, improving the treatment of chronic HCV 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, liver cancer, and early death over time.

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 relapse 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 2007, and approximately one out of every two men, and one out of every three women, will develop cancer during their 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.

### ***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 Aldara® (imiquimod) 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:

- *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. As part of this strategy, during 2007 we engaged in a strategic restructuring enabling us to focus our current efforts toward the development of ANA773 and ANA598
- *Advance the Development of a ANA773 in Cancer.* We are currently conducting a Phase I clinical trial of ANA773 in cancer patients. During 2008 we intend to:
  - Explore the pharmacodynamic response in cancer patients
  - Select the tumor types for Phase II evaluation
  - Select the dose and schedule for Phase II clinical trials
- *Advance the Development of ANA598 in HCV.* We are developing ANA598, a non-nucleoside inhibitor of the HCV NS5B polymerase. During 2008 we intend to:
  - File an IND application for ANA598
  - Conduct a Phase I clinical trial in healthy volunteers
  - Initiate a Phase Ib clinical trial in HCV infected patients, with the objective of obtaining clinical proof of concept reflected in viral load data in early 2009

- *Opportunistically Expand Our Product Candidate Portfolio.* We intend to continue our focus over time on finding and developing new product candidates that offer the potential to make a genuine difference in how patients with serious disease are treated
- *Establish select strategic alliances to support our drug development programs while preserving significant development and commercial rights.* In the future we intend to evaluate the potential benefits of selectively entering into strategic alliances to support our drug development programs to obtain financial support and potentially accelerate the development of our product candidates

## **Strategic Restructuring**

On July 26, 2007, we announced that we and our collaborator Novartis International Pharmaceutical Ltd. (Novartis) had decided to discontinue the development of ANA975, a Phase 1b compound for the treatment of HCV infection. Following this decision, we undertook a strategic restructuring to focus our resources on the development of ANA598 and ANA773. Included within this restructuring were the decisions to discontinue further development of ANA380, a nucleotide analog for the treatment of hepatitis B virus (HBV) infection that we had been co-developing with LG Life Sciences, Ltd. (LGLS), halt work on early discovery projects, and effect an immediate reduction in force of approximately one-third of the Company's employees, with several additional positions eliminated in early 2008.

## **Collaboration Agreements Concluded During 2007**

### *Novartis International Pharmaceuticals Ltd.*

On December 11, 2007, we and Novartis entered into an agreement terminating the License and Co-Development Agreement dated June 1, 2005 between us and Novartis. This mutual termination of the collaboration agreement followed the parties' joint decision to discontinue the development of ANA975. As a result of the termination of the collaboration agreement, the licenses granted by Anadys to Novartis terminated. Neither party owed an early termination penalty to the other. Pursuant to the collaboration agreement, we were collaborating with Novartis around the development and potential commercialization of ANA975. Under the collaboration agreement, Novartis funded 80.5% of the development costs of ANA975 and we funded 19.5% of such development costs. Upon the termination of the activities under the collaboration agreement in the third quarter of 2007, we accelerated the recognition of the remaining unrecognized portion of revenue from payments received from Novartis in 2005.

### *LG Life Sciences, Ltd.*

On December 18, 2007, we and LGLS entered into a letter agreement terminating the Joint Development and License Agreement by and between us and LGLS dated April 18, 2004. This mutual termination of the development agreement with LGLS followed our decision, announced on August 1, 2007, to discontinue our involvement with the development of ANA380 in connection with our strategic restructuring. The parties had been jointly developing ANA380, a nucleotide analog for the treatment of hepatitis B virus infection, since 2004. All rights to ANA380 reverted to LGLS and neither party owed an early termination penalty to the other.

### *Aphoenix, Inc.*

During 2007, we concluded work under the drug discovery collaboration agreement with Aphoenix, Inc. which we entered into in September 2004 to discover and advance lead compounds against Aphoenix targets for multiple therapeutic indications. Under the agreement, we received research funding totaling \$1.5 million over the three-year term of the agreement.

We currently have no ongoing collaborations.

## **Our Development Programs**

### **ANA598**

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.

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, there are only a few compounds in this class that are currently in early or mid-stage clinical development and none, to our knowledge that are in late stage clinical development. We believe that the future evolution of HCV therapy will likely include a protease inhibitor, a nucleoside and a non-nucleoside. Therefore, we view ANA598 as complementary to, rather than competitive with, protease inhibitors and nucleosides that are currently in development as HCV therapies.

In June 2007, we announced the nomination of ANA598 as a clinical development candidate. The selection of ANA598 represented the culmination of a comprehensive structure-based drug design program directed towards NS5B. ANA598 was selected based on an optimized balance of preclinical properties, including intrinsic potency as an NS5B inhibitor, cellular activity in the HCV replicon assay, oral bioavailability and early indicators of safety and tolerability. In vivo, ANA598 was well tolerated in 14-day dose range finding (DRF) animal toxicology studies.

In January 2008, we announced positive results for ANA598 from two studies in a widely utilized primate model of chronic hepatitis C virus infection. In the first study, which was conducted to assess the pharmacokinetics (PK), safety, tolerability and preliminary antiviral activity of ANA598, two HCV genotype 1a infected animals received a single oral dose of ANA598 at 30 mg/kg. At 24 hours after dosing, plasma levels of ANA598 exceeded the replicon EC95 values. The EC95 is the concentration required in vitro to suppress hepatitis C viral RNA levels by 95% in the replicon assay. At 48 hours after dosing, the mean viral load decline in the two animals was 1.0 log<sub>10</sub>.

In the second study, two animals chronically infected with HCV genotype 1b each received once-daily oral doses of ANA598 at 30 mg/kg for four days. A rapid viral load decline was seen in both animals. At 48 hours (24 hours after the second dose), viral load declines were 2.2 and 2.6 log<sub>10</sub> in the individual animals. In one animal the viral load reduction was sustained throughout the remaining dosing period, while in the second animal a modest rise in viral load was seen over days 3 and 4, although the rise observed (0.6 log<sub>10</sub>) was within the baseline variability seen in this animal prior to dosing. ANA598 was well tolerated by all of the animals in both studies.

We are currently completing IND enabling activities for ANA598 and an IND submission is targeted for the second quarter of 2008. Pending FDA allowance, we plan to initiate clinical trials of ANA598 in the second quarter of 2008. Our planned clinical development timelines are structured with the objective that if ANA598 is successful in early stage clinical trials, we expect to be in a position to establish clinical proof of concept (viral load reduction in patients) during the first quarter of 2009.

## Cancer Program

### *ANA773*

We are developing ANA773, an immunomodulator, 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 this information in hand by the end of 2008, which will position us for subsequent clinical investigations of ANA773 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 expect to 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 Aldara® (imiquimod). While the FDA-approved indications for imiquimod 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 Anadys 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 produces the desired blood concentrations of the active agent and provides immune stimulation. For our clinical investigations, we intend to administer 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 has a significant effect on the profile of immune stimulation induced by ANA773. Alternating dosing with periods of no dosing leads to more robust NK cell activation and more stable levels of interferon-alpha induction, compared to chronic daily administration. We anticipate utilizing different dosing schedules in different tumor settings as we advance the development of ANA773.

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 will be monitored for pharmacodynamic responses indicative of immunological stimulation. Initially, patients will be dosed every other day. We expect to investigate additional schedules during this first clinical trial and estimate that up to 60 patients will be enrolled in the study. During 2008, we intend to select the tumor types for Phase II exploration and identify the dose and schedule for Phase II clinical trials. As we advance the development of ANA773, we continue to conduct toxicology studies to support clinical trials of longer duration.

Longer term, our clinical program is designed to enable exploration of the TLR7 mechanism in a number of settings. Pending positive data from our Phase I trial regarding the magnitude of immune stimulation at tolerated doses, we expect to explore ANA773 in selected solid tumors, where the effect of activated NK cells and CTLs as well as the induction of cytokines, may have the ability to reduce and eliminate tumors. Positive Phase I data will also position us to explore the benefit in B cells arising from direct effects due to the expression of the receptor in the cancerous cell. In both solid tumors and B cell diseases, we expect to explore the benefit of combining ANA773 with other agents.

## **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 ANA773 and ANA598 for use in clinical trials. We intend to continue this practice for any future clinical trials and large-scale commercialization of ANA773 and ANA598. 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.

As of December 31, 2007, we had one non-U.S. patent issued related to our NS5B hepatitis C drug discovery and drug development program and one non-U.S. patent issued related to our ANA773 drug discovery and drug development program. We also have numerous patent applications pending in the U.S. and in foreign countries relating to these programs. In addition, our patent portfolio contains a number of issued patents and pending patent applications relating to our discovery technologies and currently inactive programs.

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. According to the National Institutes of Health, harsh side effects have caused discontinuation of treatment in approximately 10 to 14 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 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 or competitive with ANA598 include Albuferon, in development by Human Genome Sciences and Novartis, VX-950 (telaprevir), in development by Vertex Pharmaceuticals, Janssen Pharmaceutica and Mitsubishi Tanabe Pharma, SCH503034 (boceprevir), in development by Schering-Plough, ITMN-191, in development by Intermune and Roche, TMC-435350, in development by Tibotec and Medivir, R-1626, in development by Roche and R-7128 in development by Pharmasset and Roche.

### *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.

Several clinical observations support the importance of tumor immune surveillance in humans. Immunotherapy has had success in treating certain tumors and this approach remains of interest for improving cancer treatment options. As key regulators of both innate and adaptive immune responses, TLRs have been shown in research studies to affect several diseases, including cancer.

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 PF-3512676, in development by Pfizer, IMO-2055, in development by Idera and Merck KGaA, and a cancer program in development by Dynavax.

### *Competitive Risks*

We have only recently initiated a Phase I clinical trial of ANA773, and intend, pending acceptance of our IND by the FDA, to initiate a Phase I clinical trial of ANA598 during the second quarter of 2008. Therefore, it is difficult to predict the efficacy, safety and tolerability that these product candidates will demonstrate in humans. It is also difficult to predict whether these product candidates will be used as single agents or in combination therapies, or if these 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 U.S. Food and Drug Administration (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.

### **Employees**

As of March 1, 2008, we had 49 full-time employees, including 35 in research and development, and the balance in general and administrative positions, with 25 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, 2008:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steve Worland, Ph.D.	50	President and Chief Executive Officer
James T. Glover	58	Senior Vice President, Operations and Chief Financial Officer
James L. Freddo, M.D.	53	Chief Medical Officer
Mary Yaroshevsky-Glanville	43	Vice President, Human Capital
Elizabeth E. Reed, J.D.	37	Vice President, Legal Affairs and Corporate Secretary

*Steve Worland, Ph.D.* was appointed President and Chief Executive Officer and a member of the Board of Directors on August 24, 2007. Dr. Worland joined us as our Chief Scientific Officer 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' R&D 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 \$2.4 billion 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, 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. 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 U.S. Food and Drug Administration (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. 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**

*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. In 2007 we discontinued the development of ANA975 and ANA380, and our current product candidates have either not yet been studied in clinical trials or are at 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, 2007 we have an accumulated deficit of \$223.7 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 as we plan to fund the development costs of our product candidates, further our development activities and potentially acquire or license new technologies and product candidates. 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, and there is no guarantee that an acceptable balance between therapeutic benefit and risk will be achieved with TLR7 agonists. For example, in June 2006 we suspended dosing of ANA975, a TLR7 agonist prodrug, in our then on-going ANA975 clinical trials 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. More specifically, the use of a TLR7 agonist represents a new mechanism of action for the treatment of cancer, and there is no guarantee that an acceptable balance between therapeutic benefit and risk will be achieved with ANA773 in cancer patients. The science underlying ANA598 is also new and unproven, as no products acting at the HCV polymerase have been approved for marketing. ANA598 has not been studied in clinical trials and ANA773 is 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.

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

On August 1, 2007 we announced a re-structuring of our business and operations following the decision to discontinue the development of ANA975 as a treatment for HCV infection. As part of the restructuring of our business, we discontinued our further involvement with the development of ANA380, which we were jointly developing with LG Life Sciences LTD. as a treatment for HBV infection. We also halted our early-stage discovery programs. As a result of the restructuring, we have become substantially dependent on the future success of ANA598 and ANA773. If one or both of these compounds fail or have set-backs, our business and stock price will 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 program for cancer 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. 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 have recently initiated a Phase 1 clinical trial of ANA773 and are currently recruiting cancer patients. If patient enrollment does not move as quickly as we would like, our development timelines for ANA773 could be delayed, which could cause our stock price to decline.***

We have recently initiated a Phase 1 clinical trial of ANA773 and the investigators at our clinical sites are currently recruiting cancer patients with advanced solid tumors to participate in the trial. Our planned development timelines for ANA773 depend upon us enrolling a sufficient number of patients in this Phase I clinical trial during 2008. These timelines could be delayed if there is 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 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 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, 2007 cash, cash equivalents and marketable securities balance was \$56.5 million. We believe that this balance will be sufficient to satisfy our anticipated cash needs for at least the next fiscal year. However, we may need or choose to seek additional funding within this period of time. In addition, we will need to raise additional capital at least within the next couple of years 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;
- 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 preclinical development activities;
- our ability to establish and maintain strategic collaborations;
- 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, corporate collaboration 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.

***Raising additional funds by issuing securities or through debt or project financing or collaboration 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 or corporate collaborations 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 collaboration 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.

***If we fail to establish new collaborations, we may be unable to advance our programs, which could cause our stock price to decline.***

Our near and long-term viability will depend in part on our ability to successfully establish new strategic collaborations with pharmaceutical and biotechnology companies. Since we do not currently possess the resources necessary to independently fully develop and commercialize ANA598 and ANA773, we will either need to develop or acquire these resources on our own, which will require substantial funding, time and effort, or will need to enter into collaborative agreements to assist in the development and commercialization of these potential products. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on existing collaborations. If we fail to establish a sufficient number of additional collaborations on acceptable terms, we may not generate sufficient revenue. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of any product candidates or the generation of sales or royalty revenue.

***Our operating results may be harmed if our restructuring plans do not achieve the anticipated results or cause undesirable consequences.***

In August 2007, we implemented a restructuring, including an immediate reduction of approximately one-third of our workforce and a subsequent identification of several additional positions that were eliminated in early 2008. Our restructuring activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale which may cause our employees to seek alternate employment. Additional attrition could have a material adverse effect on our financial performance. In addition, as a result of the restructuring and the reduction in our workforce, we face an increased risk of employment litigation.

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

***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 preclinical 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, and were involved with Phase IIa trials only as part of our former collaboration with LG Life Sciences. 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 pre-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.

***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; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

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 collaborations 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.***

Although we have designed and managed our preclinical studies relating to ANA598 and ANA773 to date, we plan to 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 will 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 under 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. We may also experience recruitment challenges due to our recent restructuring. 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 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 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, if 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 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, VX-950, in development by Vertex Pharmaceuticals and Janssen Pharmaceutica, SCH503034, in development by Schering-Plough, ITMN-191, in development by Intermune and Roche, TMC-435350, in development by Tibotec and Medivir, R-1626, in development by Roche and R-7128 in development by Pharmasset and Roche.

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 other TLR agonists under evaluation for oncology indications, including PF-3512676, in

development by Pfizer, IMO-2055, in development by Idera and Merck KGaA and a cancer program in development by Dynavax.

***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 for 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 66 $\frac{2}{3}$ % 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 55,000 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 believe that our current facility is adequate to meet our needs for the foreseeable future. We believe that suitable additional or alternative space will be available in the future on commercially reasonable terms as needed.

**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, 2007.

## 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. Such quotations represent inter-dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

<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
<u>2006</u>	<u>High</u>	<u>Low</u>
First Quarter . . . . .	\$16.60	\$8.39
Second Quarter . . . . .	16.10	2.92
Third Quarter . . . . .	4.25	2.64
Fourth Quarter . . . . .	5.65	2.81

#### Holders

As of February 19, 2008, there were approximately 1,900 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.

#### Securities Authorized for Issuance Under Equity Compensation Plans

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.

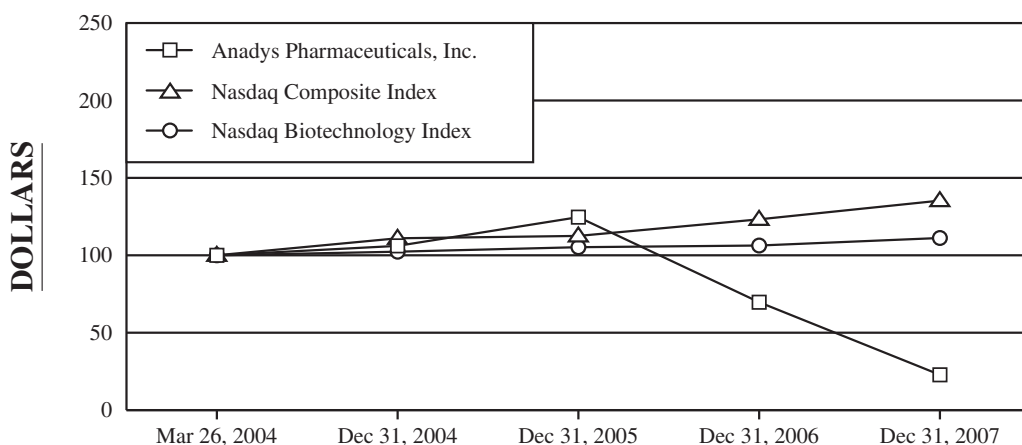
In connection with the hiring of certain executive officers during 2006, the Compensation Committee of our Board of Directors approved inducement grants of non-qualified stock options. These option awards were granted without security holder approval pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv). 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.

	(a) <u>Number of Securities to be Issued Upon Exercise of Outstanding Options</u>	(b) <u>Weighted-Average Exercise Price of Outstanding Options</u>	(c) <u>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 . . . . .	5,054,077	\$4.55	1,265,328
Equity compensation plans not approved by security holders . . . . .	493,750	\$3.32	—

### Performance Measurement Comparison(1)

The following graph shows the total stockholder return of an investment of \$100 in cash on March 26, 2004 in (i) the Company’s common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. All values assume reinvestment of the full amount of all 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
Anadys Pharmaceuticals, Inc.	\$100.00	\$106.09	\$124.65	\$ 69.69	\$ 22.80
NASDAQ Composite Index	100.00	110.99	112.52	123.23	135.32
NASDAQ Biotechnology Index	100.00	102.33	105.23	106.31	111.18

(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 following selected financial data has been derived from our audited consolidated financial statements. 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 Form 10-K.

	For the Years Ended December 31,				
	2007	2006	2005	2004	2003
	(In thousands, except net loss per share)				
<b>Consolidated Statements of Operations Data:</b>					
Revenues . . . . .	\$ 24,118	\$ 5,420	\$ 4,887	\$ 1,762	\$ 2,286
Operating expenses:					
Research and development(1) . . . . .	28,192	25,419	20,901	26,711	18,819
General and administrative(1) . . . . .	<u>8,692</u>	<u>11,308</u>	<u>7,705</u>	<u>8,260</u>	<u>7,156</u>
Total operating expenses(1) . . . . .	<u>36,884</u>	<u>36,727</u>	<u>28,606</u>	<u>34,971</u>	<u>25,975</u>
Loss from operations . . . . .	<u>(12,766)</u>	<u>(31,307)</u>	<u>(23,719)</u>	<u>(33,209)</u>	<u>(23,689)</u>
Other income (expense):					
Interest income . . . . .	3,611	4,727	2,103	525	229
Interest expense . . . . .	—	(69)	(189)	(228)	(266)
Other, net . . . . .	<u>(17)</u>	<u>(111)</u>	<u>(118)</u>	<u>(67)</u>	<u>(272)</u>
Total other income, (expense) net . . . . .	<u>3,594</u>	<u>4,547</u>	<u>1,796</u>	<u>230</u>	<u>(309)</u>
Net loss . . . . .	(9,172)	(26,760)	(21,923)	(32,979)	(23,998)
Accretion to redemption value of redeemable convertible preferred stock . . . . .	—	—	—	(175)	(674)
Deemed dividend-beneficial conversion feature for Series C preferred stock . . . . .	—	—	—	—	<u>(6,942)</u>
Net loss applicable to common stockholders . . . . .	<u>\$ (9,172)</u>	<u>\$ (26,760)</u>	<u>\$ (21,923)</u>	<u>\$ (33,154)</u>	<u>\$ (31,614)</u>
Basic and diluted net loss per share(2): . . . . .	<u>\$ (0.32)</u>	<u>\$ (0.94)</u>	<u>\$ (0.89)</u>	<u>\$ (1.92)</u>	<u>\$ (21.58)</u>
Shares used to compute basic and diluted net loss per share(2): . . . . .	<u>28,646</u>	<u>28,512</u>	<u>24,756</u>	<u>17,233</u>	<u>1,465</u>

- (1) As a result of the adoption of Statement of Accounting Standards 123R, “Share-Based Payment” 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 123R on our research and development expenses and our general and administrative expenses.
- (2) As a result of the conversion of our preferred stock into 13,330,000 shares of our common stock upon completion of our initial public offering on March 31, 2004, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented prior to the completion of our initial public offering.

	As of December 31,				
	2007	2006	2005	2004	2003
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and securities available-for-sale . . . . .	\$ 56,495	\$ 82,149	\$ 104,851	\$ 33,674	\$ 14,499
Working capital . . . . .	52,084	75,054	98,682	28,001	12,304
Total assets . . . . .	61,526	89,401	116,976	40,949	20,242
Long-term debt, net of current portion . . . . .	—	—	682	1,193	1,401
Redeemable convertible preferred stock . . . . .	—	—	—	—	45,012
Accumulated deficit . . . . .	(223,652)	(214,480)	(187,720)	(165,797)	(132,643)
Total stockholders' equity (deficit) . . . . .	55,679	60,325	78,936	31,285	(30,059)

**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 this Annual Report.

**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 virus (HCV) infection and ANA773, an oral Toll-like receptor 7 (TLR7) agonist prodrug for cancer. On June 20, 2007, we announced that we nominated ANA598 as a candidate for clinical development as an orally-administered direct antiviral for the treatment of chronic HCV infection. We plan to file an Investigational New Drug (IND) application for ANA598 during the second quarter of 2008, and subject to Food and Drug Administration (FDA) allowance, initiate a Phase 1 clinical trial of ANA598 in the second quarter of 2008. We filed an IND application for ANA773 in the third quarter of 2007 and have received clearance from the FDA to proceed with a Phase 1 clinical trial in cancer patients. We are currently conducting a Phase I clinical trial of ANA773 in the United States. On July 26, 2007, we announced that we and our collaborator Novartis had decided to discontinue the development of ANA975 for the treatment of HCV infection. Following this decision, on August 1, 2007, we announced that we were effecting a strategic restructuring to focus our resources on the development of ANA598 and ANA773. As part of this restructuring, we discontinued further development of ANA380, a nucleotide analog we had been jointly developing with LG Life Sciences (LGLS) as a treatment for hepatitis B virus (HBV) infection. All rights to ANA380 have reverted to LGLS. We also halted our early stage discovery efforts. The strategic restructuring included an immediate reduction in our workforce of approximately one-third, with several additional positions eliminated in early 2008. We expect the reduction in force to generate annual savings of between \$4.0 million and \$5.0 million. We incurred a charge of approximately \$0.9 million in severance costs, continuation of benefits and outplacement services in connection with the workforce reduction as of December 31, 2007. In addition, we incurred a non-cash charge of \$0.4 million associated with the modification of stock options for individuals included in the reduction in force.

On August 24, 2007, Steve Worland, Ph.D., the Company's President, Pharmaceuticals, was appointed as the Company's President and Chief Executive Officer and was also appointed to the Company's Board of Directors. Effective August 24, 2007, Lawrence C. Fritz, Ph.D. resigned as President and Chief Executive Officer and from the Board of Directors of the Company.

We have incurred significant operating losses since our inception and, as of December 31, 2007, our accumulated deficit was \$223.7 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 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**

Our research and development expenses consist primarily of costs associated with the discovery and preclinical and clinical development of our product candidates. Research and development expenses may include direct external costs such as fees paid to consultants, joint development collaboration costs and related contract research, and internal direct and indirect costs such as compensation and other expenses for research and development personnel, supplies and materials, facility costs and depreciation.

Under our former collaboration with Novartis for the development of ANA975, Novartis funded 80.5% of the development costs and we funded 19.5% of such development costs. Reimbursements of development costs for ANA975 from Novartis were recorded as an offset to research and development expense. Payments to Novartis for its portion of development costs for ANA975 were recorded as a component of research and development expense. For the years ended December 31, 2007, 2006, and 2005, we have recorded as offsets to research and development expense \$0.5 million, \$3.7 million, and \$5.8 million, respectively, which represents Novartis' share of ANA975 expenses incurred by us.

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

Clinical development timelines, likelihood of success and total costs vary widely. We are currently focused on advancing the development of ANA598, a small-molecule, non-nucleoside inhibitor of the NS5B polymerase for the treatment of hepatitis C and ANA773, an oral TLR7 agonist prodrug for cancer.

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

	<b>For the Years Ended December 31,</b>	
	<u>2007</u>	<u>2006</u>
ANA975 . . . . .	\$ 1,038	\$ 4,495
ANA773 . . . . .	6,136	3,944
ANA598 . . . . .	8,390	4,328
ANA380 . . . . .	700	935
Discovery stage programs . . . . .	1,936	5,041
Infrastructure and support personnel . . . . .	7,194	7,464
Severance related to reduction in force . . . . .	813	—
Non-cash employee and non-employee share-based compensation . . . . .	2,463	2,889
Reimbursement of ANA975 costs by Novartis . . . . .	<u>(478)</u>	<u>(3,677)</u>
Total research and development expense . . . . .	<u>\$28,192</u>	<u>\$25,419</u>

Prior to January 1, 2006, we allocated only direct external costs such as fees paid to consultants, joint development collaboration costs and related contract research to projects. Other costs such as internal direct and indirect costs which included compensation and other expenses for research and development personnel, supplies and materials, facility costs and depreciation were not allocated directly to projects.

The following summarizes our research and development expenses for the year ended December 31, 2005 (in thousands):

Direct external costs:	
Isatoribine family of compounds, excluding ANA975 . . . . .	\$ 558
ANA975 . . . . .	8,613
ANA380 . . . . .	417
ANA773 . . . . .	110
Other . . . . .	—
Unallocated direct internal costs . . . . .	3,535
Unallocated indirect internal costs and overhead . . . . .	12,534
Reimbursement of ANA975 costs by Novartis . . . . .	(5,790)
Deferred compensation . . . . .	<u>924</u>
Total research and development . . . . .	<u>\$20,901</u>

### **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:

*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 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 collectibility 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. Research services may include activities in which we deploy our internal capabilities such as our medicinal chemistry and screening capabilities to assist a collaborator in advancing their drug discovery effort.

*Drug Development Costs.* We review and accrue drug development costs based on work performed, which relies on estimates of total costs incurred based on subject enrollment, estimated timeline for completion of studies and other events. These costs and estimates vary based on the type of clinical trial, the site of the clinical trial and the length of dose period for each subject as well as other factors. Drug development costs are subject to revisions as trials and studies 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 Standard 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 Black-Scholes model requires various highly judgmental assumptions including volatility, forfeiture rates, and expected option life. 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.

#### **Adoption of Statement of Financial Accounting Standard No. 123R, Share-Based Payment**

We adopted SFAS No. 123R using the modified prospective method on January 1, 2006. Under the modified prospective method, compensation cost is recognized in the financial statements beginning with the effective date of SFAS No. 123R, based on the requirements of SFAS No. 123R

for all share-based payments granted after that date, and based on the requirements for SFAS No. 123 for all unvested awards granted prior to the effective date of SFAS No. 123R.

### **Recent Accounting Pronouncements**

In December 2007, the Financial Accounting Standards Board (FASB) ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 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 GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 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 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for us beginning on January 1, 2009. The adoption of EITF 07-1 is not expected to have a material effect on our consolidated financial statements.

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 07-3). EITF 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 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 07-3 will be effective for us beginning on January 1, 2008. The adoption of EITF 07-3 is not expected to have a material effect on our 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 159). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 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 159 will be effective for us beginning on January 1, 2008. If adopted, the adoption of SFAS 159 is not expected to have a material effect on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 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 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 157 will be effective for us beginning on January 1, 2008. The adoption of SFAS 157 is not expected to have a material effect on our consolidated financial statements.

### **Results of Operations**

#### ***Comparison of the Years Ended December 31, 2007, 2006 and 2005***

**Revenue.** We recorded revenues of \$24.1 million, \$5.4 million and \$4.9 million for the years ended December 31, 2007, 2006 and 2005, respectively. During 2007, we and Novartis decided to discontinue the development of ANA975. As a result, during the year ended December 31, 2007 we recognized \$23.1 million of previously deferred revenue representing the remaining unrecognized portion of the \$20.0 million up-front payment, received from Novartis in 2005, and the \$10.0 million IND milestone payment, received from Novartis in 2005, which were previously being recognized into revenue over the estimated development period of ANA975. This completed the recognition of the deferred revenue under the Novartis collaboration. The \$18.7 million increase from 2006 to 2007 was primarily attributed to the recognition of the remainder of the \$20 million up-front payment and

the \$10 million IND milestone payment. During the years ended December 31, 2006 and 2005, we recorded revenues of \$4.5 million and \$2.3 million, respectively, associated with the amortization of our \$20.0 million up-front payment and \$10 million IND milestone payment from Novartis. This increase in revenue was offset by a decrease in revenue from our collaboration with Roche. We recorded revenue of \$0.1 million and \$1.7 million during the years ended December 31, 2006 and 2005, respectively, from our collaboration with Roche. In January 2006, we completed our portion of our collaboration with Roche. During the years ended December 31, 2006 and 2005 we recorded revenue of \$0.1 million and \$0.5 million, respectively, related to our Phase II SBIR grant. During the year ended December 31, 2006, we concluded our performance under the Phase II SBIR grant.

Fluctuations in our collaboration-related revenue were dependent upon a number of factors including but not limited to, the timing of agreements, the conclusion of agreements, the timing of the workflow under the agreements, our collaborators' abilities to provide us with the materials and information necessary for us to conduct our portion of the collaboration effort and the occurrence of events that may trigger milestone payments to us. We are not currently party to any revenue generating agreements. Our revenues may fluctuate in future periods if we enter into new agreements.

*Research and Development Expenses.* Research and development expenses were \$28.2 million, \$25.4 million and \$20.9 million for the years ended December 31, 2007, 2006 and 2005, respectively. 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. We included, as a component of research and development expense during the year ended December 31, 2007, \$2.5 million of share-based compensation expense in accordance with SFAS No. 123R. The \$4.5 million increase in research and development expense from 2005 to 2006 was primarily attributable to our adoption of SFAS No. 123R effective January 1, 2006 and an increase in personnel related expenses. We included, as a component of research and development expense during the year ended December 31, 2006, \$2.9 million of share-based compensation expense in accordance with SFAS No. 123R. During the year ended December 31, 2005, we included \$0.9 million as a component of research and development expense with respect to amortization of deferred compensation on employee stock options in accordance with Accounting Principals Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). Personnel related expenses increased by \$2.3 million from the year ended December 31, 2005 to the year ended December 31, 2006. This personnel related expense was driven by an overall increase in research and development personnel.

*General and Administrative Expenses.* General and administrative expenses were \$8.7 million, \$11.3 million and \$7.7 million for the years ended December 31, 2007, 2006 and 2005, 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. We calculated the additional share-based expense associated with the modification and acceleration of Dr. Xanthopoulos' unvested stock options upon his termination in accordance with SFAS 123R. Included as a component of share-based compensation expense during the year ended December 31, 2006 was \$3.0 million of share-based compensation expense related to the stock options granted to Dr. Xanthopoulos. The \$3.6 million increase from 2005 to 2006 was primarily the result of the modification of Dr. Xanthopoulos' unvested stock options during 2006.

*Interest Income.* Interest income was \$3.6 million, \$4.7 million and \$2.1 million for the years ended December 31, 2007, 2006 and 2005, respectively. 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. The \$2.6 million increase in our interest income from 2005 to 2006 was the result of a higher average cash balance in 2006 compared to 2005. Our average balance of cash and cash equivalents and securities available-for-sale was \$93.0 million in 2006 compared to \$59.1 million in 2005. The higher average cash balance was driven by the receipt of the following amounts which were invested into interest bearing securities during 2005: an up-front license payment of \$20.0 million from Novartis in July 2005, \$66.4 million, net of underwriting discounts and commissions and offering costs, from our follow-on public offering of common stock in August 2005 and a \$10.0 million milestone payment from Novartis triggered by the acceptance of our IND application by the FDA received in September 2005.

*Interest Expense.* Interest expense was \$69,000 and \$0.2 million for the years ended December 31, 2006 and 2005, respectively. The decrease in our interest expense of \$0.13 million from the year ended December 31, 2005 to the year ended December 31, 2006 is the result of our payment in full of our outstanding principle balance of \$1.6 million on our equipment financing line of credit in February 2006.

### Liquidity and Capital Resources

Our cash, cash equivalents and available-for sale securities decreased by \$25.7 million from December 31, 2006 to December 31, 2007 which represents the use of our cash, cash equivalents and securities available-for-sale to fund our operations during the year ended December 31, 2007. This decrease in cash, cash equivalents and securities available-for-sale includes the receipt of \$1.8 million from Novartis which represented Novartis' share of ANA975 development costs for the period July 1, 2006 through June 30, 2007.

### Cash Flows from Operating Activities and Investing Activities

Our consolidated statements of cash flows are summarized as follows:

	<b>For the Years Ended December 31,</b>		
	<u>2007</u>	<u>2006</u>	<u>2005</u>
	(In thousands)		
Net cash (used in) provided by operating activities . . . . .	<u>\$(25,658)</u>	<u>\$(20,585)</u>	<u>\$ 5,999</u>
Cash provided by (used in) investing activities			
Purchase of securities available-for-sale . . . . .	\$(15,131)	\$(14,310)	\$(11,886)
Proceeds from sale of securities available-for-sale . . . . .	13,170	5,750	28,416
Purchase of property and equipment . . . . .	(356)	(1,522)	(1,338)
Proceeds from disposal of property and equipment . . . . .	<u>—</u>	<u>—</u>	<u>2</u>
Net cash (used in) provided by investing activities . . . . .	<u>\$ (2,317)</u>	<u>\$(10,082)</u>	<u>\$ 15,194</u>

Cash flows used in operating activities increased by \$5.1 million from the year ended December 31, 2006 to the year ended December 31, 2007. This increase was primarily a result of the termination of our collaboration with Novartis during 2007. Under our former collaboration with Novartis for the development of ANA975, Novartis funded 80.5% of the development costs and we funded 19.5% of such development costs. During 2007, most of our resources were directed toward the development of ANA598 and ANA773 which resulted in a higher usage of cash since both of these product candidates are 100% funded by us. Cash flows (used in) provided by operating activities decreased by \$26.6 million from the year ended December 31, 2005 to the year ended December 31, 2006. This decrease was primarily a result of the receipt of the up-front license payment of \$20.0 million from Novartis in July 2005 and the receipt in September 2005 of a \$10.0 million milestone payment from Novartis triggered by the acceptance of our IND application by the FDA during the year ended December 31, 2005. Also contributing to the fluctuation in our cash flows provided by (used in) operating activities during the year ended December 31, 2005 to the year ended

December 31, 2006 was the fluctuation in our accounts receivable balance as a result of the timing of payments from Novartis associated with its portion or our development costs for ANA975 and the reduction in development costs associated with ANA975 as a result of the halting of our Phase Ib clinical trial in June 2006. As of December 31, 2005, we had included \$5.9 million from Novartis in our accounts receivable balance for its portion of development costs for the period June 1, 2005 through December 31, 2005. This amount was paid during 2006. In comparison, we included \$1.2 million due from Novartis in our accounts receivable balance as of December 31, 2006 for Novartis' portion of development costs for the period July 1, 2006 through December 31, 2006. The overall decrease in the accounts receivable balance from 2005 to 2006 reflects a reduction in spending on the ANA975 project as a result of the halting of our Phase Ib clinical trial for ANA975 during 2006.

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 the operations of the Company during 2007. The overall reduction in the cash flows provided by (used in) investing activities from 2006 to 2005 is primarily related to the Company shifting its investment portfolio from investments with maturities over three months, to investments with maturities less than three months. During 2005 as investments classified as available-for-sale matured, the proceeds from these securities were either used to fund operations of the Company or the proceeds were reinvested in investments classified as cash equivalents to take advantage of their shorter maturity terms. During 2005 and 2006, the Company continued to invest in investments with shorter maturities to take advantage of the rising interest rate environment.

### Cash Flows from Financing Activities

Our consolidated statements of cash flows are summarized as follows:

	<b>For the Years Ended December 31,</b>		
	<u>2007</u>	<u>2006</u>	<u>2005</u>
	(In thousands)		
Cash provided by (used in) financing activities			
Proceeds from exercise of stock options and employee stock purchase plan . . . . .	\$257	\$ 954	\$ 1,057
Proceeds from sale of common stock, net of issuance costs . . . . .	—	—	66,437
Proceeds from long-term debt . . . . .	—	—	393
Principal payments on long-term debt . . . . .	—	(1,559)	(1,409)
Net cash provided by (used in) financing activities . . . . .	<u>\$257</u>	<u>\$ (605)</u>	<u>\$66,478</u>

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 with GATX Ventures and General Electric Capital Corporation being paid in full during February 2006.

Cash flows used in financing activities decreased by \$67.1 million from 2005 to 2006. The decrease was primarily a result of the receipt of \$66.4 million, net of underwriting discounts and commissions and offering costs, from our follow-on public offering of common stock completed during August 2005.

## Aggregate Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2007 (in thousands):

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less than 1 Year</u>	<u>2009 to 2010</u>	<u>2011 to 2012</u>	<u>Thereafter</u>
Operating leases. . . . .	\$3,463	\$2,160	\$1,303	\$ —	\$ —
Minimum royalty commitment . . . .	<u>900</u>	<u>100</u>	<u>200</u>	<u>200</u>	<u>400</u>
	<u>\$4,363</u>	<u>\$2,260</u>	<u>\$1,503</u>	<u>\$200</u>	<u>\$400</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 and timing of the development activities. 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.

## 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 preclinical development activities;
- the progress of our clinical trials; our ability to establish and maintain strategic collaborations;
- 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.

We believe that our existing cash, cash equivalents, and securities available-for-sale will be sufficient to meet our projected operating requirements for at least the next fiscal year. We expect to incur substantial expenses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. We continue to review our programs and resource requirements. Changes to our current operating plan may require us to consume available capital resources significantly sooner than we expect.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities or received under former collaboration agreements. In addition, we likely will need to finance future cash needs through the sale of other equity securities, strategic collaboration agreements, project financing and/or debt financing. However, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that our existing cash and securities available-for-sale resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, reduce the scope of or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. Other financing arrangements, such as project financings, may also have an equity component, also resulting in dilution to existing stockholders. If we raise additional funds by incurring 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.

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

As of December 31, 2007, 2006 and 2005, 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 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, 2007 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, 2007.

The effectiveness of our internal control over financial reporting as of December 31, 2007 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 Shareholders of Anadys Pharmaceuticals, Inc.

We have audited Anadys Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2007, 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, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 of Anadys Pharmaceuticals, Inc. and our report dated February 22, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 22, 2008

## **Item 9B. Other Information**

### **Bonus Plan**

On February 29, 2008, the Compensation Committee of the Board of Directors of Anadys Pharmaceuticals, Inc. (the "Company") approved the Anadys Pharmaceuticals, Inc. Executive Officer Bonus Plan (the "Bonus Plan"). The terms of the Bonus Plan establish for each executive officer an annual cash bonus opportunity, expressed as a percentage of base salary. For the Company's President and Chief Executive Officer, the total bonus opportunity is 50% of base salary, with corporate performance accounting for 90% of the bonus payment and individual performance accounting for 10% of the bonus payment. For the Company's Senior Vice President, Operations and Chief Financial Officer and the Company's Chief Medical Officer, the total bonus opportunity is 40% of base salary, with corporate performance accounting for 85% of the respective officer's bonus payment and individual performance accounting for 15% of the respective officer's bonus payment. For the Company's other executive officers, the total bonus opportunity is 30% of base salary, with corporate performance accounting for 80% of the respective officer's bonus payment and individual performance accounting for 20% of the respective officer's bonus payment. Bonus award determinations will be based on an annual evaluation by the Compensation Committee, or the independent members of the Board of Directors, of the Company's achievement of corporate performance goals for each year and on an assessment of the individual performance of each executive officer. Notwithstanding the percentages set forth above, for exceptional performance, award components may exceed the total bonus opportunity by up to 25%. The Company's corporate performance goals for 2008 were previously established by the Board of Directors and may be periodically revised to reflect changing business dynamics. In general, the corporate performance goals include the achievement of performance objectives with respect to the Company's development programs, financial results and corporate activities. Notwithstanding the terms of the Bonus Plan, the Compensation Committee retains absolute discretion to approve bonus awards that fall above or below any amounts set forth in the Bonus Plan, or no bonus awards.

The foregoing description is a summary only, is not necessarily complete, and is qualified by the full text of the underlying plan, which is filed as a Exhibit 10.23 to this Annual Report on Form 10-K.

### **Amended and Restated Severance and Change in Control Benefits**

On March 3, 2008, the Company entered into an Amended and Restated Severance and Change in Control Agreement (the "Amended and Restated Agreement") with each of the following executive officers: Steve Worland, Ph.D., President and Chief Executive Officer, James T. Glover, Senior Vice President, Operations and Chief Financial Officer, James L. Freddo, M.D., Chief Medical Officer, Elizabeth E. Reed, Vice President, Legal Affairs and Corporate Secretary and Mary Yaroshevsky-Glanville, Vice President, Human Capital. The following description of the severance and change in control benefits is qualified in its entirety by reference to the Amended and Restated Agreements, filed as Exhibit 10.16, 10.17, 10.18, 10.19 and 10.20 to this Annual Report on Form 10-K.

#### ***Severance Benefits***

The Amended and Restated Agreement for each of the executive officers referenced above provides certain benefits in the event that the executive officer's employment with the Company is terminated by the Company without Cause or the executive officer resigns with Good Reason (as such terms are defined in the Amended and Restated Agreement). In such event, and contingent upon delivery of a waiver and release, the executive officer will be entitled to the following benefits: (a) a payment equal to twelve (12) months of the executive officer's annual base salary, less standard deductions and withholdings; (b) the Company will pay the executive officer's COBRA group health insurance premiums for the executive officer and his or her eligible dependents for a period of twelve (12) months; (c) outplacement services for a period of six (6) months will be made available to the executive officer upon the executive officer's request, (d) the partial acceleration of vesting of stock options to purchase the Company's common stock that are granted less than one (1) year prior to the date of termination will be provided so that such stock options will be 25% vested on the date of termination, and (e) the vested stock options held by the executive officer will be automatically

amended so that the executive officer will be able to exercise such vested stock options during the fifteen (15) month period following the date of termination.

### ***Change in Control Benefits***

The Amended and Restated Agreement for each of the executive officers referenced above also provides certain benefits if the executive officer's employment with the Company is terminated by the Company without Cause or for Good Reason (as such terms are defined in the Amended and Restated Agreement) within the six (6) month period immediately preceding or the twenty-four (24) month period immediately following a Change in Control (as defined in the Amended and Restated Agreement) of the Company. In such event, and contingent upon delivery of a waiver and release, the executive officer will be entitled to the following benefits: (a) a payment equal to twelve (12) months of the executive officer's annual base salary plus a payment equal to a pro rated bonus amount for the current year based on the bonus opportunity the executive officer would be eligible for under the Anadys Pharmaceuticals, Inc. Executive Officer Bonus Plan, less standard deductions and withholdings; (b) the Company will pay the executive officer's COBRA group health insurance premiums for the executive officer and his or her eligible dependents for a period of twelve (12) months; (c) outplacement services for a period of six (6) months will be made available to the executive officer upon the executive officer's request, and (d) all outstanding options held by the executive officer will be automatically amended to provide for the full acceleration of vesting and exercisability of the stock options.

In addition to the Change in Control benefits described above, the Amended and Restated Agreement for Dr. Freddo provides that if Dr. Freddo's employment is terminated without Cause or for Good Reason (as such terms are defined in the Amended and Restated Agreement) within the six (6) month period immediately preceding or the twenty-four (24) month period immediately following a Change in Control (as defined in the Amended and Restated Agreement) of the Company, then he is entitled to the full acceleration of his anniversary bonus of \$50,000 per year to be paid to him each year until 2011 under the terms of his offer letter dated June 21, 2006. Also, in addition to the Change in Control benefits described above, the Amended and Restated Agreement for Dr. Worland provides that in the event of a Change in Control (as defined in the Amended and Restated Agreement) of the Company, the unvested portion of Dr. Worland's on-hire stock option grant will fully vest and become immediately exercisable. This benefit is consistent with the terms of Dr. Worland's offer letter dated February 1, 2001.

## **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 2008 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 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” in our Proxy Statement.

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

The 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. Information regarding equity compensation plans under which our common stock may be issued as of December 31, 2007 is set forth in Item 5 of Part II of this report under the caption “Securities Authorized for Issuance Under Equity Compensation Plans.”

**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.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
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.
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#	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.
10.6#	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.
10.7#	2004 Non-Employee Directors' Stock Option Plan	Incorporated by reference to Exhibit 10.9 in the Registrant's Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
10.8#	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.
10.9#	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.
10.10#	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.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
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.
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.	Attached Hereto.
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.	Attached Hereto.
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.	Attached Hereto.
10.19#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and Elizabeth E. Reed.	Attached Hereto.
10.20#	Amended and Restated Severance and Change in Control Agreement dated March 3, 2008 by and between the Registrant and Mary Yaroshevsky-Glanville.	Attached Hereto.
10.21#	Terms of Employment dated June 21, 2006 by and between the registrant and James L. Freddo, M.D.	Attached Hereto.
10.22#	Terms of Employment dated March 6, 2001 by and between the registrant and Mary Yaroshevsky-Glanville.	Attached Hereto.
10.23#	Executive Officer Bonus Plan	Attached Hereto.
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.
23.1	Consent of Independent Registered Public Accounting Firm	Attached Hereto.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
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 5th day of March, 2008.

### 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 5, 2008
<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 5, 2008
<u>/s/ GEORGE A. SCANGOS, PH.D.</u> George A. Scangos, Ph.D.	Chairman of the Board	March 5, 2008
<u>/s/ MARK G. FOLETTA</u> Mark G. Foletta	Director	March 5, 2008
<u>/s/ MARIOS FOTIADIS</u> Marios Fotiadis	Director	March 5, 2008

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ STEVEN H. HOLTZMAN</u> Steven H. Holtzman	Director	March 5, 2008
<u>/s/ STELIOS PAPADOPOULOS, PH.D.</u> Stelios Papadopoulos, Ph.D.	Director	March 5, 2008
<u>/s/ DOUGLAS E. WILLIAMS, PH.D.</u> Douglas E. Williams, Ph.D.	Director	March 5, 2008
<u>/s/ KLEANTHIS G. XANTHOPOULOS, PH.D.</u> Kleanthis G. Xanthopoulos, Ph.D.	Director	March 5, 2008

**ANADYS PHARMACEUTICALS, INC.**  
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## **Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying consolidated balance sheets of Anadys Pharmaceuticals, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Anadys Pharmaceuticals, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the Consolidated Financial Statements, effective January 1, 2006 the Company changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards (SFAS) No. 123 (revised in 2004), "Share-Based Payment."

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, 2007, 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 22, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 22, 2008

**ANADYS PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	<u>December 31,</u> <u>2007</u>	<u>December 31,</u> <u>2006</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 34,669	\$ 62,387
Securities available-for-sale . . . . .	21,826	19,762
Accounts receivable . . . . .	—	1,175
Prepaid expenses and other current assets . . . . .	<u>1,004</u>	<u>941</u>
Total current assets . . . . .	57,499	84,265
Property and equipment, net . . . . .	2,647	3,749
Other assets, net . . . . .	<u>1,380</u>	<u>1,387</u>
Total assets . . . . .	<u>\$ 61,526</u>	<u>\$ 89,401</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 1,084	\$ 794
Accrued expenses . . . . .	3,766	3,317
Current portion of deferred rent . . . . .	565	467
Current portion of deferred revenue . . . . .	<u>—</u>	<u>4,633</u>
Total current liabilities . . . . .	5,415	9,211
Long-term portion of deferred rent . . . . .	367	931
Long-term portion of deferred revenue . . . . .	—	18,934
Other long-term liabilities . . . . .	65	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2007 and December 31, 2006; no shares issued and outstanding at December 31, 2007 and December 31, 2006 . . . . .	—	—
Common stock, \$0.001 par value; 90,000,000 shares authorized at December 31, 2007 and December 31, 2006; 28,696,948 and 28,596,198 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively . . . . .	29	29
Additional paid-in capital . . . . .	279,221	274,798
Accumulated other comprehensive gain (loss) . . . . .	81	(22)
Accumulated deficit . . . . .	<u>(223,652)</u>	<u>(214,480)</u>
Total stockholders' equity . . . . .	<u>55,679</u>	<u>60,325</u>
Total liabilities and stockholders' equity . . . . .	<u>\$ 61,526</u>	<u>\$ 89,401</u>

See accompanying notes to consolidated financial statements.

**ANADYS PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<u>For the Years Ended December 31,</u>		
	<u>2007</u>	<u>2006</u>	<u>2005</u>
	(In thousands, except net loss per share)		
<b>Revenues:</b>			
Collaborative agreements . . . . .	\$ 24,118	\$ 5,354	\$ 4,408
Grants . . . . .	<u>—</u>	<u>66</u>	<u>479</u>
Total revenues . . . . .	24,118	5,420	4,887
<b>Operating Expenses:</b>			
Research and development . . . . .	28,192	25,419	20,901
General and administrative . . . . .	<u>8,692</u>	<u>11,308</u>	<u>7,705</u>
Total operating expenses . . . . .	<u>36,884</u>	<u>36,727</u>	<u>28,606</u>
Loss from operations . . . . .	(12,766)	(31,307)	(23,719)
<b>Other income (expense):</b>			
Interest income . . . . .	3,611	4,727	2,103
Interest expense . . . . .	—	(69)	(189)
Other, net . . . . .	<u>(17)</u>	<u>(111)</u>	<u>(118)</u>
Total other income (expense) . . . . .	<u>3,594</u>	<u>4,547</u>	<u>1,796</u>
Net loss . . . . .	<u>\$ (9,172)</u>	<u>\$ (26,760)</u>	<u>\$ (21,923)</u>
Net loss per share, basic and diluted . . . . .	<u>\$ (0.32)</u>	<u>\$ (0.94)</u>	<u>\$ (0.89)</u>
Shares used in calculating net loss per share, basic and diluted . . . . .	<u>28,646</u>	<u>28,512</u>	<u>24,756</u>

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, 2004 . . .	—	\$—	22,334,521	\$22	\$199,990	\$(2,862)	\$ (68)	\$(165,797)	\$ 31,285
Issuance of common stock from a follow-on public common stock offering, net of underwriters' discount and offering expenses . . . . .	—	—	5,750,000	5	66,432	—	—	—	66,437
Issuance of common stock pursuant to the exercise of stock options . . . . .	—	—	222,593	1	702	—	—	—	703
Issuance of common stock pursuant to the Company's Employee Stock Purchase Plan . . . . .	—	—	67,022	—	354	—	—	—	354
Compensation related to stock options and warrants issued to non-employees . . . . .	—	—	—	—	333	—	—	—	333
Amortization of deferred compensation . . . . .	—	—	—	—	—	1,711	—	—	1,711
Reversal of deferred compensation associated with cancelled stock options to employees . . . . .	—	—	—	—	(312)	312	—	—	—
Comprehensive loss:									
Unrealized gain on short-term investments . . . . .	—	—	—	—	—	—	36	—	36
Net loss . . . . .	—	—	—	—	—	—	—	(21,923)	(21,923)
Comprehensive loss . . . . .	—	—	—	—	—	—	—	—	(21,887)
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

See accompanying notes to consolidated financial statements.

**ANADYS PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>For the Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	(In thousands)		
<b>Operating Activities:</b>			
Net loss	\$ (9,172)	\$(26,760)	\$(21,923)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	1,431	1,509	1,468
Stock-based compensation	4,065	6,859	—
Amortization of deferred compensation	—	—	1,711
Compensation related to stock option issuances to non-employees	52	276	280
Interest expense related to warrants issued in connection with debt	—	23	49
Rent expense related to warrants issued in connection with lease	49	50	53
Loss from disposal of property and equipment	27	73	89
Changes in operating assets and liabilities:			
Accounts receivable	1,175	4,850	(5,839)
Prepaid expenses and other current assets	(63)	(290)	487
Other assets, net	7	253	281
Accounts payable	290	(222)	(104)
Accrued expenses	449	(546)	256
Deferred rent	(466)	(405)	(31)
Deferred revenue	(23,567)	(6,255)	29,222
Other long-term liabilities	65	—	—
Net cash (used in) provided by operating activities	(25,658)	(20,585)	5,999
<b>Investing Activities:</b>			
Purchase of securities available-for-sale	(15,131)	(14,310)	(11,886)
Proceeds from sale and maturity of securities available-for-sale	13,170	5,750	28,416
Purchase of property and equipment	(356)	(1,522)	(1,338)
Proceeds from the sale of property and equipment	—	—	2
Net cash provided by (used in) investing activities	(2,317)	(10,082)	15,194
<b>Financing Activities:</b>			
Proceeds from exercise of stock options and employee stock purchase plan	257	954	1,057
Proceeds from the sale of common stock, net of issuance costs	—	—	66,437
Proceeds from issuance of long-term debt	—	—	393
Principal payments on long-term debt	—	(1,559)	(1,409)
Net cash provided by (used in) financing activities	257	(605)	66,478
Net (decrease) increase in cash and cash equivalents	(27,718)	(31,272)	87,671
Cash and cash equivalents at beginning of year	62,387	93,659	5,988
Cash and cash equivalents at end of year	\$ 34,669	\$ 62,387	\$ 93,659
<b>Supplemental Disclosure of Cash Flow Information:</b>			
Cash paid during the year for interest	\$ —	\$ 69	\$ 189
<b>Supplemental Disclosure of Non-Cash Investing and Financing Activities:</b>			
Reversal of deferred compensation upon the adoption of SFAS 123R	\$ —	\$ 839	\$ —
Unrealized gain on securities available-for-sale	\$ 103	\$ 10	\$ 36

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

*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 December 31, 2007, neither Anadys Pharmaceuticals Europe GmbH nor Anadys Development Limited had active operations.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted (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.

*Securities Available-for-Sale*

Investments with an original maturity of more than three months 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 portfolio 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 receivable, 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, securities available-for-sale and accounts receivable. 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

## ANADYS PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

The Company derives its revenues from a relatively small number of collaborators. For the year ended December 31, 2007, revenues from Novartis International Pharmaceutical Ltd. (Novartis) accounted for 96% of total revenues; there were no related accounts receivable as of December 31, 2007. During 2007, the Company and Novartis entered into an agreement terminating the License and Co-Development Agreement dated June 1, 2005 between the Company and Novartis for the development of ANA975. For the year ended December 31, 2006, revenues from Novartis accounted for 89% of total revenues; there were no related accounts receivable as of December 31, 2006. For the year ended December 31, 2005, revenues from two collaborators accounted for 52% and 34%, respectively, of total revenues; there were no related accounts receivable as of December 31, 2005.

#### ***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 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, 2007.

#### ***Research and Development***

Research and development expenses consist primarily of costs associated with the discovery and preclinical and clinical development of the Company's product candidates. In addition, research and development expenses may include external costs such as fees paid to consultants, joint development collaboration costs and related contract research, and internal costs of compensation and other expenses for research and development personnel, supplies and materials, facility costs, amortization of purchased technology and depreciation.

Under the Company's former License and Co-Development Agreement with Novartis for the development of ANA975, Novartis funded 80.5% of the global development costs and the Company funded 19.5% of such development costs. Reimbursements of development costs for ANA975 from Novartis were recorded as an offset to research and development expense. Payments to Novartis for their portion of development costs for ANA975 were recorded as a component of 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.

## ANADYS PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments 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 will be amortized on a straight-line basis over the life of the lease of 62 months. As of December 31, 2007 and 2006, the Company has \$0.5 million and \$0.8 million, respectively, of unamortized deferred rent associated with the lease incentive.

#### *Stock-Based Compensation*

Prior to January 1, 2006, the Company had elected to follow Accounting Principals Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25) and related interpretations in accounting for its employee stock options. Effective January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment*, (SFAS No. 123R) using the modified prospective method.

The Company continues to account for compensation expense for options granted to non-employees other than directors in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), 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.

#### *Net Loss Per Share*

The Company calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share (EPS) is calculated by dividing the net income or 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 income or 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 5.6 million, 5.3 million and 3.5 million were excluded from the calculation of net loss per share for the years ended December 31, 2007, 2006 and 2005, 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

## ANADYS PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

recognition as outlined in 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 Securities and Exchange Commission (SEC) and EITF Issue 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 collectibility 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. Research services may include activities in which the Company deploys its internal capabilities such as its medicinal chemistry and screening capabilities to assist a collaborator in advancing their drug discovery effort.

#### ***Recent Accounting Pronouncements***

In December 2007, the Financial Accounting Standards Board (FASB) ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 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 GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 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 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for the Company beginning on January 1, 2009. The adoption of EITF 07-1 is not expected to have a material effect on the Company's consolidated financial statements.

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 07-3). EITF 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 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 07-3 will be effective for the Company beginning on January 1, 2008. The adoption of EITF 07-3 is not expected to 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 159). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

value. Furthermore, SFAS 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 159 will be effective for the Company beginning on January 1, 2008. If adopted, the adoption of SFAS 159 is not expected to have a material effect on the Company's consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 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 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 157 will be effective for the Company beginning on January 1, 2008. The adoption of SFAS 157 is not expected to 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, 2007 and 2006, respectively (in thousands):

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

	<u>Amortized Cost</u>	<u>December 31, 2006 Unrealized</u>		<u>Market Value</u>
		<u>Gain</u>	<u>Loss</u>	
U.S. Government sponsored enterprise securities . . . . .	\$ 8,944	\$—	\$(20)	\$ 8,924
Corporate debt securities . . . . .	<u>10,840</u>	<u>—</u>	<u>(2)</u>	<u>10,838</u>
	<u>\$19,784</u>	<u>\$—</u>	<u>\$(22)</u>	<u>\$19,762</u>

The amortized cost and estimated fair value of the Company securities available-for-sale by contractual maturity as of December 31, 2007 and 2006 are shown below (in thousands):

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

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

	<u>Amortized Cost</u>	<u>December 31, 2006</u> <u>Unrealized</u>		<u>Market Value</u>
		<u>Gain</u>	<u>Loss</u>	
Within one year . . . . .	\$ 9,950	\$—	\$(20)	\$ 9,930
After one year through three years . . . . .	<u>9,834</u>	<u>—</u>	<u>(2)</u>	<u>9,832</u>
	<u>\$19,784</u>	<u>\$—</u>	<u>\$(22)</u>	<u>\$19,762</u>

**3. Property and Equipment**

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

	<u>As of December 31,</u>	
	<u>2007</u>	<u>2006</u>
Furniture and fixtures . . . . .	\$ 72	\$ 68
Equipment . . . . .	6,406	7,012
Computers and software . . . . .	2,220	2,141
Leasehold improvements . . . . .	<u>1,833</u>	<u>1,829</u>
	10,531	11,050
Less accumulated depreciation and amortization . . . . .	<u>(7,884)</u>	<u>(7,301)</u>
	<u>\$ 2,647</u>	<u>\$ 3,749</u>

Depreciation and amortization expense relating to property and equipment for the years ended December 31, 2007, 2006 and 2005 was \$1.4 million, \$1.5 million and \$1.5 million, respectively.

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**4. Other Balance Sheet Captions**

	<b>As of December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
Prepaid expenses and other current assets consisted of the following:		
Prepaid expenses . . . . .	\$ 436	\$ 475
Prepaid insurance . . . . .	227	195
Interest receivable . . . . .	341	271
	<b>\$1,004</b>	<b>\$ 941</b>
Other assets consisted of the following:		
Lab compounds, net . . . . .	\$ —	\$ 127
Note receivable . . . . .	120	—
Deposits . . . . .	1,260	1,260
	<b>\$1,380</b>	<b>\$1,387</b>
Accrued expenses consisted of the following:		
Accrued personnel costs . . . . .	\$ 345	\$ 509
Accrued employee bonus . . . . .	907	905
Accrued drug development . . . . .	1,523	1,325
Accrued legal and patent costs . . . . .	150	100
Accrued facility costs . . . . .	191	106
Accrued severance costs . . . . .	205	—
Other accrued expenses . . . . .	445	372
	<b>\$3,766</b>	<b>\$3,317</b>

**5. Restructuring**

During 2007, the Company initiated a strategic restructuring following the decision it announced on July 26, 2007 regarding Novartis' and its discontinuation of the development of ANA975 for the treatment of hepatitis C virus (HCV). As part of the restructuring, the Company discontinued its involvement with the development of ANA380, a nucleotide analog it had been jointly developing with LG Life Sciences LTD. (LGLS) for the treatment of hepatitis B virus (HBV) infection. The Company also halted its early stage discovery efforts and directed its resources toward the development of ANA598, a NS5B polymerase inhibitor, for the treatment of HCV, and ANA773, a TLR7 agonist prodrug for the treatment of cancer. The strategic restructuring resulted in a reduction in the Company's workforce which the Company expects will generate annual savings of between \$4.0 million and \$5.0 million. The Company provided cash severance payments, continuation of benefits and outplacement services to employees directly affected by the workforce reduction. The Company incurred a charge of approximately \$0.9 million in severance costs, continuation of benefits and outplacement services in connection with the workforce reduction which have been recorded as components of both research and development and general and administrative expense. In addition, the Company incurred a noncash charge of \$0.4 million associated with the modification of stock options for individuals included in the reduction in force. As of December 31, 2007, the Company had a remaining accrual of \$0.2 million associated with this strategic restructuring.

**6. Commitments and Contingencies**

As of December 31, 2007, the Company leases its corporate headquarters and research and development facility under a non-cancelable lease, which expires on August 1, 2009. The lease

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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, 2007, 2006 and 2005 was approximately \$2.0 million, \$1.9 million and \$1.4 million, respectively.

Future minimum lease payments under equipment and facility leases are as follows as of December 31, 2007 (in thousands):

2008 .....	2,160
2009 .....	<u>1,303</u>
Total .....	<u>\$3,463</u>

Total future minimum lease payments for the years ended December 31, 2008 and 2009 have not been reduced by \$0.4 million and \$0.2 million, respectively, of sublease rentals to be received in the future under a non-cancelable sublease.

**7. Collaboration and License Agreements**

***Hoffman-La Roche, Inc.***

On July 28, 2004, the Company entered into a drug discovery collaboration with Hoffman-La Roche Inc. (Roche). Under the terms of the agreement, the Company received \$2.6 million in research and development funding from Roche of which \$0.1 million and \$1.7 million was recorded as revenue for the years ended December 31, 2006 and 2005, respectively. The agreement included potential milestone payments if certain research and commercial milestones are achieved and royalties on net sales of any new drug resulting from the collaboration that may be commercialized by Roche. During the first quarter of 2006, the Company completed its performance under this agreement.

***Aphoenix, Inc.***

On September 3, 2004, the Company entered into a drug discovery collaboration agreement with Aphoenix, Inc. to discover and advance lead compounds against Aphoenix targets for multiple therapeutic indications. As of December 31, 2007, the Company has received \$1.5 million in research funding from Aphoenix of which \$1.0 million, \$0.4 million and \$0.1 million was recorded as revenue for the years ended December 31, 2007, 2006 and 2005, respectively. During the fourth quarter of 2007, the Company completed its performance under this agreement.

***Novartis International Pharmaceutical Ltd.***

On June 1, 2005, the Company entered into a License and Co-Development Agreement with Novartis, for the development and potential commercialization of ANA975 and potentially additional Toll-Like Receptor oral prodrugs for chronic hepatitis C virus and hepatitis B virus infections, as well as other potential infectious disease indications.

In July 2005, the Company received from Novartis an upfront license payment of \$20.0 million, and in September received a \$10.0 million milestone payment triggered by the acceptance of its Investigational New Drug (IND) application for ANA975 with the United States Food and Drug Administration. The Company deferred the up-front payment of \$20.0 million and the \$10.0 million IND milestone payment and amortized both amounts into revenue on a straight-line basis over the estimated development period for ANA975 which was concurrent with the period during which the Company has significant performance obligations under the collaboration. During 2007, the Company and Novartis decided to discontinue the development of ANA975, a Phase 1b compound for the treatment of HCV infection, and that no further activities will be pursued under the current collaboration. As a result, during 2007 the Company recognized \$21.0 million of previously deferred

## ANADYS PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

revenue representing the remaining unrecognized portion of the \$20.0 million up-front payment and the \$10.0 million IND milestone payment that were previously being recognized into revenue over the estimated development period of ANA975. This completed the recognition of the deferred revenue under the Novartis collaboration.

Under the collaboration agreement, Novartis funded 80.5% of the global development costs of the lead product candidate, and the Company funded 19.5% of the global development costs, subject to certain limitations. During the years ended December 31, 2007, 2006 and 2005, the Company recorded \$0.5 million, \$3.7 million and \$5.8 million as offsets to research and development expense, which represent an estimate of Novartis' share (80.5%) of ANA975 expenses incurred by the Company from June 1, 2005 through December 31, 2007. At December 31, 2006 and 2005, \$1.2 million and \$5.8 million, respectively, due from Novartis was recorded as a component of accounts receivable.

#### *LG Life Sciences, Ltd.*

In February 2004, the Company obtained an exclusive option from LGLS to enter into a joint development and license agreement for the development and potential commercialization of ANA380, a compound currently in Phase II clinical trials, for the treatment of chronic HBV infection. On December 18, 2007, the Company and LGLS entered into a letter agreement terminating the Joint Development and License Agreement by and between the Company and LGLS

The Company has recorded drug development costs, which are recorded as a component of research and development expense, associated with the Company's share of joint development costs of ANA380 of \$0.3 million, \$0.3 million and \$0.4 million for the years ended December 31, 2007, 2006 and 2005, respectively.

#### *Valeant Pharmaceuticals International*

In December 2002, the Company entered into an agreement with Valeant and Ribapharm, Inc., relating to an exclusive worldwide license to six antiviral compounds (including isatoribine), their prodrugs, metabolites, and the methods of using such compounds, prodrugs and metabolites. In connection with this agreement the Company has made a minimum royalty commitment of \$0.08 million during the year ended December 31, 2007. To maintain the license, the Company will be required to pay \$0.1 million for the year ended December 31, 2008 and \$0.1 million for each of the eight years thereafter.

#### *Grants*

In September 2004, the Company was awarded a Phase II Small Business Innovation Research grant from The National Institutes of Health (NIH). The funding period of the grant terminated on August 31, 2006. Through December 31, 2006 and 2005, the Company had recorded revenue of \$0.07 million and \$0.5 million under the grant, respectively.

## 8. Stockholders' Equity

#### *Warrants*

As of December 31, 2007, 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

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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 September 5, 2007, 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 299,194 shares at December 31, 2007. 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. The total number of shares which remain available for grant under the NEDSOP Plan is 190,083 shares at December 31, 2007. 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.

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 a total of 945,000 shares of Anadys’ Common Stock. 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, 2007:

<u>Range of Exercise Price</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$2.00-\$2.32 . . . . .	1,564,250	9.8	\$ 2.20	2,710	\$ 2.25
\$2.40-\$2.99 . . . . .	1,220,816	5.9	\$ 2.94	1,009,080	\$ 2.95
\$3.00-\$4.88 . . . . .	1,200,142	7.7	\$ 4.14	454,888	\$ 4.23
\$5.00-\$8.16 . . . . .	1,215,251	6.8	\$ 7.03	1,019,944	\$ 6.91
\$8.37-\$15.91 . . . . .	347,368	6.9	\$11.73	227,267	\$11.72
	<u>5,547,827</u>			<u>2,713,889</u>	

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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

	<u>Options Outstanding</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u> (In thousands)
Balance at December 31, 2004 ..	2,365,154	\$4.12		
Granted . . . . .	1,178,351	9.13		
Exercised . . . . .	(222,593)	3.16		
Cancelled . . . . .	<u>(231,641)</u>	4.65		
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>	<u>6.52</u>	<u>—</u>	<u>—</u>
Balance at December 31, 2007 ..	<u>5,547,827</u>	<u>\$4.44</u>	<u>7.62</u>	<u>\$—</u>
Exercisable at December 31, 2007 . . . . .	<u>2,713,889</u>	<u>\$5.39</u>	<u>6.00</u>	<u>\$—</u>

The total intrinsic value of options exercised during the years ended December 31, 2007 and 2006 was \$0.05 million and \$1.0 million, respectively, determined as of the date of exercise. The Company settles employee stock option exercises with newly issued common shares.

The Company granted stock options to non-employees as follows: 15,000 shares and 47,500 shares for the years ended December 31, 2006 and 2005, respectively. Compensation expense related to non-employee stock option grants was \$0.05 million, \$0.3 million and \$0.3 million for the years ended December 31, 2007, 2006 and 2005, respectively.

There were no stock options granted to non-employees during the year ended December 31, 2007.

***Adoption of SFAS No. 123R, Share-Based Payment***

SAB No. 107 requires that stock-based compensation expense be reported on the same line on the Statement of Operations as the related cash wages. Historically, the Company has reported stock-based compensation expense as a separate line in the operating expenses section of the consolidated Statement of Operations. Under SFAS No. 123R, the Company has reported the following amounts of

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

stock-based compensation expense in the consolidated Statements of Operations for the years ended December 31, 2007 and 2006 (in thousands, except per share data):

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

During 2006, Dr. Xanthopoulos provided notice of his resignation as President and Chief Executive Officer and the Company agreed to accelerate in full all of Dr. Xanthopoulos' unvested stock options. The Company calculated the additional share-based expense associated with the modification and acceleration of his unvested stock options upon his termination with the Company in accordance with SFAS 123R. For the year ended December 31, 2006, the Company included \$3.0 million of share-based expense as a component of general and administrative expense related to stock options granted to Dr. Xanthopoulos.

As of December 31, 2007, there was an additional \$6.2 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 2.66 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, 2007, 2006 and 2005.

	<u>For the Years Ended December 31,</u>		
	<u>2007</u>	<u>2006</u>	<u>2005(1)</u>
Risk-free interest rate . . . . .	4.20%	4.66%	4.27%
Dividend yield . . . . .	0%	0%	0%
Volatility factors of the expected market price of the Company's common stock . . . . .	70%	67%	67%
Weighted-average expected life of option (years) . . . . .	6	6	6

(1) Assumptions relate to pro-forma disclosures under SFAS No. 123.

The estimated weighted-average fair value of stock options granted during 2007, 2006 and 2005 was \$1.67, \$3.43 and \$5.77, 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 similar 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 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.

***Pro Forma Information under SFAS No. 123 for Periods Prior to January 1, 2006***

As permitted by SFAS No. 123, the Company had elected to follow APB No. 25, and related interpretations in accounting for its employee stock options. Under APB No. 25, when the exercise price of the Company's employee and non-employee director stock options equals or exceeds the fair value of the underlying stock on the date of issuance or grant, no compensation expense was recognized. In conjunction with the Company's IPO, the Company reviewed its historical exercise prices through March 25, 2004 and, as a result, revised the estimate of fair value for all stock options granted on or after July 1, 2002. With respect to these options granted, the Company had recorded deferred stock compensation for the difference between the original exercise price per share determined by the Board of Directors and the revised estimate of fair value per share at the respective grant dates. Deferred stock compensation related to employee stock options issued between July 1, 2002 and March 25, 2004 was recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options, generally four years. Upon the adoption of and in accordance with SFAS No. 123R, on January 1, 2006, the Company reclassified the remaining \$0.8 million of unamortized deferred compensation balance calculated in accordance with APB No. 25 into additional paid-in capital. For purposes of pro forma disclosures, the estimated fair value of the options is amortized on a straight-line basis to expense over the vesting period of the related options.

The Company's pro forma information, prior to adopting SFAS No. 123R, for employee and director stock options and stock purchase plan follows (in thousands):

	<u>For the Year Ended December 31, 2005</u>
Net loss applicable to common shareholders, as reported . . . . .	\$ (21,923)
Add: Stock-based employee compensation included in reported net loss . . . . .	1,711
Deduct: Total stock-based employee compensation determined under fair value based method for all awards . . . . .	<u>(4,205)</u>
Adjusted pro forma net loss . . . . .	<u>\$ (24,417)</u>
Adjusted pro forma basic and diluted net loss per share . . . . .	<u>\$ (0.99)</u>

***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 \$0.04 million in stock-based compensation for the year ended December 31, 2007 related to the Purchase Plan.

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

For the years ended December 31, 2007, 2006 and 2005, 70,558 shares, 78,727 shares and 67,022 shares of common stock were issued under the Purchase Plan, respectively. On September 5, 2007, the Company registered an additional 429,766 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 \$2.38, \$4.97 and \$5.28 per share for 2007, 2006 and 2005, respectively.

***Shares Reserved for Issuance***

Shares of common stock reserved for future issuance as of December 31, 2007 are as follows:

	<b>December 31, 2007</b>
Warrants . . . . .	71,366
Employee Stock Purchase Plan . . . . .	775,390
Stock options under the Company's Plans:	
Granted and outstanding . . . . .	5,547,827
Reserved for future grant . . . . .	489,938
	<b>6,884,521</b>

**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, 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 \$67.6 million and \$78.6 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, 2007 and 2006, respectively.

	<b>As of December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 38,784	\$ 40,853
Research and development credits . . . . .	3,430	7,256
Depreciation and amortization . . . . .	—	1,497
Non-qualified stock options . . . . .	3,474	2,793
Capitalized research and development expense . . . . .	21,396	16,227
Accruals . . . . .	475	376
Deferred Revenue . . . . .	—	9,603
Other . . . . .	24	11
Total deferred tax assets . . . . .	67,583	78,616
Valuation allowance for deferred tax assets . . . . .	(67,583)	(78,616)
Net deferred taxes . . . . .	<b>\$ —</b>	<b>\$ —</b>

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

As of December 31, 2007 the Company had federal and state tax net operating loss (NOL) carryforwards of approximately \$99.3 million and \$70.0 million, respectively. The federal and state loss carryforwards will begin expiring in 2008 and 2012, respectively, unless previously utilized. The Company also has federal and state research tax credit (R&D credit) carryforwards of approximately \$1.0 million and \$3.8 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 not completed its analysis but has determined that, as of December 31, 2007, approximately \$15.4 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. Until the analysis is completed and any additional limitation known, no amounts are being presented as an uncertain tax position under FIN 48. Management believes that the amount subject to limitation could be significant. Any amounts that are determined will 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, 2007, the Company did not record any interest or penalties.

The tax years 1992 to 2007 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.

**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. Beginning January 1, 2006, the Company matches 25% of employee contributions up to 6% of eligible compensation. Employer contributions were \$0.1 million for the years ended December 31, 2007 and 2006.

**ANADYS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**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 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 income (loss) . . . . .	(6,683)	(6,996)	12,307	(7,800)
Basic and diluted net income (loss) per share . . . . .	(0.23)	(0.24)	0.43	(0.27)
<u>Fiscal Year 2006</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 . . . . .	\$ 1,542	\$ 1,582	\$ 1,145	\$ 1,151
Net loss . . . . .	(5,805)	(7,078)	(6,259)	(7,618)
Basic and diluted net loss per share . . . . .	(0.20)	(0.25)	(0.22)	(0.27)

## Executive Management

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.  
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  
General Partner,  
TVM Capital

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

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

Douglas E. Williams, Ph.D.  
President & Chief Scientific 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 LLC

## Corporate Counsel

Cooley Godward Kronish LLP  
San Diego, CA

## Independent Auditors

Ernst & Young LLP  
San Diego, CA

## Transfer Agent & Registrar

Computershare Shareholder Services  
250 Royall Street  
Canton, MA 02021  
(781) 575-2879

## Corporate Headquarters

3115 Merryfield Row  
San Diego, CA 92121  
(858) 530-3600  
www.anadyspharma.com

## Investor Relations

(858) 530-3667  
(858) 527-1540 (fax)

## Common Stock

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

## Annual Meeting

Friday, May 30, 2008  
9:00 a.m. Pacific Daylight Time  
Anadys Pharmaceuticals, Inc.  
3115 Merryfield Row  
San Diego, CA 92121

Important Note About Forward-Looking Statements.  
This Annual Report contains forward-looking statements as to future outcomes, such as plans for our development programs, including the expected timing of future IND filings and clinical trials. Forward-looking statements are based on the Company's current beliefs and expectations. A number of risks and uncertainties could cause actual results to differ materially. 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 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 that accompanies this Annual Report. Anadys does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.



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