

PHARMASSET INC

FORM 10-K (Annual Report)

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Address	303-A College Road East Princeton, NJ 08540
Telephone	(609) 613-4100
CIK	0001301081
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

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

For the Fiscal Year Ended September 30, 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 1-33428

Pharmasset, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

98-0406340
(I.R.S. Employer Identification No.)

**303-A College Road East
Princeton, New Jersey**
(Address of principal executive offices)

08540
(Zip Code)

Registrant's telephone number, including area code (609) 613-4100

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$0.001 Par Value Per Share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Exchange Act: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on November 30, 2007 was \$194.0 million. The registrant has provided this information as of November 30, 2007 because its common stock began publicly trading on April 27, 2007, which was after the last business day of its most recently completed second fiscal quarter. Prior to that time, there was no established public trading market for the registrant's common stock.

As of November 30, 2007, the registrant had 21,288,615 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for the 2008 Annual Meeting of Stockholders to be held on March 25, 2008 are incorporated by

reference into Part III of this Annual Report on Form 10-K.

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The “Company,” “Pharmasset,” “we” and “us” as used in this Annual Report on Form 10-K, refer to Pharmasset, Inc., a Delaware corporation. Pharmasset and our logo are our trademarks, and Racivir is our registered trademark. Other trademarks mentioned in this Annual Report on Form 10-K are the property of their respective owners.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The forward-looking statements are principally contained in the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We may, in some cases, use words such as “project,” “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “potential,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These forward-looking statements include statements about the following:

- our product development efforts, in particular with respect to the clinical trial results and regulatory approval of clevudine, Racivir[®], R7128 and DFC;
- the initiation, completion or success of preclinical studies and clinical trials;
- clinical trial initiation and completion dates, anticipated regulatory filing dates and regulatory approval for our product candidates;
- the commercialization of our product candidates;
- our collaboration agreement with F. Hoffmann-LaRoche Ltd. and Hoffmann- La Roche Inc. (collectively, “Roche”), including potential milestone or royalty payments thereunder;
- our intentions regarding the establishment of collaborations or the licensing of product candidates or intellectual property;
- our intentions to expand our capabilities and hire additional employees;
- anticipated operating losses, future revenues, research and development expenses, and the need for additional financing; and
- our financial performance.

Forward-looking statements reflect our current views with respect to future events and are subject to risks and uncertainties. We discuss many of the risks and uncertainties associated with our business in greater detail under the heading “Risk Factors.” Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. All forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K.

You should read this Annual Report on Form 10-K and the documents that we reference in it completely and with the understanding that our actual future results may be materially different from what we expect. Our business, financial condition, results of operations, and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. The forward-looking statements contained in this Annual Report on Form 10-K are subject to the safe-harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (“Exchange Act”).

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections. Our primary focus is on the development of oral therapeutics for the treatment of hepatitis B virus, or HBV, hepatitis C virus, or HCV and human immunodeficiency virus, or HIV. Our research and development efforts focus on a class of compounds known as nucleoside analogs, which act to inhibit the natural enzymes required for viral replication. We are currently focusing on three product candidates, two of which we are developing ourselves and one of which we are developing with a strategic partner:

- Clevudine, for the treatment of chronic HBV infection, is enrolling Phase 3 clinical trials for registration in North, Central and South America (“the Americas”) and Europe;
- R7128, a pro-drug of PSI-6130 for the treatment of HCV, in Part 3 of a Phase 1 clinical trial; and
- Racivir, for the treatment of HIV, has completed a Phase 2 clinical trial.

We are developing clevudine and Racivir ourselves, and we have formed a strategic collaboration with F. Hoffmann-LaRoche Ltd. and Hoffmann- La Roche Inc. (collectively, “Roche”) for the development of PSI-6130 and its pro-drugs, including R7128. Under the collaboration, Roche pays all development costs and provides us with potential income from milestone payments that can be used to fund the advancement of our proprietary product candidates. We are also continuing to identify the best path forward for the development of dexelvucitabine, or DFC, for the treatment of HIV following the completion of a Phase 2b clinical trial.

Although there are many currently approved antiviral drugs, there are unmet medical needs in HCV, HBV and HIV. In the treatment of HCV, pegylated interferon in combination with ribavirin is the standard of care and has demonstrated, for some patients, the ability to offer a sustained virologic response, or SVR, defined as a virus that is undetectable by a standard test utilizing polymerase chain reaction, or PCR, six months after discontinuation of therapy. However, pegylated interferon is injectable and has side effects, including fatigue, bone marrow suppression, anemia and neuropsychiatric effects. In HCV we believe there is an unmet medical need for drugs that offer an improved SVR rate with fewer side effects. In the treatment of HBV, interferon is not widely used because it produces an SVR in too few patients to justify its side effects. For HBV patients, treatment involves a chronic regimen of antiviral drugs to keep their viral load as low as possible. We believe that there is an unmet medical need for an HBV product which has the limited treatment period and SVR of pegylated interferon coupled with the fewer side effects and greater convenience of orally administered small molecule drugs. For HIV patients, treatment also involves a chronic regimen of antiviral drugs. During such prolonged treatment, viral mutations occur that make the viruses resistant to the drugs being used. We believe there is an unmet medical need for new HIV drugs that are effective against resistant viruses and can replace existing therapies that have lost effectiveness.

We believe nucleoside analogs are well suited to treat viral diseases because they can be designed to be highly specific and potent, are relatively simple to manufacture, and have the potential for oral administration. Nucleoside analog drugs have demonstrated a higher barrier to viral resistance than non-nucleoside and protease inhibitor drugs, and have a well-established development and regulatory history. There are 14 nucleoside analogs for the treatment of HBV, HCV or HIV that have been approved by the FDA and additional nucleoside analogs have been approved by the FDA for the treatment of influenza virus, cytomegalovirus and herpes simplex virus. In addition to clevudine, R7128, Racivir and DFC, we also have other nucleoside analog discovery programs focused on HIV and HCV. Our scientific team of virologists, biologists and nucleoside chemists has experience discovering and developing nucleoside analog drugs for antiviral indications. Collectively, our management team’s product development experience includes 40 therapeutic and diagnostic product approvals. Our discovery platform includes a library of nucleoside analogs and a collection of viral and cellular assays that we use to evaluate new product candidates.

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We were initially incorporated as Pharmasset, Ltd. on May 29, 1998 under the laws of Barbados. We redomiciled under the laws of Delaware on June 8, 2004 as Pharmasset, Inc., and Pharmasset, Ltd. was dissolved on June 21, 2004. Pharmasset, Inc., then-existing as a Georgia corporation, incorporated on June 5, 1998 and our only subsidiary of Pharmasset, Ltd., was merged with and into us on July 23, 2004.

Strategy

Our primary objective is to become a leader in discovering, developing and commercializing novel antiviral therapeutics that provide a competitive advantage and address unmet medical needs. Our primary focus is on the development of oral therapeutics for the treatment of HBV, HCV and HIV. To achieve this goal, we are pursuing the following strategies:

- ***Focus on developing our current clinical-stage product candidates and advancing them toward marketing approval.*** We are increasing our internal clinical development capabilities to enhance our ability to advance these product candidates. Our development team is responsible for planning and managing our clinical trials and supporting our partner, Roche, in its future clinical trials of R7128.
- ***Maintain a broad pipeline of potential product candidates to diversify commercial opportunities and reduce our dependence on any one product candidate's clinical or commercial success.*** Our development capabilities not only advance our clinical-stage product candidates, but also can be used to evaluate product opportunities from sources outside our company. We intend to leverage our research and development capabilities to evaluate external opportunities and may in-license products or technologies that we believe will complement our antiviral therapeutic focus. By maintaining a broad pipeline, we hope to create a portfolio of products that reduces our dependence on any one product and creates synergy within our pipeline through potential combination products.
- ***Leverage our core competency in nucleoside chemistry for research innovation and the discovery of additional product candidates.*** Our core competency is the discovery and development of nucleoside analogs for use as antiviral therapeutics. We believe our nucleoside chemistry expertise and our nucleoside library provide us with a strong foundation from which to identify additional product candidates. We intend to continue to invest in our nucleoside research capabilities and expand our nucleoside analog library.
- ***Commercialize our products ourselves or through collaborations, where appropriate, to optimize economic returns while managing financial risk.*** We allocate our limited resources to efforts that we believe will provide the greatest returns. Accordingly, we enter into collaborations to leverage our development capabilities and capitalize on commercialization opportunities that we cannot accomplish by ourselves. We believe this strategy will enable us to obtain the greatest returns from our antiviral discovery and development efforts.

Background on Viral Disease

A virus is a cellular parasite that cannot reproduce by itself and therefore must infect a susceptible host cell to replicate. A viral infection begins when the virus encounters a susceptible host cell and attaches to the cell membrane. The virus then enters the host cell and directs the host cell's metabolic machinery to participate in copying the viral genetic information, which is either RNA or DNA, and to produce the proteins encoded by that genetic information. This viral genetic information is packaged within a shell of newly produced viral proteins, forming an immature virus. In the case of HBV, HCV or HIV, this immature virus then acquires a coating or envelope of specific viral proteins and cellular lipids, forming a mature virus particle that is capable of infecting other cells. There are a wide variety of viruses, some of which are associated with a low rate of mortality, such as viruses causing the common cold, while others, including HBV, HCV and HIV, are associated with higher mortality rates.

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The challenge in developing antiviral therapies is to inhibit viral replication without injuring the host cell. For many years, it appeared that the development of safe and effective antiviral therapies would not be possible because the processes of viral replication were so intertwined with the cell's metabolic processes that the inhibition of viral functions would result in cell death. A breakthrough occurred with the identification of viral enzymes, such as viral polymerases, which are required for viral replication. These enzymes differ enough from cellular enzymes to permit their selective inhibition and thus prevent viral replication without harming the cell. HBV, a DNA virus, has two such polymerase enzymes: a reverse transcriptase which makes one strand of viral DNA from an RNA template; and a DNA polymerase, which makes a second strand of viral DNA from a DNA template, whose activity is the primary target for the treatment of HBV. HCV, an RNA virus, has an RNA polymerase which makes new viral RNA strands from an RNA template. HIV, an RNA virus, has a reverse transcriptase which makes viral DNA from an RNA template.

A major challenge of antiviral therapy is the emergence of viral mutations that result in forms of the virus that are resistant to current therapies. Viral mutations result from mistakes that occur during the natural viral replication process when the genetic information is copied. The mutated form of the virus infects other cells and replicates in its mutated form. Some mutations make the virus resistant to certain types of antiviral medications. When a drug-resistant form of virus first arises, it usually comprises a very small percentage of the virus circulating within the blood. As the original or wild-type virus continues to be suppressed by antiviral therapy and the drug-resistant virus continues to replicate, the mutated virus eventually becomes the dominant virus type. To reduce the likelihood of a dominant drug-resistant mutation, patients must comply with their treatment regimens; however, current studies show that at any given time only approximately 70% of patients strictly adhere to their therapy. Each of the FDA-approved oral viral therapies is susceptible to a mutation that confers drug resistance. New drug-resistant forms of virus continue to emerge, and as a result, new therapies to fight drug-resistant virus will continue to be needed.

HBV, HCV and HIV patients are classified as treatment-naïve or treatment-experienced. Treatment-naïve patients have not been exposed to antiviral therapies. Once viral mutations begin to occur and the virus develops resistance to the therapy, physicians either switch treatment regimens or add new drugs to existing regimens for the now treatment-experienced patients.

Our Product Candidates

Our research and development programs are focused on developing drugs that treat HBV, HCV and HIV infections. Our product candidates are nucleoside analogs that we believe have potential competitive advantages with respect to safety, efficacy, resistance profile and/or convenience of dosing as compared to currently approved drugs and other investigational agents. The following table summarizes the three product candidates on which we are focusing:

Product Candidate	Indication	Status	Next Expected Milestone	Commercialization Partners
Clevudine	HBV	Enrolling Phase 3 registration clinical trial	Complete full enrollment in Phase 3 registration studies by the end of 2008	—
R7128	HCV	In Part 3 of Phase 1 clinical trial	Report results of Part 3 of a Phase 1 study during first calendar quarter of 2008	Roche
Racivir	HIV	Completed Phase 2	Complete evaluation of clinical data and engage a development partner for a combination drug study	—

We are continuing to identify the best path forward for the development of DFC for the treatment of HIV following the completion of a Phase 2b clinical trial.

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Clevudine for the Treatment of HBV

HBV Background

Hepatitis B viruses can cause liver disease leading to significant morbidity and death. HBV can cause either acute or chronic (lifelong) infection. The World Health Organization, or WHO, has reported that approximately 350 million people worldwide have chronic HBV infection, including approximately 4.4 million people in the United States, Italy, Spain, Germany, the United Kingdom and France. According to the Centers for Disease Control and Prevention, or CDC, approximately 1.25 million people in the United States are chronically infected with HBV, and approximately 5,000 people in the United States die each year from chronic liver disease related to HBV infection. In addition, the Hepatitis B Foundation reports that 100,000 people will become infected with HBV this year. In the United States, about half, or 680,000, of the chronic HBV carriers have been diagnosed, and about 300,000 of these are under a physician's care, and only approximately 34,000, or 11.3%, of these patients are currently prescribed oral HBV drugs, according to estimates by independent third-party sources. We believe this poor use of oral antiviral drugs indicates an unmet medical need in the treatment of HBV. At present, treating physicians are more likely to monitor a patient and delay use of pegylated interferon or an oral HBV drug. Our market research suggests that many hepatologists delay or avoid HBV treatment with pegylated interferon due to adverse events, such as fatigue, bone marrow suppression and neuropsychiatric effects and delay or avoid HBV treatment with small molecule drugs due to the cost of therapy or a preference to delay the initiation of chronic therapy. Accordingly, we believe that there is an unmet medical need for an HBV product which has the limited treatment period and SVR of pegylated interferon coupled with the fewer side effects and greater convenience, resulting in improved patient compliance with dosing schedules, of orally administered small molecule drugs. We believe this is due to the lack of sustained antiviral response after stopping therapy with currently approved drugs, which results in chronic, lifetime use of these drugs once treatment with them is begun. HBV therapeutic sales in the United States and EU were approximately \$434 million in 2006 and are forecasted to reach nearly \$1.0 billion by 2010.

Acute asymptomatic infection, which is the most common type of HBV infection, lasts several weeks with few, if any, detectable symptoms. Acute symptomatic infection is more serious, and is associated with more severe symptoms such as flu-like illness and mild jaundice. In rare circumstances, acute symptomatic infection can lead to nonfatal hepatic necrosis or fatal fulminant hepatitis. In both symptomatic and asymptomatic acute HBV infection, an individual's broad-based immune responses develop and can clear the virus. If this occurs, immunity usually remains with the patient for the rest of the patient's life.

When HBV develops into a chronic infection, infected individuals cannot clear the virus with their immune system. A person is considered to have chronic HBV infection based on the presence of hepatitis B surface antigen for more than six consecutive months in the blood. This chronic state is typically marked by both replicative and non-replicative phases of disease progression, which are further characterized by four primary markers in the blood: elevated liver enzymes, viral DNA load, viral antigens and virus-specific antibodies. The relative level of these blood markers indicates whether the disease presents in either active or inactive form. Chronic hepatitis B subjects are classified into two groups: e-antigen positive individuals are those in whom the e-antigen is present and e-antigen negative persons are those in whom the e-antigen is not present. The e-antigen is a viral protein that indicates active replication of HBV or a persistent disease carrier state. A carrier is an infected individual that does not develop the disease, but can transmit the virus to others. The e-antigen negative form of the disease has been more difficult to treat effectively than the e-antigen positive form. Chronic hepatitis, left untreated, can result in cirrhosis of the liver, liver cancer, liver failure, or death.

HBV uses human cellular machinery to replicate and spread virus throughout the body. When an individual is exposed to HBV, the virus infects human liver cells and its DNA is transported to the cell nucleus. Subsequently, the partially circular viral DNA is converted to covalently closed circular DNA ("cccDNA"), which serves as a template for transcription of messenger RNA and the synthesis of the viral proteins that are required for replication. Newly synthesized RNA can be used to direct the synthesis of several viral proteins or is packaged into immature virus particles where it is converted into viral DNA by the process of reverse

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transcription (similar to HIV). Synthesis of viral DNA is performed by a DNA polymerase that is specific to HBV. Because the HBV polymerase is required for the virus to replicate, its activity is the primary target for the treatment of HBV. Mature DNA-containing viruses are assembled with envelopes of viral proteins and cellular lipids and transported out of the cell, which completes the replication process. A reservoir of cccDNA remains inside the infected cell, from which additional copies of the virus are made in a continuing cycle. Despite the reduction in HBV viral load levels resulting from currently approved therapies, these drugs have little effect on cccDNA and cannot truly resolve the infection. Since cccDNA is the reservoir responsible for persistent infection and long-term latency, any attempts to eradicate HBV have become increasingly focused on eradicating the cccDNA form of the virus.

A safe and effective vaccine against HBV has been available since 1982, and the WHO guidelines recommend this vaccination for all newborns universally. According to the WHO, however, only 153 countries had introduced the hepatitis B vaccine in routine infant immunization as of the end of 2003. Moreover, the vaccine only benefits those not yet infected with HBV. In the United States, four oral nucleoside analogs, lamivudine, adefovir dipivoxil (“adefovir”), telbivudine and entecavir, and one injectable protein, alpha interferon, which is available in standard and pegylated forms, have been approved for the treatment of HBV. While these products have demonstrated some patient benefits, we believe there is a market opportunity for new antiviral HBV therapies with different mechanisms of action that provide sustained viral response, improved potency, efficacy in patients with drug-resistance, and reduced side effects.

Long-term therapy with nucleoside analog anti-HBV drugs has led to the development of drug-resistant strains of the virus that reduce the efficacy of the therapy. Since HBV is so prolific, producing 10 billion to 1 trillion virions per day, a large number of spontaneous mutations could potentially be generated at every site in the HBV genome per day. The combination of a rapid virus replication cycle coupled with a relatively long half-life of infected cells suggests the need for prolonged antiviral therapy to eradicate HBV with currently approved drugs. The longer the treatment period, however, the greater likelihood that mutations will arise and resistance will develop. This has been demonstrated by mutations found in the HBV polymerase following lamivudine, adefovir, entecavir and telbivudine therapy. Clinical studies have reported the emergence of resistance to lamivudine, adefovir, entecavir and telbivudine.

As a result of drug resistance, HBV therapeutic trends with currently approved drugs have become similar to HIV treatment regimens, whereby patients who no longer receive benefit from their original therapy change prescriptions to a new therapeutic alternative. This has been demonstrated by patients who begin to use adefovir or entecavir, after resistance to lamivudine arises and treatment becomes less efficacious. In addition to the four approved nucleoside analogs for HBV, there are a number of therapeutics in development or seeking regulatory approval, including tenofovir. As more data and more drug products become available for HBV, there is a high likelihood that physicians may begin to prescribe combination therapy for HBV. We also believe that a combination of two therapies may delay the onset of drug-resistant virus. In addition, individuals co-infected with HIV and HBV may become candidates for combination therapy.

Clevudine

Clevudine is an oral, once-daily pyrimidine nucleoside analog that we are developing for the treatment of HBV. Clevudine has been studied in 14 completed clinical trials in a total of more than 800 patients. We license clevudine from Bukwang Pharm. Co., Ltd., or Bukwang, a Korean pharmaceutical company. Bukwang completed two Korean Phase 3 clinical trials, Studies 301 and 302, in which clevudine demonstrated the ability to significantly reduce HBV viral load in 337 patients. Based on the results of these trials, Bukwang received Korean approval in November 2006. Bukwang initiated the commercial launch of clevudine in the Korean market in February 2007 under the brand name Levovir.

We believe there is an unmet medical need for HBV drugs that offer a sustained virologic response, or SVR, without serious side effects. Physician surveys, our discussions with key opinion leaders in HBV, and the history of the HCV drug market lead us to believe that the global market for HBV therapeutics may grow significantly

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from its current level of approximately \$500 million when an HBV drug becomes available that provides an SVR in a significant percentage of patients. The only approved HBV therapy that offers an SVR is pegylated interferon, which is an injectable drug and is not well tolerated by patients. In the treatment of HBV, pegylated interferon is not widely used because it produces an SVR in too few patients to offset its side effects. Clevudine has the potential to provide a significant SVR without the side effects of pegylated interferon. In Study 302, clevudine sustained, for 24 weeks, a viral load that was undetectable by PCR in 16% of e-antigen negative HBV patients following 24 weeks of therapy. In clevudine Study 303, 80% of e-antigen negative HBV patients had a viral load that was undetectable by PCR 12 weeks after following a 48 week course of therapy.

For the many HBV patients that do not achieve an SVR, treatment is a chronic regimen of antiviral drugs to keep their viral load as low as possible. During such prolonged treatment, viral mutations occur that make the viruses resistant to the drugs being used. Treatment with several drugs at once in combination may slow the rate of mutation and the rise of the related drug resistance. Clevudine has the potential to be used in combination with other HBV therapies because its mechanism of action is different from that of other nucleoside analogs. Clevudine inhibits viral replication by primarily acting on the HBV polymerase enzyme to reduce its ability to incorporate nucleosides into a new viral DNA chain. In contrast, other nucleoside analog inhibitors currently in use or in development for the treatment of HBV, including lamivudine, adefovir, entecavir, telbivudine and tenofovir, act by competing with natural nucleosides for incorporation into the growing HBV DNA chain, causing the premature termination of the viral DNA chain and halting viral replication. Laboratory data suggests that clevudine may be additive or synergistic when used in combination with existing therapies. As such, we believe clevudine's mechanism of action is complementary to that of other HBV drugs and could be used either as a single agent for treatment-naïve patients or in combination with existing HBV therapies for treatment-experienced patients.

As part of our agreement with Bukwang, we have the exclusive rights to commercialize clevudine in the Americas, the Caribbean, Europe and Israel. Bukwang has retained rights to the rest of the world, excluding those Asian territories that were licensed to Eisai Pharmaceuticals in November 2004. Under the agreement, we have the right to use the clinical data generated by Bukwang or Eisai, as well as all historical data collected by Triangle Pharmaceuticals (acquired by Gilead Sciences in 2003) and Gilead Sciences, the prior licensee of clevudine, for regulatory and other cross-filing needs.

If clevudine receives marketing approval in the United States, we intend to commercialize clevudine ourselves with a sales force of approximately 40 to 45 employees. We believe this sales force size is comparable to those for competing HBV products in the United States. If clevudine receives marketing approval in Europe, we may commercialize clevudine ourselves or we may engage a marketing partner.

Clinical Development. We intend to seek regulatory approval for clevudine in North, Central and South America and Europe. Marketing approval by the FDA and European regulatory authorities will be based primarily on the data resulting from our two 48 week Phase 3 registration studies, one in approximately 376 e-antigen positive patients, Study 305, and one in approximately 480 e-antigen negative patients, Study 306, each comparing clevudine treatment to the approved HBV antiviral adefovir. In these trials, which commenced dosing patients in October 2007, patients will be randomized and will receive either adefovir or 30 mg of clevudine once-daily for the 48-week duration of the studies. The primary endpoint of these registration studies is a composite endpoint measuring the percentage of patients with undetectable HBV DNA (less than 300 copies/ml) and the normalization of liver enzyme levels at the 48th week on therapy. The registration studies will also assess improvement in liver histology, hepatitis B e-antigen (eAg) seroconversion (which is the loss of eAg together with an undetectable level of HBV DNA and normalized levels of liver enzyme), decreases in the reservoir of HBV hepatic cccDNA, and quantitative eAg and surface antigen (sAg). These trials are designed to test the superiority of clevudine over adefovir on these endpoints. We will continue these studies from week 48 to week 96. The number of patients to be enrolled in the e-antigen positive and e-antigen negative studies are intended to provide sufficient statistical support to detect a 20% and a 19% difference, respectively, between clevudine and adefovir for the primary endpoint with a 95% confidence level.

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Both Study 305 and Study 306 will continue for an additional 48 weeks after the registration data has been obtained to gather additional safety and efficacy data through week 96, as well as to assess clevudine's SVR rate. We expect that a portion of the e-antigen negative patients treated with clevudine will continue to be evaluated against adefovir through week 96. We expect that the remaining clevudine e-antigen negative patients, if they continue to meet the primary composite endpoint, will be taken off clevudine therapy at week 72 to measure SVR at week 96 after 24 weeks without treatment. Additionally, we expect that a portion of the e-antigen positive patients treated with clevudine will continue to be evaluated against a portion of the e-antigen positive patients treated with adefovir through week 96. We expect the remaining e-antigen positive patients treated with clevudine and adefovir, if they meet certain criteria, will be taken off therapy at week 72. These criteria include undetectable HBV DNA, alanine aminotransferase, or ALT, normalization and the loss of e-antigen and the presence of anti-HBV e antibody. We will then measure SVR in these e-antigen positive patients for clevudine and adefovir at week 96, 24 weeks after stopping treatment. There can be no assurances as to the results of these planned registration and continuation studies or as to any particular patient's response to clevudine.

Bukwang received marketing approval for clevudine from the Korean equivalent of the FDA based on two placebo-controlled, double-blinded, randomized, multi-center Korean Phase 3 clinical trials, Study 301 and Study 302, designed to determine the efficacy of clevudine over a 24-week period. Patients were evaluated for an additional 24 weeks of follow-up care without treatment. Study 301 enrolled e-antigen positive hepatitis B patients, and Study 302 enrolled e-antigen negative hepatitis B patients.

Study 301 involved 248 e-antigen positive patients who received 30 mg of clevudine or a placebo once daily. At week 24, 59% of patients receiving clevudine in this study had HBV DNA levels below those detectable by a PCR test, indicating very low viral infection or clearance of the virus from the body versus 0% of patients receiving placebo. Furthermore, 68% of e-antigen positive patients had normalized liver enzyme levels. Study 302 comprised 89 e-antigen negative patients who received 30 mg of clevudine or a placebo once daily. At week 24, 92% of patients receiving clevudine in this study had undetectable HBV DNA levels, versus 0% of patients receiving placebo. Furthermore, 75% of e-antigen negative patients had normalized liver enzyme levels. These viral load reductions were statistically significant when compared to the placebo groups. Clevudine's effect on viral load observed after 24 weeks of treatment in Study 301 and Study 302 was comparable to the effect observed in independent clinical studies after 48 or 52 weeks of treatment with other HBV drugs that are currently available or in development based on historical data for those therapies.

In Study 301, 24 weeks after the cessation of therapy, average HBV DNA levels in patients who received clevudine remained lower than baseline by 2.02 log (99.1% reduction) compared to patients who received placebo, whose average HBV DNA levels were lower than baseline by only 0.68 log (79.1% reduction), a statistically significant difference. In Study 302, 24 weeks after the cessation of therapy, the reduction in HBV DNA levels was 3.11 log (99.9% reduction) for treated patients versus 0.66 log (78.1% reduction) for the placebo group, a statistically significant difference. Furthermore, in Study 302, 24 weeks after the cessation of treatment, 16% of the patients who had received clevudine had an SVR versus 0% of the patients who had received placebo. We believe that patients whose viral load remains undetectable after 24 weeks off-treatment demonstrate the potential for a limited duration of therapy.

In March 2006, Bukwang completed Study 303, a Korean follow-on study of clevudine Studies 301 and 302. The goal of Study 303 was to evaluate the safety, antiviral activity, biochemical improvement, and serologic response in patients treated with clevudine for a total of 48 weeks. This open label follow-on study enrolled 55 treatment-naïve patients (40 e-antigen positive patients and 15 e-antigen negative patients) who were receiving placebo in Studies 301 and 302. Although, based on the results of the prior Phase 1 and Phase 2 dose-ranging studies, we expect clevudine's commercial dosing regimen to be 30 mg per day for the entire duration of treatment, Study 303 used a dosing regimen of 30 mg of clevudine for 24 weeks followed by a maintenance dose for an additional 24 weeks of 10 mg of clevudine, a dose which has previously been shown to be suboptimal. Results show that, at week 48, 63% of e-antigen positive patients and 87% of e-antigen negative patients had HBV DNA levels below those detectable by PCR tests. Furthermore, 83% of e-antigen positive patients and 87% of e-antigen negative patients had normalized liver enzyme levels. No serious adverse events were observed, and

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all adverse events were mild and transient. At week 60, twelve weeks after stopping treatment, the viral load had been sustained at undetectable levels in 28% of e-antigen positive patients and 80% of e-antigen negative patients. To our knowledge, no other HBV oral therapeutic has demonstrated this sustained antiviral effect.

The table below summarizes historical data for approved HBV nucleoside therapies. This historical data was derived from independent clinical trials reported in patient information inserts, New Drug Application, or NDA filings, medical journals and company reports and presentations. We have not conducted any clinical trials comparing clevudine to any of these other therapies.

Results from Independent Clinical Trials of Approved Nucleoside HBV Therapies	e-Antigen Positive Patients	e-Antigen Negative Patients
At 24 Weeks on Treatment		
Patients with Undetectable Virus (PCR Negative)		
clevudine	59%	92%
entecavir	45%	76%
telbivudine	44%	80%
lamivudine	32%	64%
adefovir	12%	36%
At 48 or 52 Weeks on Treatment		
Patients with Undetectable Virus (PCR Negative)		
clevudine	63%	87%
entecavir	67%	90%
telbivudine	60%	88%
lamivudine	36%	72%
adefovir	21%	52%
Patients with Normalized Liver Enzyme Levels		
clevudine	83%	87%
entecavir	68%	78%
telbivudine	77%	74%
lamivudine	60%	71%
adefovir	48%	72%
Patients with SVR, or Undetectable Virus (PCR Negative)		
24 Weeks After Stopping 48 or 52 Weeks of Therapy		
All approved nucleoside HBV therapies		3–7%
12 Weeks After Stopping 48 Weeks of Therapy		
clevudine 303 study		80%
24 Weeks After Stopping 24 Weeks of Therapy		
clevudine 302 study		16%

In Study 302, 16% of e-antigen negative patients sustained a viral load that was undetectable by PCR 24 weeks after completing the 24-week course of therapy. In Study 303, 80% of e-antigen negative patients receiving clevudine sustained a viral load that was undetectable by PCR 12 weeks after completing the 48-week course of therapy. This compares to one year of pegylated interferon therapy, which produces a viral load that is undetectable by PCR 6 months after stopping therapy in 19% of e-antigen negative patients, and other nucleoside HBV treatments that have reported viral load undetectable by PCR in approximately 3% to 7% of e-antigen negative patients, 24 weeks after completing a one year course of therapy. We note that while these results are not directly comparable because the clevudine data represents viral load 12 weeks after completing therapy, while the data for the competing products represents viral load 24 weeks after completing therapy, we believe the results indicate the potential for a higher rate of SVR with clevudine.

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Overall, clevudine was generally well-tolerated by patients with chronic hepatitis due to HBV. Serious adverse events during treatment in Studies 301 and 302 and during follow-up indicated that a higher percentage of placebo-treated patients had seriously elevated ALT levels or flares. ALT (also called alanine aminotransferase) is an enzyme found mainly in the liver. High levels of ALT in the bloodstream mean that the liver may be damaged or diseased. Otherwise, there was no meaningful difference between clevudine and placebo in the incidence of serious adverse events.

Clevudine has been the subject of six completed Phase 2 studies. Three of these studies were conducted by Bukwang in Korea. In Study 201, 99 patients with chronic hepatitis B received either placebo, 30 mg, or 50 mg of clevudine each day for 12 weeks with a follow-up period of 12 weeks. At the end of the trial, 63% of patients receiving 30 mg and 52% of patients receiving 50 mg had HBV below measurable levels compared to 0% of patients in the placebo group. Positive results were also observed in the other two trials conducted by Bukwang, Study 203 and Study 204. In addition, Gilead Sciences conducted a trial with 163 patients testing a 10 mg dose of clevudine in combination with 200 mg of emtricitabine versus 200 mg of emtricitabine alone over a 24-week period. Although 10 mg of clevudine has been shown to be a suboptimal dose in previous clinical trials, treatment-naïve e-antigen negative patients experienced a statistically significant improvement of an endpoint that combined reduction of HBV DNA levels with a normalization of liver enzyme levels when taking clevudine in addition to emtricitabine versus emtricitabine alone. Based on these studies, we believe that clevudine may be complementary to existing HBV treatments and could therefore be used as either a single agent or in combination with existing therapies.

Clevudine was also the subject of four completed Phase 1 trials designed to test the safety, tolerability and pharmacokinetic profile of the drug at various doses. In these Phase 1 trials and all other trials to date, clevudine has been generally well-tolerated.

Mechanism of Action. We believe clevudine inhibits viral replication by inhibiting the HBV polymerase enzyme through a mechanism of action that may or may not prevent the binding of other nucleoside inhibitors of the HBV polymerase enzyme. Unlike several other nucleoside analogs in development for the treatment of HBV, clevudine is not incorporated into normal human cellular DNA, and therefore is unlikely to interfere with cellular replication. Cell-based assays of clevudine in combination with other nucleoside analogs demonstrated that clevudine was not antagonistic with certain nucleoside analogs and may be active in combination with lamivudine, adefovir and emtricitabine. Laboratory data show clevudine to be additive or synergistic when used in combination with existing therapies. In vitro resistance studies showed that the HBV mutation, M204V, which confers resistance to lamivudine, was not resistant to clevudine, however, the M204I mutation was resistant to clevudine.

In woodchucks infected with woodchuck hepatitis virus (“WHV”), a common animal model for human HBV, clevudine demonstrated a significant reduction of the cccDNA form of the virus after treatment with clevudine. The cccDNA form of the viral genome is believed to be responsible for the persistence of chronic HBV infection and for reactivation of hepatitis B after stopping therapy.

R7128 for the Treatment of HCV

HCV Background

HCV is a leading cause of chronic liver disease and liver transplants. The WHO estimates that nearly 180 million people worldwide, or approximately 3% of the world’s population, are infected with HCV. 130 million of these individuals are chronic HCV carriers who are at increased risk of developing liver cirrhosis or liver cancer, approximately 15 million of whom are in the United States, Europe and Japan. The CDC has reported that 4.1 million people in the United States have been infected with HCV, of whom 3.2 million were chronically infected. Approximately 2.2%, or 71,000, of these HCV patients are treated each year, and there are an estimated 400,000 treatment-experienced patients who were unable to obtain an SVR. Although chronic HCV infection varies greatly in its course and outcomes, 70% of chronically infected patients develop some form of

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chronic liver disease, including, in some cases, cirrhosis or liver cancer. Worldwide sales of HCV drugs in 2005 were approximately \$2.2 billion, and are forecasted to reach more than \$4.0 billion by 2010 and more than \$8.0 billion in 2015. We believe that historical sales of HCV drugs increased as new therapies that improved the SVR rate were introduced. For example, when adding ribavirin to interferon in 1998 increased the SVR rate from a range of about 13% to 19% to a range of about 38% to 43%, sales of HCV drugs increased significantly from approximately \$400 million in 1996 to approximately \$600 million in 1998. Additionally, when the replacement of interferon with pegylated interferon in 2000 further increased the SVR rate to a range of about 47% to 54%, sales of HCV drugs again increased significantly from more than \$1.3 billion in 2000 to more than \$2.0 billion in 2002.

In the United States, the current standard of care for the treatment of HCV is a combination of pegylated interferon and a nucleoside analog named ribavirin. Pegylated interferon is a modified version of alpha interferon, a protein that occurs naturally in the human body and boosts the immune system's ability to fight viral infections. Patients treated with a combination of ribavirin and interferon respond better than those treated with interferon alone. According to the WHO, treatment with interferon in combination with ribavirin is effective in 30% to 50% of patients, while interferon alone is effective in approximately 10% to 20% of patients. In HCV genotypes 1a and 1b, which account for over 70% of HCV infections in the United States, less than 50% of patients respond to standard therapy consisting of pegylated interferon plus ribavirin. In addition, these therapies have side effects that include fatigue, bone marrow suppression, anemia and neuropsychiatric effects. As a result of the limited benefits and side effects of existing therapies, we believe treatment rates remain low and there are significant opportunities for new antiviral therapies to fight HCV.

HCV's inherent ability to mutate enables the virus to generate every possible genetic mutation twice each day, although not all mutated viruses are viable. Amino acid changes that occur at the active sites of essential viral enzymes may not allow the viral enzymes to function while changes at other locations on these viral enzymes are generally tolerated. Genes that give rise to components of the active sites of essential viral enzymes are much more highly conserved, that is, mutations of these genes are less likely to be found, since they reduce the activity of the enzymes needed to produce viable viruses. Genes that give rise to the components of non-active sites of viral enzymes are less conserved, since mutations at these sites do not generally reduce the activity of the enzymes needed to produce viable viruses. When a patient is exposed to a new anti-HCV drug that inhibits a specific viral function, the ability of that virus to reproduce is reduced or stopped. If the site of action of a drug is in one of the more conserved locations on the viral enzyme then the drug will inhibit more of the virus since there will be less chance that it will encounter an amino acid change that would reduce its activity, giving rise to drug resistance. On the other hand, if the drug acts on a region of the protein that is less well conserved and which can tolerate multiple changes, the drug will have a higher probability of encountering an amino acid change that either reduces or prevents its activity.

There are currently two approaches to inhibiting the activity of the HCV polymerase. One is the use of nucleoside analogs that mimic the nucleotides normally recognized by the enzyme as it builds a new copy of the viral genome. These nucleoside analogs take advantage of the fact that the virus can tolerate few mutations in their active sites. Any amino acid changes that might occur which would reduce the ability of the nucleoside analog to bind may also reduce the ability of the polymerase to bind the normal nucleotides. The other approach involves non-nucleoside molecules that can bind to various regions on the polymerase away from the active site. This kind of binding generally prevents the polymerase from assuming the correct configuration and in turn either reduces or prevents its activity. Since these regions can tolerate more changes, many of the differences seen in the genomes of the different variants of HCV can be found in these regions. The activity of these non-nucleoside drugs depends on their ability to bind relatively tightly to specific amino acid sequences and often involves multiple molecular interactions. If any of these interactions are missing due to a change in the polymerase sequence then binding can not occur properly. The chances of this happening are much greater with non-nucleoside drugs than with nucleoside analog drugs that act at more conserved sites. Another way of describing this is referred to as the "genetic barrier" to developing resistance to a drug. A site of inhibition that is naturally conserved would have a higher genetic barrier than one that is naturally variable or polymorphic.

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Early clinical trials with nucleoside analog drug candidates and non-nucleoside drug candidates have demonstrated this phenomenon. In monotherapy studies with the nucleoside analogs NM283 and R1626 over 14 days, viral breakthrough or viral rebound while on therapy did not occur. On the other hand, in studies with the non-nucleoside inhibitors HCV-796 and A-837093 in humans and chimpanzees infected with HCV, viral breakthrough or viral rebound was seen as early as 3 to 4 days into the 14-day treatment period. Analysis of the virus that appeared showed single amino acid changes that prevented or significantly reduced the binding of these non-nucleoside inhibitors. The rapidity of the rebound strongly suggested that these variant viruses existed in the patient prior to drug exposure and that the presence of the drug did not prevent these viruses from replicating and becoming the predominant variant in the patient. It is likely that resistance will arise with most if not all anti-HCV drugs, but the rapidity with which this occurs will likely have significant consequences for the patient.

Recent clinical studies have demonstrated the development of drug-resistant mutations in HCV. As such, the practice of using combination therapies may be applicable to the treatment of HCV infections. We also believe that a combination of HCV therapies may delay the onset of drug-resistant virus.

R7128

Roche and we are developing R7128 for the treatment of HCV. Roche is a market leader in HCV therapy through their FDA-approved products, Pegasys and Copegus. We believe R7128 represents an HCV product candidate that could complement Roche's expanding HCV franchise. R7128 is a pro-drug of a molecule we discovered named PSI-6130, an oral cytidine nucleoside analog. A pro-drug is a chemically modified form of a molecule designed to enhance the absorption, distribution and metabolic properties of that molecule. PSI-6130 is the active component of R7128. At low concentrations, PSI-6130 was shown to be an inhibitor of HCV replication, specifically targeting the HCV RNA polymerase.

In October 2004, we entered into a collaboration with Roche for the development and commercialization of PSI-6130 and related compounds. In exchange for these rights, Roche agreed to make milestone payments upon the achievement of predetermined clinical or regulatory events and pay royalties on sales of the products arising from the collaboration. Under this collaboration, Roche will reimburse us for all of the currently expected external expenses (up to an agreed-upon amount) associated with, and we will be responsible for, certain preclinical work, the investigational new drug ("IND") filing, and the Phase 1 clinical trials. Roche will fund all of the expenses of, and be responsible for, other preclinical studies, future clinical development and commercialization of R7128. We will continue to develop and retain worldwide rights to ongoing and future HCV programs unrelated to the PSI-6130 series of nucleoside polymerase inhibitors.

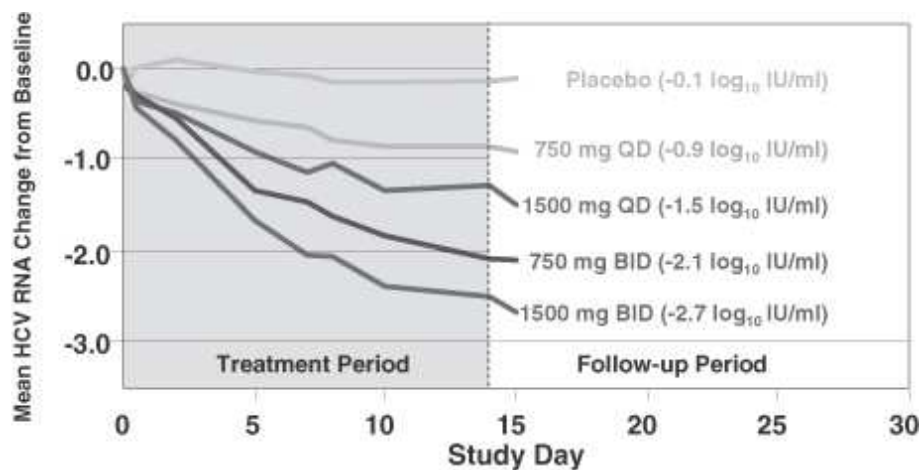
Clinical Development. In October 2007, Roche and we initiated oral dosing of R7128 in Part 3 of a Phase 1 clinical trial under an IND. This expanded Phase 1 trial is a multiple center, observer-blinded, randomized and placebo-controlled study designed to investigate the pharmacokinetics, pharmacodynamics, safety, tolerability and food effect of R7128 in healthy volunteers and in patients chronically infected with HCV genotype 1, as well as provide antiviral potency data over 14 and 28 days in patients chronically infected with HCV genotype 1. This adaptive Phase 1 study is comprised of three parts:

- Part 1 was a single ascending dose study conducted in 46 healthy volunteers. The primary objective of Part 1 was to assess the safety, tolerability and pharmacokinetics of R7128 following single ascending doses under fasting conditions. The secondary objective of Part 1 was to explore the effect of food on the pharmacokinetics of R7128. Single oral doses of R7128 were administered to 46 healthy volunteers in five sequential dose groups ranging from 500 mg to 9,000 mg and one food effect group (1,500 mg). Results from the single ascending dose portion of the study indicated:
 - All doses of R7128 studied were generally safe and well-tolerated.

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- All patients completed the study, and there were no dose related gastrointestinal adverse events or serious adverse events during the study.
- No hematological or laboratory abnormalities of clinical significance were noted.
- Part 2 was a multiple ascending dose study conducted in 40 patients chronically infected with HCV genotype 1 who had previously failed interferon therapy. The primary objective of Part 2 was to assess the safety, tolerability, and pharmacokinetics of R7128 after once-daily (“QD”) or twice-daily (“BID”) dosing for 14 days. The secondary objective was to assess antiviral efficacy by measuring the change in HCV RNA. Results from the multiple ascending dose portion of the study indicated:
 - R7128 demonstrated potent, dose-dependent antiviral activity in four patient cohorts (8 active, 2 placebo per cohort) receiving 750 mg or 1,500 mg administered either QD or BID for 14 days as monotherapy. Both the greatest mean decrease and maximum decrease in HCV RNA from baseline were demonstrated in the patient cohort that received 1,500 mg BID. R7128 demonstrated mean HCV RNA decreases of 0.9 log (87.4% reduction), 1.5 log (96.8% reduction), 2.1 log (99.2% reduction) and 2.7 log (99.8% reduction) in patients receiving 750mg QD, 1,500mg QD, 750mg BID and 1,500 mg BID, respectively. All four dose groups reached nadir values at Day 15. A maximum 4.2 log (99.9% reduction) HCV RNA decrease was demonstrated in a patient following 14 days of monotherapy with 1,500 mg BID of R7128, a value also below the level of detection, which was less than 15 International Units per milliliter (IU/ml).
 - There was no evidence of viral rebound in any dose cohort during the 14 days of dosing. In addition, R7128 was generally safe and well tolerated.
 - There were no serious adverse events, no adverse events requiring dose modification, no dose-related gastrointestinal adverse events and no clinically significant changes in hematologic or other laboratory parameters.

Results of Phase 1—Part 2 Study of R7128



- Part 3 is a 28-day study of R7128 in combination with Pegasys (pegylated interferon) plus Copegus (ribavirin) in up to 75 treatment-naïve patients chronically infected with HCV genotype 1. The primary objective of this study is to assess the safety, tolerability, and pharmacokinetics of R7128 in the clinically-relevant setting of combination therapy with the current standard of care for chronic HCV infection. The secondary objective of Part 3 is to evaluate the short-term change in HCV RNA. The study will include two to three oral doses of R7128 (500 mg to 1,500 mg) that are being administered twice-daily with Pegasys plus Copegus for 28 days. There will be 25 patients in each dose cohort with 20 patients randomized to receive R7128 and 5 patients randomized to receive placebo, all administered in combination with Pegasys plus Copegus. After completing 28 days of the triple

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combination regimen and a follow-up period of 4 weeks of Pegasys plus Copegus, all patients will then receive 40 weeks of open-label standard of care dosing under a separate protocol. We currently anticipate that the preliminary results from this combination study will be available in the first calendar quarter of 2008.

On October 12, 2007, we were informed by the FDA that R7128 received fast track designation.

In November 2005, Roche and we conducted a single ascending-dose, randomized, blinded study of PSI-6130 outside of the United States in healthy volunteers. The study evaluated the safety, tolerability, and pharmacokinetics of sequential ascending levels of single doses of PSI-6130, as compared with placebo. A total of 24 subjects were enrolled in three sequential dose groups with eight subjects per group (six subjects assigned to PSI-6130, two subjects assigned to placebo). This early stage clinical study was conducted in a small number of subjects and was not designed to achieve statistical significance at the end of the trial or test any formal statistical hypothesis about PSI-6130. In this completed clinical study, single oral doses of PSI-6130 were generally well tolerated with no serious adverse events in doses up to 3,000 mg and achieved bioavailability and pharmacokinetic properties that may be associated with antiviral activity in people infected with HCV.

Mechanism of Action. In a study evaluating the mechanism of action of PSI-6130, the compound was found to be active against the HCV RNA polymerase by terminating HCV RNA synthesis.

Preclinical Development. In preclinical studies, no toxicity was observed in various human cells, including liver cells, bone marrow cells, and white blood cells. When compared in laboratory studies to several other compounds in development for the treatment of HCV, PSI-6130 was found to be more active at low concentrations and/or less toxic. In combination with interferon, PSI-6130 was active and additive to the activity of interferon alone in these preclinical assays. We have performed and will continue to perform several animal studies to determine the pharmacokinetics and preclinical safety of PSI-6130. The goal of these animal studies is to help identify the potential toxicities which may appear at doses significantly higher than those expected to be tested in long-term studies in humans so as to be able to monitor human patients for such toxicities and to establish human doses at levels that provide sufficient margins of safety. Since animals metabolize PSI-6130 differently than humans, the dose levels found to be safe in animals do not directly correspond to human doses, but do provide guidance in the choice of human doses. For example, in monkeys, 40% of PSI-6130 is converted into a uridine metabolite, whereas, in humans, only 10% is converted. Hence, monkeys may be more sensitive to PSI-6130 or its metabolite than are humans, and toxicities may appear at lower doses in monkeys than in humans.

Pharmacokinetic studies in rats and monkeys demonstrated that the compound can be dosed orally. No toxicity was observed after six days of oral administration in mice and after 14 days of oral administration in rats and monkeys. Additional preclinical studies showed that PSI-6130 did not cause genetic mutations or damage in either cell or animal models. In a 14-day toxicity study in monkeys, no adverse events were observed at doses as high as 900 mg/kg per day, which was the highest dose tested. The systemic toxicity of R7128 has been studied following repeated daily oral administration over 28 days in monkeys, dogs and rats. The No-Observed-Adverse-Effect-Level (NOAEL) for R7128 over 28 days was 600 mg/kg/day in monkeys and 2,000 mg/kg/day (the highest dose tested) in dogs and rats. In July 2007, Roche began a six month safety study in monkeys at doses of 200 to 2000 mg/kg per day, which is approximately seven to 140 times the range of doses expected to be tested in long-term human studies. After 13 weeks, preliminary results indicated that the dose levels had been set too high to find the NOAEL dose over six months in monkeys, without which the study would not have provided the desired guidance for the choice of a safe dose for long-term human studies. The study was stopped and is expected to restart in the near future at a lower range of doses to find the NOAEL dose. In July 2007, we began a six month rat study. At five months, no toxicities have been observed at any dose level tested, which range from 200 to 2,000 mg/kg per day and is approximately seven to 140 times the range of doses expected to be tested in long-term human studies.

Racivir and DFC for the Treatment of HIV

HIV Background

HIV destroys the body's ability to fight infections by attacking cells of the immune system. In 1981, the first cases of Acquired Immunodeficiency Syndrome, or AIDS, were documented, and in 1983, HIV was identified as

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the cause of AIDS. According to a 2007 AIDS epidemic update by UNAIDS and the WHO, over 33 million people worldwide are living with HIV, and at least 25 million people worldwide have died from AIDS since the epidemic began. In the United States, the CDC has reported that the HIV mortality rate has steadily declined since the mid-to-late 1990s, while the incidence of infection continues to rise. This decrease in mortality can be attributed, in part, to the increased availability of HIV therapeutics used in the long-term treatment of HIV. According to a 2007 UNAIDS/WHO report, by the end of 2007, approximately 1.3 million people in North America and 760,000 people in Western and Central Europe were living with HIV and an additional 46,000 new patients in North America and 31,000 new patients in Western and Central Europe are diagnosed each year. The current market for HIV therapeutics is approximately \$6.5 billion and is estimated to reach \$10.0 billion by 2010.

The FDA has approved 25 single agents and six fixed-dose combination therapies for the treatment of HIV. The single agents are classified as nucleoside reverse transcriptase inhibitors, or NRTIs, non-nucleoside reverse transcriptase inhibitors, or NNRTIs, protease inhibitors, or PIs, or entry inhibitors. Both NRTIs and NNRTIs target the reverse transcriptase enzyme, while PIs and entry inhibitors target other proteins.

NRTIs mimic natural nucleosides and are commonly referred to as nucleoside analogs. Each NRTI is an analog of one of the following naturally occurring nucleosides: 2'-deoxy cytidine ("cytidine"), 2'-deoxy thymidine ("thymidine"), 2'-deoxy adenosine ("adenosine") or 2'-deoxy guanosine ("guanosine"). In the body, NRTIs block viral replication by interfering with the ability of reverse transcriptase to make a DNA copy of HIV RNA. This occurs because this enzyme incorporates the nucleoside analogs instead of the natural nucleosides into newly synthesized viral DNA, causing the premature termination of the DNA chain. This impairs either the synthesis or the functionality of the new viral genome, thereby suppressing viral replication. There are nine NRTIs approved by the FDA for the treatment of HIV.

NNRTIs are composed of a diverse group of compounds unrelated to nucleosides that also directly target reverse transcriptase. These drugs bind to the enzyme, causing a change in the shape of the enzyme that makes it less efficient in producing DNA. There are three NNRTIs approved by the FDA for the treatment of HIV.

PIs, integrase inhibitors and entry inhibitors are the other three classes of approved HIV therapeutics. Protease is an HIV enzyme that is required to make fully mature and infectious virus. This enzyme processes the viral proteins required to create a protective protein shell that surrounds the HIV RNA. The protease inhibitor class of compounds prevents the HIV protease from making mature virus capable of infecting other cells. Integrase inhibitors represent the newest class of HIV drugs to be approved by the FDA. These drugs prevent the integrase enzyme from integrating the viral genetic material into human chromosomes, a critical step in the pathogenesis of HIV. Entry inhibitors work outside the cell by inhibiting a virus from entering and infecting the cell. There are 10 PIs, one integrase inhibitor, and two entry inhibitors approved by the FDA for the treatment of HIV.

The standard treatment for HIV infection, as recommended by the U.S. Department of Health and Human Services, includes two NRTIs combined with a third drug from another class, either an NNRTI or a protease inhibitor, to form a triple combination therapy known as Highly Active Anti-Retroviral Therapy, or HAART. The two NRTIs in HAART are usually analogs of different nucleosides. Typically, a cytidine analog is paired with a thymidine or an adenosine analog in an effort to ensure the broadest activity against viral mutations and delay the onset of drug resistance. Racivir and DFC are cytidine analogs. It has been estimated that lamivudine and emtricitabine currently are the most commonly prescribed cytidine analogs, alone or as components of fixed dose combination products.

NRTIs, NNRTIs and PIs are generally administered orally as a tablet or capsule. In addition, several of the drugs in these classes are effective when taken only once each day. In treatment-naïve individuals, a once-daily therapy has been shown to improve compliance with the prescribed treatment regimen, which leads to better treatment outcomes. To provide additional convenience, companies have developed combination therapies that combine two or more NRTIs into a single tablet or capsule. These fixed-dose combination therapies have become

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leaders in the HIV marketplace. We believe that the most commonly prescribed combination therapies are Combivir, which combines lamivudine and zidovudine, and Truvada, which combines emtricitabine and tenofovir disoproxil fumarate (“tenofovir”). In 2006, a triple-combination called Atripla was approved by the FDA, which combines tenofovir, emtricitabine and efavirenz. In the near future, we anticipate that Atripla could become the most commonly prescribed combination therapy due to its ease of compliance as a once-daily triple combination. As patients develop resistance to their therapies, they are switched to other treatments. Increasingly, potency against drug-resistant virus becomes more important than convenience in treatment-experienced patients.

In HIV there is a class of mutations called thymidine analog mutations, or TAMs. These mutations typically confer resistance to thymidine nucleoside analogs such as zidovudine and stavudine. In addition to TAMs, other mutations include M184V, which typically confers resistance to cytidine analogs such as lamivudine and emtricitabine; K65R, which typically is associated with resistance to tenofovir; L74V, which is associated with resistance to abacavir, didanosine, and zalcitabine; and K103N, which is associated with resistance to efavirenz.

The following table describes the approved NRTIs for the treatment of HIV and their primary resistance mutations:

<u>Brand Names</u>	<u>Generic Name</u>	<u>Chemical Name Abbreviation</u>	<u>Analog Type</u>	<u>Primary Resistance Mutations</u>
Epivir	lamivudine	3TC	cytidine	M184V
Emtriva	emtricitabine	FTC	cytidine	M184V
Retrovir	zidovudine	AZT	thymidine	TAMs
Zerit	stavudine	d4T	thymidine	TAMs
Viread	tenofovir	TDF	adenosine	K65R, three or more TAMs
Videx/Videx EC	didanosine	ddI	adenosine	TAMs, K65R, L74V, M184V
Ziagen	abacavir	ABC	guanosine	TAMs, K65R, L74V, M184V
Hivid	zalcitabine	ddC	cytidine	TAMs, K65R, L74V, M184V

HIV’s inherent ability to mutate results in the occurrence of about one mutation in every new virus particle produced. With over ten million virus particles produced within a 24-hour period, it is possible to observe every conceivable genetic mutation each day, although not all mutated viruses are viable. When a drug-resistant form of HIV first arises, it usually comprises a very small percentage of the HIV circulating within the blood. As the original or wild-type virus continues to be suppressed by antiviral therapy and the drug-resistant HIV continues to replicate, the mutated virus eventually becomes the dominant virus type. To reduce the likelihood of a dominant drug-resistant mutation, patients must comply with their treatment regimens; however, it has been estimated that at any given time only approximately 70% of patients strictly adhere to their therapy. Each of the FDA-approved HIV therapies is susceptible to a mutation that confers drug resistance. New drug-resistant forms of HIV continue to emerge, and as a result, new therapies to fight drug-resistant HIV will continue to be needed.

From their experience with HIV, clinicians have learned much about how to optimally treat infected patients and delay the emergence of drug-resistant virus. As previously described, HAART, the current standard of care for patients infected with HIV, is comprised of three or more drugs that are ideally directed against different targets. This approach is based on two principles. First, the onset of viral resistance can be delayed by using multiple drugs that maximally suppress viral replication, thereby making it more difficult for a virus to generate the mutations that allow for the emergence of dominant drug-resistant virus. Second, based on scientific studies, it is much more difficult for drug-resistant virus to arise in the presence of drugs that inhibit different viral targets (such as reverse transcriptase and protease).

Racivir

Racivir is an oral, once-daily cytidine nucleoside analog that we are developing as an HIV therapy for use in combination with other approved HIV drugs. Racivir contains a racemic mixture, half of which is (–) FTC and half of which is (+) FTC. A racemic mixture is comprised of two forms of the same chemical structure that are

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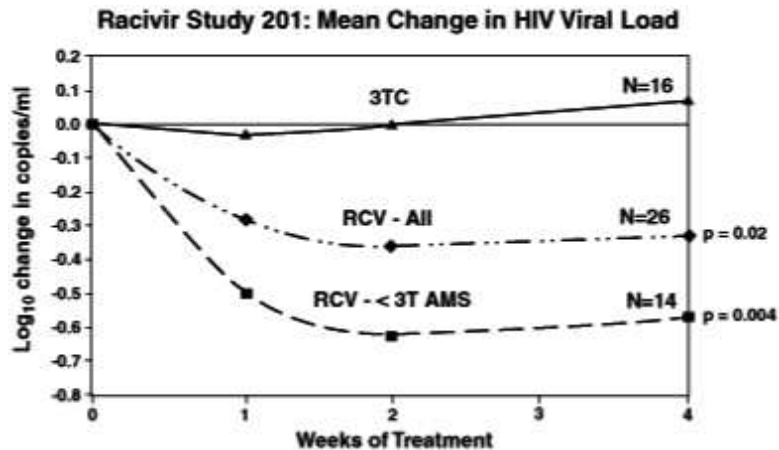
mirror images of each other. (–) FTC is a chemical name abbreviation for emtricitabine, an FDA-approved HIV therapy marketed as Emtriva by Gilead, and one of the components of Truvada and Atripla, which are fixed-dose combination HIV therapies. Racivir has been generally well-tolerated in three clinical trials. In a completed Phase 2 clinical trial, for those treatment-experienced patients carrying the M184V mutation and less than three TAMs, replacing lamivudine (a component of the first treatment regimen for HIV patients, with annual sales of approximately \$1 billion) with Racivir in their existing therapies caused a mean decrease in viral load of 0.7 log (80% reduction) in the second week of treatment, with 28% of these patients achieving an undetectable level of virus (less than 400 copies per milliliter) and 64% of these patients achieving at least a 0.5 log decrease (68% reduction) in viral load.

We are developing Racivir to be used with other HIV drugs for possible use in a combination therapy for patients failing their first treatment regimen. Our goal is to conduct future clinical trials with a collaborator that will study combination therapies that include Racivir for HIV patients receiving second-line therapy. Based on the results of our preclinical studies demonstrating activity against the HBV polymerase, we may also develop Racivir for the treatment of HBV or HIV/HBV co-infected individuals.

Clinical Development. We have completed a Phase 2 clinical trial, Study 201, to assess the safety, tolerability and antiviral effect of a 600 mg dose of Racivir head-to-head against lamivudine in HIV-infected, treatment-experienced patients with the M184V mutation who have been on lamivudine therapy. The study was a randomized, double-blind, placebo-controlled, multicenter study of 54 patients in the United States, Argentina, Mexico and Panama. Patients were randomized into two groups: one substituting Racivir in place of lamivudine in their existing therapies, and one continuing on their current lamivudine-containing therapy without any change. The study entry criteria included patients who were failing a HAART regimen. Specifically, participants were required to have received lamivudine as part of their antiviral therapy for the previous 60 days, to carry the M184V HIV mutation, and to have an HIV RNA viral load of greater than or equal to 2,000 viral copies per milliliter of blood plasma. The study had a blinded treatment period of up to 28 days, followed by an open label treatment period of up to 20 weeks. Patients are subsequently being followed for an additional four weeks after the conclusion of the study treatment periods. The goal of this study was to evaluate the benefit of Racivir in patients carrying the M184V mutation by replacing lamivudine with Racivir in existing therapies.

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In this study, 42 subjects were randomized to receive either Racivir (n=26) in place of lamivudine or to continue with lamivudine (n=16) in a double-blind manner for 28 days. HIV viral loads and genotypes were determined at baseline (mean viral load = 4.1 log) and throughout the study. After the blinded treatment period, subjects were allowed to continue Racivir in an open label manner with or without optimized background therapy for an additional 20 weeks, based on their primary care physicians' advice. After 28 days of blinded treatment, the mean viral load rose by 0.13 log (a 34.9% increase) in the lamivudine group and dropped by 0.4 log (60.2% reduction) in the Racivir group (p=0.02). A subset analysis of the Racivir-treated group revealed that the change in viral load was largely due to a positive antiviral response in subjects who had an HIV mutation pattern that included M184V and less than 3 TAMs with or without NNRTI or PI mutations. In this subset of patients (n=14), replacing lamivudine with Racivir in their existing therapies caused a mean drop in viral load of 0.7 log (80% reduction, p=0.004) in the second week of treatment, with 28% of these patients achieving an undetectable level of virus (less than 400 copies per milliliter) and 64% of these patients achieving at least a 0.5 log (68%) drop in viral load. No serious adverse events attributed to therapy were noted in either group over the 28 days. Clonal genotypic analysis of virus from responders indicated that the M184V mutation was found in all clones in addition to multi-drug resistance-associated mutations observed with first line therapy failure.



In summary, Racivir demonstrated antiviral activity in patients harboring HIV with the M184V mutation and less than three TAMs. These patients have genotypes consistent with first-line therapy failure and may be candidates for second line treatment regimens that contain Racivir. Future studies will be designed to explore this potential use of Racivir in a combination therapy for second-line therapy.

We conducted a Phase 1 clinical trial with Racivir as a single agent and a Phase 1 clinical trial, Study 101, with Racivir in combination with two FDA-approved therapies for the treatment of HIV infection. Racivir was shown to be generally well-tolerated in both studies. In Study 101, Racivir was tested at 200, 400 and 600 mg doses against lamivudine once daily for 14 days in combination with stavudine and efavirenz in 32 HIV-infected, treatment-naïve individuals. In this study, mean viral loads of 4.7 log to 4.85 log were reduced by approximately 99% on average by day 14 at all dose levels and in the lamivudine control arm. In this study, replacing lamivudine with Racivir did not affect the efficacy of stavudine and efavirenz. The purpose of the Phase 1 study was to assess the safety of Racivir and was not designed to provide statistical evidence of efficacy. Therefore, a "p" value measuring the statistical significance of this viral load reduction was not calculated.

Mechanism of Action. Racivir's primary resistance mutation in vitro is M184V. In our head-to-head preclinical studies, the M184V viral mutation took longer to emerge when using Racivir than lamivudine or emtricitabine. In collaboration with the National Institutes of Health, or the NIH, we compared the activity of Racivir to emtricitabine against common HIV mutations in a head-to-head laboratory study and observed that both Racivir and emtricitabine were similarly active in inhibiting naturally occurring HIV, as well as viruses containing the T215Y (which is one of the TAMs), K65R, and other drug-resistant mutations. In this laboratory

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study, Racivir lost activity against viruses containing the M184V mutation, but to a lesser degree than emtricitabine. In other head-to-head preclinical studies, we evaluated Racivir's time to selection of resistant mutants. We observed *in vitro* that -FTC selected for the M184V mutation in 9 weeks, +FTC selected for the T215Y mutation in 17 weeks and Racivir selected for the M184V mutation in 14 weeks. We believe that the +FTC component of Racivir is delaying the selection of M184V by Racivir.

In head-to-head preclinical studies, we evaluated Racivir's potency and cytotoxicity. We observed that +FTC has potent antiviral activity, although it is approximately 10-fold less potent than -FTC. Neither -FTC or +FTC demonstrated cytotoxicity.

DFC

DFC is an oral, once-daily cytidine nucleoside analog that we are evaluating for the treatment of HIV. In clinical and preclinical studies, DFC was active against most viruses containing drug-resistant mutations arising from the use of Viread, Epivir, Emtriva, Retrovir and others. DFC may potentially be used as a therapy for treatment-experienced individuals when taken in combination with other drugs, because it may be active against viruses containing the M184V, K65R, L74V and TAMs mutations that arise after prolonged therapy. No resistance mutations specific to DFC have been observed to date in preclinical studies and clinical trials with DFC. While preclinical and early clinical studies showed DFC to be generally well-tolerated, more recent studies have shown DFC to be associated with increases in pancreatic enzymes.

Clinical Development. We had been developing DFC in collaboration with Incyte Corporation until April 3, 2006, when Incyte announced its decision to discontinue its development of DFC. Incyte has now terminated our license agreement and returned its rights related to DFC to us. As a result of this termination, we will no longer be eligible to receive milestone payments or royalties from Incyte with respect to DFC, and we will be solely responsible for any additional expenses that we may incur in connection with the development of DFC. We have analyzed the preclinical and clinical data on DFC generated by Incyte. Based on our review of the data provided to us, we believe that identifying a path for further development of DFC is warranted.

Results of prior clinical trials do not provide enough evidence to support an NDA filing with the FDA and additional trials will be needed. Results of our ongoing trials and any future trials we may conduct may not corroborate earlier results.

Incyte made its decision to discontinue its development of DFC after observing an increased incidence of grade 4 hyperlipasemia in the rollover portion of a Phase 2b clinical trial. Hyperlipasemia can be a marker of pancreatic inflammation. In Study 901, 69 patients received 200 mg once-daily doses of DFC. There was no placebo or comparator drug arm to act as a control to help differentiate the effects of DFC from other factors. Of the 69 patients receiving the 200 mg dose not treated with didanosine, 8 (12%) experienced grade 4 hyperlipasemia. 48 of these patients were receiving 3TC or FTC concurrently with DFC, and 20 patients were not receiving 3TC or FTC. Of the 48 patients receiving 3TC or FTC, one (2.1%) experienced grade 4 hyperlipasemia. Of the 20 patients not receiving 3TC or FTC, 7 (35%) experienced grade 4 hyperlipasemia. Incyte based its decision to discontinue development of DFC on its observation of the increase in frequency of grade 4 hyperlipasemia in patients not being treated with 3TC or FTC. However, for 6 of these 7 patients, we believe, based on our preliminary analysis of case histories, that pre-existing conditions may have contributed to their hyperlipasemia. One of these 7 patients had a history of pancreatitis, two others had a history of hepatitis, one other had a history of uncontrolled diabetes, one other experienced a significant elevation of liver enzymes (ALT) and one other had a history of hypertriglyceridemia and abdominal lipoatrophy. All of these pre-existing conditions have been associated with hyperlipasemia.

In December 2005, Incyte completed Study 203, a double-blind, placebo-controlled Phase 2b clinical trial evaluating the safety, tolerability and virological effect of 50, 100 and 200 mg once-daily doses of DFC in 199 treatment-experienced HIV-infected patients who were failing their current therapies. This 24-week study

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enrolled patients who had been infected with more than one drug-resistant form of HIV, including HIV with the M184V, TAMs and K65R mutations. This study included a two-week treatment period with DFC or placebo as an add-on treatment to the failing therapy, followed by up to 14 weeks of treatment with DFC or placebo as part of an optimized regimen, at which time the patient's dose was selected for an additional eight weeks of optimized treatment. An optimized regimen includes antiviral therapeutics that was selected based on data from resistance testing. The purpose of this study was to select a dose for Phase 3 clinical trials and to evaluate the safety and tolerability of DFC.

Incyte reported to the FDA that the first 16-week results of this study, summarized in the table below, showed that the 52 patients who received the 200 mg dose of DFC as an add-on therapy in either an optimized or non-optimized regimen achieved a mean 1.2 log drop (94% reduction) in viral load versus a 0.8 log drop (84% reduction) for the patients receiving placebo. In this group, 44% of the treated patients achieved more than a 1.0 log drop (90% reduction) in viral load versus 34% of the patients receiving placebo.

A retrospective analysis of the 16 week efficacy data showed that a subset of 14 patients receiving the 200 mg dose of DFC and who were not receiving Epivir or Emtriva (two approved cytidine analogs) in their background regimen achieved a 1.3 log drop (95% reduction) in viral load versus a 0.7 log drop (80% reduction) for the placebo group. In this group, 71% of the treated patients achieved more than a 1.0 log drop (90% reduction) in viral load versus 27% of the patients receiving placebo.

Some patients treated with DFC had an elevation of lipase (hyperlipasemia) up to the Grade 4 level. Grade 4 hyperlipasemia in the absence of any clinical symptoms occurred primarily in patients receiving DFC in combination with ddI (Videx). During 24 weeks of therapy, asymptomatic increases in serum lipase to greater than 5 times the upper limit of the normal range (Grade 4) were seen in 44% of patients receiving 200 mg DFC with ddI. In the absence of ddI, Grade 4 hyperlipasemia occurred in 5.4% of patients receiving the 200 mg dose of DFC versus 2.6% of patients receiving placebo. Based on the data from this study, it appeared that the 200 mg dose of DFC, when used without ddI, was generally well tolerated.

Study 203: 16-week Efficacy Results (1)

Group	Decrease in Viral Load		% > 1 log Decrease	
	Placebo	200 mg	Placebo	200 mg
All Patients	-0.8 N=47	-1.2 N=52	34% N=47	44% N=52
Subgroup of All Patients with No Epivir or Emtriva in background treatment regimen	-0.7 N=11	-1.3 N=14	27% N=11	71% N=14

(1) Results are shown on a Last Observation Carried Forward basis (LOCF)

Based on these results, the FDA requested that Incyte conduct another Phase 2b trial to provide additional data to support the efficacy and safety of DFC in patients not receiving Epivir, Emtriva or Videx prior to beginning Phase 3 trials. Prior to the start of this new trial, Incyte announced its decision to discontinue its development of DFC.

In February 2004, we completed a Phase 2a multiple dose clinical trial using DFC in 30 treatment-naïve and 10 treatment-experienced HIV-infected individuals measuring pharmacokinetics, safety and efficacy. In this double-blind, placebo-controlled trial, no serious drug-related adverse events were reported. After ten days of oral, once-daily monotherapy at the 200 mg dose, all eight (or 100%) of the patients receiving DFC achieved greater than a 95% reduction in HIV RNA. Seven or (87.5%) of these patients had viral load reduced to undetectable levels. In addition, the eight treatment-experienced patients receiving DFC experienced an average 84% decrease in viral load after ten days, despite on average having failed more than five previous therapeutic regimens, including, but not limited to, Epivir, Retrovir and Viread.

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An earlier Phase 1 clinical trial in 18 HIV-infected patients measured pharmacokinetics, safety and tolerance of a single dose. The data demonstrated a statistically significant antiviral effect of a 64% reduction in viral load after a single dose. When DFC was administered orally at doses from 10 to 200 mg, there was rapid absorption of the compound and the target peak concentration levels of the product candidate in the individual's blood were achieved with a dose as low as 100 mg.

Our Research Programs

We have a library of cataloged nucleoside analogs, as well as several other chemically diverse antiviral, anticancer and antibacterial compounds. This library is the result of substantial collective effort, and we continue to enhance the compound library's value through the addition of new compounds. We screen potential new targets against this library as a means of identifying promising chemical compounds to pursue for further development. We use preclinical discovery and development technologies and viral and cellular assays that we believe form a reasonable basis for anticipating clinical results. Developing additional compounds to treat HCV, HBV and HIV is the primary focus of our nucleoside research and development activities.

Collaborations and Licensing Agreements

University of Cincinnati

In October 2007, we entered in a research collaboration and license agreement with the University of Cincinnati ("UC") on behalf of its Genome Research Institute ("GRI") to identify active and selective compounds against antiviral targets for HBV, HCV and HIV. As part of the agreement, UC granted us access to the GRI Lead Generation Library, which includes over 250,000 compounds. We will also gain access to GRI's drug discovery capabilities, including high-throughput screening, computational chemistry and in silico docking expertise. UC granted us commercial rights for any lead compounds that are identified for HBV, HIV and HCV. We will make an annual payment to UC in support of the research collaboration and shall be responsible for all development expenses of products that may result from the collaboration. If a lead compound progresses through clinical development activities and achieves regulatory approval, we will make certain milestone payments to UC and pay to UC a royalty on any net sales of the product.

Bukwang Pharm. Co., Ltd.

Bukwang Pharm. Co., Ltd. is a pharmaceutical, oral hygiene, and cosmetics company based in Seoul, Korea. On December 28, 1995, Bukwang entered into an exclusive, worldwide license agreement with the University of Georgia Research Foundation, or UGARF, and Yale University to develop and commercialize clevudine. On June 23, 2005, Bukwang granted us exclusive rights to develop, manufacture, and market clevudine in North America, Europe, Central and South America, the Caribbean, and Israel. Bukwang retained rights to the rest of the world, excluding those Asian territories that were licensed to Eisai Pharmaceuticals in November 2004. The agreement permits us to sublicense these rights, without Bukwang's consent, to any of the top one hundred pharmaceutical companies based on sales ranked by IMS Health Incorporated.

We paid Bukwang an up-front payment of \$6.0 million and may pay up to an aggregate of \$24.0 million in milestone payments related to development, regulatory and commercialization events, as well as future royalties on net sales, including a minimum royalty obligation in certain years. We incurred our first milestone payment to Bukwang in the amount of \$1.0 million upon initiation of our Phase 3 registration study during the quarter ended September 30, 2007. Other than the up-front payment and this \$1.0 milestone payment, we have made no additional milestone payments through September 30, 2007 to Bukwang under this agreement. We have the right to use the clinical data generated by Bukwang or Eisai, as well as all historical data collected by the prior licensee, Triangle Pharmaceuticals (acquired by Gilead Sciences in 2003) or Gilead Sciences. We will be responsible for conducting any future clinical trials, regulatory filings, and the commercialization of clevudine in our territories. Bukwang and Eisai are responsible for all ongoing clinical trials, regulatory filings, and the

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commercialization of clevudine in their respective territories. Subject to the rights of any third party, including Gilead, we granted Bukwang a right of first refusal for Racivir for the treatment of HBV in Korea, the royalties for which would be based on net sales, and without any license fee or milestone obligations.

With respect to patents owned by Bukwang, we are primarily responsible for the patent prosecution and maintenance activities with respect to the licensed patent applications and patents in our licensed territories, at our expense. With respect to the licensed patent applications and patents owned by the primary licensors, UGARF and Yale University, the primary licensors are primarily responsible for the patent prosecution and maintenance activities with respect to the licensed patents, while we are afforded reasonable opportunities to advise the primary licensors on, and cooperate with the primary licensors in, such activities. Under the primary license agreement, Bukwang and the primary licensors agreed that in the event of any suspected infringement, (i) Bukwang and the primary licensors may first agree to institute suit jointly, (ii) in the absence of such agreement, the primary licensors may institute suit, and (iii) in the absence of agreement and if the primary licensors do not institute suit, then Bukwang may institute suit. Bukwang granted us the sole right to exercise its enforcement rights with respect to our territories.

Our collaboration and license agreement with Bukwang will terminate on a country-by-country basis upon the expiration of the last to expire of the licensed patents, including any renewals or extensions, or the invalidation of such patents. The last expiration of these patents is scheduled to occur in March 2022. In the event that there are no valid patent claims in a country, the agreement will terminate with respect to that country in 2015. We may terminate the agreement by providing written notice to Bukwang six months prior to termination. In addition, either party may terminate the agreement if the other party commits a material breach of the agreement that is not timely cured. In the event of termination at will by us or for our breach, we must license or transfer to Bukwang all regulatory filings, trademarks, patents, preclinical and clinical data related to this agreement. In the event of termination for Bukwang's breach, Bukwang must license or transfer to us all patents, know-how, and manufacturing processes related to this agreement.

University of Georgia Research Foundation, Inc. and Yale University

As part of the collaboration and license agreement with Bukwang, we sublicensed certain patents and technology related to clevudine. On June 23, 2005, we, along with UGARF and Yale University, signed a memorandum of understanding with regard to the patents and technology related to clevudine that had been exclusively licensed to Bukwang, and which we currently sublicense from Bukwang. The memorandum of understanding provides that UGARF and Yale will grant us a license to these patents and technology in the event that the primary license with Bukwang is terminated, under substantially the same terms as the primary license with Bukwang, including term, termination and financial provisions, provided that the reason for such termination does not relate to any breach of our sublicense by us or on our behalf. We made no up-front payments to UGARF or Yale University in connection with this agreement. The memorandum of understanding contains no stated termination date.

Incyte Corporation

On September 3, 2003, we entered into a collaboration and license agreement with Incyte to develop and commercialize DFC. On April 3, 2006, Incyte announced its decision to discontinue its development of DFC. Incyte has subsequently terminated our license agreement and returned its rights related to DFC to us. We are analyzing the clinical data on DFC generated by Incyte and will decide on the next steps for further development of DFC after we have completed this analysis.

Hoffmann-La Roche Inc.

Hoffmann-La Roche Inc. is the U.S. affiliate of F. Hoffmann-La Roche Ltd, a Swiss company (collectively "Roche"). In October 2004, we entered into a collaboration and license agreement with Roche to develop PSI-6130, its pro-drugs and chemically related nucleoside polymerase inhibitors for all indications, including the

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treatment of chronic HCV infections. Roche paid us an up-front payment of \$8.0 million. Roche has also agreed to make milestone payments to us for PSI-6130 or a pro-drug of PSI-6130, including R7128, of up to an aggregate of approximately \$105 million, assuming successful development and regulatory approval in Roche's territories. In addition, we will receive royalties paid as a percentage of total annual net product sales, if any, and we will be entitled to receive up to \$30 million of one-time performance payments should net sales from the product exceed specified thresholds. Under this collaboration, Roche will reimburse us for all of the currently expected external expenses (up to \$4.5 million) associated with, and we will be responsible for, certain preclinical work, the IND filing, and the initial clinical trial. Roche will fund all of the expenses of, and be responsible for, other preclinical studies, future clinical development and commercialization of R7128. In addition to the \$8.0 million up-front payment, we have received payments of \$25.0 million from Roche under this agreement as of September 30, 2007.

We granted Roche worldwide rights, excluding Latin America and Korea, to which we refer as our retained territory, to PSI-6130 and its pro-drugs and derivatives. With respect to our retained territory, we may grant rights to a third party to distribute, promote, market or sell a product covered by this collaboration agreement, so long as we first offer these rights to Roche, subject to certain exceptions. We retained certain co-promotion rights in the United States, including the right to market and promote products comprising these compounds to physicians who treat HIV patients. We will be required to pay to Roche royalties on our net product sales, if any, in the territories we have retained.

We also granted Roche an option to license from us additional nucleoside polymerase inhibitors related to PSI-6130 and its pro-drugs and other product candidates developed through our research collaboration. We will continue to discover, develop and retain worldwide rights to ongoing and future HCV programs unrelated to the Roche collaboration.

With respect to patents owned by us that are the subject of this collaboration, we have the right to prosecute, maintain, enforce and defend these patents, while Roche has the same right with respect to certain designated territories if we choose not to exercise our rights. With respect to Roche's patents that are the subject of this collaboration, Roche has the right to prosecute, maintain, enforce and defend these patents, while we have the same right with respect to certain designated territories if Roche chooses not to exercise its rights. With respect to joint patents that are the subject of this collaboration, Roche and we are each responsible for prosecuting, maintaining, enforcing and defending those joint patents in our respective territories. Subject to certain exceptions, we have agreed to share with Roche any damages, monetary awards and other amounts recovered, after costs and expenses, in connection with patent litigation related to this collaboration.

This agreement will terminate once there are no longer any royalty or payment obligations. Additionally, Roche may terminate the agreement in whole or in part by providing six months' written notice to us. Provided that Roche has not terminated the agreement, our royalty obligations under this agreement terminate on a product-by-product and country-by-country basis upon either the expiration of the last to expire patent that covers a licensed compound in each country, or 10 years from the launch of such licensed compound in such country, whichever occurs later. Otherwise, either party may terminate the agreement in whole or in part in connection with a material breach of the agreement by the other party that is not timely cured. In the event of termination, Roche must assign or transfer to us all regulatory filings, trademarks, patents, preclinical and clinical data related to this collaboration.

In conjunction with the agreement, Roche purchased 400,000 shares of our Series R redeemable convertible preferred stock and received warrants to purchase up to an additional 470,588 shares of our Series R-1 redeemable convertible preferred stock for \$4.0 million. These shares and warrants were initially recorded at fair value for financial reporting purposes. The 400,000 shares of Series R redeemable convertible preferred stock were converted into 266,666 shares of our common stock on May 2, 2007 when we completed our IPO, and the related warrants expired without exercise on October 26, 2006.

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Emory University

Emory University is a non-profit Georgia corporation located in Atlanta, Georgia. In December of 1998, we entered into two licensing arrangements with Emory University related to the active pharmaceutical ingredients in DFC and Racivir.

DFC. On December 30, 1998, Emory University granted us an exclusive license to make, have made, use, import, offer for sale and sell medical products based on a compound now known as DFC, including certain of its analogs and derivatives. As part of the consideration for this agreement, we issued to Emory University 66,667 shares of our redeemable common stock valued at \$1.50 per share and agreed to pay Emory University royalties as a percentage of net product sales and up to an aggregate of \$1.0 million in future marketing milestone payments. Beginning in the second year after NDA registration, these royalties are subject to specified minimums. The agreement permits us to sublicense these rights, subject to Emory University's prior written consent, provided that we pay a percentage of milestone and royalty payments that we receive from a sublicensee. In September 2003, we sublicensed the rights to DFC in certain territories to Incyte, under a collaboration and license agreement, which was terminated as described above.

Emory University is primarily responsible for the patent prosecution and maintenance activities pertaining to the licensed patents, while we are afforded reasonable opportunities to advise Emory University on, and cooperate with Emory University in, such activities. In the event of any suspected infringement, (i) we and Emory University may first agree to institute suit jointly, (ii) in the absence of such agreement, Emory University may institute suit, and (iii) in the absence of agreement and if Emory University does not institute suit, then we may institute suit.

Our agreement with Emory University will expire upon the expiration of all licensed patents. The last expiration of these patents is scheduled to occur in April 2020. Emory University has the right to terminate the agreement if we fail to make required payments or reports when due, if we become insolvent or bankrupt, or if we materially breach the agreement. To exercise this right, Emory University must give us 60 days' written notice, after which time the agreement automatically terminates unless we have cured the breach. We have the right to terminate the agreement at our sole discretion on three months' written notice.

Racivir. On December 8, 1998, Emory University granted us an exclusive, worldwide license, which we refer to as the Racivir License Agreement, to make, have made, use, import, offer for sale and sell drug products based on a specified range of mixtures of (-) – FTC and (+) – FTC, or enriched FTC, which includes the mixture that we are developing as Racivir. As part of the consideration for this agreement, we issued to Emory University 66,667 shares of our redeemable common stock valued at \$1.50 per share, and agreed to pay Emory University royalties as a percentage of net product sales. We subsequently issued to Emory University an additional 13,307 shares of our redeemable common stock valued at \$4.95 per share pursuant to an anti-dilution provision in our agreement. We may also pay Emory University up to an aggregate of \$1.0 million in future marketing milestone payments. Beginning in the second year after NDA registration, these royalties are subject to specified minimums. The agreement permits us to sublicense these rights under certain circumstances, provided that we pay a percentage of milestone and royalty payments that we receive from a sublicensee.

Emory University is primarily responsible for the patent prosecution and maintenance activities pertaining to the licensed patent applications and patents, while we are afforded, pursuant to a license agreement relating to emtricitabine that Emory University entered into with Triangle Pharmaceuticals, now Gilead Sciences, Inc., in 1996, which we refer to as the Emory/Gilead License Agreement, reasonable opportunities to advise Emory University on, and cooperate with Emory University in, such activities. Pursuant to the Emory/Gilead License Agreement, in the event of any suspected infringement, (i) we and Emory University may first agree to institute suit jointly, (ii) in the absence of such agreement, Emory University may institute suit, and (iii) in the absence of agreement and if Emory University does not institute suit, then we may institute suit.

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The Racivir License Agreement will expire upon the expiration of all licensed patents. The last expiration of these patents is scheduled to occur in November 2020. Emory University has the right to terminate the agreement if we fail to make required payments or reports when due, if we become insolvent or bankrupt, or if we materially breach the agreement. To exercise this right, Emory University must give us 60 days' written notice, after which time the agreement automatically terminates unless we have cured the breach. We have the right to terminate the Racivir License Agreement at our sole discretion on three months' written notice.

In the Emory/Gilead License Agreement, Emory University previously had granted a right of first refusal to Gilead that is applicable to any license or assignment relating to enriched FTC (which includes Racivir). The terms of this right of first refusal contains an exception permitting Emory University to license or assign its rights in respect of enriched FTC to a permitted transferee, which includes any of the inventors (which included two of our founders) or to any corporate entity formed by or on behalf of the inventors for purposes of clinically developing enriched FTC so long as the licensee agrees in writing to be bound by the terms of Gilead's right of first refusal to the same extent as Emory University. Our license to Racivir was granted to us by Emory University pursuant to this exception and therefore we are bound by the terms of Gilead's right of first refusal to the same extent as Emory University. The terms of this right of first refusal as set forth in the Emory/Gilead License Agreement require that, prior to the entry into any license or assignment agreement with a third party relating to any of Emory University's rights in respect of enriched FTC, Emory University shall notify Gilead of the terms of the proposed agreement and provide a copy of the proposed agreement to Gilead together with all data and information in Emory University's possession relating to enriched FTC and its use as a therapeutic agent. Gilead has 30 days to accept or decline the offer. Although Emory University considers us to be a permitted transferee under the Emory/Gilead License Agreement, Emory University has subsequently taken the position that its grant of commercialization rights (i.e., the rights to offer for sale and sell Racivir) to us exceeded the rights that were permitted to be granted to a permitted transferee under its agreement with Gilead. While we believe that Gilead is aware of the Racivir License Agreement through both our and Emory University's communications with Gilead, Gilead has not contacted us regarding its interpretation of the terms of the Racivir License Agreement.

In March 2004, we entered into a supplemental agreement with Emory University in which we and Emory University agreed that, prior to any commercialization of enriched FTC by us, or by any licensee or assignee of our rights under the Racivir License Agreement, we and Emory University would adhere strictly to the terms of the right of first refusal granted to Gilead in the Emory/Gilead License Agreement and offer to Gilead the same terms and conditions under which we, our licensee or our assignee, propose to commercialize enriched FTC. The supplemental agreement also outlines a procedure by which Emory University and we would jointly offer the terms of a proposed license and commercialization agreement between us and a third party to Gilead after Emory University has the opportunity to approve them. Therefore, before we could enter into a commercialization agreement for Racivir with a third party or commercialize Racivir on our own, we would be required to offer Gilead the opportunity to be our commercialization partner on the same terms on which we intend, or our prospective partner intends, to commercialize Racivir. It is uncertain whether a third party would be willing to negotiate the terms of a commercialization agreement with us knowing that Gilead can take their place as licensee by accepting the negotiated terms and exercising its right of first refusal.

These uncertainties related to our commercialization rights may result in our being prevented from obtaining the expected economic benefits from developing Racivir. In addition, we could become involved in litigation or arbitration related to our commercialization rights to Racivir in the future.

Apath, LLC

Apath, LLC is a Missouri company that is engaged in the commercial application of molecular virology and viral genetics. On October 18, 2000, as amended on January 30, 2004, Apath granted us a non-exclusive right to use its HCV Replicon technology for the design, discovery, development and commercialization of compounds inhibiting HCV in humans. The agreement required us to pay Apath royalties on sales of compounds discovered

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using this technology, and on any consideration received by us from a licensee of such compounds. Although this agreement is not related to the development of a specific product candidate, we used this technology in our development of PSI-6130.

We do not have the right to advise or to consult with Apath regarding the prosecution or maintenance of the licensed patent rights. We are one of several sublicensees of the licensed patents and have no rights to enforce such patents.

This agreement was terminated on August 26, 2005, on which date we entered into a new agreement with Apath. Under the terms of the new agreement, we paid Apath a one-time sublicense fee of \$550,000, and an annual maintenance fee of \$75,000, subject to annual renewals, retroactive to October 18, 2000. Going forward, we will only pay the annual maintenance fee for any year for which we choose to renew this agreement, and we will have no other financial obligations to Apath in connection with the design, discovery, development and commercialization of compounds inhibiting HCV in humans.

This agreement expires on the date of expiration of the last-to-expire U.S. patent in the licensed patent rights. The last expiration of these patents is scheduled to occur in March 2018. Apath retains no rights to the compounds we discover, and they will receive no payments for any of the compounds we discover. We are entitled to sublicense these compounds to a third party without Apath's permission or consent. We may terminate the agreement for any reason or no reason by giving Apath 30 days' prior written notice without any penalties. Apath is entitled to terminate the contract, but only should we breach the agreement, on 30 days' notice in the event of any uncured breach.

RFS Pharma LLC

As of February 10, 2006, we entered into a license agreement with RFS Pharma LLC ("RFS Pharma") to pursue the research, development and commercialization of an antiviral nucleoside analog product candidate called dioxolane thymine ("DOT"). Dr. Schinazi, one of our significant stockholders, is the founder and majority stockholder of RFS Pharma and is a named inventor of DOT. Under this agreement, we paid to RFS Pharma an upfront payment of \$400,000 and we may also pay up to an aggregate of \$3.9 million in future milestone payments, royalties on future sales, and expense reimbursements for reasonable out-of-pocket costs incurred by RFS Pharma in assisting us in complying with all regulatory obligations, for certain orders of DOT by RFS Pharma and, upon obtaining regulatory approval for the sale of a product containing DOT in one of the countries listed below, for certain administrative costs and expenses associated with RFS Pharma's performance of its obligations under the license agreement. For the first five years after we initially sell a product containing DOT in any of the U.S., Japan, China, Germany, France, Great Britain, Italy or Spain, we have agreed to pay minimum royalty payments. To date, other than the initial upfront payment we have paid a total of \$119,120 to RFS Pharma under these provisions. Additionally, this license agreement provided for the purchase of specified amounts of DOT by us from RFS Pharma for \$82,000. With respect to licensed patent applications and patents owned by the primary licensors which claim DOT, the primary licensors, UGARF and Emory University, are primarily responsible for the prosecution and maintenance activities. With respect to licensed patent applications and patents owned by RFS Pharma which claim DOT, RFS Pharma is primarily responsible for the prosecution and maintenance activities through patent counsel reasonably acceptable to us. Under the primary license agreement, RFS Pharma and the primary licensors agreed that, in the event of any suspected patent infringement, (i) RFS Pharma and the primary licensors may first agree to institute suit jointly, (ii) in the absence of such agreement, RFS Pharma may institute suit, and (iii) in the absence of agreement and if RFS Pharma does not institute suit, then the primary licensors may institute suit. RFS Pharma granted us all its enforcement rights under the primary license agreement. We may terminate the license agreement on a country-by-country basis and/or product-by-product basis or in its entirety at any time upon 30 days advance written notice to RFS Pharma prior to the launch of any licensed product, or upon 180 days advance written notice to RFS Pharma following the launch of any licensed product. Additionally, upon a material breach of this agreement by either party, if the breaching party fails to cure the material breach during a 90 day period after notice of the breach has been

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provided, then the non-breaching party may terminate the agreement on a country-by-country or product-by-product basis with respect to the country(ies) and licensed product(s) to which the breach relates. The license agreement may also terminate on a country-by-country and licensed product-by-licensed product basis upon the expiration of the obligation to pay royalties on the sale of each licensed product in such country. Such royalties shall be payable for so long as there exists in such country a valid claim of an issued patent covering a licensed product, or, if longer, the term of the license agreement among UGARF, Emory University and RFS Pharma with respect to such licensed product in such country.

Manufacturing and Supply

We do not have our own manufacturing capabilities and we rely on third-party manufacturers for supply of the active pharmaceutical ingredients, or APIs, we use in our preclinical studies and clinical trials. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce commercial quantities of any drugs that we market.

We have a sufficient quantity of clevudine for our future preclinical studies and Phase 3 clinical trials, but if we obtain marketing approval for clevudine, we will need to procure additional supplies of clevudine from qualified third-party manufacturers. We are negotiating an agreement for the manufacture of clevudine with a supplier that manufactured clevudine used in previous clinical trials, however our negotiations are ongoing and we have not entered into a definitive agreement with this potential supplier.

Roche has responsibility for establishing a single source of API for R7128 for both the Roche territory and our territory. We also have the right to establish ourselves as the secondary source of API supply for R7128, provided, however, that we may not supply in excess of 20% of the requirements for the global supply.

We may need to procure additional supplies of Racivir to complete our future preclinical studies and clinical trials. Our goal is to conduct future clinical trials with a collaborator that will study combination therapies that include Racivir for HIV patients receiving second-line therapy. If necessary, we plan to enter into a supply agreement after an evaluation of potential suppliers that could manufacture Racivir, including the company that manufactures our current supply of Racivir.

Incyte was responsible for the clinical trials of DFC and for obtaining a sufficient supply of DFC for its trials. If we conduct our own clinical trials of DFC, we will need to establish our own source of supply of DFC.

We have relied on contract manufacturers specializing in nucleoside chemistry to provide us with drug product. The company that manufactured our current supply of Racivir and PSI-6130 made a \$1.5 million equity investment in us in 1999. All of the materials required for the manufacture of our product candidates are currently available from more than one qualified source.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture and marketing of pharmaceutical products and in ongoing research and development activities. Government authorities in the United States at the federal, state, and local levels and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, and import and export of pharmaceutical products, biologics, and medical devices. All of our products will require regulatory approval by governmental agencies prior to commercialization. Various federal, state, local and foreign statutes and regulations also govern testing, manufacturing, safety, labeling, storage and record-keeping related to such products and their marketing. The

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process of obtaining these approvals and subsequent process of maintaining substantial compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. In addition, these statutes, rules, regulations and policies may change and our products may be subject to new legislation or regulations.

Pharmaceutical Regulation in the United States

In the United States, drugs are subject to rigorous regulation by the FDA. The Federal Food, Drug and Cosmetic Act, or the FDCA, and other federal and state statutes and regulations govern, among other things, the research, development, testing, safety, effectiveness, manufacture, quality control, storage, record keeping, labeling, promotion, marketing, and distribution of pharmaceutical products. The failure to comply with the applicable regulatory requirements may subject a company to a variety of administrative or judicially imposed sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. The FDA also administers certain controls over the export of drugs and biologics from the United States.

The steps ordinarily required before a new drug product may be marketed in the United States include preclinical laboratory tests, animal tests and formulation studies, the submission to the FDA of a notice of claimed exemption for an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication for which FDA approval is sought. The following paragraphs provide a general overview of the development and approval process for a new drug.

Preclinical Phase. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA.

If a company wants to test a new drug in human patients, an IND must be prepared and filed with the FDA to request FDA authorization to begin human testing of the drug. The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the adequacy of the preclinical studies, the preclinical product characterization and/or the proposed conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The submission of an IND may not result in FDA authorization to commence a clinical trial. A separate supplemental submission to an existing IND must also be made for each successive clinical trial conducted during product development, and the FDA must review each supplemental IND before each clinical trial can begin. Furthermore, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center, and the IRB must monitor the study until completed.

Certain preclinical tests must be conducted in compliance with the FDA's good laboratory practice regulations and the United States Department of Agriculture's Animal Welfare Act. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be reconducted.

Clinical Phase. The clinical phase of development follows successful IND submission and involves the activities necessary to demonstrate safety, tolerability, efficacy and dosage of the substance in humans, as well as the ability to produce the substance and finished drug product in accordance with the FDA's current Good Manufacturing Practice, or cGMP, requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the efficacy of the drug. Each protocol must be submitted to the FDA as part of the IND prior to beginning the trial. Each trial must be reviewed, approved and conducted under the auspices of an IRB, and each trial, with limited exceptions,

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must include the patient's informed consent. Sponsors, investigators, and IRBs also must satisfy extensive Good Clinical Practice, or GCP, including regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and reporting adverse events timely. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Foreign studies performed under an IND must meet the same requirements that apply to U.S. studies. The FDA will accept a foreign clinical study not conducted under an IND only if the study is well-designed, well-conducted, performed by qualified investigators, and conforms to the ethical principles contained in the Declaration of Helsinki, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, Phases 1, 2 and 3, with Phase 4 clinical trials conducted after marketing approval. Phase 4 clinical trials are generally required for products that receive accelerated approval. FDA also may require sponsors to conduct Phase 4 clinical trials to study certain safety issues. Data from these activities are compiled in an NDA for submission to the FDA requesting approval to market the drug. These phases may be compressed, may overlap or may be omitted in some circumstances.

- *Phase 1 Clinical Trials:* After an IND becomes effective, Phase 1 human clinical trials can begin. These studies are initially conducted in a limited population to evaluate a drug candidate's safety and tolerability. Phase 1 clinical trials also determine how a drug candidate is absorbed, distributed, metabolized and excreted by the body, and its duration of action. In some cases, a sponsor may decide to run what is referred to as a "Phase 1b" evaluation, which is a second, safety-focused Phase 1 clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently approved drugs.
- *Phase 2 Clinical Trials:* Studies are generally conducted in a limited patient population to identify possible adverse events and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. These trials are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 2 clinical trials of antiviral drugs typically are designed to evaluate the potential efficacy of the drug on patients and to further ascertain the safety of the drug, at the dosage given, in a larger patient population. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, a sponsor may decide to run what is referred to as a "Phase 2b" evaluation, which is a second, confirmatory Phase 2 clinical trial that could, if positive and accepted by the FDA, serve as a registrational clinical trial in the approval of a drug candidate.
- *Phase 3 Clinical Trials:* These are commonly referred to as registrational (or pivotal) studies, and are undertaken when Phase 2 clinical trials suggest that a dose range of the drug candidate is effective and has an acceptable safety profile. In Phase 3 clinical trials, the drug is usually tested in a controlled randomized trial comparing the investigational new drug to an approved form of therapy in an expanded and well-defined patient population and at multiple clinical sites. The goal of these studies is to obtain definitive statistical evidence of safety and efficacy of the investigational new drug regimen as compared to an approved standard treatment in defined patient populations with a given disease and stage of illness. Phase 3 trials usually include from several hundred to several thousand subjects.

In the case of products for life-threatening diseases, the initial human testing is often conducted in patients with the target disease rather than in healthy volunteers. These studies may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials, and so these trials are frequently referred to as Phase 1/2 clinical trials.

In addition, a company may hold an "End-of-Phase 2 Meeting" with the FDA to assess the safety of the drug regimen to be tested in the Phase 3 clinical trial, to evaluate the Phase 3 plan, and to identify any additional information that will be needed to support an NDA. If the Phase 3 clinical trials had been the subject of

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discussion at an “End-of-Phase 2 Meeting,” the company is eligible for a Special Protocol Assessment, or SPA, by the FDA, a process by which the FDA, at the request of the sponsor, will evaluate protocols and issues relating to the protocols within 45 days to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. If the FDA and the sponsor reach agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA, the FDA will reduce the agreement to writing. The SPA agreement, however, is not a guarantee of product approval by FDA or approval of any permissible claims about the product.

Success in early-stage clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from clinical activities is not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval.

Throughout the clinical phase, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed.

Phase 1, 2, and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA’s assessment of the risk/benefit ratio to the patient. The FDA or the sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, IRBs, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

Certain information about clinical trials, including a description of the study, participation criteria, location of study sites, and contact information, shall be sent to the National Institutes of Health (“NIH”) for inclusion in a publicly-accessible database. Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the Food and Drug Administration Amendments Act of 2007 directs the FDA to issue regulations that will require sponsors to submit to the NIH the results of all controlled clinical studies, other than Phase I studies.

New Drug Application. After successful completion of the required clinical testing of a drug candidate, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. An NDA is a comprehensive, multi-volume application that includes, among other things, the results of all preclinical and clinical studies, information about the drug’s composition, and the sponsor’s plans for producing, packaging, and labeling the drug. If the FDA determines that a risk evaluation and mitigation strategy (“REMS”) is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include as part of the application a proposed REMS, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug’s distribution, or a medication guide to provide better information to consumers about the drug’s risks and benefits. Under the Pediatric Research Equity Act of 2003, an application is also required to include an assessment, generally based on clinical study data, on the safety and efficacy of drugs for all relevant pediatric populations before the NDA is submitted. The statute provides for waivers or deferrals in certain situations. The cost of preparing and submitting an NDA is substantial. Under federal law, in most cases, the submission of an NDA is also subject to substantial application user fees. The manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually.

The submission of the application is no guarantee that the FDA will find it complete and accept it for filing. The FDA reviews all NDAs submitted before it accepts them for filing. It may refuse to file the application and request additional information rather than accept the application for filing, in which case, the application must be

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resubmitted with the supplemental information. After the application is deemed filed by the FDA, agency staff of the FDA reviews an NDA to determine, among other things, whether a product is safe and efficacious for its intended use. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of physicians, for review, evaluation, and an approval recommendation. For any drug containing an active ingredient not previously approved under the FDCA, the application automatically will be referred to an appropriate advisory committee for review prior to approval of the drug, unless the FDA decides otherwise and specifies such reasons in a complete response letter to the sponsor. The FDA is not bound by the opinion of the advisory committee. Drugs that successfully complete NDA review may be marketed in the United States, subject to all conditions imposed by the FDA.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to specific performance goals in the review of NDAs. The FDA assigns a goal of 10 months from acceptance of the application to return a first "complete response," in which the FDA may approve the product or request additional information. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission.

Prior to granting approval, the FDA generally conducts an inspection of the facilities, including outsourced facilities that will be involved in the manufacture, production, packaging, testing and control of the drug substance and finished drug product for cGMP compliance. The FDA will not approve the application unless cGMP compliance is satisfactory. If the FDA determines that the marketing application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter.

If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter or, in some cases, an "approvable" letter followed by an approval letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling and distribution restrictions that can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The length of the FDA's NDA review ranges from a few months, for drugs related to life-threatening conditions, to many years.

Fast-Track Review. The Food and Drug Administration Modernization Act of 1997, or the Modernization Act, establishes a statutory program for the approval of "Fast-Track" products, which are defined under the Modernization Act as new drugs or biologics intended for the treatment of a serious or life-threatening condition that demonstrate the potential to address unmet medical needs for this condition. To determine whether a condition is "serious" for the purposes of Fast-Track designation, the FDA considers several factors, including the condition's impact on survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. If awarded, the Fast-Track designation applies to the product only for the indication for which the designation was received. Under the Fast-Track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast-Track product

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in writing at any time during the clinical development of the product. The Modernization Act specifies that the FDA must determine if the product qualifies for Fast-Track designation within 60 days of receipt of the sponsor's request.

Fast-Track designation offers a product the benefit of approval based on surrogate endpoints that generally would not be acceptable for approval and possible early or rolling acceptance of the marketing application for review by the agency. Traditional approval requires data demonstrating that the product has an effect on clinically meaningful endpoints or well-established surrogate endpoints. The FDA may approve the application of a Fast-Track product on the basis of clinical trials using less than well-established surrogate endpoints where the agency determines that the effect on the surrogate endpoint is reasonably likely to predict clinical benefit. If a preliminary review of the clinical data suggests that a Fast-Track product may be effective, the FDA may also initiate review of sections of a marketing application for a Fast-Track product before the sponsor completes the application. This rolling review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees. However, the time periods to which the FDA has committed in reviewing an application do not begin until the sponsor actually submits the application.

The FDA may subject approval of an application for a Fast-Track product to post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint, and the FDA will also subject such approval to prior review of all promotional materials. In addition, the FDA may withdraw its approval of a Fast-Track product on a number of grounds, including the sponsor's failure to conduct any required post-approval study with due diligence and failure to continue to meet the criteria for designation.

Fast-Track designation should be distinguished from the FDA's other programs for expedited development and review although products awarded Fast-Track status may also be eligible for these other benefits. Accelerated approval refers to the use of less than well-established surrogate endpoints discussed above. Priority review is a designation of an application after it has been submitted to the FDA for approval. The agency sets the target date for agency actions on the applications of products that receive priority designation for six months where products under standard review receive a 10-month target.

Post-Approval Phase. As a condition of NDA approval, the FDA may require post-marketing "Phase 4" clinical trials to confirm that the drug is safe and efficacious for its intended uses. After NDA approval, if the FDA becomes aware of new safety information, the agency may require post-approval studies, including clinical trials to investigate known serious risks or signals of serious risks, or identifying unexpected serious risks. If required to conduct a post-approval study, periodic status reports must be submitted to the FDA. Failure to conduct such post-approval studies in a timely manner may result in substantial civil fines.

Where drugs are approved under accelerated approval regulations or the FDA otherwise requests, additional studies will likely be required to document a clinical benefit and to monitor the long-term effects of the therapy. We expect that for any product for which a single pivotal clinical trial is authorized for approval, we will be required to conduct extended Phase 4 clinical trials to monitor the long-term effects of the therapy. Recent developments have prompted heightened government awareness of safety reporting and pharmacovigilance. The FDA may require applicants to implement a REMS or risk minimization action plan ("RiskMAP") to minimize known and preventable safety risks or otherwise impose burdens, such as limits on prescribing and/or distribution and on direct-to-consumer advertising, on an applicant's ability to commercialize its drug products.

In addition, following FDA approval of a product, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved marketing application, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or efficacy data may require changes to an approved product's distribution or labeling including the addition of new warnings and contraindications.

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Any products manufactured or distributed under FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and, where appropriate, state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies to ensure compliance with applicable regulations, including cGMP, which impose manufacturing procedural, documentation and quality control requirements. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties.

FDA Regulation of Post-Approval Marketing and Promotion. The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion for uses of the product not approved by the FDA, industry-sponsored scientific and educational activities and promotional activities involving the internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, enforcement letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label uses.

Drug Price Competition and Patent Term Restoration Act of 1984. Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. In order to preserve the incentives of pioneer drug manufacturers to innovate, the Hatch-Waxman Act also provides for patent term restoration and the award, in certain circumstances, of non-patent marketing exclusivities.

Abbreviated New Drug Application ("ANDA"). An ANDA is a type of application in which approval is based on a showing of "sameness" to an already approved drug product. ANDAs do not contain full reports of safety and efficacy, as do NDAs, but rather demonstrate that their proposed products are "the same as" reference products with regard to their conditions of use, active ingredient(s), route of administration, dosage form, strength, and labeling. ANDA applicants are also required to demonstrate the "bioequivalence" of their products to the reference product. Bioequivalence generally means that there is no significant difference in the rate and extent to which the active ingredient(s) in the products becomes available at the site of drug action.

An applicant may obtain permission from the FDA to submit an ANDA for a product that differs from the reference product in active ingredient (in combination products), route of administration, dosage form, or strength by submitting a suitability petition to the FDA. The FDA will approve a suitability petition unless investigations must be conducted to show the safety and efficacy of the altered product, or unless significant labeling changes would be required. If the FDA approves the suitability petition, the applicant may submit an ANDA for its proposed product. When approving a suitability petition, the FDA may also inform the applicant of any additional information that the FDA may require to support the ANDA. The FDA has the authority during its review of the ANDA to request additional information regarding the change in the product that was the subject of the suitability petition, and may also withdraw its approval of the suitability petition.

All ANDAs must contain data relating to product formulation, raw material suppliers, stability, manufacturing, packaging, labeling, and quality control, among other information. Approval limits manufacturing to a specifically identified site(s). Supplemental filings, which generally require FDA review and approval, may allow the manufacture of such products at new sites also generally require review and approval. In addition, certain changes to manufacturing processes, ingredients, and labeling can require FDA review and approval.

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The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant has challenged any patents claiming the reference product and whether the pioneer manufacturer is entitled to one or more periods of non-patent marketing exclusivity. In certain circumstances, these marketing exclusivities can extend beyond the life of a patent, and block the approval of ANDAs after the date on which the patent expires. If the FDA concludes that all substantive ANDA requirements have been satisfied, but final approval is blocked because of a patent or a non-patent marketing exclusivity, the FDA may issue the applicant a “tentative approval” letter.

505(b)(2) Applications. If a proposed product represents a change from an already approved product, yet does not qualify for submission under an ANDA or pursuant to an approved suitability petition, the applicant may be able to submit a type of NDA referred to as a “505(b)(2) application.” A 505(b)(2) application is an NDA for which one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigation was conducted. The FDA has determined that 505(b)(2) applications may be submitted for products that represent changes from approved products in conditions of use, active ingredient(s), route of administration, dosage form, strength, or bioavailability. A 505(b)(2) applicant also has the flexibility to reference more than one approved product.

A 505(b)(2) applicant must provide the FDA with any additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed change(s). Consequently, although duplication of preclinical and certain clinical studies is avoided through the use a 505(b)(2) application, specific studies may be required.

Patent Term Restoration. The Hatch-Waxman Act also provides for the restoration of a portion of the patent term lost during product development and FDA review of an application. However, the maximum period of restoration cannot exceed 5 years, or restore the total remaining term of the patent to greater than 14 years from the date of FDA approval of the product. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term restoration. In the future, we may consider applying for patent term restoration for some of our currently owned or licensed patents, depending on the expected length of clinical trials and other factors involved in the filing of an NDA.

ANDA and 505(b)(2) Applicant Challenges to Patents and Generic Exclusivity. NDA and 505(b)(2) applicants are required to list with the FDA each patent that claims their approved products and for which claims of patent infringement could reasonably be asserted against unauthorized manufacturers. ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the product (s) it references. An applicant can certify that there is no listed patent, that the listed patent has expired, that the application may be approved upon the date of expiration of the listed patent, or that the patent is invalid or will not be infringed by the marketing of the applicant’s product. This last certification is referred to as a “Paragraph IV certification.”

If a Paragraph IV certification is filed, the applicant must also provide notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant’s opinion that the patent is invalid or not infringed. The NDA holder or patent owner may sue the ANDA or 505(b)(2) applicant for patent infringement. If the NDA holder or patent owner files suit within 45 days of receiving notice of the application, a one-time 30-month stay of the FDA’s ability to approve the ANDA or 505(b)(2) application is triggered. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or shortens the period because parties have failed to cooperate in expediting the litigation.

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As an incentive to encourage generic drug manufacturers to undertake the expenses associated with Paragraph IV patent litigation, the first ANDA applicant to submit a substantially complete ANDA with a Paragraph IV certification to a listed patent may be eligible for a 180-day period of marketing exclusivity. For ANDAs that use a reference product for which no Paragraph IV certification was made in any ANDA before that date, this exclusivity blocks the approval of any later ANDA with a Paragraph IV certification referencing the same product. For these ANDAs, the exclusivity period runs from the date when the generic drug is first commercially marketed.

For other ANDAs, the 180-day exclusivity period blocks the approval of any later ANDA with a Paragraph IV certification referencing at least the same patent, if not the same product, and may be triggered on the date the generic drug is first commercially marketed or the date of a decision of a court holding that the patent that was the subject of the Paragraph IV certification is invalid or not infringed. This decision must be from a court from which no appeal can be or has been taken, other than a petition to the United States Supreme Court.

If multiple generic drug manufacturers submit substantially complete ANDAs with Paragraph IV certifications on the same day, all of these manufacturers will share in a single 180-day exclusivity period. Note also that these periods of 180-day exclusivity may be subject to forfeiture provisions, requiring relinquishment of the exclusivity in some situations, including cases where commercial marketing of the generic drug does not occur within a certain time period.

Non-Patent Marketing Exclusivities. Under the Hatch-Waxman Act, newly approved drug products and changes to the conditions of use of approved products may benefit from periods of non-patent marketing exclusivity. The Hatch-Waxman Act provides five years of “new chemical entity” marketing exclusivity to the first applicant to gain approval of an NDA for a product that does not contain an active ingredient found in any other approved product. Where this exclusivity is awarded, the FDA is prohibited from accepting any ANDAs or 505(b)(2) applications during the five-year period (this period is shortened to four years for ANDAs containing Paragraph IV certifications). This exclusivity protects the entire new chemical entity franchise, including all products containing the active ingredient for any use and in any strength or dosage form. This exclusivity will not prevent the submission or approval of stand-alone NDAs, but such applicants would be required to conduct their own adequate and well-controlled clinical studies to demonstrate the safety and effectiveness of their products.

The Hatch-Waxman Act also provides three years of “new use” marketing exclusivity for the approval of NDAs, 505(b)(2) applications, and supplements, where those applications contain the results of new clinical investigations (other than bioavailability studies) essential to the FDA’s approval of the applications. Such applications may be submitted for new indications, dosage forms, strengths, or new conditions of use of already approved products. So long as the new clinical investigations are essential to the FDA’s approval of the change, this three-year exclusivity prohibits the final approval of ANDAs or 505(b)(2) applications for products with the specific changes associated with those clinical investigations. It does not prohibit the FDA from approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient.

Pediatric Exclusivity. The Modernization Act included a pediatric exclusivity provision that was reauthorized by the Best Pharmaceuticals for Children Act of 2002. Pediatric exclusivity provides an incentive to pioneer drug manufacturers for conducting research into the safety and efficacy of their products in children. Manufacturers are eligible for pediatric exclusivity when they conduct and submit the results of pediatric studies requested by the FDA. When granted, pediatric exclusivity provides an additional six months of marketing exclusivity or patent protection in the United States. The current pediatric exclusivity provision is scheduled to expire in October 2012.

Orphan Drug Designation and Exclusivity. Some jurisdictions, including the United States and the European Union, designate drugs intended for relatively small patient populations as “orphan drugs.” The FDA, for example, grants orphan drug designation to drugs intended to treat rare diseases or conditions that affect

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fewer than 200,000 individuals in the United States or drugs for which there is no reasonable expectation that the cost of developing and making the drugs available in the United States will be recovered. In the United States, orphan drug designation must be requested before submitting an application for approval of the product.

Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to a marketing exclusivity. For seven years, the FDA may not approve any other application, including NDAs, ANDAs, or 505(b)(2) applications, to market the “same drug” for the same indication. The only exception is where the second product is shown to be “clinically superior” to the product with orphan drug exclusivity, as that phrase is defined by the FDA and if there is an inadequate supply.

Foreign Regulatory Requirements

Outside the United States, our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, as described above. Under EU regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Evaluation Agency (“EMA”) leads to an approval granted by the European Commission that permits the marketing of the product throughout the European Union. The centralized procedure is mandatory for certain classes of medicinal products but is optional for others. We assume that the centralized procedure will apply to our products. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that are not required to be authorized by the centralized procedure and those products for which the centralized procedure is optional but which shall be marketed in select EU member countries only.

Under the decentralized procedure, the holder of a national marketing authorization may submit further applications to the competent authorities of the remaining member states, which will then be requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. The recognition process should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, we have the option to withdraw the application from that country or take the application to arbitration by the Committee for Proprietary Medicinal Products (“CPMP”) of the EMA. If a referral for arbitration is made, the procedure is suspended, and in the intervening time, the only EU country in which the product can be marketed will be the country where the original authorization has been granted, even if all the other designated countries are ready to recognize the product. The opinion of the CPMP, which is binding, could support or reject the objections or alternatively could reach a compromise position acceptable to all EU countries concerned. Arbitration can be avoided if the application is withdrawn in the objecting country, but once the application has been referred to arbitration, it cannot be withdrawn. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval, we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

Hazardous Materials

Our research and development processes involve the controlled use of numerous hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations, and may be subject to foreign laws and regulations, governing the use, manufacture, storage,

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handling and disposal of hazardous materials and waste products, including certain regulations promulgated by the U.S. Environmental Protection Agency, or EPA. The EPA regulations to which we are subject require that we register with the EPA as a generator of hazardous waste. Although we have safety procedures for handling and disposing of these materials, we cannot assure investors that accidental contamination or injury from these materials will not occur. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposures to blood-borne pathogens and the handling, transporting and disposing of biohazardous or radioactive materials. We do not expect the cost of complying with these laws and regulations to be material.

Competition

We face a broad range of current and potential competitors, from established global pharmaceutical companies with significant resources to development-stage companies. In addition, we face competition from academic and research institutions and government agencies for the discovery, development and commercialization of novel therapeutics to treat HBV, HCV and HIV. Many of our competitors, either alone or with their collaborative partners, have significantly greater financial, product development, technical, manufacturing, sales and marketing resources than we do. In addition, many of our direct competitors are large pharmaceutical companies with internal research and development departments that have significantly greater experience in testing pharmaceutical products, obtaining FDA and other regulatory approvals of products and achieving widespread market acceptance for those products.

We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HBV, HCV and HIV. We anticipate that we will face intense and increasing competition as new products enter the marketplace and advanced technologies become available. Our competitors' products may be safer, more effective, or more effectively marketed and sold, than any product we may commercialize. Competitive products may render one or more of our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. It is also possible that the development of a cure, effective vaccine, or new treatment methods for HBV, HCV and HIV could render one or more of our product candidates non-competitive or obsolete or reduce the demand for our product candidates.

We believe that our ability to compete depends, in part, upon our ability to develop products, complete the clinical trials and regulatory approval processes, and effectively market any products we develop. Further, we need to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary product candidates or processes and secure sufficient capital resources for the substantial time period between the discovery of lead compounds and their commercial sales, if any.

HBV Therapeutics Competition

In the United States, the current standard of care for the treatment of HBV infection is monotherapy with one of four nucleoside analog drugs, or one of two alpha interferon protein therapies, as listed in the following table.

FDA-Approved Therapies for the Treatment of HBV

Brand Name	Chemical Name	Chemical Name Abbreviation	Drug Class	Company
Epivir-HBV	lamivudine	3TC	nucleoside analog	GlaxoSmithKline
Hepsera	adefovir	ADV	nucleotide analog	Gilead Sciences
Baraclude	entecavir	ETV	nucleoside analog	Bristol-Myers Squibb
Tyzeka	telbivudine	LdT	nucleoside analog	Novartis
Intron-A	interferon alfa-2b	IFN	interferon	Schering Plough
Pegasys	peginterferon alfa-2a	PEG IFN	interferon	Roche

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As of September 2007, Hepsera represented approximately 48% of approved HBV nucleoside prescriptions, while Baraclude, Epivir-HBV and Tyzeka represented approximately 28%, 20% and 3% of approved HBV nucleoside prescriptions, respectively. From March 2000 through September 2007, the total prescriptions for approved HBV nucleosides grew at a compound annual growth rate, or CAGR, of approximately 40%. Gilead Sciences has a drug candidate for the treatment of HBV named Viread that recently completed Phase 3 clinical trials and during October 2007, Gilead filed marketing applications for Viread in the United States and Europe.

Although a safe and effective vaccine against HBV has been available for decades, it only benefits those not yet infected with this virus. We believe that additional drugs will become available in the future for the treatment of HBV, considering the major medical need for therapy. We also believe that the introduction of new HBV therapeutics will expand the current market and increase the likelihood of combination therapy for HBV. Our HBV product candidate may compete directly or be used in combination with the current standard of care, with the drug candidates that are currently in development, and with those that may be developed in the future. As a result of its mechanism of action, we believe that clevudine may be complementary to some existing HBV treatments and could therefore be used as either a single agent or in combination with existing therapies.

In March 2007, we engaged MEDACorp to conduct a survey to assess the current market for HBV therapies and opportunities for new HBV therapies, including clevudine. In this market study, 99 U.S. physicians participated, and they represent the medical specialties of gastroenterology, hepatology, infectious disease and primary care. The physicians surveyed reported currently managing an average of approximately 80 HBV patients, an average increase of more than 30% in their HBV patient volume as compared to the previous year. These physicians reported prescribing, on average, oral nucleoside HBV therapies for 80% of all their HBV patients and 50% of their treatment-naïve HBV patients. Additionally, a majority of the physicians surveyed indicated that achieving sustained undetectable levels of HBV DNA off-treatment, or SVR, is the most important factor for them in making treatment decisions, while maintaining undetectable levels of HBV DNA on-treatment is the second most important factor for them in making treatment decisions.

The physicians surveyed were asked to consider hypothetical patient scenarios and describe their related prescribing patterns for HBV therapies. There were a number of important trends that emerged from this portion of the market survey. For example, 97% of physicians surveyed indicated that SVR is a meaningful measure of efficacy and will likely be an important criterion in the future development of novel HBV therapies and the survey results indicated that oral HBV therapies with higher SVR rates were selected more often for HBV therapeutic utilization. This marketing study was based on a small survey sample size and the results may have been different if a larger survey were conducted. Also, clevudine has not completed long-term clinical studies to quantify its SVR rate and we cannot assure you that clevudine will have the efficacy profile that doctors surveyed indicated was important.

HCV Therapeutics Competition

In the United States, the current standard of care for the treatment of HCV is a combination of alpha interferon and a nucleoside analog named ribavirin. Alpha interferon is approved in several chemically modified forms and is marketed by Roche, Schering-Plough, Valeant Pharmaceuticals International, and InterMune, Inc. Roche, Schering-Plough, and several generic manufacturers market ribavirin. We are aware that Roche and other companies are also developing new drugs for the treatment of HCV. For example, Novartis, Vertex, Anadys, Human Genome Science, Migenix Inc., Rigel Pharmaceuticals, Inc. and ViroPharma have advanced their drug candidates into Phase 2 clinical trials.

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The following table presents information about approved drugs and drug candidates for the treatment of HCV.

FDA-Approved HCV Therapeutics or HCV Therapeutics in Development

Brand Name	Chemical Name or Abbreviation	Drug Class	Phase of Development	Company
Pegasys plus Copegus	peginterferon alfa-2a + ribavirin	Interferon	Approved	Roche
Peg-Intron plus Rebetol	peginterferon alfa-2b + ribavirin	Interferon	Approved	Schering-Plough
Infergen	interferon alfacon-1	Interferon	Approved	Valeant
Albuferon	interferon alfa-2b R1626	Interferon	Phase 3	Human Genome Sciences/ Novartis
	Valopicitabine (NM283)	Nucleoside Polymerase Inhibitor	Phase 2	Roche
	R7128	Nucleoside Polymerase Inhibitor	Phase 2	Novartis
	HCV-796	Nucleoside Polymerase Inhibitor	Phase 1	Pharmasset/Roche
	GS-9190	Non-nucleoside Polymerase Inhibitor	Phase 2	Viropharma/Wyeth
	Telaprevir (VX-950)	Non-nucleoside Polymerase Inhibitor	Phase 1	Gilead
	Bocepravir R7227 (ITMN-191)	Protease Inhibitor	Phase 2	Vertex/ Johnson & Johnson
		Protease Inhibitor	Phase 2	Schering-Plough
		Protease Inhibitor	Phase 1	InterMune/Roche

HIV Therapeutics Competition

HAART, the standard of care for the treatment of HIV infection, generally includes two NRTIs combined with a third drug from another class (either an NNRTI or a protease inhibitor). Racivir and DFC are NRTIs and, therefore, our primary competitors are those companies that develop and market other NRTIs.

There are nine NRTIs approved by the FDA for the treatment of HIV infection, as shown in the table below.

FDA-Approved NRTIs for the Treatment of HIV

Brand Name	Generic Name	Chemical Name Abbreviation	Analog Type	Company
Epivir	lamivudine	3TC	cytidine	GlaxoSmithKline
Emtriva	emtricitabine	FTC	cytidine	Gilead Sciences
Retrovir	zidovudine	AZT	thymidine	GlaxoSmithKline
Zerit	stavudine	d4T	thymidine	Bristol-Myers Squibb
Viread	tenofovir	TDF	adenosine	Gilead Sciences
Videx/Videx EC	didanosine	ddI	adenosine	Bristol-Myers Squibb
Ziagen	abacavir	ABC	guanosine	GlaxoSmithKline
Hivid	zalcitabine	ddC	cytidine	Roche

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To provide additional convenience to HIV patients, companies have developed combination therapies that combine two or more NRTIs into a single tablet or capsule. These fixed-dose combination therapies have become leaders in the HIV marketplace. The following table presents information about these combination therapies.

FDA-Approved NRTI Combination Products

Brand Name	Component Generic Name	Chemical Name Abbreviation	Component Analog Type	Company
Combivir	lamivudine	3TC	cytidine	GlaxoSmithKline
	zidovudine	AZT	thymidine	
Truvada	emtricitabine	FTC	cytidine	Gilead Sciences
	tenofovir	TDF	adenosine	
Atripla	emtricitabine	FTC	cytidine	Gilead Sciences/ Bristol Myers Squibb
	tenofovir	TDF	adenosine	
Epzicom	efavirenz	EFV	NNRTI	GlaxoSmithKline
	lamivudine	3TC	cytidine	
Trizivir	abacavir	ABC	guanosine	GlaxoSmithKline
	lamivudine	3TC	cytidine	
	abacavir	ABC	guanosine	
	zidovudine	AZT	thymidine	

Several of the FDA-approved individual NRTIs and combination products face patent expiration in the next several years. As a result, generic versions of these drugs may become available. We expect to face competition from these generic drugs, including price-based competition.

Other classes of HIV therapeutics include NNRTIs, PIs, integrase inhibitors, and entry or fusion inhibitors. Although NNRTIs and PIs are often complementary to NRTIs, there are certain protease-based regimes that are competitors to NRTIs. There are three NNRTIs and ten PIs approved by the FDA. Entry inhibitors have a unique mechanism of action, but are often used only to treat individuals who have failed other treatment options because they are administered by injection. There is one fusion inhibitor, one entry inhibitor and one integrase inhibitor approved by the FDA.

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The following table presents information about these other classes of HIV therapeutics.

FDA-Approved NNRTIs, PIs, Integrase Inhibitor, and Entry Inhibitors for the Treatment of HIV

Brand Name	Generic Name	Chemical Abbreviation	Drug Class	Company
Rescriptor	delavirdine	DLV	NNRTI	Pfizer
Sustiva	efavirenz	EFV	NNRTI	Bristol Myers-Squibb
Viramune	nevirapine	NVP	NNRTI	Boehringer Ingelheim
Agenerase	amprenavir	APV	PI	GlaxoSmithKline
Aptivus	tipranavir	TPV	PI	Boehringer Ingelheim
Crixivan	indinavir	IDV	PI	Merck
Invirase	saquinavir mesylate	SQV	PI	Hoffmann-La Roche
Kaletra	lopinavir and ritonavir	LPV/RTV	PI	Abbott Laboratories
Lexiva	fosamprenavir calcium	FOS-APV	PI	GlaxoSmithKline
Norvir	ritonavir	RTV	PI	Abbott Laboratories
Prezista	darunavir	TMC114	PI	Tibotec, Inc.
Reyataz	atazanavir sulfate	ATV	PI	Bristol-Myers Squibb
Viracept	nelfinavir mesylate	NFV	PI	Agouron Pharmaceuticals
Fuzeon	enfuvirtide	T-20	Fusion Inhibitor	Hoffmann-La Roche & Trimeris
Selzentry	maraviroc	UK-427857	Entry Inhibitor	Pfizer
Isentress	raltegravir	MK-0518	Integrase Inhibitor	Merck

We are aware that many other companies are developing compounds targeting HIV, including pharmaceutical companies such as Pfizer Inc., Merck & Co., Inc., GlaxoSmithKline plc, Bristol-Myers Squibb Co., Schering-Plough Corp., Johnson & Johnson and biotechnology companies such as Gilead Sciences, Inc., Panacos Pharmaceuticals, Inc., Tibotec Pharmaceuticals Limited, Incyte Corporation, Avexa Limited and Achillion Pharmaceuticals, Inc. We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HIV. These drug candidates include NRTIs as well as drugs that block HIV protein functions and interactions, including integrase and maturation inhibitors. We are aware that Merck and other companies are pursuing the development of a prophylactic vaccine, which is a vaccine that prevents infections. If a prophylactic vaccine is successful, it could reduce the size of the market for our products.

Intellectual Property

Our policy is to pursue patents and to otherwise endeavor to defend our technologies, inventions, and improvements to inventions that are commercially important to the development of our business. We seek U.S. and international patent protection on the novel compounds, product candidates, and therapeutic processes we discover or improve, as well as the chemical synthesis and manufacturing of such compounds and product candidates. As of September 30, 2007, we hold or have licensed 678 issued patents and pending patent applications directed to our technologies, including recently discovered product candidates. As of September 30, 2007, our owned patent portfolio includes 9 issued U.S. patents, 21 issued foreign patents, 21 U.S. applications and 223 foreign applications, while our in-licensed patent portfolio includes 49 issued U.S. patents, 260 issued foreign patents, 8 U.S. applications and 87 foreign applications.

We have an exclusive sublicense in North, Central and South America, Europe, the Caribbean and Israel from Bukwang to issued U.S. and corresponding foreign patents covering the composition of matter, methods of using clevudine to treat HBV and synthetic processes for clevudine, which expire between 2014 and 2022. Bukwang is the primary licensee from Yale University and the University of Georgia Research Foundation, Inc.,

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who are the primary licensors that jointly own the intellectual property for this technology. Our sublicense with Bukwang also encompasses nonexclusive rights in the aforementioned territories to pending patents in the U.S. and certain foreign countries covering the use of clevudine in combination with other therapeutics for the treatment of HBV. Any patent issuing from these patent applications would expire no earlier than 2023.

On December 8, 1998, Emory University granted us an exclusive, worldwide license pursuant to the Racivir License Agreement to issued U.S. patents covering the composition of matter, methods of synthesizing Racivir and methods of using Racivir to treat HIV and HBV, which expire between 2010 and 2020. This license also encompasses rights to corresponding patents and pending patent applications in Europe, Japan, South Africa and other foreign countries.

In the Emory/Gilead License Agreement, Emory University previously had granted a right of first refusal to Gilead that is applicable to any license or assignment relating to enriched FTC (which includes Racivir). The terms of this right of first refusal contains an exception permitting Emory University to license or assign its rights in respect of enriched FTC to a permitted transferee, which includes any of the inventors (which included two of our founders) or to any corporate entity formed by or on behalf of the inventors for purposes of clinically developing enriched FTC so long as the licensee agrees in writing to be bound by the terms of Gilead's right of first refusal to the same extent as Emory University. Our license to Racivir was granted to us by Emory University pursuant to this exception and therefore we are bound by the terms of Gilead's right of first refusal to the same extent as Emory University. The terms of this right of first refusal as set forth in the Emory/Gilead License Agreement require that, prior to the entry into any license or assignment agreement with a third party relating to any of Emory University's rights in respect of enriched FTC, Emory University shall notify Gilead of the terms of the proposed agreement and provide a copy of the proposed agreement to Gilead together with all data and information in Emory University's possession relating to enriched FTC and its use as a therapeutic agent. Gilead has 30 days to accept or decline the offer. Although Emory University considers us to be a permitted transferee under the Emory/Gilead License Agreement, Emory University has subsequently taken the position that its grant of commercialization rights (i.e., the rights to offer for sale and sell Racivir) to us exceeded the rights that were permitted to be granted to a permitted transferee under its agreement with Gilead. While we believe that Gilead is aware of the Racivir license agreement through both our and Emory University's communications with Gilead, Gilead has not contacted us regarding its interpretation of the terms of the Racivir License Agreement.

In March 2004, we entered into a supplemental agreement with Emory University in which we and Emory University agreed that, prior to any commercialization of enriched FTC by us, or by any licensee or assignee of our rights under the Racivir License Agreement, we and Emory University would adhere strictly to the terms of the right of first refusal granted to Gilead in the Emory/Gilead License Agreement and offer to Gilead the same terms and conditions under which we, our licensee or our assignee, propose to commercialize enriched FTC. The supplemental agreement also outlines a procedure by which Emory University and we would jointly offer the terms of a proposed license and commercialization agreement between us and a third party to Gilead after Emory University has the opportunity to approve them. Therefore, before we could enter into a commercialization agreement for Racivir with a third party or commercialize Racivir on our own, we would be required to offer Gilead the opportunity to be our commercialization partner on the same terms on which we intend, or our prospective partner intends, to commercialize Racivir. It is uncertain whether a third party would be willing to negotiate the terms of a commercialization agreement with us knowing that Gilead can take their place as licensee by accepting the negotiated terms and exercising its right of first refusal.

These uncertainties related to our commercialization rights may result in us being prevented from obtaining the expected economic benefits from developing Racivir. In addition, we could become involved in litigation or arbitration related to our commercialization rights to Racivir in the future.

We own pending U.S. and foreign patent applications directed to the PSI-6130 chemical compound, pro-drugs (including R7128), pharmaceutical formulations, therapeutic combinations and use to treat HCV infections. Any patent issuing from these patent applications would expire no earlier than 2024. We own pending

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U.S. and foreign patent applications directed to the synthesis of PSI-6130 chemical compound, including synthetic intermediates thereof. To date, no patents have issued from these applications. Any patent issuing from these patent applications would expire no later than 2025. To date, no patents have issued from these applications.

We have an exclusive, worldwide license from Emory University to issued U.S. patents covering a formulation of DFC in combination with other antiviral nucleoside analogs and methods of using DFC to treat HIV infection, which expire in 2015. This license also encompasses rights to corresponding patents and pending patent applications in Europe, Japan, South Africa and other foreign countries, which will expire in 2016. In addition, we own pending U.S. patent applications and corresponding foreign patent applications that cover methods of synthesizing DFC and its related compounds and pharmaceutical formulations of DFC. Any patent issuing from these patent applications would expire no earlier than 2022 and 2024, respectively.

The patent expiration dates stated above do not take into account any patent term adjustments that may accrue due to procedural delays by the United States Patent and Trademark Office or patent term extensions that may accrue due to regulatory delays.

Attempts to obtain patent protection both in the United States and abroad can be expensive, take years to complete, and may not be successful. In addition, issued patents are subject to attack, may not be enforceable, and may otherwise fail to protect our business. Moreover, the trade secret laws and other sources of intellectual property protection may also be insufficient to protect our product candidates. For more information on these and other risks related to intellectual property rights, see “Risk Factors—Risks Related to Our Intellectual Property.”

Employees

As of September 30, 2007, we had 36 employees, 22 of whom performed research and development functions. Approximately 78% of our employees hold advanced degrees. We plan to add additional employees as we expand our business.

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ITEM 1A. RISK FACTORS

Risks Related to Our Business

Risks Related to Drug Discovery, Development and Commercialization

We are subject to significant regulatory requirements, which could delay, prevent or limit our ability to market our product candidates, including clevudine, Racivir, R7128 and DFC.

Our research and development activities, preclinical studies, clinical trials, manufacturing and the anticipated marketing of our product candidates are subject to extensive regulation by a wide range of governmental authorities in the United States, including the FDA and by comparable authorities in Europe and elsewhere. To date, none of our product candidates has been approved for sale by the FDA or any foreign regulatory authority except clevudine, for which Bukwang has received marketing approval in Korea. Neither we nor our collaborators, independently or collectively, will be able to commercialize any of our product candidates until we or they obtain FDA approval in the United States or approval by comparable regulatory agencies in Europe or other countries. To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must, among other requirements, demonstrate in adequate and well-controlled clinical trials that our product candidates are safe and effective. We, IRBs, the FDA or applicable foreign regulatory authorities could suspend the clinical trials of a drug candidate at any time if there is a concern that the patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons. Adverse side effects of a product candidate on patients in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve a particular drug candidate for any and all indications of use.

We have conducted initial preclinical studies and early-stage clinical trials of Racivir, PSI-6130, R7128 and DFC. These trials were not primarily designed to demonstrate the efficacy of Racivir, PSI-6130, R7128 or DFC as therapeutic agents, but rather to collect data on safety and assist in determining the appropriate dose. Even if our product candidates achieve positive results in preclinical and early clinical trials, similar results may not be observed in subsequent trials and results may not prove to be statistically significant or demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies.

The FDA also regulates the manufacturing facilities of our third-party manufacturers. Prior to approval, the FDA inspects manufacturing facilities to ensure compliance with cGMP, including quality control and record-keeping measures. Post-approval, the FDA and certain state agencies subject these facilities to unannounced inspections to ensure continued compliance with cGMP. Failure to satisfy the pre-approval inspection or subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in an inability to receive approval, recall of products, delay in approval or restrictions on the product or on the manufacturing post-approval, including a withdrawal of the drug from the market or suspension of manufacturing.

We will also require foreign regulatory approval with respect to the sale of our products outside of the United States. Foreign regulatory approval processes include all of the risks associated with the FDA approval processes described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not assure approval by foreign regulatory authorities, and the fact that clevudine has been approved by Korean regulatory authorities does not mean that the FDA will approve clevudine. Many foreign regulatory authorities have different approval standards from those required by the FDA and may impose additional testing requirements for our product candidates. Furthermore, international ethical review boards may cause the start dates of our clinical trials to be delayed pending their review of safety data, clinical procedures, and comments provided by foreign regulatory authorities. We have had limited interaction with foreign regulatory authorities. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for foreign regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

The regulatory approval process is expensive, and the time required to complete clinical trials and for FDA and foreign regulatory approval processes is uncertain and typically takes many years. Our analysis of data

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obtained from our preclinical and clinical trials is subject to confirmation and interpretation by different regulatory authorities who may have different views on the design, scope or results of our clinical trials, which could delay, limit or prevent regulatory approval. Changes in the regulatory approval policy during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval. We could also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA or foreign regulatory policies during the period of product development, clinical trials or regulatory review.

As a result of the foregoing factors, our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot assure you that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability. Regulatory approval, if obtained, may be made subject to limitations on the distribution of and indicated uses for which we may market a product, which could limit the size of the market for a product and adversely affect our potential product revenues.

Our product candidates must undergo rigorous clinical trials, the results of which are uncertain and could substantially delay or prevent us from bringing drugs to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical trials in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new product candidates sufficient to obtain regulatory marketing approval are complex and expensive and take years to complete. In addition, the results obtained in earlier-stage testing may not be indicative of results in future trials. For example, estimates of viral load reduction and activity against HBV, HCV and HIV obtained from preclinical studies and small-scale clinical trials are not necessarily indicative of results that could be achieved in larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier preclinical studies and clinical trials. We cannot assure you that we or our collaborators will successfully complete the planned clinical trials. Our collaborators or we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following events:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical studies or to abandon development programs;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- we, IRBs, or regulators, may suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use.

We have limited experience in conducting clinical trials which could impair our timing or ability to obtain regulatory approval for our product candidates.

We have limited experience in conducting and managing the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. Our past clinical experience has been limited to a small number of drug candidates relating to a limited number of therapeutic areas. By contrast, large and established

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pharmaceutical companies often have staffs conducting clinical trials with multiple drug candidates across multiple indications. As a result, we may experience delays in obtaining regulatory approvals, if at all, for our product candidates for which we conduct or manage the clinical trial process.

Delays in clinical trials could result in increased costs to us and delay our ability to obtain regulatory approval and commercialize our product candidates.

Significant delays in clinical trials could materially affect our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an IRB to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA's Good Clinical Practices;
- unforeseen safety issues;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations or meet expected deadlines; and
- determination by regulators that the clinical design of the trials is not adequate.

Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.

We have experienced, and expect to experience in the future, delays in patient enrollment in our clinical trials for a variety of reasons. The completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's therapeutic endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- competition for patients by clinical trial programs for other treatments.

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Our clinical trials compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and such competition reduces the number and types of patients available to us, because some patients who might have opted to enroll in our trials instead opt to enroll in a trial being conducted by one of our competitors. We conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which reduces the number of patients that are available for our clinical trials in such clinical trial site. Delays in patient enrollment in the future as a result of these and other factors may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent us from completing these trials and adversely affect our ability to advance the development of our product candidates.

For example, in our Phase 2 study of Racivir, we anticipated that enrollment would take less than one year to complete, but it actually took 20 months. The primary reasons for this unexpected delay in enrollment included competition for patients with other longer-term clinical studies, larger investigator budgets and greater payments to study subjects for other clinical trials, very specific patient enrollment criteria for our clinical study, and protocol modifications that were required to increase the duration of treatment. As a result of these delays, it took us longer to complete this study than we had initially planned, and we had to commit human and financial resources to this project for an extended period that could have otherwise been allocated to other research programs.

Our product candidates may have undesirable side effects when used alone or in combination with other products that prevent their regulatory approval or limit their use if approved.

We must demonstrate the safety of our product candidates to obtain regulatory approval. Although in clinical trials to date, clevudine, Racivir, PSI-6130 and R7128 were generally well tolerated, these trials involved a small number of patients and we may observe significant adverse events for these product candidates in the future. With respect to DFC, on April 3, 2006, Incyte announced its decision to discontinue its development of DFC after observing an increased incidence of grade 4 hyperlipasemia in the rollover portion of a Phase 2b clinical trial. Any side effects associated with our product candidates may outweigh the benefits of our product candidates and prevent regulatory approval or limit their market acceptance if they are approved. Recent developments in the pharmaceutical industry have prompted heightened government awareness of safety reporting and pharmacovigilance. Global health authorities may impose regulatory requirements to monitor safety that may burden our ability to commercialize our drug products.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates, which would negatively affect our ability to achieve profitability.

If approved for marketing, the commercial success of our product candidates will depend upon their acceptance by physicians and the medical community, patients, and private, government and third-party payors as clinically useful, safe and cost-effective therapeutics. The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the indication for which the product is approved, as well as its approved labeling;
- the establishment and demonstration in the medical community of the safety and efficacy of the product;
- the prevalence and severity of adverse side effects;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- sufficient third-party reimbursement.

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We are aware that a significant number of drug candidates are currently under development and may become available in the future for the treatment of HIV, HBV and HCV, and may be approved prior to any of our drugs coming to market. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new therapeutics are introduced that are more favorably received than our products or that render our products obsolete, or if unacceptable levels of drug resistance or significant adverse events occur. If our products do not achieve and maintain market acceptance, we will not be able to generate sufficient revenue from product sales to attain profitability.

Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and foreign regulations, we could lose our marketing approvals and our business would be seriously harmed.

Following initial regulatory approval of any drugs we or our collaborators may develop, we and our collaborators will be subject to continuing regulatory review by the FDA or other regulatory authorities, including the review of adverse drug events and clinical results that are reported after product candidates become commercially available. This would include results from any post-marketing follow-up studies or other reporting required as a condition to approval. The manufacturing, distribution, labeling, packaging, storage, advertising, promotion, reporting and record-keeping related to the product will also be subject to extensive ongoing regulatory requirements. In addition, incidents of adverse drug reactions, unintended side effects or misuse relating to our products could result in additional regulatory controls or restrictions, or even lead to withdrawal of a product from the market.

Furthermore, our third-party manufacturers and the manufacturing facilities that they use to make our product candidates are regulated by the FDA. Quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug and biologics manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA, state and/or other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product, or on the manufacturing or laboratory facility, including a withdrawal of the drug from the market or suspension of manufacturing. In addition, any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information. If we, our collaborators or our third-party manufacturers fail to comply with applicable continuing regulatory requirements, our business could be seriously harmed because a regulatory agency may:

- issue warning letters;
- suspend or withdraw our regulatory approval for approved products;
- seize or detain products or recommend a product recall;
- refuse to approve pending applications or supplements to approved applications filed by us;
- suspend any of our ongoing clinical trials;
- impose restrictions on our operations, including costly new manufacturing requirements;
- close the facilities of our contract manufacturers; or
- impose civil or criminal penalties.

The FDA's policies may change and additional federal, state, local or foreign governmental regulations may be enacted that could affect our ability to maintain compliance. We cannot predict the likelihood, nature, or extent of adverse governmental regulation that may arise from future legislation or administrative action, either in the United States or abroad.

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Our research and development efforts may not result in additional product candidates being discovered, which could limit our ability to generate revenues in the future.

Our research and development efforts may not lead to the discovery of any additional product candidates that would be suitable for further preclinical or clinical development. The discovery of additional product candidates requires significant research and preclinical studies, as well as a substantial commitment of resources. Many lead compounds that appear promising in preclinical studies fail to progress to become product candidates in clinical trials. There is a great deal of uncertainty inherent in our research and development efforts and, as a consequence, in our ability to fill our drug development pipeline with promising additional product candidates.

We have no sales, marketing or distribution experience. We expect to develop these capabilities, and expect to invest significant amounts of financial and management resources.

If clevudine receives marketing approval in the United States, we intend to commercialize clevudine ourselves with a sales force of approximately 40 to 45 employees. To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources. As a result, we could face a number of risks, including:

- we may not be able to attract and build a significant marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

We and our collaborators will be subject to stringent federal, state and foreign regulation of sales and marketing of any approved drug candidate and a failure to comply with these regulations could result in substantial penalties.

The marketing and advertising of our drug products by our collaborators or us will be regulated by the FDA, certain state agencies or foreign regulatory authorities. Violations of these laws and regulations, including promotion of our products for unapproved uses or failing to disclose risk information, are punishable by criminal and civil sanctions and may result in the issuance of enforcement letters or other enforcement action by the FDA, Department of Justice, state agencies, or foreign regulatory authorities that could jeopardize our ability to market the product.

In addition to FDA, state or foreign regulations, the marketing of our drug products by us or our collaborators will be regulated by federal, state or foreign laws pertaining to health care “fraud and abuse,” such as the federal anti-kickback law prohibiting bribes, kickbacks or other remuneration for the order or recommendation of items or services reimbursed by federal health care programs. Many states have similar laws applicable to items or services reimbursed by commercial insurers. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including the Medicare, Medicaid and Veterans Affairs healthcare programs. Because of the far-reaching nature of these laws, we may be required to discontinue one or more of our practices to be in compliance with these laws. Health care fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against us for violations of these laws, even if we successfully defend against it, could have a material adverse effect on our business, financial condition and results of operations.

We could also become subject to false claims litigation under federal statutes, which can lead to civil money penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state health care programs. These false claims statutes include the False Claims Act, which allows any person to bring a suit on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other

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violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against pharmaceutical companies have increased significantly in volume and breadth in recent years. Some of these suits have been brought on the basis of certain sales practices promoting drug products for unapproved uses. This new growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay fines or restitution, or be excluded from the Medicare, Medicaid, Veterans Affairs and other federal and state healthcare programs as a result of an investigation arising out of such action. We may become subject to such litigation and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Financial Performance and Business Operations

We have incurred net losses since our inception and our future profitability is uncertain and we anticipate that we will incur significant continued net losses for the next several years.

We are a clinical-stage pharmaceutical company with a limited operating history upon which an investor can evaluate our operations and future prospects. We have incurred net losses in each year since our inception in 1998. For the years ended September 30, 2007 and 2006 and for the nine months ended September 30, 2005, we had net losses of \$5.1 million, \$11.3 million, and \$13.7 million, respectively. As of September 30, 2007, we had an accumulated deficit of \$57.1 million. We do not expect to generate significant revenue from our product candidates for the next several years and we expect to continue to incur significant operating losses in future periods. We expect to incur substantial costs to further our drug discovery and development programs and that our rate of spending will accelerate as a result of the increased costs and expenses associated with preclinical and clinical development of clevidine, Racivir, R7128 and DFC, particularly our Phase 3 clinical trials for clevidine. In addition, as we expand our operations, we will need to continue to improve our facilities and hire additional personnel. As a result, we expect that our annual operating losses will increase significantly over the next several years.

Our revenue and profit potential is unproven, and our limited operating history makes our future operating results difficult to predict. To attain profitability, we and our collaborators will need to successfully develop products and effectively market and sell them. We have never generated revenue from the sale of products, and there is no guarantee that we will be able to do so in the future. If any of our drug candidates fail to show positive results in ongoing clinical trials, and we or our collaborators do not receive regulatory approval, or if our product candidates do not achieve market acceptance even if approved, we may never become profitable. If we fail to become profitable, or if we are unable to continue to fund our continuing losses, we may be unable to continue our clinical development programs, and you could lose your entire investment.

We will require substantial funds in the future and we may be unable to raise capital when needed, which could force us to delay, reduce or eliminate some of our drug discovery, product development and commercialization activities.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash resources as of September 30, 2007, together with available borrowings under our venture loan and security agreement and anticipated payments under our existing collaboration agreement, will be sufficient to fund our projected cash requirements for the next 18 months, we will require significant additional financing in the future to fund our operations. Such financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;

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- the costs and timing of obtaining regulatory approval of our product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the amount of revenues we receive under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses; and
- any costs that we may incur under current and future licensing arrangements relating to our product candidates.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. Additional financing may not be available when we need it or, if available, may not be on terms that are favorable to us. If we are unable to obtain adequate funding on a timely basis, we may be required to delay, reduce the scope of, or eliminate one or more of our drug discovery or development programs.

Raising additional capital may dilute our stockholders' equity and may limit our flexibility, or require us to relinquish rights.

We may need to raise additional capital to fund our operations through public or private equity offerings or debt financings. To the extent that we raise additional capital by issuing equity or equity-linked securities, our stockholders' ownership will be diluted. Any debt financing we enter into may include covenants that limit our flexibility in conducting our business. We also could be required to seek funds through arrangements with collaborators or others, which might require us to relinquish valuable rights to our intellectual property or product candidates that we would have otherwise retained.

Our success depends in part on our ability to retain and recruit key personnel, and if we fail to do so, it may be more difficult for us to successfully develop our products or achieve our business objectives.

Our success depends in part on our ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent on our senior management and scientific staff, particularly P. Schaefer Price, our President and Chief Executive Officer and Kurt Leutzinger, our Chief Financial Officer. We do not maintain key man insurance for our senior management or scientific staff. The loss of the services of any of our senior management or key members of our scientific staff may significantly delay or prevent the successful completion of our clinical trials or the commercialization of our product candidates. To date, we are not aware that any member of our senior management or scientific staff plans to leave the company.

The employment of each of our employees with us is "at will," and each employee can terminate his or her employment with us at any time. We currently have an employment agreement in place with P. Schaefer Price.

Our success will also depend on our ability to hire and retain additional qualified scientific and management personnel. Competition for qualified individuals in the pharmaceutical field is intense, and we face competition from numerous pharmaceutical and biotechnology companies, universities and other research institutions. We

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may be unable to attract and retain qualified individuals on acceptable terms given the competition for such personnel. For example, we encountered delays in hiring a Chief Medical Officer, since there were only a small number of qualified candidates and many of our competitors had the same or similar needs as we. Furthermore, there is a possibility that a qualified candidate we are recruiting might opt to accept a position with one of our competitors instead of with us because our competitor may have products that are already on the market and generating revenue. If we are unsuccessful in our recruiting efforts, we may be unable to execute our strategy.

The requirements of being a public company may strain our administrative and operational infrastructure and will increase our operating costs.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 and the listing requirements of the NASDAQ Stock Market LLC. Section 404 of the Sarbanes-Oxley Act requires that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our auditors to assess the effectiveness of our internal control over financial reporting beginning with our fiscal year ending on September 30, 2008. In order to comply with Section 404, we will need to incur substantial accounting expenses and expend significant management efforts.

The obligations of being a public company require significant additional expenditures and place additional demands on our management, administrative, operational, internal audit and accounting resources as we comply with the reporting requirements of a public company. If we are unable to accomplish our objectives in a timely and effective manner, our ability to comply with the rules that apply to public companies could be impaired. We will also need to upgrade our systems, implement additional financial and management controls, reporting systems and procedures, implement an internal audit function, and hire additional accounting, audit and financial staff with appropriate public company experience and technical accounting knowledge, which will increase our general and administrative expenses and capital expenditures. The rules and any related regulations that may be proposed in the future that are applicable to public companies may make it more difficult and more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher premiums to obtain the same or similar coverage. We cannot predict or estimate the amount or timing of the additional costs we may incur as a result of the reporting requirements applicable to public companies, but we expect our operating results will be adversely affected by the costs of operating as a public company.

We will need to increase the size of our organization, and we may encounter difficulties managing our growth.

As of September 30, 2007, we had 36 employees, 22 of whom perform research and development functions. We plan to hire a significant number of additional employees in the future. For example, we expect to hire 30 to 40 employees in the next year and plan to hire several additional employees as required in the future to add depth and specialized expertise to our scientific and management team. We expect that this substantial growth will place a strain on our administrative and operational infrastructure. If the product candidates that we are developing continue to advance in clinical trials, we will need to expand our development, regulatory, manufacturing, quality, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to develop additional relationships with various collaborators, contract research organizations, suppliers, manufacturers and other organizations. We may not be able to establish such relationships or may incur significant costs to do so. Our ability to manage our growth will also require us to continue to improve our operational, financial and management controls, reporting systems and procedures, which will further increase our operating costs. If we are unable to successfully manage the expansion of our operations or operate on a larger scale, we will not achieve our strategic objectives.

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Our debt obligations include covenants which may adversely affect us.

On September 30, 2007, we entered into a Venture Loan and Security Agreement (“Loan Agreement”) with a lender that allows us to borrow up to \$30.0 million in \$10.0 million increments. We agreed that in the event our market capitalization is below \$90.0 million for 15 consecutive days in which the principal market for our common stock is open for trading to the public, we will be required to repay 50% of the then outstanding principal balance of the loans. We further agreed that in the event our market capitalization is below \$40.0 million for 15 consecutive days in which the principal market for our common stock is open for trading to the public, we will be required to repay all of the then outstanding principal balance of the loans. In addition, all of our assets other than our intellectual property secure the loans. There is a risk that the lender could obtain rights to the secured assets in the event we default on our obligations under the Loan Agreement.

The Loan Agreement also contains covenants that, among other things, require us to obtain consent from the lender prior to paying dividends, making certain investments, changing the nature of our business, assuming or guaranteeing the indebtedness of another entity or individual, selling or otherwise disposing of a substantial portion of our assets, or merging or consolidating with another entity.

A breach of any of the covenants in the Loan Agreement could result in a default under that agreement. Upon the occurrence of an event of default, the lender could elect to declare all amounts outstanding under the Loan Agreement to be immediately due and payable, and terminate all commitments to extend further credit.

Changes in foreign currency exchange rates could result in increased costs.

We have entered into some agreements denominated, wholly or partly, in foreign currencies, and, in the future, we may enter into additional, agreements denominated in foreign currencies. If the values of these currencies increase against the United States dollar, our costs would increase. To date, we have not entered into any contracts to reduce the risk of fluctuations in currency exchange rates. In the future, depending upon the amounts payable under any such agreements, we may enter into forward foreign exchange contracts to reduce the risk of unpredictable changes in these costs. However, due to the variability of timing and amount of payments under any such agreements, foreign exchange contracts may not mitigate the potential adverse impact on our financial results.

Risks Related to Our Dependence on Third Parties

We have licensed PSI-6130 and its pro-drugs, including R7128, to Roche, and we will depend on Roche to continue its development and commercialization.

We are developing R7128 under a collaborative licensing agreement that we entered into with Roche in October 2004. We are dependent on Roche to continue the development of R7128 and successfully commercialize it. Roche may terminate its agreement with us without cause on six months’ notice. If Roche fails to aggressively pursue the development and marketing approval of R7128, or if a dispute arises with Roche over the terms or the interpretation of the collaboration agreement or an alleged breach of any provision of the agreement, or if Roche terminates its agreement, then the development and commercialization of R7128, or our ability to receive the expected payments under this agreement, could be delayed or adversely affected.

Roche is subject to many of the same development and commercialization risks to which we are subject. If Roche decides to devote resources to alternative products, either on its own or in collaboration with other pharmaceutical companies, Roche may not devote sufficient resources to the development of R7128. Further, if Roche decides to pursue additional therapies for HCV, future sales of R7128 could be adversely affected. We are aware that Roche has an internal program to develop another molecule, known as R1626, as a treatment for HCV. Both R7128 and R1626 act as inhibitors of the HCV RNA polymerase. Any adverse development in Roche’s operations or financial condition could adversely affect the development and commercialization of R7128 or other pro-drugs of PSI-6130, and our receipt of future milestone payments and royalties on its sales.

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

We and our collaborators engage clinical investigators and medical institutions to enroll patients in our clinical trials and contract research organizations to perform data collection and analysis and other aspects of our preclinical studies and clinical trials. As a result, we depend on these clinical investigators, medical institutions and contract research organizations to perform these activities on a timely basis in accordance with the protocol, good laboratory practices, good clinical trial practices, and other regulatory requirements. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, 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, terminated or our data may be rejected by the FDA. If it became necessary to replace a third party that was conducting one of our clinical trials, we believe that there are a number of other third-party contractors whom we could engage to continue these activities, although it may result in a delay of the applicable clinical trial. If there are delays in testing or obtaining regulatory approvals as a result of a third party's failure to perform, our drug discovery and development costs will increase, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

If parties on whom we rely to manufacture our products or product candidates do not manufacture the active pharmaceutical ingredients or finished products of satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

We do not currently own or operate manufacturing facilities; consequently, we rely on third parties as sole suppliers of clinical investigational quantities of our product candidates. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce commercial quantities of any drugs that we market. Our current and anticipated future dependence on third parties for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

To date, our product candidates have only been manufactured in quantities sufficient for preclinical studies or initial clinical trials. We do not currently have any long-term supply agreements in place for our product candidates and will need to enter into supply agreements for additional supplies of each of our product candidates to complete clinical development. Additionally, in connection with our application for commercial approvals and if any product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to procure commercial quantities from qualified third-party manufacturers. We may not be able to contract for increased manufacturing capacity for any of our product candidates in a timely or economic manner or at all. A significant scale-up in manufacturing may require additional validation studies. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed, or there may be a shortage of supply, which could limit our sales.

Other risks associated with our reliance on contract manufacturers include the following:

- Contract manufacturers may encounter difficulties in achieving volume production, quality control, and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our products.
- If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance. This would involve pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

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- Contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our present or future contract manufacturers may not be able to comply with cGMP and other FDA requirements or other regulatory requirements outside the United States. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business.
- Contract manufacturers may breach the manufacturing agreements that we or our development partners have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

Changes to the manufacturing process during or following the completion of clinical trials also require sponsors to demonstrate to the FDA that the product manufactured under the new conditions complies with cGMP requirements. This requirement applies to moving manufacturing functions to another facility. In each phase of investigation, sufficient information about changes in the manufacturing process must be submitted to the FDA.

We may experience difficulties in entering into contracts on favorable terms for supplies of our products for future preclinical studies and clinical trials, which could prevent us from completing these studies and delay the commercialization of our products.

We will need to enter into supply agreements for additional supplies of each of our product candidates to complete clinical development and/or commercialize them. We cannot assure you that we will be able to do so on favorable terms, if at all. We have a sufficient quantity of clevudine for our planned Phase 3 clinical trials, but if we obtain marketing approval for clevudine, we will need to procure additional commercial supplies of clevudine from qualified third-party manufacturers. We are negotiating an agreement for the manufacture of clevudine with a supplier that manufactured clevudine used in previous clinical trials, however, our negotiations are ongoing and we have not entered into a definitive agreement with this potential supplier.

We will need to procure additional supplies of R7128 to complete our future preclinical studies and clinical trials. Roche is supplying R7128 for our current preclinical studies and clinical trials. We are currently considering additional supply options of R7128. However, we have not yet entered into a definitive supply agreement with any company.

We will need to procure additional supplies of Racivir to complete our future preclinical studies and clinical trials. We are currently in the process of identifying and evaluating the qualifications of potential suppliers that could manufacture Racivir, including the company that manufactured our current supply of Racivir; however, we have not yet entered into a definitive supply agreement with any company.

Incyte was responsible for the clinical trials of DFC and for obtaining sufficient supply of DFC for its trials. If we conduct our own clinical trials of DFC, we will need to establish our own source of supply of DFC.

If conflicts arise between our collaborators and us, our collaborators may act in their best interest and not in our best interest, which could adversely affect our business.

Conflicts may arise with our collaborators if they pursue alternative therapies for the diseases that we have targeted or develop alternative products either on their own or in collaboration with others. Competing products, either developed by our collaborators or any future collaborators or to which our present collaborators or any future collaborators have rights, may result in development delays or the withdrawal of their support for our product candidates.

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Additionally, conflicts may arise if there is a dispute about the progress of, or other activities related to, the clinical development of a product candidate, the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of the collaborative arrangement. Similarly, the parties to a collaboration agreement may disagree as to which party owns newly developed products. Should an agreement be terminated as a result of a dispute and before we have realized the benefits of the collaboration, our reputation could be harmed and we might not obtain revenues that we anticipated receiving.

We may rely on other collaborators in the future and if future collaborations are not successful, we may not be able to effectively develop and commercialize our product candidates.

We may decide to enter into future collaboration agreements for the development and commercialization of clevudine, Racivir, DFC or other product candidates that we may identify in the future. We may not be successful in entering into any additional collaborative arrangements.

Relying on collaborative relationships poses a number of risks to us, including the following:

- we may be required to relinquish important rights, including intellectual property, marketing and distribution rights;
- we will not be able to control whether our collaborators will devote sufficient resources to the development or commercialization of the product candidates we license;
- we will not have access to all information regarding the products being developed and commercialized by our collaborators, including information about clinical trial design and execution, regulatory affairs, process development, manufacturing, marketing and other areas known by our collaborators. Thus, our ability to keep our stockholders informed about the status of our collaborated products will be limited by the degree to which our collaborators keep us informed;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness to actively pursue the development and commercialization of any products resulting from a collaboration;
- a collaborator may separately move forward with a competing product candidate either developed independently or in collaboration with others, including our competitors;
- collaborators with marketing rights may choose to devote fewer resources to the marketing of our products than they do to other products they are selling;
- our collaborators may experience financial difficulties and may be unable to fund the clinical trials, fulfill their obligations under collaboration agreements with us or delay paying us agreed-upon milestone payments, reimbursements, royalties or other committed amounts; and
- disputes may arise between us and our collaborators delaying or terminating the research, development or commercialization of our drug candidates, resulting in litigation or arbitration that could be time-consuming and expensive.

A collaborator may terminate its agreement with us or simultaneously pursue alternative products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by us or our collaborative effort or us. If a partner terminates its agreement, the development or commercialization of our products could be delayed or terminated, or we could be required to undertake unforeseen additional responsibilities or devote unbudgeted additional resources to such development or commercialization.

If we fail to enter into additional in-licensing agreements or if these arrangements are unsuccessful, our ability to fill our clinical pipeline may be adversely affected.

In addition to entering into collaborative agreements with third parties for the development and commercialization of our product candidates, we intend to continue to explore opportunities to further enhance our discovery and development capabilities and develop our clinical pipeline by in-licensing product candidates

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that fit within our expertise and research and development capabilities. We will face substantial competition for in-licensing opportunities from companies focused on antiviral therapies, many of which may have greater resources than we do. Additional in-licensing agreements for product candidates may not be available to us, or if available, the terms may not be favorable. We may also need to license additional technologies in order to continue to develop our clinical pipeline. If we are unable to enter into additional agreements to license product candidates or technologies, or if these arrangements are unsuccessful, our clinical pipeline may not contain a sufficient number of promising future product candidates and our research and development efforts could be delayed.

Risks Related to Our Intellectual Property

We licensed Racivir, one of our lead product candidates, from Emory University, and our rights to commercialize Racivir are subject to a right of first refusal held by Gilead, and uncertainties related to these rights may result in us being prevented from obtaining the expected economic benefits from developing Racivir.

We licensed Racivir from Emory University pursuant to an exclusive, worldwide license agreement to make, have made, use, import, offer for sale and sell Racivir, which we entered into in 1998, referred to as the Racivir License Agreement. In a license agreement relating to emtricitabine that Emory University entered into with Triangle Pharmaceuticals, now Gilead Sciences, Inc., or Gilead, in 1996, which we refer to as the Emory/Gilead License Agreement, Emory University previously had granted a right of first refusal to Gilead that is applicable to any license or assignment relating to a specified range of mixtures of (–) – FTC and (+) – FTC, referred to as enriched FTC (which includes Racivir). The terms of this right of first refusal contains an exception permitting Emory University to license or assign its rights in respect of enriched FTC to a permitted transferee, which includes any of the inventors (which included two of our founders) or to any corporate entity formed by or on behalf of the inventors for purposes of clinically developing enriched FTC so long as the licensee agrees in writing to be bound by the terms of Gilead’s right of first refusal to the same extent as Emory University. Our license to Racivir was granted to us by Emory University pursuant to this exception and therefore we are bound by the terms of Gilead’s right of first refusal to the same extent as Emory University. The terms of this right of first refusal as set forth in the Emory/Gilead License Agreement require that, prior to the entry into any license or assignment agreement with a third party relating to any of Emory University’s rights in respect of enriched FTC, Emory University shall notify Gilead of the terms of the proposed agreement and provide a copy of the proposed agreement to Gilead together with all data and information in Emory University’s possession relating to enriched FTC and its use as a therapeutic agent. Gilead has 30 days to accept or decline the offer. Although Emory University considers us to be a permitted transferee under the Emory/Gilead License Agreement, Emory University has subsequently taken the position that its grant of commercialization rights (i.e., the rights to offer for sale and sell Racivir) to us exceeded the rights that were permitted to be granted to a permitted transferee under its agreement with Gilead. While we believe that Gilead is aware of the Racivir license agreement through both our and Emory University’s communications with Gilead, Gilead has not contacted us regarding its interpretation of the terms of the Racivir License Agreement.

In March 2004, we entered into a supplemental agreement with Emory University in which we and Emory University agreed that, prior to any commercialization of enriched FTC by us, or by any licensee or assignee of our rights under the Racivir License Agreement, we and Emory University would adhere strictly to the terms of the right of first refusal granted to Gilead in the Emory/Gilead License Agreement and offer to Gilead the same terms and conditions under which we, our licensee or our assignee, propose to commercialize enriched FTC. The supplemental agreement also outlines a procedure by which Emory University and we would jointly offer the terms of a proposed license and commercialization agreement between us and a third party to Gilead after Emory University has the opportunity to approve them. Therefore, before we could enter into a commercialization agreement for Racivir with a third party or commercialize Racivir on our own, we would be required to offer Gilead the opportunity to be our commercialization partner on the same terms on which we intend, or our prospective partner intends, to commercialize Racivir. It is uncertain whether a third party would be willing to negotiate the terms of a commercialization agreement with us knowing that Gilead can take their place as licensee by accepting the negotiated terms and exercising its right of first refusal.

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These uncertainties related to our commercialization rights may result in us being prevented from obtaining the expected economic benefits from developing Racivir. In addition, we could become involved in litigation or arbitration related to our commercialization rights to Racivir in the future.

If we are unable to obtain and maintain adequate patent protection for our product candidates, we may be unable to commercialize our product candidates or to prevent other companies from using our intellectual property in competitive products in certain countries.

Our commercial success will depend, in large part, on our ability and the ability of our licensors to obtain and maintain patents and proprietary intellectual property rights sufficient to prevent others from marketing our product candidates, as well as to successfully defend and enforce those patents against infringement and to avoid infringing the proprietary rights of others, both in the United States and in foreign countries. Roche and we have filed patent applications for R7128, and we have filed and may in the future file our own patent applications for our other technology. We have also licensed certain patents, patent applications and other proprietary rights from third parties. We have licensed patents for clevudine, Racivir and DFC. The patent covering the composition of matter for clevudine that we have licensed from Bukwang is scheduled to expire in January 2014. The patent covering the composition of matter for Racivir that we have licensed from Emory University is scheduled to expire in September 2015. The patent covering methods of using DFC to treat HIV that we have licensed from Emory University is scheduled to expire in January 2015. The patent expiration dates stated above do not take into account any patent term adjustments that may accrue due to procedural delays by the United States Patent and Trademark Office or patent term extensions that may accrue due to regulatory delays.

Our patent position, like that of many pharmaceutical and biotechnology companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we or our licensors do obtain patents, such patents may not adequately protect the products or technologies we own or have licensed. In addition, we generally do not control the patent prosecution of subject matter that we license from others. Generally, the patent holders are primarily responsible for the patent prosecution and maintenance activities pertaining to the licensed patent applications and patents, while we are afforded opportunities to advise the primary licensors on such activities with respect to our licensed territories. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license, and rights we receive under those patents may not provide competitive advantages to us. We cannot assure you as to the degree of protection that we will be afforded by any patents issued to, or licensed by, us. The laws of many countries may not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on or restricts the prices of life-saving drugs. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property.

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

- we or our licensors might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we or our licensors might not have been the first to file patent applications for these inventions;
- our or our licensors' pending patent applications may not result in issued patents;
- our or our licensors' issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;

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- others may design around our or our licensors' patent claims to produce competitive products which fall outside the scope of our or our licensors' patents; or
- the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology and our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent or potential patent extension may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may incur substantial costs or lose important rights as a result of litigation or other proceedings relating to patent and other intellectual property rights.

The defense and prosecution of intellectual property rights, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and elsewhere are costly and time-consuming and their outcome is uncertain. In general, there is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry. Litigation may be necessary to:

- assert or defend claims of infringement;
- enforce patents we own or license;
- protect trade secrets; or
- determine the enforceability, scope and validity of the proprietary rights of others.

If we become involved in any litigation, interference or other administrative proceedings, we will incur substantial expense and it will divert the efforts of our scientific and management personnel. Uncertainties resulting from the initiation and continuation of litigation, interference or other administrative proceedings could have a material adverse effect on our ability to compete in the marketplace pending resolution of the disputed matters. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially reasonable terms, if at all. We or our collaborators may be restricted or prevented from developing and commercializing our products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses. In such event, we may attempt to redesign our processes or technologies so that they do not infringe, which may not be possible.

While our product candidates are in clinical trials, we believe that the use of our product candidates in these clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

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If we find during clinical evaluation that our product candidates for the treatment of HIV, HBV or HCV should be used in combination with a product that is 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, infringement of the third-party patents covering the product recommended for co-administration with our product. In such a case, we could 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 commercially reasonable terms, or at all.

We may be subject to claims that our board members, employees or consultants or we have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals that are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the biotechnology and pharmaceutical industries, some of our board members, employees and consultants are or have been employed at, or associated with, other biotechnology or pharmaceutical companies that compete with us. For example, two of our directors were also members of the board of directors of Idenix Pharmaceuticals and another of our directors was a former executive at Gilead Sciences. These companies are focused on the same therapeutic areas as us. From time to time, these directors may face conflicts of interest because of their affiliation with companies with which we may compete. While employed at or associated with these companies, these board members may have been exposed to or involved in research and technology similar to the areas of research and technology in which we are engaged. We may be subject to claims that we, or our employees, board members or consultants, have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims.

We have entered into confidentiality agreements with all of our employees. However, we do not have, and are not planning to enter into, any confidentiality agreements with our directors because they have a fiduciary duty of confidentiality as directors. There is the possibility that any of our former board members, employees or consultants who are currently employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

The rights we rely upon to protect our unpatented trade secrets may be inadequate.

We rely on unpatented trade secrets, know-how and technology, which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or our collaboration partners, board members, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets could have been, or could, in the future, be shared by any of our former employees with and be used to the benefit of any company that competes with us. For example, a former director and founder of Pharmasset has, along with several of our former scientists, started a new pharmaceutical company to develop drugs to treat viral infections (including human retroviral and hepatitis infections), cancer and dermatological products, which may compete with us in the future. These individuals left Pharmasset in 2005. We have a confidentiality agreement in place with our former director, and have both confidentiality agreements and covenant not to compete agreements in place with the former scientists. The term of the confidentiality agreements is indefinite with regard to any confidential information that is not subsequently made public. The covenant not to compete agreements expired on February 28, 2007.

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If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

Risks Related to Our Industry

Our industry is extremely competitive. If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase, particularly in the area of antiviral drugs. Many companies are pursuing the development of novel drugs that target the same diseases we are targeting. There are a significant number of drugs that are approved or currently under development that will become available in the future for the treatment of HBV, HCV and HIV and other viral infections. If any of the product candidates that our competitors are developing are successful, we will have difficulty gaining market share.

We face a broad range of current and potential competitors, from established global pharmaceutical companies with significant resources to development-stage companies. Listed below are some of the pharmaceutical and biotechnology companies developing compounds targeting HBV, HCV and HIV and other viral infections.

- **HBV:** Gilead Sciences has a drug candidate for the treatment of HBV named Viread that recently completed Phase 3 clinical trials and during October 2007, Gilead filed marketing applications for Viread in the United States and Europe. Our HBV product candidate may compete directly or be used in combination with the current standard of care, with the drug candidates that are currently in development and with those that may be developed in the future.
- **HCV:** Roche, Schering-Plough, and several generic manufacturers market ribavirin, which is a component of the current standard of care for HCV. Roche and other companies, such as Valeant Pharmaceuticals International, Vertex Pharmaceuticals Incorporated, ViroPharma Incorporated, Gilead Sciences, Inc, Intermune, Human Genome Sciences, Schering-Plough, Novartis and Idenix, are also developing new drugs for the treatment of HCV.
- **HIV:** Pharmaceutical companies such as Pfizer Inc. and Merck & Co., Inc., and biotechnology companies such as Gilead Sciences, Inc., Incyte Corporation, Avexa Limited, Achillion Pharmaceuticals, Inc., Panacos Pharmaceuticals, Inc. and Human Genome Sciences, Inc. are developing compounds targeting HIV. We also believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HIV. In addition, we are aware that Merck and other companies are pursuing the development of a prophylactic vaccine, which would prevent infections. If a prophylactic vaccine is successful, it could reduce the size of the market for our products.

In addition, we face competition from academic and research institutions and government agencies for the discovery, development and commercialization of novel therapeutics to treat HIV, HBV and HCV. Some early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products;

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- more extensive experience in preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing products; and
- products that have already been approved or are in the late stage of development and operate large, well-funded research and development programs.

Our competitors may succeed in developing or commercializing more effective, safer or more affordable products, which would render our product candidates less competitive or noncompetitive. Our competitors may discover technologies and techniques, or enter into partnerships with collaborators, in order to develop competing products that are more effective or less costly than the products we develop. This may render our technology or products obsolete and noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trials sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before we do, and competitors who have already done so, will enjoy a significant competitive advantage. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

If we successfully develop and obtain approval for our product candidates, we will face competition for market share based on the safety and efficacy of our products, the timing and scope of regulatory approvals, the availability of supply, marketing and sales capability, reimbursement coverage, price, patent position and other factors.

If third-party payors do not adequately reimburse patients for any of our product candidates, if approved for marketing, we may not be successful in selling them.

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow our products to compete effectively with products that are reimbursed at a higher level. If the price we are able to charge for any products we develop is inadequate in light of our development costs, our profitability could be adversely affected.

Reimbursement by governmental and other third-party payors may depend upon a number of factors, including the governmental and other third-party payor's determination that the use of a product is:

- a covered benefit under its health plan or part of their formulary;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already

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reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

The health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, or the MMA, created a broader prescription drug benefit for Medicare beneficiaries. The MMA also contains provisions intended to reduce or eliminate delays in the introduction of generic drug competition at the end of patent or nonpatent market exclusivity. The impact of the MMA on drug prices and new drug utilization over the next several years is unknown. The MMA also made adjustments to the physician fee schedule and the measure by which prescription drugs are presently paid. The effects of these changes are unknown but may include decreased utilization of new medicines in physician prescribing patterns, and further pressure on drug company sponsors to provide discount programs and reimbursement support programs. There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. Future legislation may also limit the prices that can be charged for drugs we develop.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly in the European Union, prescription drug pricing and/or reimbursement is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

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Even if we achieve market acceptance for our products, we may experience downward pricing pressure on the price of our drugs because of generic competition and social pressure to lower the cost of drugs to treat HIV, HBV and HCV.

Several of the FDA-approved individual and combination products face patent expiration in the next several years. The following table lists expected patent expiration dates of FDA-approved individual and combination products the patents for which are expected to expire in the next several years and that we expect may compete with our product candidates, according to the FDA's compilation of patents covering approved drug products in a collection entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known universally as the "Orange Book").

<u>Drug Brand Name</u>	<u>Patent Expiry Date or Range of Patent Expiry Dates*</u>
Epivir-HBV	November 17, 2009 to May 18, 2016
Hepsera	April 21, 2006 to July 23, 2018
Baraclude	October 18, 2010
Epivir	November 17, 2009 to May 18, 2016
Emtriva	May 11, 2010 to March 9, 2021
Zerit	June 24, 2008
Videx	August 29, 2006 to July 22, 2011
Ziagen	December 18, 2011 to May 14, 2018
Hivid	November 7, 2006 to July 2, 2008
Combivir	September 17, 2005 to May 18, 2016
Truvada	May 11, 2010 to March 9, 2021
Atripla	May 11, 2010 to March 9, 2021
Epzicom	December 18, 2011 to May 14, 2018
Trizivir	September 17, 2005 to May 14, 2018
Tyzeka	August 10, 2019

* These dates do not take into account any patent term adjustments that may accrue due to procedural delays by the United States Patent and Trademark Office or patent term extensions that may accrue due to regulatory delays nor any exclusivity periods granted by the FDA.

As a result, generic versions of these drugs may become available. We expect to face competition from these generic drugs, including price-based competition.

Pressure from AIDS awareness and other social activist groups to reduce HIV drug prices may also put downward pressure on the prices of HIV drugs, including Racivir and DFC if they are commercialized. Similar trends of generic competition or social pressure may occur for HBV or HCV, which would result in downward pressure on the price for clevudine or R7128, if they are commercialized.

We face a risk of product liability claims and if we are not able to obtain adequate liability insurance, a product liability claim could result in substantial liabilities.

Our business exposes us to the risk of significant potential product liability claims that are inherent in the manufacturing, testing and marketing of human therapeutic products, and we will face an even greater risk if our collaborators or we sell any products commercially. Regardless of their merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants and difficulty in recruiting participants;
- inability to commercialize our product candidates;
- decreased demand for our product candidates;

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- injury to our reputation;
- inability to establish new collaborations;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

Product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval.

We currently have product liability insurance that covers our clinical trials for up to \$15.0 million for each occurrence and up to a \$15.0 million annual aggregate limit, subject to deductibles of \$50,000 per occurrence and \$250,000 annual aggregate limit and coverage limitations. We intend to increase our insurance coverage and include the sale of commercial products if marketing approval is obtained. Because insurance coverage is becoming increasingly expensive, we may not be able to obtain or maintain adequate protection against potential product liabilities at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

We may incur significant costs to comply with laws regulating the protection of health and human safety and the environment, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities involve the controlled use of numerous hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations, and may be subject to foreign laws and regulations, governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products, including certain regulations promulgated by the U.S. Environmental Protection Agency, or EPA. The EPA regulations to which we are subject require that we register with the EPA as a generator of hazardous waste. The risk of accidental contamination or injury from the handling, transporting and disposing of hazardous materials and waste products cannot be entirely eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposures to blood-borne pathogens and the handling, transporting and disposing of biohazardous or radioactive materials. Although we maintain workers' compensation insurance to cover us for the costs and expenses we may incur if our employees are injured as a result of using these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain, nor do we plan to obtain, additional insurance coverage relating to damage claims arising from our use of hazardous materials. Further, we may be required to indemnify our collaborators or licensees against damages and other liabilities arising out of our development activities or products. Compliance with the applicable environmental and workplace laws and regulations is expensive. Future changes to environmental, health, workplace and safety laws could cause us to incur additional expenses or may restrict our operations or impair our research, development and production efforts.

Risks Related to our Common Stock

A significant portion of our total outstanding shares recently became available for sale. If there are substantial sales of our common stock by our existing stockholders, our stock price could decline.

On October 19, 2007, lock-up agreements that were executed in conjunction with the initial public offering of our common stock were terminated, enabling the future sale of approximately 16.0 million shares of our common stock. Sales of substantial amounts of our common stock in the public market or otherwise, or the

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perception that such sales could occur, could adversely affect the price of our common stock. In addition, as of September 30, 2007, holders of approximately 13,490,969 shares of our common stock have rights, subject to some conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file on our behalf or on behalf of our stockholders. We also have registered all common stock that we may issue under our employee benefit plans. As of September 30, 2007, 3,680,168 shares of our common stock were reserved and available for future issuance under our 1998 Stock Plan and 2007 Equity Incentive Plan. These shares can be freely sold in the public market upon issuance. If any of these stockholders causes a large number of securities to be sold in the public market, or if there is an expectation that such sales may occur, the sales could cause the trading price of our common stock to decline.

Our amended and restated certificate of incorporation permits the issuance of up to approximately 78,767,009 additional shares of common stock as of September 30, 2007. Thus, we will have the ability to issue substantial amounts of common stock in the future, which would dilute the percentage ownership held by current stockholders.

Our stock price is volatile.

The stock market in general, and the market for clinical-stage pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated or disproportionate to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price for our common stock.

In this market environment, the sale of a substantial number of shares of our common stock in the public market or the perception that such a sale might occur would likely have an adverse effect on the market price of our common stock. We have a number of investors who hold relatively large positions in our securities. A decision by any of these investors to sell all or a block of their holdings of our common stock could cause our stock price to drop significantly.

The market also continues to experience significant price and volume fluctuations, some of which are unrelated to the operating performance of particular companies. Since our IPO, the price of our common stock has fluctuated significantly and may continue to do so in the future. Many factors could have a significant effect on the market price for our common stock, including:

- adverse results or delays in our clinical trials or the clinical trials of our collaborators;
- announcements of FDA non-approval of our products, or delays in the FDA or other foreign regulatory agency review process;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities;
- introductions or announcements of new products or technological innovations or pricing by our competitors;
- the loss of a significant collaborator;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to patent our product candidates and technologies;
- changes in estimates of our financial performance by securities analysts or failure to meet or exceed securities analysts' or investors' expectations of our annual or quarterly financial results, clinical results or our achievement of any milestones or changes in securities analysts' recommendations regarding the common stock, other comparable companies or our industry generally;
- fluctuations in stock market prices and trading volumes of similar companies or of the markets generally;

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- changes in accounting principles;
- 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;
- issuance of new shares of common stock in future offerings, or upon the exercise of existing warrants;
- issuance of convertible debt;
- 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 United States and abroad;
- third-party healthcare reimbursement policies;
- conditions or trends in the pharmaceutical and biotechnology industries;
- departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, clinical trial results, joint ventures or capital commitments; and
- actual or anticipated variations in our annual or quarterly operating results.

Any litigation brought against us as a result of this volatility could result in substantial costs and a diversion of our management's attention and resources, which could negatively impact our financial condition, results of operations, and the price of our common stock.

If we raise additional capital by issuing equity securities in a fluctuating market, many or all of our existing stockholders may experience substantial dilution, and if we need to raise capital by issuing equity securities at a time when our stock price is lower, we may have difficulty raising sufficient capital to meet our requirements. If any of the risks described in these "RISK FACTORS" occurred, or if any unforeseen risk affected our performance, it could have a dramatic and adverse impact on the market price of our common stock.

Provisions of our amended and restated certificate of incorporation, bylaws and Delaware law could delay or discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of our amended and restated certificate of incorporation, bylaws and Delaware law may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable. In addition, these provisions could make it more difficult for our stockholders to replace or remove our board of directors.

These provisions include:

- the application of a Delaware law prohibiting us from entering into a business combination with the beneficial owner of 15% or more of our outstanding voting stock for a period of three years after such 15% or greater owner first reached that level of stock ownership, unless we meet specified criteria;
- authorizing the issuance of preferred stock with rights that may be senior to those of the common stock without any further vote or action by the holders of our common stock;
- providing for a classified board of directors with staggered terms;
- requiring that our stockholders provide advance notice when nominating our directors or proposing matters that can be acted on by stockholders at stockholders' meetings;
- eliminating the ability of our stockholders to convene a stockholders' meeting; and
- prohibiting our stockholders from acting by written consent.

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Our executive officers, directors and current principal stockholders own a large percentage of our voting common stock and could limit new stockholders' influence on corporate decisions.

As of September 30, 2007, our executive officers, directors, current holders of more than 5% of our outstanding common stock and their respective affiliates beneficially own, in the aggregate, approximately 74.2% of our outstanding common stock. These stockholders, acting together, would be able to control all matters requiring approval by our stockholders, including mergers, sales of assets, the election of directors, the approval of mergers or other significant corporate transactions. The interests of these stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

In July 2005, we relocated our operations to Princeton, New Jersey from Atlanta, Georgia. On May 23, 2005, we entered into a lease for a 30,800 square foot building that has 12,000 square feet of laboratory space and approximately 18,000 square feet of administrative offices in Princeton, New Jersey. The annual occupancy expense under this lease is approximately \$825,333. This lease expires on May 22, 2010 and may be extended for a total of an additional 10 years. These facilities are equipped to perform drug research activities. In April 2007, we also entered into a lease for office space in Durham, North Carolina. The annual occupancy expense under this lease is approximately \$80,138. This lease expires on April 30, 2009 and may be extended for a total of an additional three years.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock began trading on the Global Market of The NASDAQ Stock Market LLC (“NASDAQ”) on April 27, 2007 under the symbol “VRUS.” Prior to that time, there was no established public trading market for our common stock. The following table sets forth for the periods indicated the high and low closing sale prices per share of our common stock as reported by NASDAQ:

Fiscal Year Ended September 30, 2007:	High	Low
Fourth fiscal quarter	\$12.60	\$8.06
Third fiscal quarter (beginning April 27, 2007)	\$ 9.42	\$7.54

Holders of Record

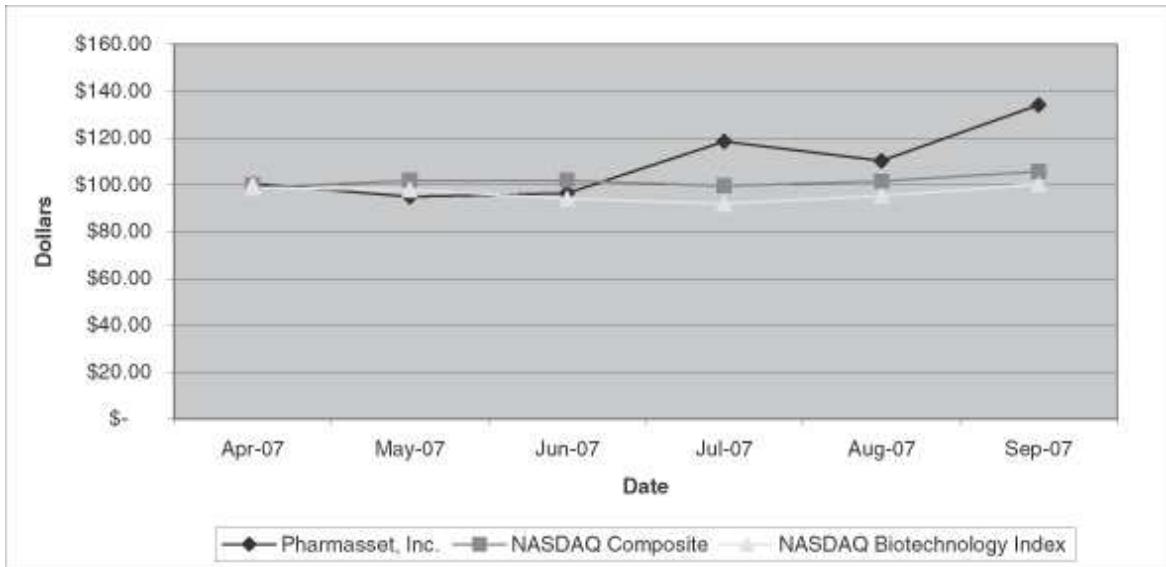
As of November 30, 2007, there were approximately 79 holders of record of our common stock.

Comparative Stock Performance

The following graph and related information should not be deemed “soliciting material” or to be “filed” with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

CUMULATIVE TOTAL RETURN

(Based on an initial investment of \$100.00 on April 27, 2007 using end of the month closing prices for each of the three investment options.)



Dividends

We have never paid or declared any cash dividends on our common stock. We currently intend to retain any earnings for future growth and, therefore, do not expect to pay cash dividends in the foreseeable future. Moreover, under the terms of our Loan Agreement with our lender, we are not permitted to pay any dividends without its written consent.

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ITEM 6. SELECTED FINANCIAL DATA

The following table presents our selected financial information. In 2005, we changed our fiscal year end from December 31 to September 30 for financial reporting purposes. The change was effective for the nine-month period ended September 30, 2005. The following selected statement of operations data for the nine months ended September 30, 2005 and the years ended September 30, 2006 and 2007 and the balance sheet data as of September 30, 2005, 2006 and 2007 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. In the opinion of management, the unaudited selected financial data presented below reflect all adjustments necessary for a fair presentation of this data. The statement of operations data for the years ended December 31, 2003 and 2004 and the balance sheet data as of December 31, 2004 have been derived from our audited financial statements that are not included in this Annual Report on Form 10-K. The balance sheet data as of December 31, 2003 is derived from our unaudited financial data that are not included in this Annual Report on Form 10-K. The results from the nine-month period ended September 30, 2005 are not indicative of results that would have been achieved for the twelve-month period ended September 30, 2005.

The selected financial data set forth below should be read together with our financial statements and the related notes to those financial statements, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” appearing elsewhere in this Annual Report on Form 10-K and with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in Item 7. below. The historical results are not necessarily indicative of results to be expected in any future period.

	<u>Years Ended September 30,</u>		<u>Nine Months</u> <u>Ended</u> <u>September 30,</u>	<u>Years Ended December 31,</u>	
	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>
(in thousands, except share and per share data)					
Statement of Operations Data:					
Revenues:					
Contract revenues	\$ 22,009	\$ 5,425	\$ 3,719	\$ 2,208	\$ 509
Government grant revenues	—	—	—	545	538
Total revenues	<u>\$ 22,009</u>	<u>\$ 5,425</u>	<u>\$ 3,719</u>	<u>\$ 2,753</u>	<u>\$ 1,047</u>
Cost and expenses:					
Research and development	20,319	10,498	10,468	5,317	4,809
General and administrative	9,211	7,911	8,096	2,898	1,761
Total costs and expenses	<u>29,530</u>	<u>18,409</u>	<u>18,564</u>	<u>8,215</u>	<u>6,570</u>
Operating loss	(7,520)	(12,984)	(14,845)	(5,462)	(5,523)
Investment income (1)	2,471	1,659	1,136	495	182
Interest expense	(15)	—	—	—	—
Loss before income taxes	(5,065)	(11,325)	(13,709)	(4,967)	(5,341)
Provision for income taxes	—	—	—	17	337
Net loss	<u>(5,065)</u>	<u>(11,325)</u>	<u>(13,709)</u>	<u>(4,984)</u>	<u>(5,678)</u>
Redeemable preferred stock accretion (1)	1,776	1,111	2,287	1,317	37
Net loss attributable to common stockholders	<u>\$ (6,840)</u>	<u>\$ (12,436)</u>	<u>\$ (15,996)</u>	<u>\$ (6,301)</u>	<u>\$ (5,715)</u>
Net loss per common share:					
Basic	\$ (0.46)	\$ (1.19)	\$ (2.42)	\$ (1.53)	\$ (1.40)
Diluted	\$ (0.46)	\$ (1.19)	\$ (2.42)	\$ (1.53)	\$ (1.40)
Weighted average number of shares used in per common share calculations:					
Basic (1)	14,990,472	10,462,369	6,630,463	4,110,997	4,107,473
Diluted (1)	14,990,472	10,462,369	6,630,463	4,110,997	4,107,473

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	<u>As of September 30,</u>		<u>As of</u>	<u>As of December 31,</u>	
	<u>2007</u>	<u>2006</u>	<u>September 30,</u>	<u>2004</u>	<u>2003</u>
			<u>2005</u>		
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents (1)	\$68,746	\$26,182	\$ 33,442	\$ 307	\$ 1,823
Short-term investments	1,252	1,250	12,007	54,932	7,975
Working capital	60,764	25,004	38,822	51,687	7,955
Total assets (1)	75,844	32,998	47,441	57,417	12,363
Deferred revenue	7,583	9,168	12,044	12,136	5,769
Redeemable convertible preferred stock (1)	—	19,641	18,530	50,178	11,270
Total stockholders' equity (deficit) (1)	\$58,936	\$ (220)	\$ 11,668	\$ (7,431)	\$ 5,473

(1)— On May 2, 2007, we completed our IPO of 5,050,000 shares of our common stock at a public offering price of \$9.00 per share. Net cash proceeds from the initial public offering were \$40.7 million after deducting offering costs paid during fiscal 2007 and \$39.1 million after deducting additional offering costs paid in fiscal 2006.

In connection with the IPO, the outstanding shares of our Series B, Series C, Series D and Series R Redeemable Convertible Preferred Stock, our Series A Convertible Preferred Stock, and our Redeemable Common Stock were converted into 4,405,683 shares of our common stock as of May 2, 2007. In addition, holders of our Series D Redeemable convertible preferred stock were entitled to receive quarterly dividends at a rate equal to 7.5% per annum of the purchase price per share. Such dividends accrued from February 4, 2006 through May 2, 2007 and were paid out in the form of 131,864 shares of our common stock. Our Series D-1 warrants were also exercised in full in connection with our IPO on a “net exercise” basis, which resulted in us issuing 822,689 shares of our common stock to the warrant holders.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements based on current expectations that involve risks, uncertainties and assumptions, such as our plans, objectives, expectations and intentions set forth in the "Cautionary Statement Regarding Forward-Looking Statements," which can be found at the beginning of this report, and in Item 1A, Risk Factors. Our actual results and the timing of events may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the "Risk Factors" section and elsewhere in this report.

Overview

We are a clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections. Our primary focus is on the development of oral therapeutics for the treatment of hepatitis B virus, or HBV, hepatitis C virus, or HCV and human immunodeficiency virus, or HIV. We currently have three product candidates:

- Clevudine, for the treatment of chronic HBV infection, is enrolling Phase 3 clinical trials for registration in North, Central, and South America ("the Americas") and Europe;
- R7128, a pro-drug of PSI-6130 for the treatment of HCV, in Part 3 of a Phase 1 clinical trial through a collaboration with F. Hoffmann-LaRoche Ltd. and Hoffmann-La Roche Inc. (collectively, Roche); and
- Racivir, for the treatment of HIV, which has completed a Phase 2 clinical trial.

Additionally, we are continuing to identify the best path forward for the development of DFC for the treatment of HIV following the completion of a Phase 2b clinical trial. Our research and development efforts focus on a class of compounds known as nucleoside analogs, which act to inhibit the natural enzymes required for viral replication. We are applying our expertise in nucleoside chemistry to the discovery and development of additional antiviral therapeutics.

Clevudine is an oral, once-daily pyrimidine nucleoside analog that we are developing for the treatment of HBV. We licensed clevudine from Bukwang, a Korean pharmaceutical company. Bukwang received final product approval from Korean regulators in December 2006 and commercially launched clevudine in the Korean market in February 2007 under the brand name Levovir. In two completed Korean Phase 3 clinical trials in 337 patients, Studies 301 and 302, clevudine demonstrated the ability to significantly reduce HBV viral load in patients to undetectable levels and normalized liver enzyme levels. Furthermore, in Study 302, 16% of the e-antigen negative patients who had received clevudine demonstrated a sustained virologic response ("SVR") 24 weeks after stopping therapy, versus 0% of the patients who had received the placebo. In March 2006, Bukwang completed Study 303, a Korean open-label follow-on study of clevudine in 55 HBV patients, including 15 e-antigen negative patients and who were treatment-naïve patients. The results of Study 303 are consistent with the results of Studies 301 and 302 in terms of significantly reducing HBV viral load in patients to undetectable levels and normalizing liver enzyme levels. Additionally, in Study 303, 80% of e-antigen negative patients sustained a viral load that was undetectable 12 weeks after completing the 48-week course of therapy.

We initiated two Phase 3 clinical trials of clevudine for registration in the Americas and Europe during the third calendar quarter of 2007. The clevudine registration studies include two 48-week Phase 3 clinical trials designed to test the superiority of once-daily doses of clevudine 30mg over Hepsera 10mg (adefovir) on predetermined primary and secondary endpoints. Study 305 will be conducted in approximately 376 e-antigen positive patients, and Study 306 will be conducted in approximately 480 e-antigen negative patients. The primary endpoint of these registration studies is expected to be a composite endpoint measuring the percentage of patients

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with undetectable HBV DNA (less than 300 copies/ml) and the normalization of liver enzyme levels at 48 weeks on therapy. We plan to continue the clevidine Phase 3 studies from week 48 to week 96 to gather additional safety and efficacy data, as well as assess clevidine's SVR rate for HBV.

In October 2007, Roche and we initiated oral dosing of R7128 in Part 3 of a Phase 1 clinical trial under an IND. This trial is a multiple center, observer-blinded, randomized and placebo-controlled study designed to investigate the pharmacokinetics, pharmacodynamics, safety, tolerability and food effect of R7128 in healthy volunteers and in patients chronically infected with HCV genotype 1, as well as provide antiviral potency data over 14 and 28 days in patients chronically infected with HCV genotype 1. This adaptive Phase 1 study is comprised of three parts:

- Part 1 was a single ascending dose study conducted in 46 healthy volunteers. The primary objective of Part 1 was to assess the safety, tolerability and pharmacokinetics of R7128 following single ascending doses under fasting conditions. The secondary objective of Part 1 was to explore the effect of food on the pharmacokinetics of R7128. Single oral doses of R7128 were administered to 46 healthy volunteers in five sequential dose groups (500 mg, 1500 mg, 4500 mg, 6000 mg, and 9000 mg) and one food effect group (1500 mg). Results from the single ascending dose portion of the study indicated:
 - All doses of R7128 studied (500 mg to 9000 mg) were generally safe and well-tolerated.
 - All patients completed the study, and none experienced gastrointestinal adverse events or serious adverse events during the study.
 - No hematological or laboratory abnormalities of clinical significance were noted.
- Part 2 was a multiple ascending dose study conducted in 40 patients chronically infected with HCV genotype 1 who had previously failed interferon therapy. The primary objective of Part 2 was to assess the safety, tolerability, and pharmacokinetics of R7128 after once-daily ("QD") or twice-daily ("BID") dosing for 14 days. The secondary objective was to assess antiviral efficacy by measuring the change in HCV RNA. Results from the multiple ascending dose portion of the study indicated:
 - R7128 demonstrated potent, dose-dependent antiviral activity in four patient cohorts (8 active, 2 placebo per cohort) receiving 750 mg or 1,500 mg administered either QD or BID for 14 days as monotherapy. Both the greatest mean decrease and maximum decrease in HCV RNA from baseline were demonstrated in the patient cohort that received 1,500 mg BID. R7128 demonstrated mean HCV RNA decreases of 0.9 log (87.4% reduction), 1.5 log (96.8% reduction), 2.1 log (99.2% reduction) and 2.7 log (99.8% reduction) in patients receiving 750mg QD, 1,500mg QD, 750mg BID and 1,500 mg BID, respectively. All four dose groups reached nadir values at Day 15. A maximum 4.2 log (99.9% reduction) HCV RNA decrease was demonstrated in a patient following 14 days of monotherapy with 1,500 mg BID of R7128, a value also below the level of detection, which was less than 15 International Units per milliliter (IU/ml).
 - There was no evidence of viral rebound in any dose cohort during the 14 days of dosing. In addition, R7128 was generally safe and well tolerated.
 - There were no serious adverse events, no adverse events requiring dose modification, no dose-related gastrointestinal adverse events and no clinically significant changes in hematologic or other laboratory parameters.
- Part 3 is a 28-day study of R7128 in combination with Pegasys (pegylated interferon) plus Copegus (ribavirin) in up to 75 treatment-naïve patients chronically infected with HCV genotype 1. The primary objective of this study is to assess the safety, tolerability, and pharmacokinetics of R7128 in the clinically-relevant setting of combination therapy with the current standard of care for chronic HCV infection. The secondary objective of Part 3 is to evaluate the short-term change in HCV RNA. The study will include two to three oral doses of R7128 (500 mg to 1500 mg) that are being administered twice-daily with Pegasys plus Copegus for 28 days. There will be 25 patients in each dose cohort with 20 patients randomized to receive R7128 and five patients randomized to receive placebo, all

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administered in combination with the standard of care. After completing 28 days of the triple combination regimen and a follow-up period of four weeks of Pegasys plus Copegus, all patients will then receive 40 weeks of open-label standard of care dosing under a separate protocol. We currently anticipate that the preliminary results from this combination study will be available in the first calendar quarter of 2008. We cannot guarantee that the results of this study will corroborate earlier results, and further testing will be required to provide enough evidence regarding safety and efficacy to support an application with the FDA in the future.

On October 12, 2007, we were informed by the FDA that R7128 received fast track designation.

Racivir is an oral, once-daily deoxycytidine nucleoside analog that we are developing as an HIV therapy for use in combination with other approved HIV drugs. In a recently completed Phase 2 clinical trial, for the subset of patients carrying the M184V mutation and less than three thymidine analog mutations, replacing lamivudine with Racivir in their existing combination therapies caused a mean decrease in plasma HIV RNA of 0.7 log (80% reduction) in the second week of treatment. Twenty-eight percent of these patients achieved an undetectable level of virus (less than 400 copies per milliliter) and 64% of these patients achieved at least a 0.5 log decrease (68% reduction) in plasma HIV RNA.

DFC is an oral, once-daily deoxycytidine nucleoside analog that we are evaluating for the treatment of HIV. We had been developing DFC in collaboration with Incyte Corporation (“Incyte”) until April 2006 when Incyte terminated our collaborative and license agreements and returned its rights related to DFC to us. We have analyzed the preclinical and clinical data on DFC generated by Incyte. Based on our review of the data provided to us, we believe that identifying a path for further development of DFC is warranted.

Results of all prior clinical trials do not provide enough evidence to support an NDA filing with the FDA and additional trials will be needed. Results of all of our ongoing trials and any future trials we may conduct may not corroborate earlier results.

We have incurred substantial operating losses since our inception because we have devoted substantially all of our resources to our research and development activities and have not generated any revenue from the sale of approved drugs. As of September 30, 2007, we had an accumulated deficit of \$57.1 million. We expect our operating losses to increase for at least the next several years as we continue to pursue the clinical development of clevidine, Racivir and our other product candidates, and as we expand our discovery and development pipeline. We expect our compensation expense to increase in the future as well, as we implement our planned increase in the number of our employees.

We have funded our operations primarily through the sale of equity securities, payments received under collaboration agreements, government grants and interest earned on investments. We expect to continue to fund our operations over the next several years through the net proceeds of our IPO completed on May 2, 2007, our existing cash resources, borrowings under our existing Loan Agreement, potential future milestone payments that we expect to receive from Roche if certain conditions are satisfied, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. We will require significant additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. As of September 30, 2007, we had approximately \$68.7 million of cash and cash equivalents and approximately \$1.3 million of short-term investments.

In 2005, we changed our fiscal year end from December 31 to September 30 for financial reporting purposes. The change was effective for the nine-month period ended September 30, 2005. For tax reporting purposes in 2005, we retained a twelve-month year ended December 31, 2005.

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Revenues

All of our product candidates are currently in development, and, therefore, we do not expect to generate any direct revenues from drug product sales for at least the next several years, if at all. Our revenues to date have been generated primarily from milestone payments under our collaboration agreements, license fees, research funding and grants. We currently have one collaboration agreement with Roche for the development of PSI-6130, its pro-drugs and related compounds. We entered into our collaboration agreement with Roche in October 2004. Roche subsequently paid us an up-front payment of \$8.0 million. Pursuant to the terms of our collaboration agreement with Roche, we received \$20.0 million in milestone payments during the year ended September 30, 2007. As of September 30, 2007, we had received an aggregate of \$33.0 million in payments under the Roche collaboration agreement, including research funding and related fees as well as up-front and milestone payments.

Under the current terms of the Roche collaboration agreement, if we succeed in obtaining all of the regulatory approvals specified in the agreement for PSI-6130 or a pro-drug of PSI-6130, including R7128, as of September 30, 2007 the maximum future development and commercialization milestone payments payable to us are \$115.0 million. Receipt of any additional milestone payments depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments. Additional milestone funding may be payable to us if molecules in addition to PSI-6130 or its pro-drugs are developed under the Roche agreement.

We expect our revenues for the next several years to be derived primarily from payments under our current collaboration agreement with Roche and any additional collaborations that we may enter into in the future. In addition to the payments described above, we may receive future royalties on product sales, if any, under our collaboration agreement with Roche.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. Our development activities are primarily focused on the development of clevudine, Racivir and R7128. We are responsible for all costs incurred in the future in the clinical development of clevudine for registration in the Americas, Europe and certain other territories, where we have the rights to develop and commercialize clevudine, which we in-licensed from Bukwang. We are responsible for all costs incurred in the clinical development of Racivir, as well as the research costs associated with our other internal research programs. Under our collaboration with Roche, Roche will fund the clinical development and commercialization of PSI-6130 and its pro-drugs, including R7128. Under this collaboration, Roche reimbursed us for all of the external expenses associated with, and we were responsible for, certain preclinical work, the IND filing, and the proof-of-concept clinical trial. Going forward, Roche will fund all of the expenses of, and be responsible for, other preclinical studies and future clinical development. We will continue to develop and retain worldwide rights to ongoing and future HCV programs unrelated to the PSI-6130 series of nucleoside polymerase inhibitors licensed to Roche. Incyte had been funding the clinical development and commercialization of DFC, but since its return to us by Incyte in April 2006, we are responsible for any additional expenses.

We are currently focused on advancing the clinical development of clevudine, Racivir and R7128 (in collaboration with Roche). We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis. These determinations will be made in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential. Clevudine is in Phase 3 registration clinical trials which commenced dosing during the third calendar quarter of 2007. We currently estimate it will cost approximately \$78.0 million, excluding internal personnel costs associated with conducting these two registration trials, to progress

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clevidine's clinical program to the filing of an NDA with the FDA. We do not believe, however, that it is possible at this time to accurately project total program-specific expenses through commercialization for clevidine or any of our other product candidates, as there are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Product candidates that may appear promising at early stages of development may not reach the market for a number of reasons. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals and may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality. The lengthy process of seeking FDA approvals requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining regulatory approvals could materially adversely affect our product development efforts. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of our product candidates, or the ultimate product development cost or whether we will obtain any approval required by the FDA on a timely basis, if at all.

As we obtain results from clinical trials, we may elect to discontinue or delay preliminary studies or clinical trials for a product candidate or development program in order to focus our resources on more promising product candidates or programs. We expect our research and development expenses to increase substantially as we continue the clinical development of clevidine and Racivir and as we continue our research and development activities. The maximum aggregate future milestone payments related to clevidine that we will have to pay to Bukwang if we succeed in obtaining all of the regulatory approvals and reach all marketing milestones specified in our agreement with Bukwang are \$23.0 million. Additionally, we may pay up to an aggregate of \$3.9 million in future milestone payments related to development and regulatory events under our license agreement for dioxolane thymine ("DOT") with RFS Pharma LLC.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, business development, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs and professional fees for outside accounting and legal services, travel, insurance premiums and depreciation. We expect general and administrative costs to increase significantly in connection with our planned growth. We anticipate increases in expenses associated with being a public company, such as compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

Results of Operations

Year Ended September 30, 2007 Compared with Year Ended September 30, 2006

Revenues . Revenues increased to \$22.0 million in 2007 from \$5.4 million in 2006. This \$16.6 million increase in revenues was due primarily to our receipt of milestone payments from Roche totaling \$20.0 million during 2007. In 2006, \$3.2 million of the \$5.4 million of revenues was related to our license agreement with Incyte (\$2.8 million of which represented accelerated recognition of deferred revenue caused by Incyte's termination of this license agreement in April 2006).

The following is a reconciliation between cash payments received under contract revenue agreements and contract revenues reported:

	Year Ended September 30,	
	2007	2006
	(in thousands)	
Cash received/receivable	\$20,425	\$ 2,548
Deferred	(375)	(2,500)
Amortization	1,959	5,377
Revenues	<u>\$22,009</u>	<u>\$ 5,425</u>

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Research and Development Expenses . Research and development expenses were \$20.3 million in 2007 and \$10.5 million in 2006. This net increase of \$9.8 million consists primarily of a \$6.8 million increase in Phase 3 registration clinical trial expenses for clevidine, a \$1.7 million increase in new drug discovery expenses and related laboratory operating expenses, \$0.5 million in depreciation expense, and \$0.8 million of non-cash stock compensation expenses (primarily resulting from the adoption of Statement of Financial Accounting Standards (“SFAS”) No. 123R, “Share-Based Payment” (“SFAS 123R”) on October 1, 2006). We expect our research and development expenses in 2008 to be greater than in 2007 due to increased investments in our Phase 3 registration clinical trials for clevidine, and in our new drug discovery programs.

General and Administrative Expenses . General and administrative expenses were \$9.2 million in 2007 and \$7.9 million in 2006. The increase of \$1.3 million was due to an increase in non-cash stock compensation expenses of \$1.0 million (resulting from the adoption of SFAS 123R on October 1, 2006), increased compensation expenses of \$0.2 million resulting from an increase in headcount, an increase in insurance expense of \$0.4 million, and increases in travel and other general and administrative expenses of \$0.5 million. These increases were partially offset by decreases in legal and audit fees of \$0.6 million and relocation expenses of \$0.2 million during 2007, compared to 2006.

Investment Income . Investment income was \$2.5 million in 2007 and \$1.7 million in 2006. The increase was due to higher average invested cash balances during 2007, compared to 2006, as a result of our investment of the net proceeds of our IPO, which closed on May 2, 2007.

Income Taxes . As of September 30, 2007, we had United States federal net operating loss carryforwards of approximately \$25.1 million available to offset future taxable income, if any. As of September 30, 2007 we also had research and development tax credits of approximately \$0.1 million available to offset future tax liabilities. As of September 30, 2007, we had a net deferred tax asset of \$17.0 million, before consideration of a valuation allowance. We established a full valuation allowance on our net deferred tax asset as it is more likely than not that such tax benefits will not be realized. The loss carryovers and the research and development tax credits expire over a period of 2020 to 2028.

Preferred Stock Accretion . Preferred stock accretion was \$1.8 million during 2007 and \$1.1 million in 2006. The accretion recorded during 2007 includes \$1.0 million of accretion to bring the carrying amounts of the redeemable convertible preferred stock to their redemption values as of May 2, 2007, the date we completed our IPO and converted all of our then outstanding redeemable convertible preferred stock into our common stock.

Year Ended September 30, 2006 Compared with Nine Months Ended September 30, 2005

On August 10, 2005, we changed our fiscal year-end from December 31 to September 30 for financial reporting purposes. The change was effective for the nine-month period ended September 30, 2005. For tax reporting purposes in 2005, however, we retained a twelve-month year ended December 31, 2005. The discussion below compares the twelve months ended September 30, 2006 to the nine months ended September 30, 2005.

Revenues . Revenues were \$5.4 million in 2006 compared to \$3.7 million in 2005. The increase in revenues in 2006 as compared to 2005 was due to the recognition of the entire remaining balance of \$2.8 million of deferred revenue related to the Incyte collaboration, which was terminated in April 2006.

The following is a reconciliation between cash payments received under contract revenue agreements and contract revenues reported:

	Year Ended September 30,	Nine Months Ended
	2006	September 30, 2005
	(in thousands)	
Cash received/receivable	\$ 2,548	\$ 3,627
Deferred	(2,500)	(2,125)
Amortization	5,377	2,217
Revenues	<u>\$ 5,425</u>	<u>\$ 3,719</u>

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Research and Development Expenses . Research and development expenses were \$10.5 million in 2006 and \$10.5 million in 2005. Research and development expenses in the 12 months of 2006 were approximately the same as in the nine months of 2005 due primarily to increases in research and development expenses in 2006 that approximately matched the amount of the \$6.0 million up-front payment that we made to Bukwang in 2005 for the in-license of clevudine. These increases included approximately \$1.2 million of overall research and development expense attributable to the additional three months of expenses in 2006 compared to 2005, the purchase of \$1.5 million of clevudine to supply the planned Phase 3 clinical trials, \$0.5 million of increased development expense for clevudine, \$0.9 million related to the initiation of research activities in our new laboratory facilities in Princeton, including additional supplies, compensation for additional employees, and increased depreciation, \$0.7 million of increased patent expenses, and \$1.2 million of discovery research outsourced to third parties.

General and Administrative Expenses . General and administrative expenses were \$7.9 million in 2006 and \$8.1 million in 2005. The decrease in general and administrative expenses in 2006 as compared to 2005 was primarily attributable to the existence of approximately \$2.9 million of expense in 2005 related to abandoning our facility in Atlanta, Georgia, including the lease termination payment, the write-off of leasehold improvements and relocation expense. These expenses did not recur in 2006. This decrease was largely offset by increases in overall general and administrative expenses in 2006, including approximately \$1.8 million attributable to the additional three months of expenses in 2006 compared to 2005, increased occupancy expenses of \$0.5 million and increased compensation of \$0.4 million.

Investment Income . Investment income was \$1.7 million in 2006 and \$1.1 million in 2005. The increase in investment income in 2006 as compared to 2005 was attributable primarily to higher average rates of return earned over an additional three months in 2006 compared to 2005, which more than offset the lower average cash balances during 2006 compared to 2005.

Income Taxes. As of September 30, 2006, we had United States federal net operating loss carryforwards of approximately \$18.9 million available to offset future taxable income, if any. As of September 30, 2006 we also had research and development tax credits of approximately \$0.1 million available to offset future tax liabilities. As of September 30, 2006 we had total net deferred tax asset of \$15.3 million, before consideration of a valuation allowance. We established a full valuation allowance on our net deferred tax asset as it was more likely than not that such tax benefits will not be realized. The loss carryovers and the research and development tax credits expire over a period of 2019 to 2026.

Preferred Stock Accretion. Preferred stock accretion was approximately \$1.1 million in 2006 and \$2.3 million in 2005. The decrease in 2006 was attributable to the conversion of preferred stock into common stock in June 2005.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through our IPO, which was completed on May 2, 2007, private placements of our equity securities, payments received under our collaboration agreements, and government grants. Since our inception, we have raised approximately \$102.9 million in net proceeds from sales of our equity securities, including \$40.7 million from our IPO after deducting offering costs paid during fiscal 2007 and \$39.1 million after deducting additional offering costs paid in fiscal 2006. At September 30, 2007, we held approximately \$68.7 million in cash and cash equivalents and approximately \$1.3 million of short-term investments. We have invested a substantial portion of our available cash funds in investment securities consisting of investment grade, marketable debt instruments of corporations, government agencies and financial institutions.

Net cash provided by (used in) operating activities was \$0.9 million, (\$14.6) million, and (\$10.5) million during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively. The \$15.5 million reduction in net cash used in operating activities during 2007, as compared to 2006, was due primarily to increased revenues of \$16.6 million resulting from the receipt of \$20.0 million of

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milestone payments from Roche during 2007. The increase in cash used in operations during 2006, as compared to 2005, was due primarily to the change of accrued expenses from a source of \$2.6 million of cash in 2005 to a use of \$1.7 million of cash in 2006, for a total swing of \$4.3 million; and the reduction in cash payments received from collaborators of \$1.1 million in 2006 compared to 2005.

Net cash (used in) provided by investing activities was (\$0.4) million, \$8.5 million, and \$42.7 million during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively. The net cash provided by investing activities in 2006 included proceeds from the sale of investments of \$10.8 million. Such investments were sold to fund our operations. No such investments were sold during 2007, as milestone payments received from Roche were used to fund operations. The net cash provided by investing activities in 2006 of \$8.5 million also included purchases of equipment and leasehold improvements of \$2.3 million for our lab and office space in Princeton, New Jersey. The decrease in cash provided by investing activities in 2006 as compared to 2005 was due primarily to the shift in our portfolio from investments to cash equivalents, so that our use of cash in operating activities in 2006 was partly funded by selling investments and partly funded by drawing down cash balances. In contrast, in 2005 operations were funded almost entirely by selling investments. In addition, net cash provided by investing activities was reduced in 2006 by \$2.3 million invested in the purchase of property plant and equipment, compared to \$0.8 million in 2005.

Net cash provided by (used in) financing activities was \$42.1 million, (\$1.1) million, and \$1.0 million during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively. The net cash provided by financing activities during 2007 includes net proceeds from our IPO of \$40.7 million after deducting offering costs paid during fiscal 2007, along with proceeds from the exercise of stock options of \$1.6 million. Net cash used in financing activities in 2006 resulted from offering costs paid of \$1.5 million that were partially offset by proceeds from the exercise of stock options of \$0.3 million. Net cash provided by financing activities in 2005 consisted of \$0.7 million from the exercise of stock options and \$0.3 million from the sale of stock to an employee.

On September 30, 2007, we entered into the Loan Agreement with a lender that allows us to borrow up to \$30.0 million in \$10.0 million increments as follows:

- The first \$10.0 million (“Loan A”) is subject to ordinary and customary closing procedures as noted in the Loan Agreement, including the execution of a promissory note, all of which were completed subsequent to September 30, 2007, resulting in the funding of Loan A on October 5, 2007 in the amount of \$10.0 million.
- The second \$10.0 million (“Loan B”) is subject to ordinary and customary closing procedures, including the execution of a promissory note, and has a commitment termination date of March 31, 2008.
- The third \$10.0 million (“Loan C”) is subject to ordinary and customary closing procedures, including the execution of a promissory note, and is also subject to the achievement of certain product development milestones, and has a commitment termination date of November 30, 2008.

The interest rate on each loan is equal to 12% plus the amount, if any, by which the one month LIBOR rate five days before the funding date for such loan exceeds 5.32% (12% for Loan A as determined on October 5, 2007). The loans will be repaid over a 45-month period with the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. Prepayment of the loan is subject to penalty and substantially all of our tangible and intangible assets (except for intellectual property) are collateral for the Loan Agreement.

Under the Loan Agreement, we agreed that in the event our market capitalization is below \$90.0 million for 15 consecutive days in which the principal market for our common stock is open for trading to the public, we will be required to repay 50% of the then outstanding principal balance of the loans. We further agreed that in the event our market capitalization is below \$40.0 million for 15 consecutive days in which the principal market for

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our common stock is open for trading to the public, we will be required to repay all of the then outstanding principal balance of the loans. In addition, all of our assets other than our intellectual property secure the loans. The lender could obtain rights to the secured assets in the event we default on our obligations under the Loan Agreement.

The Loan Agreement also contains covenants that, among other things, require us to obtain consent from the lender prior to paying dividends, making certain investments, changing the nature of our business, assuming or guaranteeing the indebtedness of another entity or individual, selling or otherwise disposing of a substantial portion of our assets, or merging or consolidating with another entity.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash resources, together with borrowings available under the Loan Agreement and anticipated payments under our existing collaboration agreements, will be sufficient to fund our projected cash requirements for the next 18 months, we will require significant additional financing in the future to complete our clinical trials for clevidine and fund our other operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration agreements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our product candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses; and
- any costs that we may incur under current and future licensing arrangements relating to our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. 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.

Contractual Obligations and Commitments

In May 2005, we entered into an operating lease for office and laboratory space through May 22, 2010, in Princeton, New Jersey. In April 2007, we entered into a lease for office space in Durham, North Carolina. In January 2007, we entered into a capital lease for lab equipment through December 2008.

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As of September 30, 2007, future payments under capital leases and minimum future payments under non-cancellable operating leases are as follows:

	Total	Payments Due By Period			
		Less than 1 year	1-3 Years	4-5 Years	After 5 Years
Long-term debt obligations					
Debt maturities	\$ —	\$ —	\$ —	\$ —	\$ —
Contractual interest	—	—	—	—	—
Capital lease obligations					
Debt maturities	201,081	159,440	41,641	—	—
Contractual interest	9,576	9,086	490	—	—
Operating leases	2,308,611	905,471	1,403,140	—	—
Purchase obligations	—	—	—	—	—
Total contractual obligations	<u>\$2,519,268</u>	<u>\$1,073,997</u>	<u>\$1,445,271</u>	<u>\$ —</u>	<u>\$ —</u>

The above contractual obligations table does not include amounts for milestone payments related to development, regulatory or commercialization events to licensors or collaboration partners, as the payments are contingent on the achievement of these milestones, which we have not achieved. DOT, which we licensed from RFS Pharma, is in the early stage of research and therefore it is not possible to predict when we would need to make a milestone payment. We may pay up to an aggregate of \$4.5 million in milestone payments and certain cost reimbursements if we reach milestones related to development and regulatory events under our license agreement with RFS Pharma LLC. We also agreed to pay Emory University up to an aggregate of \$1.0 million in future marketing milestone payments under our license agreement for DFC. Under our collaboration and license agreement with Bukwang, in the future we may pay up to an aggregate of \$23.0 million in milestone payments related to development, regulatory and commercialization events. Under our license agreement with Emory University for Racivir, we agreed to pay Emory University up to an aggregate of \$1.0 million in future marketing milestone payments.

Off-Balance Sheet Transactions

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosures. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Our actual results may differ substantially from these estimates under different assumptions or conditions. Our significant accounting policies are described in more detail in Note 2 of the Notes to Financial Statements included elsewhere in this Annual Report on Form 10-K; however, we believe that the following accounting policies are critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition —We recognize revenues in accordance with the Securities and Exchange Commission (“SEC”) Staff Accounting Bulletin (“SAB”) No. 104, *Revenue Recognition (“SAB No. 104”)*. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and

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collectibility is reasonably assured. For arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets, we recognize revenue in accordance with the guidance of Emerging Issues Task Force (“EITF”) No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

Our revenues are primarily related to our collaboration agreements, and these agreements provide for various types of payments to us, including non-refundable upfront license fees, research and development payments, and milestone payments.

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as revenue as the related activities are performed. The period over which these activities are to be performed is based upon our estimate of the development period. Changes in our estimate could change the period over which revenue is recognized. Payments for research funding are recognized as revenues as the related research activities are performed.

We recognize revenue from milestone payments when earned, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone. Any amounts received under the agreements in advance of performance, if deemed substantive, are recorded as deferred revenue and recognized as revenue as we complete our performance obligations.

Where we have no continuing involvement under a collaborative arrangement, we record nonrefundable license fee revenues when we have the contractual right to receive the payment, in accordance with the terms of the license agreement, and records milestones upon appropriate notification to us of achievement of the milestones by the collaborative partner.

Deferred revenues associated with a non-refundable payment received under a collaborative agreement that is terminated prior to its completion result in an immediate recognition of the deferred revenues.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves estimating the level of service performed on our behalf and the associated cost incurred in instances where we have not been invoiced or otherwise notified of actual costs. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, clinical trials and manufacturing of clinical materials. We account for expenses associated with these external services by determining the total cost of a given study based on the terms of the related contract. We accrue for costs incurred as the services are being provided by monitoring the status of the trials and the invoices received from our external service providers. In the case of clinical trials, the estimated cost normally relates to the projected costs of treating the patients in our trials, which we recognize over the estimated term of the trial according to the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, the number of clinical trials and related research service agreements has been relatively limited and our estimates have not differed significantly from the actual costs incurred. We expect, however, as clinical trials for clevidine, Racivir and R7128 advance, that our estimated accruals for clinical and research services will be more material to our operations in future periods.

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Stock-based Compensation

We account for stock-based compensation arrangements in accordance with the provisions of SFAS 123R. SFAS 123R requires companies to recognize stock compensation expense for awards of equity instruments based on grant-date fair value of those awards (with limited exceptions). We adopted SFAS 123R using the modified prospective method, which results in recognition of compensation expense for all share-based awards granted or modified after October 1, 2006 as well as all unvested awards outstanding at the date of adoption. The cost is recognized as compensation expense over the life of the instruments, based upon the grant-date fair value of the equity or liability instruments issued. Prior to October 1, 2006, we accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board (“APB”) Opinion No. 25, “*Accounting for Stock Issued to Employees*” (“APB 25”) and related interpretations and had adopted the pro forma disclosure option for stock-based employee compensation under SFAS No. 123, “*Accounting for Stock-Based Compensation*” (“SFAS No. 123”). Stock options granted to consultants are periodically valued as they vest in accordance with EITF 96-18, “*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,*” using a Black-Scholes option pricing model. The fair value of our employee and director options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions.

	Years Ended September 30,		Nine Months Ended September 30, 2005
	2007	2006	
Risk free interest rate	4.55%	4.78%	3.98%
Expected dividend yield	0.0%	0.0%	0.0%
Expected lives (years)	5.94	5.00	5.00
Expected volatility	54.33%	53.10%	59.20%
Weighted-average fair value of options granted	\$ 2.79	\$ 1.98	\$ 3.17

Recently Issued Accounting Standards

On February 15, 2007, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*” (“SFAS 159”). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and 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 fiscal years beginning after November 15, 2007. We are currently evaluating the impact this standard would have on our financial statements.

In September 2006, the FASB issued SFAS No. 157, “*Fair Value Measurements*” (“SFAS 157”). This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The adoption of SFAS 157 is not expected to have a material impact on us.

In July 2006, the FASB issued FASB interpretation No. 48, “*Accounting for Uncertainty in Income Taxes*” (“FIN 48”). FIN 48 clarifies the accounting for income taxes by prescribing a minimum probability threshold that a tax position must meet before a financial statement benefit is recognized. The minimum threshold is defined in FIN 48 as a tax position that, based solely on its technical merits, is more likely than not to be sustained upon examination by the applicable taxing authority. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. FIN 48 must be applied to all existing tax positions upon initial adoption. The cumulative effect of applying FIN 48 at adoption, if any, is to be reported as an adjustment to opening retained earnings for the year of adoption. FIN 48 is effective for fiscal years beginning after December 15, 2006, although early adoption is permitted. The adoption of FIN 48 is not expected to have a material impact on us.

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In May 2005, the FASB issued SFAS No. 154 “ *Accounting Changes and Error Corrections* ” (“SFAS 154”), which replaces APB Opinion No. 20, “ *Accounting Changes* ” and SFAS No. 3, “ *Reporting Accounting Changes in Interim Financial Statements—An Amendment of APB Opinion No. 28.* ” SFAS 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 and, accordingly, was adopted by us on October 1, 2006.

In September 2006, the SEC issued SAB 108, “ *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ” (“SAB 108”). The SEC staff has provided guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year’s financial statements are materially misstated. The SEC staff indicated that “registrants must quantify the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements.” If correcting a misstatement in the current year would materially misstate the current year’s income statement, the SEC staff indicated that the prior year financial statements should be adjusted. These adjustments to prior year financial statements are necessary even though such adjustments were appropriately viewed as immaterial in the prior year. If a company determines that an adjustment to prior year financial statements is required upon adoption of SAB 108 and does not elect to restate its previous financial statements, then it must recognize the cumulative effect of applying SAB 108 in the beginning balances of the affected assets and liabilities with a corresponding adjustment to the opening balance in retained earnings. We began applying SAB 108 as of January 1, 2007. Such application had no impact on our fiscal 2007 financial statements.

In June 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* . Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2007, and earlier application is not permitted. This consensus is to be applied prospectively for new contracts entered into on or after the effective date. We are evaluating the potential impact of this consensus and do not expect it to have a material effect on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We invest our excess cash in high quality, interest-bearing securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality marketable debt instruments of corporations, government agencies and financial institutions with maturities of less than two years. If a 10% change in interest rates were to have occurred on September 30, 2007, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Foreign Currency Exchange Rate Risk

We have entered into some agreements denominated, wholly or partly, in foreign currencies, and, in the future, we may enter into additional, agreements denominated in foreign currencies. If the values of these currencies increase against the United States dollar, our costs would increase. To date, we have not entered into any contracts to reduce the risk of fluctuations in currency exchange rates. In the future, depending upon the

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amounts payable under any such agreements, we may enter into forward foreign exchange contracts to reduce the risk of unpredictable changes in these costs. However, due to the variability of timing and amount of payments under any such agreements, foreign exchange contracts may not mitigate the potential adverse impact on our financial results.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item is included in our Financial Statements and Supplementary Data listed in Item 15 of Part IV of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of September 30, 2007. Based on that evaluation, our principal executive officer and principal financial officer concluded that these controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported as specified in SEC rules and forms. There were no changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during our last fiscal quarter, or in other factors that have materially affected, or are reasonably likely to materially affect, these controls or procedures.

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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

No change in our internal control over financial reporting occurred during the three months ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding executive officers and directors required by this Item 10 will be included in the definitive Proxy Statement for our 2008 Annual Meeting, or 2008 Proxy Statement, under “Election of Directors”, “Executive Officers of the Company” and “Corporate Governance” and is incorporated herein by reference. Other information required by this Item 10 will be included in the 2008 Proxy Statement under “Section 16(a) Beneficial Ownership Reporting Compliance” and “Code of Ethics” and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the information contained under the sections captioned “Information About Executive and Director Compensation” and “Compensation Committee Interlocks and Insider Participation” of the 2008 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated herein by reference to the information contained under the sections captioned “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Our Equity Incentive Plans” of the 2008 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference to the information contained under the sections captioned “Corporate Governance—Certain Relationships and Related Transactions” and “Corporate Governance—Board Determination of Independence” of the 2008 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated herein by reference to the information contained under the sections captioned “Fees of Independent Registered Public Accounting Firm” and “Pre-Approval Policies and Procedures” of the 2008 Proxy Statement.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

The following documents are included on pages F-2 through F-34 attached hereto and are filed as part of this Annual Report on Form 10-K.

	Page Number in this Form 10-K
Reports of Independent Registered Public Accounting Firms	F-2, F-3
Balance Sheets as of September 30, 2007 and 2006	F-4, F-5
Statements of Operations and Comprehensive Net Loss for the years ended September 30, 2007 and 2006, and for the nine months ended September 30, 2005	F-6
Statements of Redeemable Stock and Warrants for the years ended September 30, 2007 and 2006, and for the nine months ended September 30, 2005	F-7
Statements of Stockholders' Equity (Deficit) for the years ended September 30, 2007 and 2006, and for the nine months ended September 30, 2005	F-8
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(a) (2) Financial Statement Schedules

Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the financial statements or notes thereto.

(a) (3) List of Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. We are incorporating by reference to our previous SEC filings each exhibit that contains a footnote. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated in parentheses.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant
3.2	Second Amended and Restated Bylaws of the Registrant
4.1**#	Pharmasset, Ltd. 1998 Stock Plan, as amended (Exhibit 4.4) (3)
4.2**#	2007 Equity Incentive Plan (Exhibit 4.12) (3)
4.3#	Form of agreement for awards under the 2007 Equity Incentive Plan
10.1**†	Collaboration Agreement, dated October 29, 2004, between F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. and the Registrant (Exhibit 10.1) (4)
10.2**†	License Agreement, dated June 23, 2005, between Bukwang Pharm. Co., Ltd. and the Registrant (Exhibit 10.2) (4)
10.3**	Memorandum of Understanding, dated June 23, 2005, between The University of Georgia Research Foundation, Inc., Yale University and the Registrant (Exhibit 10.3) (1)
10.4**†	Exclusive Patent and Know How License Agreement, dated April 24, 2003, by and between Primagen Holding B.V. and the Registrant (Exhibit 10.4) (4)

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Exhibit Number	Description
10.5**†	Non-Exclusive Sublicense Agreement, dated August 26, 2005, between Apath, L.L.C. and the Registrant (Exhibit 10.5) (4)
10.6**†	License Agreement, dated March 1, 1999, among Pharmasset, Ltd., Dr. Raymond F. Schinazi, Dr. Mahmoud H. el Kouni and Dr. Fardos N. M. Naguib (Exhibit 10.6) (1)
10.7**†	License and Consulting Agreement, dated March 1, 1999, among Pharmasset, Ltd., Dr. Raymond F. Schinazi and Dr. Craig L. Hill (Exhibit 10.7) (1)
10.8**†	License Agreement, dated December 30, 1998, between Emory University and Pharmasset, Ltd. (Exhibit 10.8) (1)
10.9**†	License Agreement, dated December 8, 1998, between Emory University and Pharmasset, Ltd. (Exhibit 10.9) (1)
10.10**†	License Agreement, dated February 10, 2006, between RFS Pharma LLC and the Registrant (Exhibit 10.10) (4)
10.11**	First Amendment to License Agreement, dated February 13, 2006, by and between RFS Pharma LLC and the Registrant (Exhibit 10.11) (1)
10.12**†	Second Amendment to License Agreement, dated as of August 29, 2003, between Emory University and Pharmasset, Ltd. (Exhibit 10.12) (1)
10.13**	Termination and Reinstatement Agreement, dated as of June 9, 1999, between Emory University and Pharmasset, Ltd. (Exhibit 10.13) (1)
10.14**	Supplemental Agreement to the License Agreement, dated as of March 26, 2004, between Emory University and Pharmasset, Ltd. (Exhibit 10.14) (1)
10.15**#	Employment Agreement, dated as of June 15, 2004, between the Registrant and Peter Schaefer Price (Exhibit 10.15) (1)
10.16**	Lease, dated as of May 18, 2005, between 300 CRA LLC and the Registrant (Exhibit 10.18) (1)
10.17**	Mutual Termination of Lease Agreement, dated as of February 7, 2006, between C.S. Family, LLC and the Registrant (Exhibit 10.19) (1)
10.18**	Settlement Agreement and Mutual General Release, dated as of February 14, 2006, among the Registrant, Raymond F. Schinazi and the other signatories thereto (Exhibit 10.20) (1)
10.19**#	Form of Indemnity Agreement for Directors and Officers (Exhibit 10.21) (3)
10.20**#	Consulting Agreement, dated June 28, 2005, between Michael K. Inouye and the Registrant (Exhibit 10.22) (1)
10.21**#	Form of Change of Control Severance Agreement (Exhibit 10.23) (2)
10.22**#	Severance Agreement, dated as of January 5, 2007, between the Registrant and Abel De La Rosa, Ph.D. (Exhibit 10.24) (2)
10.23††	Venture Loan and Security Agreement dated as of September 30, 2007 by and between the Registrant and Horizon Technology Funding Company V LLC
23.1	Consent of Deloitte & Touche LLP
23.2	Consent of Grant Thornton LLP
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

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<u>Exhibit Number</u>	<u>Description</u>
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

** Previously filed.

† Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to an order of the SEC granting our application for confidential treatment filed pursuant to Rule 406 under the Securities Act.

†† Portions of the exhibits have been omitted pursuant to a confidential treatment request and this information has been filed separately with the SEC.

Management contract or compensatory plan or arrangement.

(1) Filed as an Exhibit to our Registration Statement on Form S-1 filed with the SEC on May 8, 2006.

(2) Filed as an Exhibit to our Registration Statement on Form S-1/A filed with the SEC on January 17, 2007.

(3) Filed as an Exhibit to our Registration Statement on Form S-1/A filed with the SEC on March 2, 2007.

(4) Filed as an Exhibit to our Registration Statement on Form S-1/A filed with the SEC on April 24, 2007.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMASSET, INC.

December 31, 2007

By: /s/ P. S CHAEFER P RICE
P. Schaefer Price
President and Chief Executive Officer

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

Each person, in so signing also makes, constitutes, and appoints Kurt Leutzinger as his true and lawful attorney-in-fact, with full power of substitution, in his name, place, and stead, to execute and cause to be filed with the Securities and Exchange Commission any or all amendments to this report

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u> /s/ P. S CHAEFER P RICE </u> P. Schaefer Price	Director, President and Chief Executive Officer (Principal Executive Officer)	December 31, 2007
<u> /s/ KURT L EUTZINGER </u> Kurt Leutzinger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 31, 2007
<u> /s/ G. S TEVEN B URRILL </u> G. Steven Burrill	Chairman of the Board of Directors	December 31, 2007
<u> /s/ W ILLIAM J. C ARNEY </u> William J. Carney, Esq.	Director	December 31, 2007
<u> /s/ F REDRIC D. P RICE </u> Fredric D. Price	Director	December 31, 2007
<u> /s/ E LLIOT F. H AHN </u> Elliot F. Hahn, Ph.D.	Director	December 31, 2007
<u> /s/ M ICHAEL K. I NOUYE </u> Michael K. Inouye	Director	December 31, 2007
<u> /s/ R OBERT F. W ILLIAMSON </u> Robert F. Williamson III	Director	December 31, 2007

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Pharmasset, Inc.

We have audited the accompanying balance sheets of Pharmasset, Inc. (the “Company”) as of September 30, 2007 and 2006, and the related statements of operations and comprehensive net loss, redeemable stock and warrants, stockholders’ equity (deficit), and cash flows for each of the two years in the period ended September 30, 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. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Pharmasset, Inc. as of September 30, 2007 and 2006, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the financial statements, on October 1, 2006 the Company changed its method of accounting for share-based compensation when it adopted SFAS No. 123R, “Share Based Payment”.

/s/ Grant Thornton LLP

Philadelphia, Pennsylvania
December 24, 2007

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying statements of operations and comprehensive net loss, redeemable stock and warrants, stockholders' (deficit) equity, and cash flows of Pharmasset, Inc. (the "Company") for the nine months ended September 30, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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 the financial statements are free of material misstatement. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the results of operations and cash flows for the nine months ended September 30, 2005, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 18, the accompanying 2005 financial statements have been restated.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey

May 5, 2006 (January 4, 2007 as to the effect of the restatement, discussed in Note 18, and April 19, 2007 as to the effect of the reverse stock split, discussed in Note 17)

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**PHARMASSET, INC.
BALANCE SHEETS**

	As of September 30,	
	2007	2006
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$68,745,694	\$26,182,316
Short-term investments	1,252,113	1,250,013
Amounts due under collaborative agreements	919,110	297,070
Prepaid expenses and other assets	783,311	359,082
Deferred offering costs	—	1,608,826
Total current assets	<u>71,700,228</u>	<u>29,697,307</u>
EQUIPMENT AND LEASEHOLD IMPROVEMENTS:		
Laboratory, office furniture and equipment	2,462,647	1,877,095
Leasehold improvements	<u>1,836,553</u>	<u>1,836,553</u>
	4,299,200	3,713,648
Less accumulated depreciation and amortization	<u>(1,437,080)</u>	<u>(544,725)</u>
Total equipment and leasehold improvements, net	<u>2,862,120</u>	<u>3,168,923</u>
OTHER ASSETS	<u>1,282,051</u>	<u>131,300</u>
TOTAL	<u><u>\$75,844,399</u></u>	<u><u>\$32,997,530</u></u>

See notes to financial statements.

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PHARMASSET, INC.
BALANCE SHEETS—(Continued)

	As of September 30,	
	2007	2006
LIABILITIES, REDEEMABLE STOCK AND WARRANTS, AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,281,600	\$ 710,386
Accrued expenses	5,513,407	2,055,025
Deferred rent	124,462	124,462
Current portion of capital lease obligation	159,440	—
Deferred revenue	1,857,136	1,803,564
Total current liabilities	10,936,045	4,693,437
DEFERRED RENT	204,256	328,718
NON CURRENT PORTION OF CAPITAL LEASE OBLIGATION	41,641	—
DEFERRED REVENUE	5,726,131	7,364,547
Total liabilities	16,908,073	12,386,702
COMMITMENTS		
REDEEMABLE STOCK AND WARRANTS:		
Series B redeemable convertible preferred stock; \$0.001 par value per share; 2,300,000 shares authorized, 367,999 shares issued, outstanding and convertible into 245,333 common shares at September 30, 2006; liquidation value of \$625,598 at September 30, 2006	—	624,843
Series C redeemable convertible preferred stock; \$0.001 par value per share; 1,357,798 shares authorized, 366,606 shares issued, outstanding and convertible into 250,121 common shares at September 30, 2006; liquidation value of \$1,997,997 at September 30, 2006	—	1,996,440
Series D redeemable convertible preferred stock; \$0.001 par value per share; 7,843,380 shares authorized, 2,505,686 shares issued, outstanding and convertible into 1,670,457 common shares at September 30, 2006; liquidation value of \$12,778,999 at September 30, 2006	—	12,958,455
Series R redeemable convertible preferred stock; \$0.001 par value per share; 400,000 shares authorized, issued, outstanding and convertible into 266,667 common shares at September 30, 2006; liquidation value of \$4,000,000 at September 30, 2006	—	3,796,941
Series R-1 warrants to purchase 470,588 shares of Series R-1 redeemable convertible preferred stock for \$12.75 per share, convertible into 313,725 common shares; exercisable starting October 26, 2004	—	264,000
Redeemable common stock; \$0.001 par value; 213,307 shares authorized, issued and outstanding at September 30, 2006	—	1,190,251
Total redeemable stock and warrants	—	20,830,930
STOCKHOLDERS' EQUITY (DEFICIT):		
Series A convertible preferred stock; \$0.001 par value per share; 3,200,000 shares authorized, 2,639,722 shares issued, outstanding and convertible into 1,759,814 common shares at September 30, 2006; liquidation value of \$3,685,176 at September 30, 2006	—	2,640
Series D-1 warrants to purchase 1,254,960 shares of D-1 convertible preferred stock for \$0.10 per share, convertible into 836,640 common shares; exercisable starting August 4, 2006	—	5,411,932
Common stock; \$0.001 par value per share; 100,000,000 shares authorized, 21,232,991 shares issued and outstanding at September 30, 2007; 30,000,000 shares authorized, 10,291,386 shares issued and outstanding at September 30, 2006	21,233	10,291
Warrants to purchase 66,390 shares of common stock for \$12.05 per share, exercisable starting September 30, 2007	526,720	—
Additional paid-in capital	115,518,201	44,480,015
Accumulated other comprehensive income	4,405	2,305
Accumulated deficit	(57,134,233)	(50,127,285)
Total stockholders' equity (deficit)	58,936,326	(220,102)
TOTAL	\$ 75,844,399	\$ 32,997,530

See notes to financial statements.

PHARMASSET, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE NET LOSS

	<u>Years Ended September 30,</u>		<u>Nine Months Ended September 30, 2005 (Restated – See Note 18)</u>
	<u>2007</u>	<u>2006</u>	
REVENUES	\$22,009,458	\$ 5,424,614	\$ 3,719,104
COSTS AND EXPENSES:			
Research and development	20,318,910	10,497,703	10,468,026
General and administrative	9,210,623	7,911,545	8,095,897
Total costs and expenses	<u>29,529,533</u>	<u>18,409,248</u>	<u>18,563,923</u>
OPERATING LOSS	(7,520,075)	(12,984,634)	(14,844,819)
INVESTMENT INCOME	2,470,563	1,658,977	1,136,035
INTEREST EXPENSE	(15,136)	—	—
LOSS BEFORE INCOME TAXES	(5,064,648)	(11,325,657)	(13,708,784)
PROVISION FOR INCOME TAXES	—	—	—
NET LOSS	(5,064,648)	(11,325,657)	(13,708,784)
REDEEMABLE PREFERRED STOCK ACCRETION	1,775,684	1,110,973	2,286,799
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$(6,840,332)</u>	<u>\$(12,436,630)</u>	<u>\$(15,995,583)</u>
COMPREHENSIVE NET LOSS:			
NET LOSS	\$ (5,064,648)	\$(11,325,657)	\$(13,708,784)
UNREALIZED GAIN (LOSS) ON AVAILABLE-FOR-SALE INVESTMENTS	2,100	(56,465)	58,454
COMPREHENSIVE NET LOSS:	<u>\$(5,062,548)</u>	<u>\$(11,382,122)</u>	<u>\$(13,650,330)</u>
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER SHARE:			
BASIC	\$ (0.46)	\$ (1.19)	\$ (2.42)
DILUTED	\$ (0.46)	\$ (1.19)	\$ (2.42)
WEIGHTED AVERAGE SHARES OUTSTANDING:			
BASIC	14,990,472	10,462,369	6,630,463
DILUTED	14,990,472	10,462,369	6,630,463

See notes to financial statements.

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PHARMASSET, INC.

STATEMENTS OF REDEEMABLE STOCK AND WARRANTS
FOR THE YEARS ENDED SEPTEMBER 30, 2007 AND 2006, AND NINE MONTHS ENDED SEPTEMBER 30, 2005

	Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series R Redeemable Convertible Preferred Stock		Series R-1 Warrants		Redeemable Common Stock		Total Redeemable Stock And Warrants
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Number	Amount	Shares	Amount	
BALANCE—													
December 31, 2004—Restated	2,300,000	\$ 3,902,368	1,357,798	\$ 7,390,634	7,843,380	\$ 34,946,544	400,000	\$ 3,674,784	470,588	\$ 264,000	213,307	\$ 947,082	\$ 51,125,412
Conversion of preferred stock to common stock	(1,932,001)	(3,284,402)	(991,192)	(5,401,996)	(5,337,694)	(25,249,025)	—	—	—	—	—	—	(33,935,423)
Accretion of redeemable preferred stock to redemption value	—	6,611	—	7,250	—	2,220,884	—	52,054	—	—	—	—	2,286,799
Accretion of redeemable common stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	31,996	31,996
BALANCE—													
September 30, 2005—Restated	367,999	624,577	366,606	1,995,888	2,505,686	11,918,403	400,000	3,726,838	470,588	264,000	213,307	979,078	19,508,784
Accretion of redeemable preferred stock to redemption value	—	266	—	552	—	1,040,052	—	70,103	—	—	—	—	1,110,973
Accretion of redeemable common stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	211,173	211,173
BALANCE—													
September 30, 2006	367,999	624,843	366,606	1,996,440	2,505,686	12,958,455	400,000	3,796,941	470,588	264,000	213,307	1,190,251	20,830,930
Accretion of redeemable common stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	729,508	729,508
Expiration of Series R-1 warrants	—	—	—	—	—	—	—	—	(470,588)	(264,000)	—	—	(264,000)
Accretion of redeemable convertible preferred stock to total redemption value	—	756	—	1,562	—	1,570,307	—	203,059	—	—	—	—	1,775,684
Payment of dividends in the form of common stock	—	—	—	—	—	(1,186,871)	—	—	—	—	—	—	(1,186,871)
Return of excess dividend accretion to retained earnings	—	—	—	—	—	(562,892)	—	—	—	—	—	—	(562,892)
Conversion of redeemable convertible preferred stock into common stock	(367,999)	(625,599)	(366,606)	(1,998,002)	(2,505,686)	(12,778,999)	(400,000)	(4,000,000)	—	—	—	—	(19,402,600)
Conversion of redeemable common stock into common stock	—	—	—	—	—	—	—	—	—	—	(213,307)	(1,919,759)	(1,919,759)
BALANCE—													
September 30, 2007	—	—	—	—	—	—	—	—	—	—	—	—	—

See notes to financial statements.

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PHARMASSET, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE YEARS ENDED SEPTEMBER 30, 2007 AND 2006, AND THE NINE MONTHS ENDED SEPTEMBER 30, 2005

	Warrants		Series A Convertible Preferred Stock		Series D-1 Warrants		Common Stock		Additional Paid-in Capital	Series A Issuable	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Number	Amount	Shares	Amount					
BALANCE—December 31, 2004—Restated	—	\$ —	3,084,545	\$ 3,085	1,254,960	\$ 5,411,932	3,994,833	\$ 3,995	8,301,077	\$ 300,719	\$ 316	\$ (21,451,903)	\$ (7,430,779)
Exercise of stock options	—	—	—	—	—	—	207,571	207	691,255	—	—	—	691,462
Conversion of preferred stock to common stock	—	—	(500,000)	(500)	—	—	5,856,048	5,856	33,930,067	—	—	—	33,935,423
Sale of common stock	—	—	—	—	—	—	100,000	100	299,900	—	—	—	300,000
Stock compensation	—	—	—	—	—	—	—	—	141,157	—	—	—	141,157
Accretion of redeemable preferred stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	(2,286,799)	(2,286,799)
Accretion of redeemable common stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	(31,996)	(31,996)
Unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	58,454	—	58,454
Net loss	—	—	—	—	—	—	—	—	—	—	—	(13,708,784)	(13,708,784)
BALANCE—September 30, 2005—Restated	—	—	2,584,545	2,585	1,254,960	5,411,932	10,158,452	10,158	43,363,456	300,719	58,770	(37,479,482)	11,668,138
Exercise of stock options	—	—	—	—	—	—	132,934	133	338,669	—	—	—	338,802
Stock compensation	—	—	—	—	—	—	—	—	477,226	—	—	—	477,226
Issuance of Series A convertible preferred stock	—	—	55,177	55	—	—	—	—	300,664	(300,719)	—	—	—
Accretion of redeemable preferred stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	(1,110,973)	(1,110,973)
Accretion of redeemable common stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	(211,173)	(211,173)
Unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	(56,465)	—	(56,465)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(11,325,657)	(11,325,657)
BALANCE—September 30, 2006	—	—	2,639,722	2,640	1,254,960	5,411,932	10,291,386	10,291	44,480,015	—	2,305	(50,127,285)	(220,102)
Expiration of Series R-1 warrants	—	—	—	—	—	—	—	—	264,000	—	—	—	264,000
Exercise of stock options	—	—	—	—	—	—	531,420	531	1,500,741	—	—	—	1,501,272
Stock compensation	—	—	—	—	—	—	—	—	2,284,778	—	—	—	2,284,778
Accretion of redeemable preferred stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	(1,775,684)	(1,775,684)
Accretion of redeemable common stock to redemption value	—	—	—	—	—	—	—	—	—	—	—	(729,508)	(729,508)
Payment of dividends in the form of common stock	—	—	—	—	—	—	131,864	132	1,186,644	—	—	—	1,186,776
Conversion of convertible preferred stock into common stock	—	—	(2,639,722)	(2,640)	—	—	4,192,377	4,193	19,400,912	—	—	—	19,402,465
Conversion of Series D-1 warrants into common stock	—	—	—	—	(1,254,960)	(5,411,932)	822,689	823	5,411,047	—	—	—	(62)
Conversion of redeemable common stock into common stock	—	—	—	—	—	—	213,306	213	1,919,541	—	—	—	1,919,754
Return of excess dividend accretion to retained earnings	—	—	—	—	—	—	—	—	—	—	—	562,892	562,892
Net proceeds from initial public offering	—	—	—	—	—	—	5,050,000	5,050	39,070,523	—	—	—	39,075,573
Unrealized loss on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	2,100	—	2,100
Sale of warrants in connection with debt financing	66,390	526,720	—	—	—	—	—	—	—	—	—	—	526,720
Net loss	—	—	—	—	—	—	—	—	—	—	—	(5,064,648)	(5,064,648)
BALANCE—September 30, 2007	66,390	\$526,720	—	\$ —	—	\$ —	21,233,042	\$ 21,233	115,518,201	\$ —	\$ 4,405	\$ (57,134,233)	\$ 58,936,326

See notes to financial statements.

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PHARMASSET, INC.
STATEMENTS OF CASH FLOWS

	<u>Years Ended September 30,</u>		<u>Nine Months Ended September 30, 2005 (Restated – See Note 18)</u>
	<u>2007</u>	<u>2006</u>	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (5,064,648)	\$(11,325,657)	\$ (13,708,784)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	403,125	351,016	181,553
Amortization	489,230	311,532	103,846
Non-cash stock compensation	2,284,778	477,226	141,157
Loss on disposal of fixed assets	—	8,227	—
Impairment of abandoned equipment and leasehold improvements	—	—	714,634
Changes in operating assets and liabilities:			
Amounts due under collaborative agreements, prepaid expenses and other assets	(1,337,622)	(700,178)	(213,807)
Accounts payable	2,571,119	397,637	43,247
Accrued expenses	3,290,479	(1,709,970)	2,633,673
Deferred offering costs	—	—	(261,863)
Deferred rent	(124,462)	453,180	(79,591)
Deferred revenue	(1,584,844)	(2,876,167)	(92,165)
Net cash provided by (used in) operating activities	<u>927,155</u>	<u>(14,613,154)</u>	<u>(10,538,100)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of investments	—	—	(68,751,153)
Proceeds from maturities or sale of investments	—	10,800,000	112,248,471
Purchase of property, plant, and equipment	(437,010)	(2,332,500)	(816,462)
Net cash (used in) provided by investing activities	<u>(437,010)</u>	<u>8,467,500</u>	<u>42,680,856</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	1,621,272	338,802	691,461
Proceeds from issuance of common stock in initial public offering, net of issuance costs of \$1,584,101 paid during the year	40,684,399	—	—
(Payments)/proceeds related to (purchase)/issuance of common stock	(120,000)	—	300,000
Principal payments on capital lease obligations	(112,438)	—	—
Offering costs paid	—	(1,452,332)	—
Net cash provided by (used in) financing activities	<u>42,073,233</u>	<u>(1,113,530)</u>	<u>991,461</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	42,563,378	(7,259,184)	33,134,217
CASH AND CASH EQUIVALENTS—Beginning of period	26,182,316	33,441,500	307,283
CASH AND CASH EQUIVALENTS—End of period	<u>\$68,745,694</u>	<u>\$ 26,182,316</u>	<u>\$ 33,441,500</u>
SUPPLEMENTAL DISCLOSURES:			
Cash paid during the period for:			
Interest	\$ 15,136	\$ —	\$ —
Income taxes paid	\$ —	\$ —	\$ 6,484
Income taxes refunded	\$ —	\$ —	\$ 110,233
Noncash transactions:			
Deferred compensation—Series A convertible preferred shares issuable	\$ —	\$ (300,719)	\$ —
Accretion of redeemable convertible preferred stock to redemption value	\$ 1,775,684	\$ 1,110,973	\$ 2,286,799
Accretion of redeemable common stock to redemption value	\$ 729,508	\$ 211,173	\$ 31,996
Fixed assets purchased on account	\$ —	\$ 164,977	\$ 37,000
Unrealized gain (loss) on available-for-sale investments	\$ 2,100	\$ (56,465)	\$ 58,454
Conversion of redeemable convertible preferred stock, redeemable common stock, and convertible preferred stock into common stock	\$21,324,999	\$ —	\$ 33,935,423
Exercise and conversion of Series D-1 warrants into common stock	\$ 5,411,932	\$ —	\$ —
Capital lease obligations incurred	\$ 313,520	\$ —	\$ —
Dividends paid on the Series D preferred stock in the form of common stock	\$ 1,186,871	\$ —	\$ —
Warrants granted in connection with debt financing	\$ 526,720	\$ —	\$ —

See notes to financial statements.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS

1. BACKGROUND

Basis of Presentation —The Company was incorporated as Pharmasset, Ltd. on May 29, 1998 under the laws of Barbados. The Company redomiciled under the laws of Delaware on June 8, 2004, as Pharmasset, Inc., and Pharmasset, Ltd. was dissolved on June 21, 2004. Pharmasset, Inc., then-existing as a Georgia corporation that was incorporated on June 5, 1998 and was the Company’s only subsidiary, was merged with and into the Delaware corporation on July 23, 2004.

Description of Business —Pharmasset, Inc. (“Pharmasset” or “the Company”) is a clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections. The Company’s primary focus is on the development of oral therapeutics for the treatment of hepatitis B virus (“HBV”), hepatitis C virus (“HCV”) and human immunodeficiency virus (“HIV”). The Company currently has three product candidates: clevudine, in Phase 3 registration clinical trials for the treatment of HBV; R7128, a pro-drug of PSI-6130, in a Phase 1 clinical trial for the treatment of HCV through a collaboration with F. Hoffmann-LaRoche Ltd. and Hoffmann- La Roche Inc. (collectively, “Roche”); and Racivir, which has completed a Phase 2 clinical trial for the treatment of HIV. Additionally, the Company is continuing to identify the best path forward for development of DFC for the treatment of HIV following the completion of a Phase 2b clinical trial. Our research and development efforts focus on a class of compounds known as nucleoside analogs, which act to inhibit the natural enzymes required for viral replication. The Company is applying its expertise in nucleoside chemistry to the discovery and development of additional antiviral therapeutics. The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, product development risks, protection of proprietary intellectual property, compliance with government regulations, dependence on key personnel, the need to obtain additional financing, uncertainty of market acceptance of products, and product liability (See Part I, Item 1A.— Risk Factors for additional information).

Initial Public Offering —On May 2, 2007, the Company completed its initial public offering (“IPO”) of 5,050,000 shares of its common stock (including the underwriters’ exercise of a portion of their over-allotment option) at a public offering price of \$9.00 per share. Net cash proceeds from the IPO were \$40.7 million after deducting offering costs paid during fiscal 2007 and \$39.1 million after deducting additional offering costs paid in fiscal 2006.

In connection with the IPO, the outstanding shares of Series B, Series C, Series D and Series R Redeemable Convertible Preferred Stock, the Series A Convertible Preferred Stock, and the Redeemable Common Stock were converted into 4,405,683 shares of common stock as of May 2, 2007. In addition, holders of the Series D Redeemable convertible preferred stock were entitled to receive quarterly dividends at a rate equal to 7.5% per annum of the purchase price per share. Such dividends accrued from February 4, 2006 through May 2, 2007 and were paid out in the form of 131,864 shares of common stock. The Series D-1 warrants were also exercised in full in connection with the Company’s IPO on a “net exercise” basis, which resulted in the Company issuing 822,689 shares of common stock to the warrant holders (See Note 9).

Reverse Stock Split — On March 1, 2007, the Company’s board of directors approved a 1.0 for 1.5 reverse stock split of the Company’s outstanding common stock which became effective on April 19, 2007. All common share and per common share amounts in the accompanying financial statements and notes to the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fiscal Year-End —Effective January 1, 2005, the Company changed its fiscal year-end from December 31 to September 30.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

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

Cash and Cash Equivalents —Cash and cash equivalents represent cash and highly liquid investments purchased within three months of the maturity date and consisted primarily of money market funds.

Investments —The Company invests available cash primarily in bank certificates of deposit and investment-grade commercial paper, corporate notes, and government securities. All investments are classified as available-for-sale and are carried at fair market value with unrealized gains and losses recorded in accumulated other comprehensive (loss) profit. For purposes of determining realized gains and losses, the cost of securities sold is based on specific identification.

Deferred Offering Costs —The Company defers specific incremental costs directly attributable to planned public stock offerings until such offerings are completed. The deferred offering costs are then applied against the proceeds from the offering.

Deferred Financing Costs —Costs incurred in connection with debt offerings are deferred (and included in prepaid expenses and other current assets and other (long-term) assets on the balance sheet), and amortized as interest expense over the term of the related debt using the effective interest method. The amortization expense is included in interest expense in the statements of operations and comprehensive net loss.

Equipment and Leasehold Improvements —Equipment and leasehold improvements are recorded at cost and are depreciated using the straight-line method over the following estimated useful lives of the assets: computer equipment—three years; laboratory and office equipment—seven years; and leasehold improvements—over the lesser of the estimated life of the asset or the lease term. Expenditures for maintenance and repairs are expensed as incurred. Capital expenditures, which improve and extend the life of the related assets, are capitalized.

Impairment of Long-Lived Assets —The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful lives of long-lived assets may require revision or that the carrying value of these assets may be impaired. To determine whether assets have been impaired, the estimated undiscounted future cash flows for the estimated remaining useful life of the respective assets are compared to the carrying value. To the extent that the undiscounted future cash flows are less than the carrying value, a new fair value of the asset is required to be determined. If such fair value is less than the current carrying value, the asset is written down to its estimated fair value. See Note 13 regarding the write-down of leasehold improvements at the Company's former Georgia facility as a result of the relocation of the Company's operations.

Fair Value of Financial Instruments —The carrying amounts of cash and cash equivalents, amounts due under collaborative agreements, accounts payable, and accrued expenses approximate fair value because of their short-term nature. Investments as of September 30, 2007 and 2006 are classified as available-for-sale securities and carried at fair market value.

Concentrations of Credit Risk, Suppliers and Revenues —The Company's financial instruments that potentially subject it to concentrations of credit risk are cash and cash equivalents, and investments. The Company invests cash that is not currently being used in operations in accordance with its investment policy. The

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

policy allows for the purchase of low-risk, investment grade debt securities issued by the United States government and very highly-rated banks and corporations, subject to certain concentration limits. The policy allows for maturities that are not longer than two years for individual securities and an average of one year for the portfolio as a whole.

The Company relies on certain materials used in its development process, some of which are procured from a single source. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development process and thereby adversely affect the Company's operating results.

During each of the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, the Company derived a majority of its revenue from one customer (See Note 6).

Revenue Recognition —The Company recognizes revenues in accordance with the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition ("SAB No. 104")*. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectibility is reasonably assured. For arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets, the Company recognizes revenue in accordance with the guidance of Emerging Issues Task Force ("EITF") No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

The Company's revenues are primarily related to its collaboration agreements, and these agreements provide for various types of payments to the Company, including non-refundable upfront license fees, research and development payments, and milestone payments.

Where the Company has continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as revenue as the related activities are performed. The period over which these activities are to be performed is based upon management's estimate of the development period. Changes in management's estimate could change the period over which revenue is recognized. Payments for research funding are recognized as revenues as the related research activities are performed.

The Company recognizes revenue from milestone payments when earned, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the Company does not have ongoing performance obligations. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone. Any amounts received under the agreements in advance of performance, if deemed substantive, are recorded as deferred revenue and recognized as revenue as we complete our performance obligations.

Where the Company has no continuing involvement under a collaborative arrangement, the Company records nonrefundable license fee revenues when the Company has the contractual right to receive the payment, in accordance with the terms of the license agreement, and records milestones upon appropriate notification to the Company of achievement of the milestones by the collaborative partner.

Deferred revenues associated with a non-refundable payment received under a collaborative agreement that is terminated prior to its completion result in an immediate recognition of the deferred revenues.

PHARMASSET, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Research and Development Expenses —Research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, costs of preclinical studies and clinical trials, drug and laboratory supplies, costs for facilities and equipment and the costs of intangibles that are purchased from others for use in research and development activities, such as in-licensed product candidates, that have no alternative future uses. Research and development expenses are included in operating expenses when incurred. Reimbursements received from the Company's collaborators for third-party research and development expenses incurred by the Company on their behalf are recorded as a contra-expense. Amounts due from collaborators for reimbursement of research and development expenses are recorded on the balance sheets as amounts due under collaborative agreements.

Stock-Based Compensation —On October 1, 2006, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment" ("SFAS 123R"). This Statement is a revision of SFAS No. 123 "Accounting for Stock-Based Compensation" ("SFAS 123") and supersedes Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued To Employees" ("APB 25") and its related implementation guidance. SFAS 123R requires companies to recognize stock compensation expense for awards of equity instruments to employees based on grant-date fair value of those awards (with limited exceptions). The Company adopted SFAS 123R using the modified prospective method, which results in recognition of compensation expense for all share-based awards granted or modified after October 1, 2006 as well as all unvested awards outstanding at the date of adoption. The cost is recognized as compensation expense over the life of the instruments, based upon the grant date fair value of the equity or liability instruments issued. The adoption of SFAS 123R resulted in stock compensation expense and therefore an increase in the loss before income taxes during fiscal 2007 of \$1,552,690. Stock options granted to consultants are periodically valued as they vest in accordance with EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," using a Black-Scholes option pricing model. Stock-based compensation expense is included in both research and development expenses and in general and administrative expenses in the statements of operations and comprehensive net loss. Since the Company's stock was not publicly traded prior to April 27, 2007, the expected volatility was calculated for each date of grant based on the "peer method." The Company identified companies that trade publicly within the pharmaceutical industry that have similar SIC codes, employee count and revenues. The Company had chosen the weekly high price volatility for these companies for a period of five years. Effective October 1, 2006 the Company has used the weekly high price for these companies for a period of six years to coordinate with the expected term calculated pursuant to Staff Accounting Bulletin ("SAB") 107 issued by the Securities and Exchange Commission ("SEC"). The volatility of the stock prices of these companies have decreased in the aggregate over the years presented, therefore the expected volatility calculated for the Company has decreased. The assumptions used and weighted-average information for employee and director grants for the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005 are as follows:

Employee and Director Grants:

	<u>Years Ended September 30,</u>		<u>Nine Months Ended September 30,</u>
	<u>2007</u>	<u>2006</u>	<u>2005</u>
Risk free interest rate	4.55%	4.78%	3.98%
Expected dividend yield	0.0%	0.0%	0.0%
Expected lives (years)	5.94	5.00	5.00
Expected volatility	54.33%	53.10%	59.20%
Weighted-average fair value of options granted	\$ 2.79	\$ 1.98	\$ 3.17

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

During the year ended September 30, 2007, the Company granted 563,231 stock options with a weighted average fair value of \$2.79 per share, weighted average risk free interest rate of 4.55%, a weighted average expected volatility of the market price of the Company's common stock of 54.3%, a dividend yield of 0%, a weighted average expected life of 5.94 years, an employee forfeiture rate of 11.03% and a director forfeiture rate of 1.70%. As a result of adopting SFAS 123R on October 1, 2006, the Company recorded non-cash compensation expense of approximately \$1,552,690, or \$0.10 per share, during the year ended September 30, 2007. As of September 30, 2007, total unrecognized stock-based compensation expense resulting from the adoption of SFAS 123R was approximately \$1,977,912, which has a weighted- average period of approximately 1.26 years to be recognized.

Prior to October 1, 2006, the Company elected to follow APB 25, and related interpretations to account for its stock-based employee compensation plans, and had adopted the pro forma disclosure option for stock-based compensation issued to employees under SFAS 123. The table below presents a summary of the pro forma effects to reported net loss prior to October 1, 2006 as if the Company had elected to recognize stock-based compensation costs based on the fair value of the options granted as prescribed by SFAS 123.

	Year Ended September 30,	Nine Months Ended September 30,
	2006	2005
Net loss attributable to common stockholders as reported	\$ (12,437)	\$ (15,996)
Add: stock based compensation expense included in reported net loss	477	141
Deduct: stock-based compensation expense determined under fair value method	(1,484)	(639)
Pro forma net loss	<u>\$ (13,444)</u>	<u>\$ (16,494)</u>
Net loss per share as reported:		
Basic and diluted	<u>\$ (1.19)</u>	<u>\$ (2.42)</u>
Pro forma net loss per share:		
Basic and diluted	<u>\$ (1.29)</u>	<u>\$ (2.49)</u>

Income Taxes —The Company accounts for income taxes under the asset and liability method. The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that is expected to be realized.

Preferred Stock Accretion —Prior to the conversion of all of the Company's redeemable convertible preferred stock into common stock in May 2007, when the Company completed the IPO, the Company used the interest method to increase the carrying amount of its redeemable convertible preferred stock on each balance sheet date, so that the carrying amount, initially the fair value of the security on the date of issue, would equal the redemption amount at the earliest redemption date. These periodic increases to the carrying amount also used the interest method to include amounts representing dividends not currently declared or paid, but which will be payable under the redemption features had they been still accrued and unpaid at the redemption date (See Note 9).

Comprehensive Net (Loss) Profit —Components of comprehensive net (loss) profit include net (loss) profit and unrealized gains (loss) on available-for-sale securities, net of tax. Comprehensive net (loss) profit is represented in the statements of operations and comprehensive net (loss) profit.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

Net (Loss) Profit Per Common Share —Basic net (loss) profit per common share is calculated by dividing net (loss) profit attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net (loss) profit per common share is calculated by dividing net (loss) profit attributable to common stockholders by the weighted average number of common shares and other dilutive securities outstanding during the period. Dilutive potential common shares resulting from the assumed exercise of outstanding stock options and warrants are determined based on the treasury stock method.

	Years Ended September 30,		Nine Months Ended September 30,
	2007	2006	2005
(In thousands, except per share amounts)			
Numerator:			
Net loss attributable to common stockholders	\$ (6,840)	\$ (12,437)	\$ (15,996)
Denominator:			
Weighted average common shares outstanding used in calculation of basic net loss per share	14,990	10,462	6,630
Effect of dilutive securities:			
Common stock options	—	—	—
Preferred Shares	—	—	—
Preferred stock warrants	—	—	—
Weighted average common shares outstanding used in calculation of diluted net loss per share	14,990	10,462	6,630
Net loss attributable to common stockholders per share:			
Basic	\$ (0.46)	\$ (1.19)	\$ (2.42)
Diluted	\$ (0.46)	\$ (1.19)	\$ (2.42)

The following table summarizes the securities outstanding at the end of each period with the potential to become common stock that have been excluded from the computation of diluted net loss (profit) attributable to common stockholders per share, as their effect would have been anti-dilutive.

	Years Ended September 30,		Nine Months Ended September 30,
	2007	2006	2005
(In thousands)			
Preferred shares	—	9,991	4,150
Preferred stock warrants	—	1,151	1,151
Common stock warrants	66	—	—
Options to purchase common stock	2,101	2,376	2,117
Total	2,167	13,518	7,418

Segment Reporting —Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. The Company, which uses financial information in determining how to allocate resources and assess performance, has determined that it operates in one segment, which focuses on developing nucleoside analog drugs for the treatment of viral infections.

PHARMASSET, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Recently Issued Accounting Standards —On February 15, 2007, the FASB issued SFAS No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*” (“SFAS 159”). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and 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 fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact this standard would have on its financial statements.

In September 2006, the FASB issued SFAS No. 157, “*Fair Value Measurements*” (“SFAS 157”). This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The adoption of SFAS 157 is not expected to have a material impact on the Company.

In July 2006, the FASB issued FASB interpretation No. 48, “*Accounting for Uncertainty in Income Taxes*” (“FIN 48”). FIN 48 clarifies the accounting for income taxes by prescribing a minimum probability threshold that a tax position must meet before a financial statement benefit is recognized. The minimum threshold is defined in FIN 48 as a tax position that, based solely on its technical merits, is more likely than not to be sustained upon examination by the applicable taxing authority. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. FIN 48 must be applied to all existing tax positions upon initial adoption. The cumulative effect of applying FIN 48 at adoption, if any, is to be reported as an adjustment to opening retained earnings for the year of adoption. FIN 48 is effective for fiscal years beginning after December 15, 2006, although early adoption is permitted. The adoption of FIN 48 is not expected to have a material impact on the Company.

In May 2005, the FASB issued SFAS No. 154 “*Accounting Changes and Error Corrections*” (“SFAS 154”), which replaces APB Opinion No. 20, “*Accounting Changes*” and SFAS No. 3, “*Reporting Accounting Changes in Interim Financial Statements—An Amendment of APB Opinion No. 28*”. SFAS 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 and, accordingly, was adopted by the Company on October 1, 2006.

In September 2006, the SEC issued SAB 108, “*Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*” (“SAB 108”). The SEC staff has provided guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year’s financial statements are materially misstated. The SEC staff indicated that “registrants must quantify the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements.” If correcting a misstatement in the current year would materially misstate the current year’s income statement, the SEC staff indicated that the prior year financial statements should be adjusted. These adjustments to prior year financial statements are necessary even though such adjustments were appropriately viewed as immaterial in the prior year. If the Company determines that an adjustment to prior year financial statements is required upon adoption of SAB 108 and does not elect to restate its previous financial statements, then it must recognize the cumulative effect of applying SAB 108 in fiscal 2007 beginning balances of the affected assets and liabilities with a corresponding adjustment to the fiscal 2007 opening balance in retained earnings. Early application of the guidance in SAB 108 is encouraged by the SEC staff in any report for

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

an interim period of the fiscal year ending after November 15, 2006. The Company began applying SAB 108 as of January 1, 2007. Such application had no impact on the Company's fiscal 2007 financial statements.

In June 2007, the Emerging Issues Task Force reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2007, and earlier application is not permitted. This consensus is to be applied prospectively for new contracts entered into on or after the effective date. The Company is evaluating the potential impact of this consensus and does not expect it to have a material effect on its financial statements.

3. RELATED PARTY TRANSACTIONS

Common Stock Issuances —On March 31, 2005, the Company sold 100,000 shares of common stock at \$3.00 per share for an aggregate purchase price of \$300,000 to Kurt Leutzinger, its Chief Financial Officer.

Agreements related to Dr. Raymond Schinazi, a founder and former director —Dr. Schinazi is one of the Company's founders and served as a director of the Company from 1998 until June 2005 and as an executive director of the Company from 1998 until June 2004. As of September 30, 2007, he and his affiliates beneficially owned 13.0% of the Company's capital stock. In February 2006, the Company entered into several agreements with Dr. Schinazi, which are described below.

Settlement Agreement —The Company settled a disagreement that arose between Dr. Schinazi and the Company related to several issues by entering into a settlement agreement and mutual general release dated as of February 14, 2006, which provides for a mutual general release of claims by him, the Company and certain of its existing stockholders. Pursuant to this settlement agreement, the Company also entered into a license agreement with RFS Pharma LLC for a molecule called dioxolane thymine, or DOT, and a mutual termination of lease agreement with C.S. Family, LLC, which is 50% owned by Dr. Schinazi, each described in more detail below. Dr. Schinazi is the founder and majority stockholder of RFS Pharma LLC and is a named inventor of DOT. Additionally, this settlement agreement provides for certain amendments to the Company's stockholders' agreement to, among other things, facilitate the transfer of 1.3 million shares of the Company's common stock that Dr. Schinazi owns to two affiliated entities, one of which is a trust of which he is the trustee and one of which is a limited partnership, of which he is a manager of its general partner. The settlement agreement also requires the Company to reimburse Dr. Schinazi for up to \$100,000 of legal fees incurred by him in connection with the negotiation of the transactions contemplated by this settlement agreement.

License Agreement with RFS Pharma LLC —As of February 10, 2006, the Company entered into a license agreement with RFS Pharma LLC to pursue the research, development and commercialization of an antiviral nucleoside analog product candidate called DOT. Under this agreement, the Company paid to RFS Pharma LLC an upfront payment of \$400,000 and the Company may also pay up to an aggregate of \$3.9 million in future milestone payments related to development and regulatory events, royalties on future sales, and expense reimbursements in specified circumstances. Additionally, this license agreement provides for specified amounts of DOT drug substance to be purchased by the Company from RFS Pharma LLC for up to \$82,000. The Company may terminate the license agreement on a country-by-country basis and/or product-by-product basis or in its entirety at any time upon 30 days advance written notice to RFS Pharma LLC prior to the launch of any licensed product, or upon 180 days advance written notice to RFS Pharma LLC following the launch of any licensed product. Additionally, upon a material breach of this agreement by either party, if the breaching party

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

fails to cure the material breach during a 90-day period after notice of the breach has been provided, then the non-breaching party may terminate the agreement on a country-by-country or product-by-product basis with respect to the country(ies) and licensed product(s) to which the breach relates.

Operating Lease and Mutual Termination of Lease Agreement —In 1998, the Company entered into an operating lease for office and laboratory space in Tucker, Georgia through October 31, 2008 with C.S. Family, LLC as the lessor, an entity with which Dr. Schinazi is affiliated. For the twelve months ended December 31, 2005 (unaudited), the Company had paid a total of \$237,604 to the lessor under this agreement. The Company completed its relocation from Georgia to New Jersey in late 2005 and no longer maintains any operations in Georgia. Effective February 7, 2006, the Company entered into a Mutual Termination of Lease Agreement with the lessor, pursuant to which the Company paid \$1.4 million (in addition to the balance of its security deposit and including repairs to the facilities) as full and final payment for and satisfaction of all amounts and other obligations due under the operating lease.

License Agreements with Emory University —In 1998, the Company entered into various license agreements with Emory University, including for two of the Company’s product candidates, Racivir and DFC, to pursue the research, development and commercialization of various licensed compounds and related technologies. The Company and Emory University will share in the proceeds, if any, received by the Company related to the development, sublicensing and commercialization of the licensed compounds, including milestone payments, fees, and royalties. Dr. Schinazi is an employee of Emory University and a named inventor of Racivir, DFC and certain of the other licensed compounds and related technologies and may receive a percentage of the milestone payments, fees and royalties paid by the Company to Emory University. In connection with several of these license agreements, the Company issued to Emory University 179,973 shares of redeemable common stock. Such amount was expensed to the statements of operations and comprehensive net loss for the year ended December 31, 1998 and the 179,973 shares of redeemable common stock were converted into 179,973 shares of common stock on May 2, 2007 when the Company completed the IPO.

Consulting Agreement —In June 2005, the Company entered into a consulting agreement with Michael K. Inouye, a member of the Board of Directors. During the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, the Company paid \$0, \$9,700 and \$5,450, respectively, to Mr. Inouye.

4. INVESTMENTS

The fair value of available-for-sale investments consist of a corporate bond with a maturity of 1.25 years as of September 30, 2007. The following table summarizes the fair value, (gross) unrealized holding gain, and cost basis as of September 30, 2007 and 2006.

	<u>Fair Value</u>	<u>Unrealized Holding Gain</u>	<u>Cost</u>
September 30, 2007			
Corporate bonds	<u>\$1,252,113</u>	<u>\$ 4,405</u>	<u>\$1,247,708</u>
September 30, 2006			
Corporate bonds	<u>\$1,250,013</u>	<u>\$ 2,305</u>	<u>\$1,247,708</u>

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of Sept. 30, 2007	As of Sept. 30, 2006
Accrued compensation	\$ 789,838	\$ 429,454
Accrued accounting fees	69,014	290,000
Accrued legal fees	700,605	377,838
Accrued license fees	1,195,000	390,000
Accrued clinical trial expenses	2,309,291	114,348
Other accrued expenses	449,659	453,385
	<u>\$ 5,513,407</u>	<u>\$ 2,055,025</u>

6. CONTRACT REVENUE AGREEMENTS

The following is a reconciliation between cash payments received and receivable under contract revenue agreements and contract revenues reported:

	Year Ended September 30,		Nine Months Ended September 30,
	2007	2006 (in thousands)	2005
Cash received/receivable	\$20,425	\$ 2,548	\$ 3,627
Deferred	(375)	(2,500)	(2,125)
Amortization	1,959	5,377	2,217
Revenues	<u>\$22,009</u>	<u>\$ 5,425</u>	<u>\$ 3,719</u>

The Company recorded revenues from the collaboration agreement with Roche comprising 99.8% and 39.3% of total revenues during the fiscal years ended September 30, 2007 and 2006. The Company recorded revenues from the collaboration agreement with Incyte comprising 0.0%, 59.8% and 92.5% of total revenues during the fiscal years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively. No other customer accounted for 10% or more of the Company's total revenues in the periods presented herein.

Roche —In October, 2004, the Company entered into a collaboration and license agreement with Roche to develop PSI-6130, PSI-6130 pro-drugs and chemically related nucleoside polymerase inhibitors for all indications, including the treatment of chronic HCV infections. Roche paid the Company an up-front payment of \$8.0 million and has agreed to pay future research and development costs. The up-front payment has been recorded as deferred revenue and is being amortized over the estimated development period. Roche has also agreed to make milestone and commercialization payments to the Company for PSI-6130 and its pro-drugs, the lead nucleoside compound of the collaboration, assuming successful development and marketing in Roche's territories. The portion of the above payments recorded as deferred revenue on the Company's balance sheets and not yet recognized as revenues as of September 30, 2007 and 2006 was \$7.6 million and \$9.2 million, respectively.

In addition, the Company will receive royalties paid as a percentage of total annual net product sales, if any, and the Company will be entitled to receive one time performance payments should net sales from the product exceed specified thresholds.

PHARMASSET, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The Company granted Roche worldwide rights, excluding Latin America and Korea, to PSI-6130 and its related compounds. The Company retained certain co-promotion rights in the United States. The Company will be required to pay Roche royalties on net product sales, if any, in the territories the Company has retained. Roche will fund research related to the collaboration. Roche will fund and the Company will be responsible for preclinical work, the IND filing, and the initial clinical trial, while Roche will manage other preclinical studies and clinical development. Roche has reimbursed the Company for \$4.2 million, \$4.7 million, and \$1.2 million during the fiscal years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively, under this agreement.

The agreement will terminate once there are no longer any royalty or payment obligations. Additionally, Roche may terminate the agreement in whole or in part by providing six months' written notice to the Company. Otherwise, either party may terminate the agreement in whole or in part in connection with a material breach of the agreement by the other party that is not timely cured. In the event of termination, Roche must assign or transfer to the Company all regulatory filings, trademarks, patents, preclinical and clinical data related to this collaboration.

In conjunction with the agreement, Roche purchased 400,000 shares of the Company's Series R redeemable convertible preferred stock and received warrants to purchase up to an additional 470,588 shares of Series R-1 redeemable convertible preferred stock for \$4.0 million. These shares and warrants were initially recorded at fair value for financial reporting purposes. The 400,000 shares of Series R redeemable convertible preferred stock were converted into 266,666 shares of the Company's common stock on May 2, 2007 when the Company completed the IPO, and the related warrants expired without exercise on October 26, 2006.

Incyte Corporation —In September 2003, the Company entered into a collaborative and license agreement with Incyte to develop and commercialize DFC for the treatment of HIV. The Company received an upfront payment of \$6.25 million as a license fee, partial reimbursement for past development study and patent costs and in-process research and development. The upfront payment and related license and other direct costs had been amortized over the estimated time to Food and Drug Administration ("FDA") approval of the drug, which coincided with the period over which the Company was to provide advisory services related to the development and regulatory approval of the drug.

On April 3, 2006, Incyte announced its decision to discontinue its development of DFC. Along with its decision, Incyte terminated the collaborative and license agreement it entered into with Pharmasset and returned its rights related to DFC to the Company. Since the upfront payment noted above was non-refundable, the termination of the collaborative and license agreement by Incyte resulted in immediate recognition of the remaining deferred revenue (relating to this upfront payment) as revenues. The Company is analyzing the preclinical and clinical data on DFC generated by Incyte. Based on the Company's preliminary review of the data provided to it, the Company believes further analysis of the merits of continuing to develop DFC is warranted.

Under the agreement, the Company was to have received milestone payments and royalties on sales of the approved product. Incyte was responsible for all clinical development, patent and commercialization costs. As a result of this termination, the Company will no longer be eligible to receive milestone payments or royalties from Incyte with respect to DFC, and the Company will be solely responsible for any additional expenses that it may incur in connection with the development of DFC.

7. IN-LICENSE AGREEMENTS

Bukwang Pharmaceutical Company Ltd. —In June 2005, the Company entered into a collaboration and license agreement with Bukwang Pharm. Co., Ltd. ("Bukwang") to develop and commercialize clevudine. Bukwang granted the Company exclusive rights to develop, manufacture, and market clevudine in North

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

America, Europe, Central and South America, the Caribbean, and Israel. Bukwang retained rights to the rest of the world, excluding those Asian territories which were licensed to Eisai Company Ltd. (“Eisai”) in November 2004.

The Company paid Bukwang an up-front payment of \$6.0 million, which was included in research and development expenses in the nine months ended September 30, 2005. The Company accrued an additional \$1.0 million payment in September 2007 upon the initiation of Phase 3 registration studies of clevudine, and may pay up to \$23.0 million in additional milestone payments related to development, regulatory and commercialization events, and future royalties on net sales. The up-front and milestone payments to date have been expensed as incurred as no alternative use exists. The Company has the right to use the clinical data generated by Bukwang or Eisai, as well as all historical data collected by the prior licensee, Triangle Pharmaceuticals (acquired by Gilead Sciences in 2003) or Gilead Sciences. The Company will be responsible for conducting any future clinical trials, regulatory filings, and the commercialization of clevudine in its territories. Bukwang and Eisai are responsible for all ongoing clinical trials, regulatory filings, and the commercialization of clevudine in their respective territories. The Company’s collaboration and license agreement with Bukwang will terminate once there are no longer any royalty obligations. The Company may terminate the agreement by providing six months written notice to Bukwang. In addition, either party may terminate the agreement if the other party commits a material breach of the agreement that is not timely cured. In the event of termination at will by the Company or for the Company’s breach, the Company must license or transfer to Bukwang all regulatory filings, trademarks, patents, preclinical and clinical data related to this agreement. In the event of termination for a breach by Bukwang, Bukwang must license or transfer to the Company all patents, know-how, and manufacturing processes related to this agreement.

On June 23, 2005, the Company, along with the University of Georgia Research Foundation, Inc., (“UGARF”), and Yale University (“Yale”), signed a memorandum of understanding with regard to the patents and technology related to clevudine that had been exclusively licensed to Bukwang, and which the Company currently sublicenses from Bukwang. The memorandum of understanding provides that UGARF and Yale will grant the Company a license to these patents and technology in the event that the primary license with Bukwang is terminated, provided that the reason for such termination does not relate to any breach of the Company’s sublicense by the Company or on the Company’s behalf.

License Agreements with University of Georgia Research Foundation, Inc., Emory University and UAB Research Foundation, Inc. — On December 30, 1998, Emory University (“Emory University”) granted to the Company an exclusive, worldwide license to make, have made, use, import, offer for sale and sell medical products based on a compound now known as DFC, including certain of its analogs and derivatives. In September 2003, the Company sublicensed the rights to DFC in certain territories to Incyte, under a collaboration and license agreement described in Note 6. On February 19, 1999, the Company issued 66,667 shares of its redeemable common stock to Emory University. The fair value was expensed in the statements of operations and comprehensive net loss for the year ended December 30, 1999. In addition, the Company agreed to pay Emory University a certain percentage of milestone payments and royalties that the Company receives from Incyte.

On December 8, 1998, Emory University granted the Company an exclusive, worldwide license pursuant to a license agreement (“Racivir License Agreement”) to make, have made, use, import, offer for sale and sell drug products based on a specified range of mixtures of (–) – FTC and (+) – FTC (“enriched FTC”), which includes the mixture that the Company is developing as Racivir. As part of the consideration for this agreement, the Company issued to Emory University 66,667 shares of redeemable common stock, and agreed to pay Emory University royalties as a percentage of net product sales. The Company subsequently issued to Emory University an additional 13,307 shares of redeemable common stock pursuant to an anti-dilution provision in the agreement. The Company may also pay Emory University up to an aggregate of \$1.0 million in future marketing milestone payments. The agreement will expire upon the expiration of all licensed patents.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

In a license agreement relating to emtricitabine that Emory University entered into with Triangle Pharmaceuticals, now Gilead Sciences, Inc., or Gilead, in 1996 (“Emory/Gilead License Agreement”), Emory University previously had granted a right of first refusal to Gilead that is applicable to any license or assignment relating to enriched FTC (which includes Racivir). The terms of this right of first refusal contains an exception permitting Emory University to license or assign its rights in respect of enriched FTC to any of the inventors (which included two of the founders of the Company) or to any corporate entity formed by or on behalf of the inventors for purposes of clinically developing enriched FTC so long as the licensee agrees in writing to be bound by the terms of Gilead’s right of first refusal to the same extent as Emory University. The Company’s license to Racivir was granted to the Company by Emory University pursuant to this exception and therefore the Company is bound by the terms of Gilead’s right of first refusal to the same extent as Emory University.

Under the above license agreements with Emory University regarding DFC and Racivir, the Company is obligated to make minimum royalty payments to Emory University if a new drug registration of a compound resulting from the licensed technology is obtained and the compound is subsequently commercialized. These minimum royalty payments would begin in the second year following a New Drug Application (“NDA”) Registration, and continue until the tenth year. The Company may also make up to \$1.0 million in marketing milestone payments under each of the two license agreements to Emory University if any products are commercialized and sold.

In March 2004, the Company entered into a supplemental agreement with Emory University in which it and Emory University agreed that, prior to any commercialization of enriched FTC by the Company, or by any licensee or assignee of the Company’s rights under the Racivir License Agreement, the Company and Emory University would adhere strictly to the terms of the right of first refusal granted to Gilead in the Emory/Gilead License Agreement and offer to Gilead the same terms and conditions under which the Company, its licensee or assignee, propose to commercialize enriched FTC. Therefore, before the Company could enter into a commercialization agreement for Racivir with a third party or commercialize Racivir on its own, it would be required to offer Gilead the opportunity to be its commercialization partner on the same terms in which the Company intends, or its prospective partner intends, to commercialize Racivir. It is uncertain whether a third party would be willing to negotiate the terms of a commercialization agreement with the Company knowing that Gilead can take their place as licensee by accepting the negotiated terms and exercising its right of first refusal.

In 1998 and 2004, the Company entered into various license agreements in addition to those described above with UGARF, Emory University and the University of Alabama at Birmingham Research Foundation, Inc. (collectively, the “Universities”) to pursue the research, development and commercialization of certain human antiviral, anticancer and antibacterial applications and uses of certain specified technologies. Under each of these agreements, the Universities have granted an exclusive right and license under the related patents to the Company. The Company and the Universities will share in any proceeds received by the Company related to internal development or sublicensing of the specified technologies, including milestone payments, fees, and royalties.

In April 2002, the license agreement between UGARF, Emory University, and the Company dated June 16, 1998 was selectively modified to terminate certain technologies and related rights and obligations.

8. VENTURE LOAN AND SECURITY AGREEMENT

On September 30, 2007, the Company entered into a Venture Loan and Security Agreement (“Loan Agreement”) with a lender that allows the Company to borrow up to \$30.0 million in \$10.0 million increments as follows:

- The first \$10.0 million (“Loan A”) is only subject to ordinary and customary closing procedures as noted in the Loan Agreement, including the execution of a promissory note, all of which were completed subsequent to September 30, 2007, resulting in the funding of Loan A on October 5, 2007 (See Note 17).

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NOTES TO FINANCIAL STATEMENTS—(Continued)

- The second \$10.0 million (“Loan B”) is subject to ordinary and customary closing procedures as noted in the Loan Agreement, including the execution of a promissory note, and has a commitment termination date of March 31, 2008.
- The third \$10.0 million (“Loan C”) is subject to ordinary and customary closing procedures as noted in the Loan Agreement, including the execution of a promissory note, and is also subject to the achievement of certain product development milestones, and has a commitment termination date of November 30, 2008.

The interest rate on each loan is equal to 12% plus the amount, if any, by which the one month LIBOR rate five days before the funding date for such loan exceeds 5.32% (12% for Loan A as determined on October 5, 2007—See Note 17). The loans will be repaid over a 45-month period with the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. Prepayment of the loan is subject to penalty and substantially all of the Company’s tangible and intangible assets (except for intellectual property) are collateral for the Loan Agreement.

In conjunction with entering into the Loan Agreement, the Company granted a warrant to the lender to purchase up to 149,377 shares of the Company’s common stock (See Note 9). Since these warrants were granted in conjunction with entering into the Loan Agreement and with the intention of executing a promissory note for Loan A, the fair value of the warrant was recorded as equity and deferred interest as of September 30, 2007. The deferred interest will be amortized over the term of the promissory note using the effective interest method. The warrants are immediately exercisable for 66,390 shares of common stock with the remaining 82,987 shares of common stock becoming exercisable in varying increments upon the achievement of certain milestones related to the Company’s product development and future advances under the Loan Agreement.

9. STOCKHOLDERS’ EQUITY (DEFICIT), REDEEMABLE STOCK CONVERSIONS, AND WARRANTS

Common Stock —As of September 30, 2007, the Company had 100,000,000 shares of common stock authorized with a par value of \$0.001 and the Company had reserved 3,680,168 shares of common stock for issuance upon the exercise of outstanding common stock options. Also, 1,578,895 shares of the Company’s common stock were reserved for future grants of stock options (or other similar equity instruments) under the Company’s 1998 Stock Plan and 2007 Equity Incentive Plan as of September 30, 2007. In addition, 66,390 shares of the Company’s common stock were reserved for future exercise of outstanding warrants as of September 30, 2007.

During fiscal 2007, 13,333 shares of common stock were purchased at a fair market value of \$9.00 per share. Such shares were immediately retired.

On May 2, 2007, the Company completed an IPO of 5,050,000 shares of its common stock (including the underwriters’ exercise of a portion of their over-allotment option) at a public offering price of \$9.00 per share. Net cash proceeds from the initial public offering were \$40.7 million after deducting offering costs paid during fiscal 2007 and \$39.1 million after deducting additional offering costs paid in fiscal 2006.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

Redeemable Stock Conversions —In conjunction with the completion of the IPO on May 2, 2007, and pursuant to the amended and restated by-laws of the Company, all outstanding shares of redeemable convertible preferred stock (Series B, C, D and R—See Note 10) were converted into an aggregate of 2,432,569 shares of common stock as follows:

Preferred Stock Series	Amount of Common Shares
Series B Conversion	245,331
Series C Conversion	250,120
Series D Conversion	1,670,452
Series R Conversion	266,666
	<u>2,432,569</u>

In addition, holders of the Series D Redeemable convertible preferred stock (See Note 10) were entitled to receive quarterly dividends at a rate equal to 7.5% per annum of the purchase price per share. Such dividends accrued from February 4, 2006 through May 2, 2007, the closing date of the IPO, and were paid out in the form of 131,864 shares of common stock. Also, all outstanding shares of redeemable common stock and Series A convertible preferred stock were converted into 213,306 and 1,759,808 shares of common stock, respectively on May 2, 2007.

Warrants —During fiscal 2007, warrants (See Note 10) were exercised, expired, and were granted as follows.

The Series D-1 warrants were exercised in full in connection with the IPO on a “net exercise” basis, which resulted in the Company issuing 822,689 shares of common stock to the warrant holders. Warrants to purchase up to 470,588 shares of Series R-1 redeemable convertible preferred stock granted in conjunction with Roche’s purchase of 400,000 shares of the Company’s Series R redeemable convertible preferred stock expired without exercise on October 26, 2006.

On September 30, 2007, in conjunction with entering into the Loan Agreement (See Note 8), the Company granted a warrant (“initial warrant”) to the lender to purchase up to 149,377 shares of the Company’s common stock at a price of \$12.05. The initial warrant is immediately exercisable for 66,390 shares of common stock and expires seven years from the date of grant or upon a change of control as defined in the Loan Agreement. The initial warrant was recorded as equity with a carrying value equal to its fair value on the date of grant calculated using the Black-Scholes warrant-pricing methodology. The Company may be required to grant additional warrants to purchase shares of the Company’s common stock to the lender if it elects to enter into promissory notes associated with Loans B and C and it meets certain borrowing conditions (See Note 8). Any additional warrants would have an exercise price of \$12.05, would be exercisable on the date of grant, and would expire seven years from the date of grant or upon a change of control.

10. REDEEMABLE STOCK AND WARRANTS

Following are descriptions of the Series A Convertible Preferred Stock, the Series B, C, D and R Redeemable Convertible Preferred Stock, the Series D-1 and R-1 Warrants, and the Redeemable Common Stock. During the fiscal year ended September 30, 2007, the Series A Convertible Preferred Stock, the Series B, C, D and R Redeemable Convertible Preferred Stock, and the Redeemable Common Stock were converted into common stock May 2, 2007, the date the Company completed the IPO, the Series D-1 Warrants were exercised in full, and the Series R-1 Warrants expired without exercise (See Note 9).

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Series A Convertible Preferred Stock —The Company authorized 3,200,000 shares of Series A convertible preferred stock (“Series A Preferred Stock”). Series A Preferred Stock was convertible into common stock at the option of each holder, and automatically upon the earlier of the completion of a qualifying underwritten public offering of the Company’s common stock, at an initial conversion ratio of one-to-one, subject to certain anti-dilution adjustments, or upon the vote of the holders of two-thirds of the shares of all preferred stock and the holders of two-thirds of the shares of Series D Redeemable Convertible Preferred Stock (“Series D Preferred Stock”). Holders of shares of Series A Preferred Stock had voting rights equal to the number of shares of common stock into which such shares were convertible. Shares of Series A Preferred Stock were not entitled to dividends unless declared by the board of directors. In the event the Company was liquidated, holders of Series A Preferred Stock were entitled to receive, prior to and in preference to the holders of common stock and redeemable common stock, an amount equal to the amount paid in plus any declared and unpaid dividends.

The Series A Preferred Stock was issued at various times between February 1999 and September 2000 for an aggregate purchase price of approximately \$5,630,000.

Series B and C Redeemable Convertible Preferred Stock —The Company authorized 2,300,000 shares of Series B redeemable convertible preferred stock (“Series B Preferred Stock”) and 1,357,798 shares of Series C redeemable convertible preferred stock (“Series C Preferred Stock”). Series B Preferred Stock and Series C Preferred Stock were convertible into common stock at the option of each holder, and automatically upon the completion of a qualifying underwritten public offering of the Company’s common stock, at an initial conversion ratio of one-to-one, subject to certain anti-dilution adjustments, or upon the vote of the holders of two-thirds of the shares of all preferred stock and the holders of two-thirds of the shares of Series D Preferred Stock. The stockholders’ agreement provided that, on or after August 4, 2009, outstanding shares were redeemable at the option of the holders of a majority of the shares of all preferred stock and a majority of the shares of the Series D Preferred Stock. The shares of Series B and C Preferred Stock were redeemable at an amount equal to the amount paid in, plus declared and unpaid dividends thereon. The redemption rights terminated upon a qualifying underwritten public offering of the Company’s common stock.

The holders of shares of Series B and C Preferred Stock had voting rights equal to the number of shares of common stock into which such preferred shares were then convertible. Holders of Series B and C Preferred Stock were entitled to dividends, on an as-if converted basis, if the board of directors declared dividends on the common stock. In the event the Company was liquidated, holders of Series B and C Preferred Stock were entitled to receive, prior to and in preference to the holders of common stock, redeemable common stock and Series A, R, D-1 and R-1 Preferred Stock, an amount equal to the initial amount paid in plus any declared and unpaid dividends. Series B and C Preferred Stockholders were also entitled to receive a pro rata portion of the amounts paid to common stockholders, on an as-if converted basis. Holders of Series B and C Preferred Stock had a right of first refusal on new shares issued by the Company, pro rata on a fully diluted basis, and on the resale of shares by certain stockholders.

The Series B Preferred Stock was issued in June 1999 for an aggregate purchase price of approximately \$3,910,000. The Series C Preferred Stock was issued in February 2001 for an aggregate purchase price of approximately \$7,399,999. As of September 30, 2006, \$755 and \$1,563 remained to be accreted for Series B and Series C Preferred Stock, respectively, over the period remaining to potential future redemption.

Series D Redeemable Convertible Preferred Stock —The Company authorized 7,843,380 shares of Series D redeemable convertible preferred stock (“Series D Preferred Stock”). Series D Preferred Stock was convertible into common stock at the option of each holder, and automatically upon the completion of a qualifying underwritten public offering of the Company’s common stock, at an initial conversion ratio of one-to-one subject to certain anti-dilution adjustments, or upon the vote of the holders of two-thirds of the shares of all preferred

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NOTES TO FINANCIAL STATEMENTS—(Continued)

stock and the holders of two-thirds of the shares of Series D Preferred Stock. The stockholders' agreement provided that, on or after August 4, 2009, outstanding shares were redeemable at the option of the holders of a majority of the shares of all preferred stock and the holders of a majority of the shares of Series D Preferred Stock. The shares of Series D Preferred Stock were redeemable at an amount equal to the amount paid in, plus declared and unpaid dividends thereon. The redemption rights terminated upon a qualifying underwritten public offering of the Company's common stock.

The holders of shares of Series D Preferred Stock had voting rights equal to the number of shares of common stock into which such preferred shares were then convertible. Holders of Series D Preferred Stock were entitled to dividends, on an as-if converted basis, if the board of directors declares dividends on the common stock. The holders of Series D Preferred Stock were also entitled to receive quarterly dividends at a rate equal to 7.5% per annum of the purchase price per share for the Series D Preferred Stock. Such dividends began to accrue on the Series D Preferred Stock commencing on February 4, 2006, and thereafter accrued quarterly, whether or not such dividends were declared and whether or not there were profits, surplus or other funds of the Company legally available for the payment of dividends. In the event the Company was liquidated, holders of Series D Preferred Stock were entitled to receive, prior to and in preference to the holders of common stock, redeemable common stock and Series A, R, R-1 and D-1 Preferred Stock, an amount equal to the initial amount paid in plus any declared and unpaid dividends. Series D Convertible Preferred Stockholders were also entitled to receive a pro rata portion of the amounts paid to common stockholders, on an as-if converted basis. Holders of Series D Preferred Stock had a right of first refusal on new shares issued by the Company, pro rata on a fully diluted basis, and on the resale of shares by certain stockholders. The Series D Preferred Stock was issued in August 2004 for an aggregate purchase price of approximately \$40,001,238. As of September 30, 2006, \$3,175,028 remained to be accreted for Series D Preferred Stock over the period remaining to potential future redemption including future accrual of dividends.

Series D-1 Warrants —In conjunction with the Series D financing in August 2004, the Company authorized the issuance of Series D-1 warrants to purchase 1,254,960 shares of Series D-1 convertible preferred stock ("Series D-1 Preferred Stock") at an exercise price of \$0.10 per share. Series D-1 warrants became exercisable August 4, 2006 and expired August 4, 2009. Series D-1 warrants were subject to earlier termination pursuant to the completion of either a qualifying underwritten public offering of the Company's common stock or a qualifying merger or acquisition on or before the expiration date. The fair value of these warrants on the effective date of the Series D financing was estimated using the Black-Scholes option-pricing methodology.

If the warrants were exercised, the Series D-1 Preferred Stock was convertible into Common Stock at the option of the Holder and automatically upon the completion of a qualifying underwritten public offering of the Company's common stock, at an initial conversion ratio of one-to-one subject to certain anti-dilution adjustments, or upon the vote of the holders of two-thirds of the shares of all preferred stock and the holders of two-thirds of the shares of Series D Preferred Stock. The par value of the Series D-1 Preferred Stock was \$0.001.

The holders of shares of Series D-1 Preferred Stock have voting rights equal to the number of shares of common stock into which such preferred shares were then convertible. Holders of Series D-1 Preferred Stock were entitled to dividends, on an as-if converted basis, if the board of directors declared dividends on the common stock. In the event the Company was liquidated, holders of Series D-1 Preferred Stock were entitled to receive, prior to and in preference to the holders of common stock and redeemable common stock, an amount equal to the initial amount paid in plus any declared and unpaid dividends. Series D-1 Preferred Stockholders were also entitled to receive a pro rata portion of the amounts paid to common stockholders, on an as-if converted basis.

PHARMASSET, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Series R Redeemable Convertible Preferred Stock —The Company authorized 400,000 shares of Series R redeemable preferred stock (“Series R Preferred Stock”). Series R Preferred Stock was convertible into common stock at the option of the holder, and automatically upon the completion of a qualifying underwritten public offering of the Company’s common stock, at an initial conversion ratio of one-to-one subject to certain anti-dilution adjustments or upon the vote of the holders of two-thirds of the shares of all preferred stock and the holders of two-thirds of the shares of Series D Preferred Stock. The stockholders’ agreement provided that, on or after August 4, 2009, outstanding shares were redeemable at the option of the holders of a majority of all preferred stock and a majority of the Series D Preferred Stock. The shares of Series R Preferred Stock were redeemable at an amount equal to the amount paid in, plus declared and unpaid dividends thereon. The redemption rights terminated upon a qualifying underwritten public offering of the Company’s common stock.

The holders of shares of Series R Preferred Stock had voting rights equal to the number of shares of common stock into which such preferred shares were then convertible. Holders of Series R Preferred Stock were entitled to dividends, on an as-if converted basis, when the board of directors declared dividends to holders of common stock. In the event the Company was liquidated, holders of Series R Preferred Stock were entitled to receive, prior to and in preference to the holders of common stock and redeemable common stock, an amount equal to the initial amount paid in plus any declared and unpaid dividends. The Series R Preferred Stock was issued in October 2004 for an aggregate purchase price of \$4,000,000. As of September 30, 2006, \$203,059 remained to be accreted for Series R Preferred Stock over the period remaining to potential future redemption.

Series R-1 Warrants —In conjunction with the issuance of Series R Preferred Stock in October 2004, the Company issued warrants to purchase 470,588 shares of Series R-1 Redeemable Convertible Preferred Stock (“Series R-1 Preferred Stock”) at an exercise price of \$12.75 per share. Series R-1 Warrants became exercisable October 26, 2004 and expired October 26, 2006. These warrants were accounted for as a separate component of redeemable stock with a carrying value equal to their fair market value on the effective date of the Series R financing, which was estimated using the Black-Scholes option-pricing methodology.

Preferred Stock Accretion —Preferred stock accretion was \$1,775,684 and \$1,110,973 for the years ended September 30, 2007 and 2006, respectively and \$2,286,799 for the nine months ended September 30, 2005. The decrease in 2006 was attributable to the conversion of preferred stock to common stock in June 2005. The accretion recorded during 2007 includes \$1.0 million of accretion to bring the carrying amounts of the redeemable convertible preferred stock to their redemption values as of May 2, 2007, the date the Company completed the IPO and converted all of our redeemable convertible preferred stock outstanding into common stock.

Redeemable Common Stock —In connection with various license agreements entered into in 1998, the Company issued to Emory University and University of Georgia Research Foundation Inc. 179,973 and 33,334 shares, respectively, of redeemable common stock (See Note 7). Redeemable common stock was redeemable at the option of the holder, at fair market value as determined by an independent appraisal. These redemption rights terminated upon the completion of a registered public offering of the Company’s common stock. The carrying value of the redeemable common stock was adjusted to an estimate of its fair market value for financial reporting purposes each quarter. This estimate was made by taking into consideration such variables as the valuations attained by other comparable biotechnology companies in recent initial public offerings; the judgment of investment bankers as to the probability of executing a successful initial public offering; the liquidation preferences of the Company’s preferred stock; the balance of the Company’s cash, cash equivalents and short term investments; and the present value of the Company’s product candidates as estimated, when available, from the market value of publicly traded companies developing comparable product candidates, and when this was not available, by a discounted cash flow analysis based on cost and revenue estimates provided by management, third party clinical research organizations and marketing consultants, using discount rates provided by an independent appraiser.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

11. STOCK COMPENSATION

The Company's 1998 Stock Plan ("1998 Plan"), as amended, was originally adopted by its board of directors during 1998 and subsequently amended in 2000, 2004 and 2006. A maximum of 3,517,015 shares of the Company's common stock are authorized for issuance under the 1998 Plan. The purpose of the 1998 Plan is to provide an incentive to officers, directors, employees, independent contractors and to other persons who provide significant services to the Company. Upon the closing of the IPO, which occurred on May 2, 2007, the Company adopted the 2007 Equity Incentive Plan ("2007 Plan"). Upon the adoption of the 2007 Plan, no additional awards will be issued under the 1998 Plan and the shares remaining for future grant under the 1998 Plan were transferred to the 2007 Plan. The 2007 Plan makes available an additional 1,166,381 shares of the Company's common stock for the grant of stock options, stock appreciation rights, restricted stock, deferred stock, restricted stock units, performance shares, phantom stock and similar types of stock awards as well as cash awards. Options granted under the 2007 Plan may be either "incentive stock options," as defined under Section 422 of the Code or nonstatutory stock options. Options granted under the 2007 Plan shall be at per share exercise prices equal to the fair value of the shares on the dates of grant. The 2007 Plan will terminate in fiscal 2017 unless it is extended or terminated earlier pursuant to its terms. Generally, options granted under these plans have a contractual life of ten years and vest pro rata over a four year term. A summary of the Company's stock option activity during the year ended September 30, 2007 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding—September 30, 2006	2,375,983	\$ 3.53
Granted	563,232	\$ 5.03
Exercised	(562,056)	\$ 3.23
Forfeited	(275,886)	\$ 3.53
Outstanding—September 30, 2007	<u>2,101,273</u>	\$ 4.01
Exercisable—September 30, 2007	<u>1,096,430</u>	\$ 4.16

The range of exercise prices of options outstanding at September 30, 2007 was \$1.50 to \$9.95. The weighted average remaining contractual life of options outstanding at September 30, 2007 was 7.18 years. The total intrinsic value of options exercised during the year ended September 30, 2007 was \$2,692,125. The Company recognized compensation expense of \$1,552,690, \$454,078 and \$141,157 during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005 related to options issued to non-employees and employees. As of September 30, 2007 and 2006, \$3,500,662 (including \$1,977,912 resulting from the adoption of SFAS 123(R)) and \$1,423,167, respectively, of deferred stock-based compensation expense related to employee stock options remained unamortized.

Outstanding as of September 30, 2007				Exercisable as of September 30, 2007		
Number of Options	Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	
141,667	\$1.50–\$2.99	1.71	\$ 1.78	141,667	\$ 1.78	
1,576,507	\$3.00–\$4.49	7.87	\$ 3.44	645,164	\$ 3.24	
53,833	\$4.50–\$5.99	7.42	\$ 5.32	22,333	\$ 5.10	
203,933	\$6.00–\$7.49	4.81	\$ 6.64	193,933	\$ 6.63	
125,333	\$7.50–\$9.95	8.43	\$ 8.82	93,333	\$ 8.76	

PHARMASSET, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

As of September 30, 2007, there were 2,011,823 options outstanding that were either vested or expected to vest in the future, of which 1,096,430 options were currently exercisable, with weighted average exercise prices of \$4.01 and \$4.16 per share, aggregate intrinsic values of \$16,398,837 and \$8,773,822, and weighted average remaining contractual terms of 7.12 and 6.15 years, respectively. As of September 30, 2007, there were 1,578,895 of securities available for future grants of stock options (or other similar equity instruments) under the Company's 1998 Stock Plan and 2007 Equity Incentive Plan.

During the periods from October 1, 2006 through April 11, 2007, the year ended September 30, 2006, and the nine months ended September 30, 2005, the Company granted stock options to employees at exercise and purchase prices deemed by the board of directors to be equal to the fair value of the common stock at the time of grant. Prior to January 1, 2006, the fair value of the common stock at the time of grant was determined by the board of directors at each stock option measurement date based on a variety of factors, including the Company's financial position and historical financial performance, the status of developments within the Company, the composition and ability of the current research and development and management team, an evaluation and benchmark of the Company's competitors, the current climate in the marketplace, the illiquid nature of the common stock, arm's length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others. In preparation for the Company's planned initial public offering, a retrospective analysis of the fair value of the common stock at option grant dates during 2005 using the methodology favored by the guidelines of the American Institute of Certified Public Accountants ("AICPA") titled "*Valuation of Privately-Held Company Equity Securities Issued as Compensation*" was performed by management. The methodology developed at that time has subsequently been applied by management to the valuation of all employee stock options granted since 2005 through April 11, 2007, the date on which the last options were granted prior to April 27, 2007 when the Company's stock began trading on The NASDAQ Stock Market LLC. The Company has not relied on an independent appraiser for stock option valuations because the Company used a methodology developed in accordance with AICPA guidelines and relied on the experience of management and members of its board of directors. Factors taken into consideration by this methodology include the judgment of management as to the probability of executing a successful initial public offering; the liquidation preferences of the Company's preferred stock; the net balance of the Company's cash, cash equivalents and short term investments; and the present value of the Company's product candidates as estimated, when available, from the market value of publicly traded companies developing comparable product candidates, and when this was not available, by a discounted cash flow ("DCF") analysis based on cost and revenue estimates provided by third party clinical research organizations, marketing consultants and management and using discount rates provided by an independent appraiser.

The application of the Company's methodology for determining the fair value of the Company's common stock at each issuance date from January 1, 2006 through April 11, 2007 is discussed below:

Between May 24, 2006 and July 10, 2006, the Company granted 447,400 options to employees and members of the Company's board of directors. The Company's technology value as a private company was based on clevidine alone due to the early stage of development of R7128 and Racivir. A DFC analysis of clevidine was used due to the absence of a comparable program with an identifiable public market value. The value of the Company's common stock to a private investor was then calculated by adding this private technology value to the Company's net cash balance and subtracting the liquidation preference payments that would be made to the holders of the Company's preferred stock out of the proceeds of a private sale of the Company prior to any participation in the proceeds by holders of the Company's common stock. This process resulted in an estimate of the value of the Company's common stock as a private company of \$3.87 per share, which the Company's board of directors deemed to be the appropriate fair value at which to set the exercise price of the options issued at that time. The theoretical value of the Company's common stock had it been publicly traded at that time was

PHARMASSET, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

calculated by applying a premium, based on published academic research, to the Company's private technology value, to account for the value of the liquidity of a publicly traded stock, and adding the Company's net cash balance. No subtraction was made for liquidity preferences, since all the preferred stock was convertible to common stock upon an IPO. This process resulted in an estimate of the theoretical public price of the Company's common stock, based on clevidine alone, of \$8.30 per share. The fair value of the Company's common stock used for financial reporting purposes was a weighted average of the private and public values, with the weights equal to the probability of executing a successful initial public offering versus a private sale of the Company, as estimated by management with the advice of investment bankers based on the recent experience of other biotechnology companies, market conditions and stockholder support for an initial public offering at that time. During this period, the probability of an IPO was considered to be 50%, resulting in a fair value of the Company's common stock for financial reporting purposes of \$6.09 per share.

On November 7, 2006, the Company granted 317,067 options to employees and members of the Company's board of directors. The methodology used to determine the fair value of the Company's common stock at that time was the same as that described above, so only variations in its application are discussed below. The estimated value of the Company's common stock as a private company increased to \$4.02 per share, based on the increase in the value of clevidine as it moved closer to market and the announcement of additional favorable clinical data that supported an increase in the revenue projection contained in the Company's DCF analysis. This increase in clevidine's value was partly offset by a reduction in the Company's net cash balance. The theoretical public price of the Company's common stock, based on clevidine alone, was estimated to be \$8.75 at that time and the probability of an IPO was considered to be 50%, resulting in a weighted average fair value for financial reporting purposes of \$6.38 per share.

From January 1, 2007 through April 11, 2007, the Company granted 147,500 options to employees and to a member of the Company's board of directors. The methodology used to determine the fair values of the Company's common stock during this time was the same as that described above, so only variations in its application are discussed below. The estimated value of the Company's common stock as a private company increased to amounts ranging from \$4.02 to \$5.63 per share, based on the increase in the value of the R7128 program as it advanced through Phase 1 clinical trials based on the valuation of a publicly traded company with an HCV program at a similar stage of development. The theoretical public price of the Company's common stock, based on clevidine and R7128, ranged from \$8.84 to \$11.28 during this time and the probability of an IPO was considered to be 90%, resulting in weighted average fair values for financial reporting purposes ranging from \$6.53 to \$10.71 per share.

During the year ended September 30, 2006, the Company granted 11,333 options to non-employees that are accounted for in accordance with EITF No. 96-18. The fair value of these awards on the initial grant date of \$30,406 was estimated using the Black-Scholes option-pricing methodology.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

12. INCOME TAXES

Income tax expense was \$0 during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005.

The reconciliation between the federal statutory rate of 34% and the Company's effective tax rate is as follows:

	<u>Years Ended September 30,</u>		<u>Nine Months Ended September 30,</u>
	<u>2007</u>	<u>2006</u>	<u>2005</u>
Federal tax	-34.0%	-34.0%	-34.0%
State tax	-4.0%	-4.0%	-4.0%
Change in valuation allowance	28.9%	36.5%	37.4%
Stock compensation	8.8%	1.3%	0.5%
Other	0.3%	0.2%	0.1%
Effective tax rate	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

The Company was originally organized in 1998 as a Barbados limited company, Pharmasset, Ltd., under Section 10 of the International Business Companies Act of Barbados. The Company was subject to United States withholding tax of 5% under the United States-Barbados tax treaty for United States sourced royalties paid to a Barbados company.

Pharmasset Ltd. owned a Georgia subsidiary which conducted research and development in the United States under a contract research and development agreement with the Company. Prior to June 8, 2004, only the Georgia subsidiary was subject to United States income taxes. The Company became domesticated as a corporation under the laws of the State of Delaware on June 8, 2004 as Pharmasset, Inc., on a tax-free basis with a carryover of the tax basis of its assets, and Pharmasset, Ltd. was dissolved on June 21, 2004. A portion of the expenses incurred by Pharmasset, Ltd. prior to the domestication have been capitalized for tax purposes and are to be amortized to offset future taxable income, if any, in the United States and a portion of these losses can not be utilized in the United States. On July 23, 2004, the Georgia subsidiary was merged into the Company.

Deferred tax assets and liabilities are determined based on the difference between financial statement and tax bases using enacted tax rates in effect for the year in which the differences are expected to reverse. The components of the deferred taxes consist of the following:

	<u>As of September 30,</u>	
	<u>2007</u>	<u>2006</u>
Deferred tax assets:		
Capitalized research and development	\$ 1,537,891	\$ 1,856,981
Net operating loss carryforwards	9,552,612	7,183,149
Payments received in collaborations	2,881,658	3,483,890
Licensing agreements	2,174,866	2,350,933
Stock compensation	449,559	115,191
Accrued liabilities	123,374	70,476
Research and development tax credits	138,159	138,159
Deferred rent	124,912	172,208
Depreciation	62,101	—
Gross deferred tax assets	<u>\$ 17,045,132</u>	<u>\$ 15,370,987</u>

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

	As of September 30,	
	2007	2006
Deferred tax liabilities:		
Depreciation	—	(76,237)
Gross deferred tax liabilities	—	(76,237)
Valuation allowance	(17,045,132)	(15,294,750)
Net deferred tax asset	\$ —	\$ —

As of September 30, 2007, the Company has United States federal net operating loss carryforwards of approximately \$25.1 million available to offset future taxable income, if any. Of the federal net operating losses, \$0.8 million was generated from windfall tax benefit stock option deductions. The tax benefit of this portion of the net operating loss will be accounted for directly to equity as additional paid in capital as the stock option related losses are utilized. As of September 30, 2007, the Company also had research and development tax credits of approximately \$138,159 available to offset future tax liabilities. The loss carryovers and the research and development tax credits expire over a period of 2020 to 2028. The Barbados net operating losses effectively do not carry over as the Company does not anticipate conducting future business in that country. The Company established a full valuation allowance on its net deferred tax assets as it is more likely than not that such tax benefits will not be realized.

13. RELOCATION

During the third quarter of 2005, the Company moved its corporate headquarters, laboratory operations and employees from Tucker, Georgia to Princeton, New Jersey. In connection with the move, the Company recorded relocation related expenses of \$0.8 million, lease termination expenses of \$1.4 million, and impairment charges of \$0.7 million related to leasehold improvements at the Georgia facility during the year ended September 30, 2006. Such expenses were included in General and Administrative expenses in the Statements of Operations and Other Comprehensive Net Loss.

14. COMMITMENTS AND CONTINGENCIES

On May 23, 2005, the Company entered into an operating lease for office and laboratory space through May 22, 2010, in Princeton, New Jersey. Monthly lease payments began May 23, 2005. The Company also leases office space in Durham, North Carolina. Monthly lease payments began May 1, 2007 and end on April 1, 2009. On February 7, 2006, the Company terminated its lease on its office and laboratory space in Atlanta, Georgia with a lease termination payment of \$1,398,000 (see Note 3). The lessor was an entity with which Dr. Schinazi was affiliated. In January 2007, the Company entered into a capital lease for lab equipment with principal and interest payments of \$14,044 due monthly through December 2008.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

As of September 30, 2007, future payments under capital leases and minimum future payments under non-cancellable operating leases are as follows:

	September 30, 2007	
	Capital Lease	Operating Leases
Fiscal 2008	\$ 168,526	\$ 905,471
Fiscal 2009	42,131	872,886
Fiscal 2010	—	530,254
Total minimum payments required	210,657	<u>\$2,308,611</u>
Less: Amounts representing interest	(9,576)	
Minimum future payments of principal	201,081	
Less: Current portion	(159,440)	
Long-term portion	<u>\$ 41,641</u>	

Rent expense under operating leases was \$777,939, \$811,513, and \$432,194 during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively. Rent expense of \$29,140 and \$177,317 during the year ended September 30, 2006 and the nine months ended September 30, 2005, respectively, was paid to C.S. Family, LLC, a related party.

The above contractual obligations table does not include amounts for milestone payments related to development, regulatory or commercialization events to licensors or collaboration partners, as the payments are contingent on the achievement of these milestones, which we have not achieved. DOT, which we licensed from RFS Pharma, is in the early stage of research and therefore it is not possible to predict when we would need to make a milestone payment. We may pay up to an aggregate of \$4.5 million in milestone payments and certain cost reimbursements if we reach milestones related to development and regulatory events under our license agreement with RFS Pharma LLC. We also agreed to pay Emory University up to an aggregate of \$1.0 million in future marketing milestone payments under our license agreement for DFC. Under our collaboration and license agreement with Bukwang, in the future we may pay up to an aggregate of \$23.0 million in milestone payments related to development, regulatory and commercialization events. Under our license agreement with Emory University for Racivir, we agreed to pay Emory University up to an aggregate of \$1.0 million in future marketing milestone payments.

15. EMPLOYEE SAVINGS PLAN

The Company maintains a contributory employee savings plan (“401(k) Plan”) for its employees. Under the plan, the Company matches certain employee contributions at the discretion of the board of directors. Expense under the plan was \$122,263, \$55,876, and \$0 during the years ended September 30, 2007 and 2006, and the nine months ended September 30, 2005, respectively. On January 11, 2006, the Company elected to implement a new 401(k) plan which provides for, among other things, a discretionary employer match of 50 cents on every dollar contributed by each employee under the plan up to a maximum annual amount of 6% of such employee’s salary up to a maximum annual match of \$3,500 per employee, such discretionary match being made automatically unless action is taken by the compensation committee to cancel the match for a given year.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

16. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables present unaudited quarterly financial data for the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	Three Months Ended			
	Dec. 31, 2006	March 31, 2007	June 30, 2007	Sept. 30, 2007
	(in thousands, except per share data)			
Revenues:	\$ 8,117	\$ 5,464	\$ 464	\$ 7,964
Net income (loss)	\$ 3,907	\$ (1,457)	\$ (5,862)	\$ (1,653)
Net income (loss) attributable to common stockholders	\$ 3,623	\$ (1,744)	\$ (7,067)	\$ (1,653)
Net income (loss) per common share:				
Basic	\$ 0.35	\$ (0.16)	\$ (0.40)	\$ (0.08)
Diluted	\$ 0.33	\$ (0.16)	\$ (0.40)	\$ (0.08)

	Three Months Ended			
	Dec. 31, 2005	March 31, 2006	June 30, 2006	Sept. 30, 2006
	(in thousands, except per share data)			
Revenues:	\$ 833	\$ 3,538	\$ 514	\$ 540
Net loss	\$ (3,092)	\$ (657)	\$ (4,123)	\$ (3,454)
Net loss attributable to common stockholders	\$ (3,365)	\$ (934)	\$ (4,402)	\$ (3,735)
Net loss per common share:				
Basic	\$ (0.33)	\$ (0.09)	\$ (0.42)	\$ (0.36)
Diluted	\$ (0.33)	\$ (0.09)	\$ (0.42)	\$ (0.36)

Basic and diluted net loss per common share are identical since common equivalent shares are excluded from the calculation as their effect is antidilutive, except for the quarter ended December 31, 2006.

17. SUBSEQUENT EVENT

Pursuant to the Loan Agreement (See Note 8) entered into on September 30, 2007, on October 5, 2007 the Company executed Loan A by signing a Secured Promissory Note ("Note") in the amount of \$10.0 million. The Note bears interest at 12% and is scheduled to be repaid over a 45-month period beginning on December 1, 2007 with the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. Prepayment of the loan is subject to penalty and substantially all of the Company's tangible and intangible assets (except for intellectual property) are collateral for the Loan Agreement.

On March 1, 2007, the Company's board of directors approved a 1.0 for 1.5 reverse stock split of the Company's outstanding common stock which became effective on April 19, 2007. All common share and per common share amounts in the accompanying financial statements and notes to the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

18. RESTATEMENT

Subsequent to the issuance of the Company's financial statements for the fiscal year 2005, the Company's management determined that accretion of dividends on Series D Preferred Stock was accounted for incorrectly. As a result, the statement of operations and comprehensive net loss, the statement of redeemable stock and warrants, the statement of stockholders' equity(deficit), and the statement of cash flows for the nine months ended September 30, 2005 have been restated from amounts previously reported to include dividends accruing from February 4, 2006 through August 4, 2009 in the periodic accretion of increases in the redemption amounts of the Series D Preferred Stock as of September 30, 2005.

On August 4, 2004, the Company issued Series D Preferred Stock for \$40,001,238 (see note 10 for additional information). The Series D Preferred Stock was redeemable at the option of the holder on or after August 4, 2009 upon a stockholder vote. Dividends did not begin to legally accrue until February 4, 2006, at the rate of 7.5% per annum of the purchase price, and accrue quarterly thereafter. These accrued dividends are payable upon a declaration of the board, not at the option of the Series D Preferred Stock holders, but are included in the redemption amount if they have not already been paid, whether or not declared.

The Company previously reported the initial carrying amount of the Series D Preferred Stock at its fair value on the date of issue. This initial carrying amount was less than the redemption amount due to the allocation of a portion of the initial fair value to the carrying amount of the D-1 Warrants which were issued together with the Series D Preferred Stock. The Company previously increased the carrying amount of its Series D Preferred Stock to accrete the discount resulting from the allocation of a portion of the proceeds to the D-1 Warrants over the period remaining to redemption.

EITF Abstracts, Topic No. D-98, "Classification and Measurement of Redeemable Securities" ("EITF Topic D-98") offers a choice of two methods for periodically increasing the carrying value of redeemable preferred stock. For periodic accretions of the warrant allocation, we applied the method described in Paragraph 16a of EITF Topic D-98, the interest method, starting on the issuance date. However, for periodic increases in the carrying amount of the Series D Preferred Stock due to the dividend, we chose the method described in paragraph 16b of EITF Topic D-98, which is to recognize changes in redemption value as they occur. This incorrectly applied accounting principles generally accepted in the United States of America, because Paragraph 17 of EITF Topic D-98 requires consistent application of the accounting method selected.

Furthermore, the Company's previously issued financial statements presented comprehensive net (loss) profit in a footnote. The Company has revised its presentation to present the statement of comprehensive net (loss) profit together with the statement of operations.

PHARMASSET, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)

The following tables show, for each of the items adjusted in the financial statements for the 2005 fiscal year, the amounts as they were previously reported and as they have been restated in the current accompanying financial statements.

	Nine Months Ended September 30, 2005		
	As Previously Reported	Effect of Adjustment	As Restated
Statement of Operations and Comprehensive Net Loss:			
Redeemable preferred stock accretion	\$ 1,223,672	\$ 1,063,127	\$ 2,286,799
Net loss attributable to common shareholders	(14,932,456)	(1,063,127)	(15,995,583)
Net loss attributable to common shareholders per share—basic and diluted	(\$2.25)	(\$0.17)	(\$2.42)
Statement of Redeemable Stock and Warrants:			
Accretion of Series D redeemable convertible preferred stock to redemption value	1,157,757	1,063,127	2,220,884
Accretion of total redeemable stock and warrants to redemption value	1,223,672	1,063,127	2,286,799
Conversion of preferred stock to common stock (Series D redeemable convertible preferred stock)	(24,115,578)	(1,133,447)	(25,249,025)
Conversion of preferred stock to common stock (Total redeemable stock and warrants)	(32,801,976)	(1,133,447)	(33,935,423)
Balance of Series D redeemable convertible preferred stock	11,204,124	714,279	11,918,403
Balance of total redeemable stock and warrants	18,794,505	714,279	19,508,784
Statement of Stockholders' Equity (Deficit):			
Change in accumulated deficit from accretion of redeemable preferred stock to redemption value	(1,223,672)	(1,063,127)	(2,286,799)
Change in total stockholders' (deficit) equity from accretion of redeemable preferred stock to redemption value	(1,223,672)	(1,063,127)	(2,286,799)
Balance of accumulated deficit	(35,631,756)	(1,847,726)	(37,479,482)
Change in additional paid-in capital from conversion of preferred stock to common stock	32,793,692	1,133,447	33,927,139
Change in total stockholders' (deficit) equity from conversion of preferred stock to common stock	32,801,976	1,133,447	33,935,423
Balance of additional paid-in capital	42,224,930	1,133,447	43,358,377
Balance of stockholders' (deficit) equity	12,382,417	(714,279)	11,668,138
Consolidated Statements of Cash Flows:			
Noncash transactions:			
Conversion of preferred stock to common stock	32,801,976	1,133,447	33,935,423
Accretion of redeemable preferred stock to redemption value	1,223,672	1,063,127	2,286,799

EXHIBIT INDEX

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant
3.2	Second Amended and Restated Bylaws of the Registrant
4.3	Form of Agreement for Awards Under 2007 Equity Incentive Plan
10.23†	Venture Loan and Security Agreement dated as of September 30, 2007 by and between the Registrant and Horizon Technology Funding Company V LLC
23.1	Consent of Deloitte & Touche LLP
23.2	Consent of Grant Thornton LLP
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

† Portions of the exhibits have been omitted pursuant to a confidential treatment request and this information has been filed separately with the SEC.

**THIRD AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
PHARMASSET, INC.**

Pharmasset, Inc., a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

1. Pharmasset, Inc. (the “Corporation”) was originally incorporated in the State of Delaware under the name “Pharmasset, Inc.” by the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware on June 8, 2004.

2. The Board of Directors of the Corporation, in accordance with the Bylaws of the Corporation and Section 141 of the General Corporation Law of the State of Delaware, duly adopted resolutions proposing and declaring advisable the adoption of this Third Amended and Restated Certificate of Incorporation.

3. This Third Amended and Restated Certificate of Incorporation, which was duly adopted in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware and which was duly adopted by the Corporation’s stockholders in accordance with Section 228 of the General Corporation Law of the State of Delaware, restates and integrates and further amends the provisions of the Certificate of Incorporation of the Corporation previously filed with the Secretary of State of Delaware on June 8, 2004, as amended to the date hereof.

4. The Certificate of Incorporation of Pharmasset, Inc. is hereby amended and restated to read in its entirety as follows:

FIRST: The name of the corporation is Pharmasset, Inc. (the “Corporation”).

SECOND: The address of the registered office of the Corporation in the State of Delaware is One Rodney Square, 10th Floor, Tenth and King Streets, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is RL&F Service Corp.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the “General Corporation Law”).

FOURTH: The total number of shares of all classes of stock that the Corporation shall have authority to issue is 110,000,000 shares, consisting of (i) 100,000,000 shares of Common Stock, \$0.001 par value per share (“Common Stock”), and (ii) 10,000,000 shares of Preferred Stock, \$0.001 par value per share (“Preferred Stock”).

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK.

(1) The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

(2) The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

(3) The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of Delaware.

(4) Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

(5) Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK.

(1) Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

(2) Subject to any limitations prescribed by law or this Certificate of Incorporation, authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto pursuant to the applicable law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or

restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall rank senior, equal or junior to any other series of Preferred Stock to the extent permitted by law.

(3) The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of Delaware.

FIFTH: This Article is inserted for the management of the business and for the conduct of the affairs of the Corporation.

(1) The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

(2) Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established by the Board of Directors and shall consist of not less than three nor more than twenty-one members; the exact number to be determined from time to time by a resolution adopted by an affirmative vote of the entire Board of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes designated as "Class I," "Class II" and "Class III," respectively. Each class shall be as nearly equal in number as the then total number of directors constituting the entire Board of Directors permits. Directors shall initially be assigned to each class in accordance with a resolution or resolutions adopted by the Board of Directors.

(3) Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting following the annual meeting at which such director was elected; provided, that each director initially appointed to Class I shall serve for a term expiring at the Corporation's annual meeting of stockholders held in 2008; each director initially appointed to Class II shall serve for a term expiring at the Corporation's annual meeting of stockholders held in 2009; and each director initially appointed to Class III shall serve for a term expiring at the Corporation's annual meeting of stockholders held in 2010; provided further, that the term of each director shall continue until the election and qualification of his successor and be subject to his earlier death, resignation or removal.

(4) At each annual meeting of stockholders, the directors of one class shall be elected to hold office for a term expiring at the third annual meeting following the election and until a successor shall have been duly elected and qualified; at the next succeeding annual meeting, the directors of the second class shall be elected to serve for such a term; and at the third succeeding annual meeting, the directors of the third class shall be elected to serve for such a term. Election of directors need not be by written ballot, except as and to the extent provided in the Bylaws of the Corporation. During the intervals between annual meetings of stockholders,

any vacancy occurring in the board of directors caused by resignation, removal, death or other incapacity, and any newly created directorships resulting from an increase in the number of directors, shall be filled by a majority vote of the directors then in office, whether or not a quorum. Each director chosen to fill a vacancy shall hold office for the unexpired term in respect of which such vacancy occurred. Each director chosen to fill a newly created directorship shall hold office until the next election of the class for which such director shall have been chosen. When the number of directors is changed, any newly created directorships or any decrease in directorships shall be so apportioned among the classes as to make all classes as nearly equal in number as possible. No decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

SIXTH: Except to the extent that the General Corporation Law of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. If the General Corporation Law of Delaware is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of Delaware, as so amended.

SEVENTH: The Company shall provide indemnification as follows:

(1) The Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

(2) The Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation,

partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the Corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

(3) To the extent that a present or former director or officer of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in Sections (1) and (2) of this Article SEVENTH, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

(4) Any indemnification under Sections (1) and (2) of this Article SEVENTH (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in such Sections (1) and (2). Such determination shall be made, with respect to a person who is a director or officer at the time of such determination, (a) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (b) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (c) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (d) by the stockholders of the Corporation.

(5) Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation authorized in this Article SEVENTH. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if any, as the Corporation deems appropriate.

(6) The indemnification and advancement of expenses provided by, or granted pursuant to, the other sections of this Article SEVENTH shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

(7) The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was

serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the Corporation would have the power to indemnify him against such liability under the provisions of Section 145 of the General Corporation Law.

(8) For purposes of this Article SEVENTH, references to “the Corporation” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article SEVENTH with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued.

(9) For purposes of this Article SEVENTH, references to “other enterprises” shall include employee benefit plans; references to “fines” shall include any excise taxes assessed on a person with respect to any employee benefit plan; and references to “serving at the request of the Corporation” shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves service by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Corporation” as referred to in this Article SEVENTH.

(10) The indemnification and advancement of expenses provided by, or granted pursuant to, this Article SEVENTH shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

EIGHTH: In furtherance and not in limitation of the powers conferred upon it by the laws of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the Corporation’s Bylaws. The affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present shall be required to adopt, amend, alter or repeal the Corporation’s Bylaws.

NINTH: Special meetings of stockholders for any purpose or purposes may be called at any time by the Board of Directors, the Chairman of the Board or the President, but such special meetings may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

TENTH: The Corporation reserves the right to amend, alter, change or repeal any provisions contained in this Certificate of Incorporation in the manner now or hereafter prescribed by law, and all the provisions of this Certificate of Incorporation and all rights conferred on stockholders, directors and officers in this Certificate of Incorporation are subject to this reserved power.

ELEVENTH: No action required to be taken or that may be taken at any annual or special meeting of stockholders of the Corporation may be taken by written consent without a meeting, and the power of stockholders to consent in writing is specifically denied.

IN WITNESS WHEREOF, the Company has caused this Third Amended and Restated Certificate of Incorporation to be executed by its duly authorized officer this the 2nd day of May, 2007.

PHARMASSET, INC.

By: /s/ P. Schaefer Price

Name: P. Schaefer Price

Title: President and Chief Executive Officer

**SECOND AMENDED AND RESTATED BYLAWS
OF
PHARMASSET, INC.**

Adopted on April 18, 2007

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SECOND AMENDED AND RESTATED BYLAWS

OF

PHARMASSET, INC.

ARTICLE I

OFFICES

SECTION 1.01. Registered Office. The registered office of Pharmasset, Inc. (the “Corporation”) in the State of Delaware shall be One Rodney Square, 10th Floor, Tenth and King Streets, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is RL&F Service Corp.

SECTION 1.02. Other Offices. The Corporation may also have an office or offices at any other place or places within or without the State of Delaware as the Board of Directors of the Corporation (the “Board”) may from time to time determine or the business of the Corporation may from time to time require.

ARTICLE II

MEETINGS OF STOCKHOLDERS

SECTION 2.01. Annual Meetings. The annual meeting of stockholders of the Corporation for the election of directors of the Corporation, and for the transaction of such other business as may properly come before such meeting, shall be held at such place, date and time as shall be fixed by the Board and designated in the notice or waiver of notice of such annual meeting.

SECTION 2.02. Special Meetings. Special meetings of stockholders for any purpose or purposes may be called by the Board, the Chairman of the Board of the Corporation (the “Chairman”) or the President of the Corporation (the “President”), but such special meetings may not be called by any other person or persons. Business transacted at any special meetings shall be limited to the purposes stated in the notice of such special meeting. Any special meetings are to be held at such place, date and time as shall be designated in the notice or waiver of notice thereof, in accordance with Section 2.03(b).

SECTION 2.03. Notice of Meetings. (a) Except as otherwise provided by law, written notice of each annual meeting of stockholders stating the place, date and time of such meeting shall be given personally or by first-class mail (air-mail in the case of international communications) to each recordholder of shares entitled to vote thereat, not less than ten (10) nor

more than sixty (60) days before the date of such meeting. If mailed, such notice shall be deemed to be given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. If, prior to the time of mailing, the Secretary of the Corporation (the "Secretary") shall have received from any stockholder a written request that notices intended for such stockholder are to be mailed to some address other than the address that appears on the records of the Corporation, notices intended for such stockholder shall be mailed to the address designated in such request. For business to be properly brought before an annual meeting by a stockholder, the stockholder must have given timely notice thereof in writing to the Secretary. To be timely, a stockholder's notice must be delivered to or mailed and received at the principal executive offices of the Corporation, in accordance with Rule 14a-8(e)(2) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), not less than one hundred and twenty (120) calendar days prior to the date of the Corporation's proxy statement released to stockholders in connection with the previous year's annual meeting of stockholders, except that, if no annual meeting of stockholders was held in the previous year, or if the date of the annual meeting of stockholders has been changed by more than thirty (30) calendar days from the date contemplated at the time of the previous year's proxy statement, the notice shall be received at the principal executive offices of the Corporation not less than the later of (i) one hundred and fifty (150) calendar days prior to the date of the contemplated annual meeting or (ii) the date that is ten (10) calendar days after the date of the first public announcement or other notification to the stockholders of the date of the contemplated annual meeting.

(b) Except as otherwise provided by law, written notice of each special meeting of stockholders stating the place, date and time of such meeting and the purpose or purposes for which such special meeting is to be held, shall be given personally or by first class mail (airmail in the case of international communications) to each recordholder of shares entitled to vote thereat, not less than 10 nor more than 60 days before the date of such meeting. If mailed, such notice shall be deemed to be given when deposited in the United States mail, postage prepaid or directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. If, prior to the time of mailing, the Secretary shall have received from any stockholder a written request that notices intended for such stockholder are to be mailed to some address other than the address that appears on the records of the Corporation, notices intended for such stockholder shall be mailed to the address designated in such request. Notice of a special meeting of stockholders may be given by the person or persons calling the meeting, or, upon the written request of such person or persons, such notice shall be given by the Secretary on behalf of such person or persons. If the person or persons calling a special meeting of stockholders give notice thereof, such person or persons shall deliver a copy of such notice to the Secretary. Each request to the Secretary for the giving of notice of a special meeting of stockholders shall state the purpose or purposes of such meeting.

SECTION 2.04. Contents of Notice for Annual Meeting . A stockholder's notice to the Secretary shall set forth, as to each matter such stockholder proposes to bring before the annual meeting: (i) a brief description of the business desired to be brought before the annual meeting and the reasons for conducting such business at the annual meeting; (ii) the name and address, as they appear on the Corporation's books, of the stockholder proposing such business; (iii) the class and number of shares of the Corporation which are beneficially owned by such stockholder; (iv) the dates upon which the stockholder acquired such shares; (v) documentary

support for any claim of beneficial ownership, (vi) any material interest of such stockholder in such business; (vii) a statement in support of the matter and any other information required by Rule 14a-8 under the Exchange Act; and (viii) as to each person whom the stockholder proposes to nominate for election or reelection as director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to Regulation 14A under the Exchange Act, and Rule 14a-1 thereunder (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected).

SECTION 2.05. Determination of Validity of Notice for Annual Meeting. The chairman of an annual meeting may, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the provisions of Sections 2.03(a) and 2.04 of this Article, and, if he or she should so determine, he or she shall so declare to the meeting that any such business so determined to be not properly brought before the meeting shall not be transacted, or in the case of persons so nominated, not be eligible for election.

SECTION 2.06. Waiver of Notice. Notice of any annual or special meeting of stockholders need not be given to any stockholder who files a written waiver of notice with the Secretary, signed by the person entitled to notice, whether before or after such meeting. Neither the business to be transacted at, nor the purpose of, any meeting of stockholders need be specified in any written waiver of notice thereof. Attendance of a stockholder at a meeting, in person or by proxy, shall constitute a waiver of notice of such meeting, except when such stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business on the grounds that the notice of such meeting was inadequate or improperly given.

SECTION 2.07. Adjournments. Whenever a meeting of stockholders, annual or special, is adjourned to another date, time or place, notice need not be given of the adjourned meeting if the date, time and place thereof are announced at the meeting at which the adjournment is taken. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder entitled to vote thereat. At the adjourned meeting, any business may be transacted which might have been transacted at the original meeting.

SECTION 2.08. Quorum. Except as otherwise provided by law or the certificate of incorporation of the Corporation, as amended and restated (the "Certificate of Incorporation"), the recordholders of a majority of the shares entitled to vote thereat, present in person or by proxy, shall constitute a quorum for the transaction of business at all meetings of stockholders, whether annual or special. If, however, such quorum shall not be present in person or by proxy at any meeting of stockholders, the stockholders entitled to vote thereat may adjourn the meeting from time to time in accordance with Section 2.07 hereof until a quorum shall be present in person or by proxy.

SECTION 2.09. Voting. Each stockholder entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of stock held by such stockholder which has voting power on the matter in question. Except as otherwise required by law or by the

Certificate of Incorporation or by these Bylaws, in all matters other than the election of directors, the affirmative vote of the majority of the shares present in person or represented by proxy at the meeting of stockholders and entitled to vote on the subject matter shall be the act of the stockholders. Directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

SECTION 2.10. Proxies. Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy. Such proxy shall be filed with the Secretary before such meeting of stockholders, at such time as the Board may require. No proxy shall be voted or acted upon more than three years from its date, unless the proxy provides for a longer period.

SECTION 2.11. No Stockholder Action by Written Consent. No action required to be taken or that may be taken at any annual or special meeting of stockholders of the Corporation may be taken by written consent without a meeting.

SECTION 2.12. Voting List. The officer who has charge of the stock ledger shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of meeting, or (ii) during ordinary business hours, at the principal place of business of the Corporation. The list of stockholders must also be open to examination at the meeting as and if required by applicable law. Except as otherwise provided by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 2.12 or to vote in person or by proxy at any meeting of stockholders.

SECTION 2.13. Inspectors of Election. The Corporation may, and shall if required by statute, regulation, rule or standard of conduct of any applicable governmental agency, exchange or trading system, in advance of any meeting of stockholders, appoint one or more inspectors of election, who may be employees of the Corporation, to act at the meeting or any adjournment thereof and to make a written report thereof. The corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. In the event that no inspector so appointed or designated is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector or inspectors so appointed or designated shall (i) ascertain the number of shares of capital stock of the Corporation outstanding and the voting power of each such share, (ii) determine the shares of capital stock of the Corporation represented at the meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares of

capital stock of the Corporation represented at the meeting and such inspectors' count of all votes and ballots. Such certification and report shall specify such other information as may be required by law. In determining the validity and counting of proxies and ballots cast at any meeting of stockholders of the Corporation, the inspectors may consider such information as is permitted by applicable law. No person who is a candidate for an office at an election may serve as an inspector at such election.

ARTICLE III

BOARD

SECTION 3.01. General Powers. The business and affairs of the Corporation shall be managed by the Board, which may exercise all such powers of the Corporation except as otherwise provided by law, the Certificate of Incorporation or these Bylaws.

SECTION 3.02. Number and Term of Office. The authorized number of directors of the Corporation shall be fixed in accordance with the Certificate of Incorporation. Directors need not be stockholders unless so required by the Certificate of Incorporation. Directors shall be elected at the annual meeting of stockholders. Each director shall hold office until his or her successor is elected and qualified, or until his or her earlier death or resignation or removal in the manner hereinafter provided.

SECTION 3.03. Resignation. Any director may resign at any time by delivering his or her written resignation to the Board, the Chairman or the Secretary. Such resignation shall take effect at the time specified in such notice or, if the time be not specified, upon receipt thereof by the Board, the Chairman or the Secretary, as the case may be. Unless otherwise specified therein, acceptance of such resignation shall not be necessary to make it effective.

SECTION 3.04. Removal. Any director may be removed at any time by vote of the recordholders of a majority of the shares then entitled to vote at an election of directors only for cause.

SECTION 3.05. Election; Vacancies; Classification of Board. At each annual meeting of stockholders the stockholders shall elect directors, each of whom shall hold office until his or her successor is duly elected and qualified, subject to such director's earlier death, resignation, disqualification or removal. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes designated as "Class I," "Class II" and "Class III," respectively, with the term of office of one class expiring each year. Each class shall be as nearly equal in number as the then total number of directors constituting the entire Board of Directors permits. At each annual meeting of stockholders, the directors of one class shall be elected to hold office for a term expiring at the third annual meeting following the election and until a successor shall have been duly elected and qualified; at the next succeeding annual meeting, the directors of the second class shall be elected to serve for such a term; and at the third succeeding annual meeting, the directors of the third class shall be elected to serve for such a term. During the intervals between annual meetings of stockholders, any vacancy occurring in the Board caused by resignation, removal, death or other incapacity, and any newly created directorships resulting from an increase in the

number of directors, shall be filled by a majority vote of the directors then in office, whether or not a quorum. In order to ensure that the three classes of directors provided for in the Certificate of Incorporation and these Bylaws remain as nearly equal in number as possible, the Board shall increase the number of directors in one or more classes as may be appropriate whenever the number of directors increases due to newly created directorships or otherwise. Each director chosen to fill a vacancy shall hold office for the unexpired term in respect of which such vacancy occurred. Each director chosen to fill a newly created directorship shall hold office until the next election of the class for which such director shall have been chosen. When the number of directors is changed, any newly created directorships or any decrease in directorships shall be so apportioned among the classes as to make all classes as nearly equal in number as possible. No decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

SECTION 3.06. Nomination of Directors. Only persons who are nominated in accordance with the following procedures shall be eligible for election as directors. Nominations of persons for election to the Board may be made at a meeting of stockholders (i) by the Board or at the direction of the Board by any nominating committee or person appointed by the Board or (ii) by any stockholder entitled to vote for the election of directors at the meeting who complies with the notice procedures set forth in Section 2.03 and 2.04 of these Bylaws. Such nominations, other than those made by or at the direction of the Board, shall be made pursuant to timely notice in writing to the Secretary. Such notice to the Secretary shall set forth the information required in Section 2.04 of these Bylaws. The Corporation may require any proposed nominee to furnish such other information as reasonably may be required by the Corporation to determine the eligibility of such proposed nominee to serve as a director of the Corporation. The chairman of the meeting may, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the foregoing procedures, and if he or she should so determine, he or she shall so declare to the meeting and the defective nomination shall be disregarded.

SECTION 3.07. Meetings.

(a) Annual Meetings. As soon as practicable after each annual election of directors by the stockholders, the Board shall meet for the purpose of organization and the transaction of other business, unless it shall have transacted all such business by written consent pursuant to Section 3.09 hereof.

(b) Other Meetings. Other meetings of the Board shall be held at such times as the Chairman, the President, the Secretary or a majority of the Board shall from time to time determine.

(c) Notice of Meetings. The Secretary shall give written notice to each director of each meeting of the Board, which notice shall state the place, date, time and purpose of such meeting. Notice of each such meeting shall be given to each director, if by mail, addressed to him or her at his or her residence or usual place of business, at least three days before the day on which such meeting is to be held, or shall be sent to him or her at such place by telecopier, telephone or other means of electronic transmission not later than the day before the day on which such meeting is to be held. A written waiver of notice, signed by the director entitled to notice, whether before or after the time of the meeting referred to in such waiver, shall

be deemed equivalent to notice. Neither the business to be transacted at, nor the purpose of any meeting of the Board need be specified in any written waiver of notice thereof. Attendance of a director at a meeting of the Board shall constitute a waiver of notice of such meeting, except as provided by law.

(d) Place of Meetings. The Board may hold its meetings at such place or places within or without the State of Delaware as the Board or the Chairman may from time to time determine, or as shall be designated in the respective notices or waivers of notice of such meetings.

(e) Quorum and Manner of Acting. A majority of the total number of directors then in office shall be present in person at any meeting of the Board in order to constitute a quorum for the transaction of business at such meeting, and the vote of a majority of those directors present at any such meeting at which a quorum is present shall be necessary for the passage of any resolution or act of the Board, except as otherwise expressly required by law, the Certificate of Incorporation or these Bylaws. In the absence of a quorum for any such meeting, a majority of the directors present thereat may adjourn such meeting from time to time until a quorum shall be present.

(f) Organization. At each meeting of the Board, one of the following shall act as chairman of the meeting and preside, in the following order of precedence:

- 1) the Chairman;
- 2) the President;
- 3) any director chosen by a majority of the directors present.

The Secretary or, in the case of his or her absence, any person (who shall be an Assistant Secretary, if an Assistant Secretary is present) whom the chairman of the meeting shall appoint shall act as secretary of such meeting and keep the minutes thereof.

SECTION 3.08. Committees of the Board. The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each committee to consist of one or more directors. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of such committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another director to act at the meeting in the place of any such absent or disqualified member. Any committee of the Board, to the extent permitted by law and to the extent provided in the resolution of the Board designating such committee, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it. Unless the Board otherwise provides, each committee designated by the Board may make, alter and repeal rules for the conduct of its business. In the absence of such rules each committee shall conduct its business in the same manner as the Board conducts its business pursuant to this Article III. Each committee of the Board shall keep regular minutes of its proceedings and report the same to the Board when so requested by the Board.

SECTION 3.09. Directors' Consent in Lieu of Meeting. Any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting, without prior notice and without a vote, if a consent in writing or by electronic transmission, setting forth the action so taken, shall be signed by all the members of the Board or such committee and such consent or electronic transmission is filed with the minutes of the proceedings of the Board or such committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

SECTION 3.10. Action by Means of Telephone or Similar Communications Equipment. Any one or more members of the Board, or of any committee thereof, may participate in a meeting of the Board or such committee by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

SECTION 3.11. Compensation. Unless otherwise restricted by the Certificate of Incorporation, the Board may determine the compensation of directors. In addition, as determined by the Board, directors may be reimbursed by the Corporation for their expenses, if any, in the performance of their duties as directors. No such compensation or reimbursement shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

ARTICLE IV

OFFICERS

SECTION 4.01. Officers. The officers of the Corporation shall be the Chairman, the President, the Secretary, a Treasurer and may include one or more Vice Presidents (some of whom may be designated as Executive Vice Presidents or Senior Vice Presidents), one or more Assistant Vice Presidents, one or more Assistant Secretaries, and one or more Assistant Treasurers. Any two or more offices may be held by the same person.

SECTION 4.02. Authority and Duties. All officers shall have such authority and perform such duties in the management of the Corporation as may be provided in these Bylaws or, to the extent not so provided, by resolution of the Board.

SECTION 4.03. Term of Office, Resignation and Removal. (a) Each officer shall be appointed by the Board and shall hold office for such term as may be determined by the Board. Each officer shall hold office until his or her successor has been appointed and qualified or his or her earlier death or resignation or removal in the manner hereinafter provided.

(b) Any officer may resign at any time by giving written notice to the Board, the Chairman, the President or the Secretary. Such resignation shall take effect at the time

specified in such notice or, if the time be not specified, upon receipt thereof by the Board, the Chairman, the President or the Secretary, as the case may be. Unless otherwise specified therein, acceptance of such resignation shall not be necessary to make it effective.

(c) All officers and agents appointed by the Board shall be subject to removal, with or without cause, at any time by the Board.

SECTION 4.04. Vacancies. Any vacancy occurring in any office of the Corporation, for any reason, shall be filled by action of the Board. Unless earlier removed pursuant to Section 4.03 hereof, any officer appointed by the Board to fill any such vacancy shall serve only until such time as the unexpired term of his or her predecessor expires unless reappointed by the Board.

SECTION 4.05. The Chairman. The Chairman shall have the power to call special meetings of stockholders, to call special meetings of the Board and, if present, to preside at all meetings of stockholders and all meetings of the Board. The Chairman shall perform all duties incident to the office of Chairman of the Board and all such other duties as may from time to time be assigned to him or her by the Board or these Bylaws.

SECTION 4.06. The President. The President shall be the chief executive officer of the Corporation and shall have general and active management of the business and affairs of the Corporation, unless the Board provides otherwise in a specific instance or generally, and shall see that all orders and resolutions of the Board are carried into effect. The President shall perform all duties incident to the office of President and all such other duties as may from time to time be assigned to him or her by the Board or these Bylaws.

SECTION 4.07. Vice Presidents. Vice Presidents (some of whom may be designated as Executive Vice Presidents or Senior Vice Presidents) and Assistant Vice Presidents, if any, in order of their seniority or in any other order determined by the Board, shall generally assist the President and perform such other duties as the Board or the President shall prescribe, and in the absence or disability of the President, shall perform the duties and exercise the powers of the President.

SECTION 4.08. The Secretary. The Secretary shall, to the extent practicable, attend all meetings of the Board and all meetings of stockholders and shall record all votes and the minutes of all proceedings in a book to be kept for that purpose, and shall perform the same duties for any committee of the Board when so requested by such committee. He or she shall give or cause to be given notice of all meetings of stockholders and of the Board, shall perform such other duties as may be prescribed by the Board, the Chairman or the President and shall act under the supervision of the Chairman. He or she shall keep in safe custody the seal of the Corporation and affix the same to any instrument that requires that the seal be affixed to it and which shall have been duly authorized for signature in the name of the Corporation and, when so affixed, the seal shall be attested by his or her signature or by the signature of an Assistant Secretary. He or she shall keep in safe custody the certificate books and stockholder records and such other books and records of the Corporation as the Board, the Chairman or the President may direct and shall perform all other duties incident to the office of Secretary and such other duties as from time to time may be assigned to him or her by the Board, the Chairman or the President.

SECTION 4.09. Assistant Secretaries. Assistant Secretaries of the Corporation (“ Assistant Secretaries ”), if any, in order of their seniority or in any other order determined by the Board, shall generally assist the Secretary and perform such other duties as the Board or the Secretary shall prescribe, and, in the absence or disability of the Secretary, shall perform the duties and exercise the powers of the Secretary.

SECTION 4.10. The Treasurer. The Treasurer shall have the care and custody of all monies and securities of the Corporation. The Treasurer shall sign or countersign such instruments as require his or her signature, and shall perform all duties incident to his or her office, or that are properly required of the Treasurer by the Board. The Treasurer shall keep a full and accurate account of all moneys received and paid on account of the Corporation and shall render a statement of his or her accounts whenever the Board, the Chairman or the President shall so request.

SECTION 4.11. Assistant Treasurers. Assistant Treasurers of the Corporation (“ Assistant Treasurers ”), if any, in order of their seniority or in any other order determined by the Board, shall generally assist the Treasurer and perform such other duties as the Board or the Treasurer shall prescribe, and, in the absence or disability of the Treasurer, shall perform the duties and exercise the powers of the Treasurer.

SECTION 4.12. Salaries. The Board shall have the power to fix the compensation of all officers and employees of the Corporation, and may delegate such authority to a committee or to one or more officers of the Corporation.

ARTICLE V

CHECKS, DRAFTS, NOTES, AND PROXIES

SECTION 5.01. Checks, Drafts and Notes. All checks, drafts and other orders for the payment of money, notes and other evidences of indebtedness issued in the name of the Corporation shall be signed by such officer or officers, agent or agents of the Corporation and in such manner as shall be determined, from time to time, by resolution of the Board.

SECTION 5.02. Execution of Proxies. The Chairman, the President or any Vice President may authorize, from time to time, the execution and issuance of proxies to vote shares of stock or other securities of other corporations held of record by the Corporation and the execution of consents to action taken or to be taken by any such corporation. All such proxies and consents, unless otherwise authorized by the Board, shall be signed in the name of the Corporation by the Chairman, the President or any Vice President.

SECTION 5.03. Facsimile Signatures. In addition to the provisions for use of facsimile signatures elsewhere specifically authorized in these Bylaws, facsimile signatures of any officer or officers of the Corporation may be used whenever and as authorized by the Board or a committee thereof.

ARTICLE VI

SHARES AND TRANSFERS OF SHARES

SECTION 6.01. Shares. Shares of the Corporation's stock may be certificated or uncertificated, as provided under Delaware law. All certificates of stock of the Company shall be numbered in the order in which they are issued, and shall be entered in the books of the Company as they are issued. Each certificate shall exhibit the holder's name and the number of shares and shall be signed by the President or a Vice President and by the Secretary or an Assistant Secretary. Any or all of the signatures on a stock certificate may be facsimiles. In the event any such officer who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to hold such office or to be employed by the Corporation before such certificate is issued, such certificate may be issued by the Corporation with the same effect as if such officer had held such office on the date of issue. Each certificate shall state upon the face or back thereof, in full or in summary, all of the powers, designations, preferences, and rights, and the limitations or restrictions of the shares authorized to be issued or shall, except as otherwise required by law, set forth on the face or back a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional, or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the Corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to this section or otherwise required by law or with respect to this section a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

SECTION 6.02. Stock Ledger. A stock ledger in one or more counterparts shall be kept by the Secretary, in which shall be recorded the name and address of each person, firm or corporation owning the shares evidenced by each certificate evidencing shares issued by the Corporation, the number of shares evidenced by each such certificate, the date of issuance thereof and, in the case of cancellation, the date of cancellation. Except as otherwise expressly required by law, the person in whose name shares stand on the stock ledger of the Corporation shall be deemed the owner and recordholder thereof for all purposes.

SECTION 6.03. Transfers of Shares. Registration of transfers of shares shall be made only in the stock ledger of the Corporation upon request of the registered holder of such shares, or of his or her attorney thereunto authorized by power of attorney duly executed and filed with the Secretary, and upon the surrender of the certificate or certificates evidencing such shares properly endorsed or accompanied by a stock power duly executed, together with such proof of the authenticity of signatures as the Corporation may reasonably require. The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the Delaware General Corporate Law.

SECTION 6.04. Addresses of Stockholders. Each stockholder shall designate to the Secretary an address at which notices of meetings and all other corporate notices may be served or mailed to such stockholder, and, if any stockholder shall fail to so designate such an address, corporate notices may be served upon such stockholder by mail directed to the mailing address, if any, as the same appears in the stock ledger of the Corporation or at the last known mailing address of such stockholder.

SECTION 6.05. Lost, Destroyed and Mutilated Certificates. Each recordholder of shares shall promptly notify the Corporation of any loss, destruction or mutilation of any certificate or certificates evidencing any share or shares of which he or she is the recordholder. The Board may, in its discretion, cause the Corporation to issue a new certificate in place of any certificate theretofore issued by it and alleged to have been mutilated, lost, stolen or destroyed, upon the surrender of the mutilated certificate or, in the case of loss, theft or destruction of the certificate, upon satisfactory proof of such loss, theft or destruction, and the Board may, in its discretion, require the recordholder of the shares evidenced by the lost, stolen or destroyed certificate or his or her legal representative to give the Corporation a bond sufficient to indemnify the Corporation against any claim made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

SECTION 6.06. Regulations. The Board may make such other rules and regulations as it may deem expedient, not inconsistent with these Bylaws, concerning the issue, transfer and registration of certificates evidencing shares.

SECTION 6.07. Fixing Date for Determination of Stockholders of Record. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board may fix, in advance, a record date, which shall not be more than 60 nor less than ten (10) days before the date of such meeting, nor more than sixty (60) days prior to any other such action. A determination of the stockholders entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of such meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

ARTICLE VII

SEAL

SECTION 7.01. Seal. The Board may approve and adopt a corporate seal, which shall be in the form of a circle and shall bear the full name of the Corporation, the year of its incorporation and the words "Corporate Seal Delaware".

ARTICLE VIII

FISCAL YEAR

SECTION 8.01. Fiscal Year. The fiscal year of the Corporation shall end on the thirtieth day of September of each year, unless changed by resolution of the Board.

ARTICLE IX

INDEMNIFICATION AND INSURANCE

SECTION 9.01. Indemnification. (a) The Corporation shall indemnify, to the fullest extent not prohibited by the Delaware General Corporation Law, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

(b) The Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the Corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

(c) To the extent that a present or former director or officer of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in Section 9.01(a) and (b) of these Bylaws, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

(d) Any indemnification under Section 9.01(a) and (b) of these Bylaws (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in Section 9.01(a) and (b) of these Bylaws. Such determination shall be made, with respect to a person who is a director or officer at the time of such determination, (i) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (ii) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (iv) by the stockholders of the Corporation.

(e) Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation as authorized in this Article IX. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if any, as the Corporation deems appropriate.

(f) The indemnification and advancement of expenses provided by, or granted pursuant to, the other Sections of this Article IX shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

(g) For purposes of this Article IX, references to "the Corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article IX with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued.

(h) For purposes of this Article IX, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a

person with respect to any employee benefit plan; and references to “servicing at the request of the Corporation” shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves service by, such director, officer, employee or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Corporation” as referred to in this Article IX.

(i) The indemnification and advancement of expenses provided by, or granted pursuant to, this Article IX shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

SECTION 9.02. Insurance for Indemnification. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person’s status as such, whether or not the Corporation would have the power to indemnify such person against such liability under the provisions of Section 145 of the Delaware General Corporation Law.

ARTICLE X

AMENDMENTS

SECTION 10.01. Amendments. Any bylaw (including these Bylaws) may be altered, amended or repealed, and new bylaws made (i) by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board at which a quorum is present or by a written consent of directors pursuant to Section 3.09 hereto, or (ii) by the affirmative vote of the recordholders of a majority of the shares then entitled to vote at an election of directors (except that Sections 2.02, 2.03, 2.04, 2.05, 2.11, 3.04, 3.05 and 3.11 and this Article X may only be amended by the affirmative vote of the holders of not less than sixty percent (60%) of the shares of the Corporation outstanding and entitled to vote at an election of directors) at any regular meeting of the stockholders or at any special meeting of the stockholders, provided notice of such alteration, amendment, repeal or adoption of new bylaws shall have been stated in the notice of such special meeting.



Pharmasset, Inc.
303-A College Road East
Princeton, NJ 08540 U.S.A.
Phone: (609) 613-4100
Fax: (609) 613-4150
www.pharmasset.com

[DATE]

[Optionee Name]
[Optionee Address 1]
[Optionee Address 2]
[Optionee Address 3]

RE: Grant of [Incentive][Nonstatutory] Stock Option

Option Shares: _____ Grant Date: _____
Price per share: _____ Vesting Base Date: _____
Fully-Vested Date: _____
Option control no.: _____ Expiration Date: _____

Dear [Optionee Name]:

Pharmasset, Inc. (the "Company") has granted you an option (the "Option") to purchase shares of the Company's common stock under the Pharmasset, Inc. 2007 Equity Incentive Plan (the "Plan"). To accept your Option, please sign the enclosed copy of this letter and return it to Legal Affairs or, alternatively, to Human Resources.

General terms

The Option granted to you is intended to be **[an incentive][a nonstatutory]** stock option. The basic terms of your option grant are identified in the information block at the top of this letter but other important terms and conditions are described in the Plan and the Stock Option Agreement. We encourage you to carefully review both the Plan and the Stock Option Agreement, copies of which are enclosed.

Vesting and Purchase

Subject to the Plan, your Option shall vest (becomes exercisable) [Vesting Schedule], so that all shares will become vested on the Fully-Vested Date shown above.



If you decide to purchase shares under the Option, you will be required to submit a completed exercise and stock purchase agreement on a form approved by and available from the Company, together with payment for the shares. You may pay for the shares (plus any associated withholding taxes) using cash, a check, a wire transfer or any other form of payment listed in section 6.4(c) of the Plan and permitted by the Administrator (as defined in the Plan) at the time you wish to exercise. Shares available under the Option must be purchased, if at all, no later than the Expiration Date.

By your signature below, you agree that your Option is granted under and governed by the terms and conditions of the Plan and the Stock Option Agreement. In addition, you agree: (i) that your rights to any Option Shares underlying the Option will be earned only as you provide services to the Company over time; (ii) that the grant of the Option is not as consideration for services you rendered to the Company prior to the Vesting Base Date; (iii) at the Company's request in connection with a transaction involving the Company's equity securities, to enter into a lock-up agreement, in a form prescribed by the Company, prohibiting the sale or other distribution of the Option Shares; and (iv) that nothing in this letter, the Plan or the Stock Option Agreement confer upon you any right to continue your employment or other relationship with the Company for any period of time, nor does it interfere in any way with your right or the Company's right to terminate that relationship at any time, for any reason, with or without cause.

We value your efforts and look forward to your continued contribution to the success of Pharmasset.

Sincerely,

[Name]

[Title]

I accept the Option and agree to the terms of this letter and the Plan.

[Optionee Name]

_____, 20____
Date

Portions of this exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934. Such portions are marked by a series of asterisks.

VENTURE LOAN AND SECURITY AGREEMENT

Dated as of September 30, 2007

by and between

HORIZON TECHNOLOGY FUNDING COMPANY V LLC,
a Delaware limited liability company
76 Batterson Park Road
Farmington, CT 06032

as Lender

and

PHARMASSET, INC.,
a Delaware corporation
303A College Road East
Princeton, New Jersey 08540

as Borrower

Commitment Amount Loan A: \$10,000,000

Commitment Amount Loan B: \$10,000,000

Commitment Amount Loan C: \$10,000,000

Commitment Termination Date Loan A: October 12, 2007

Commitment Termination Date Loan B: March 31, 2008

Commitment Termination Date Loan C: November 30, 2008

***** — Material has been omitted and filed separately with the Commission

The Lender and Borrower hereby agree as follows:

AGREEMENT

1. Definitions and Construction.

1.1 Definitions. As used in this Agreement, the following capitalized terms shall have the following meanings:

“Account Control Agreement” means an agreement acceptable to Lender which perfects via control Lender’s security interest in Borrower’s deposit accounts and/or accounts holding securities.

“Affiliate” means any Person that owns or controls directly or indirectly ten percent (10%) or more of the stock of another entity, any Person that controls or is controlled by or is under common control with such Persons or any Affiliate of such Persons and each of such Person’s officers, directors, joint venturers or partners.

“Agreement” means this certain Venture Loan and Security Agreement by and between Borrower and Lender dated as of the date on the cover page hereto (as it may from time to time be amended or supplemented in writing signed by the Borrower and Lender).

“Borrower” means the Borrower as set forth on the cover page of this Agreement.

“Borrower’s Home State” means State of Delaware.

“Business Day” means any day that is not a Saturday, Sunday, or other day on which banking institutions are authorized or required to close in Connecticut or Borrower’s Home State.

“Claim” has the meaning given such term in Section 10.3 of this Agreement.

“Closing Date” means the date on which the conditions precedent set forth in Section 3.1 shall have been satisfied, which date is September 30, 2007.

“Code” means the Uniform Commercial Code as adopted and in effect in the State of Connecticut, as amended from time to time; provided that if by reason of mandatory provisions of law, the creation and/or perfection or the effect of perfection or non-perfection of the security interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than Connecticut, the term “Code” shall also mean the Uniform Commercial Code as in effect from time to time in such jurisdiction for purposes of the provisions hereof relating to such creation, perfection or effect of perfection or non-perfection.

“Collateral” has the meaning given such term in Section 4.1 of this Agreement.

***** — Material has been omitted and filed separately with the Commission

“Commitment Amount” means collectively, Commitment Amount Loan A, Commitment Amount Loan B and Commitment Amount Loan C.

“Commitment Amount Loan A”, “Commitment Amount Loan B” and “Commitment Amount Loan C” each have the respective meanings as set forth on the cover page of this Agreement.

“Commitment Fee” has the meaning given such term in Section 2.6(c) of this Agreement.

“Commitment Termination Date” means collectively, Commitment Termination Date Loan A, Commitment Termination Date Loan B and Commitment Termination Date Loan C.

“Commitment Termination Date Loan A”, “Commitment Termination Date Loan B” and Commitment Termination Date Loan C each have the respective meanings as set forth on the cover page of this Agreement.

“Default” means any event which with the passing of time or the giving of notice or both would become an Event of Default hereunder.

“Default Rate” means the per annum rate of interest equal to five percent (5%) over the Loan Rate, but such rate shall in no event be more than the highest rate permitted by applicable law to be charged on commercial loans in a default situation.

“Disclosure Schedule” means Exhibit A attached hereto.

“Environmental Laws” means all foreign, federal, state or local laws, statutes, common law duties, rules, regulations, ordinances and codes, together with all administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authorities, in each case relating to environmental, health, safety and land use matters, including the Comprehensive Environmental Response, Compensation and Liability Act of 1980, the Clean Air Act, the Federal Water Pollution Control Act of 1972, the Solid Waste Disposal Act, the Federal Resource Conservation and Recovery Act, the Toxic Substances Control Act and the Emergency Planning and Community Right-to-Know Act.

“Equity Securities” of any Person means (a) all common stock, preferred stock, participations, shares, partnership interests, membership interests or other equity interests in and of such Person (regardless of how designated and whether or not voting or non-voting) and (b) all warrants, options and other rights to acquire any of the foregoing.

“ERISA” has the meaning given to such term in Section 7.12 of this Agreement.

“Event of Default” has the meaning given to such term in Section 8 of this Agreement.

“FDA” means the United States Food and Drug Administration.

“Funding Certificate” means a certificate executed by a Responsible Officer of Borrower substantially in the form of Exhibit B or such other form as Lender may agree to accept.

***** — Material has been omitted and filed separately with the Commission

“Funding Date” means any date on which a Loan is made to or on account of Borrower under this Agreement.

“GAAP” means generally accepted accounting principles as in effect in the United States of America from time to time, consistently applied.

“Good Faith Deposit” has the meaning given such term in Section 2.6(a) of this Agreement.

“Governmental Authority” means (a) any federal, state, county, municipal or foreign government, or political subdivision thereof, (b) any governmental or quasi-governmental agency, authority, board, bureau, commission, department, instrumentality or public body, (c) any court or administrative tribunal, or (d) with respect to any Person, any arbitration tribunal or other non-governmental authority to whose jurisdiction that Person has consented.

“Hazardous Materials” means all those substances which are regulated by, or which may form the basis of liability under, any Environmental Law, including all substances identified under any Environmental Law as a pollutant, contaminant, hazardous waste, hazardous constituent, special waste, hazardous substance, hazardous material, or toxic substance, or petroleum or petroleum derived substance or waste.

“Indebtedness” means, with respect to Borrower or any Subsidiary, the aggregate amount of, without duplication, (a) all obligations of such Person for borrowed money, (b) all obligations of such Person evidenced by bonds, debentures, notes or other similar instruments, (c) all obligations of such Person to pay the deferred purchase price of property or services (excluding trade payables aged less than one hundred eighty (180) days), (d) all capital lease obligations of such Person, (e) all obligations or liabilities of others secured by a Lien on any asset of such Person, whether or not such obligation or liability is assumed, (f) all obligations or liabilities of others guaranteed by such Person, and (g) any other obligations or liabilities which are required by GAAP to be shown as debt on the balance sheet of such Person. Unless otherwise indicated, the term “Indebtedness” shall include all Indebtedness of Borrower and the Subsidiaries.

“Indemnified Person” has the meaning given such term in Section 10.3 of this Agreement.

“Intellectual Property” means all of Borrower’s right, title and interest in and to patents, patent rights (and applications and registrations therefor), trademarks and service marks (and applications and registrations therefor), inventions, copyrights, mask works (and applications and registrations therefor), trade names, trade styles, software and computer programs, source code, object code, trade secrets, methods, processes, know how, drawings, specifications, descriptions, and all memoranda, notes, and records with respect to any research and development, all whether now owned or subsequently acquired or developed by Borrower and whether in tangible or intangible form or contained on magnetic media readable by machine together with all such magnetic media (but not including embedded computer programs and supporting information included within the definition of “goods” under the Code).

***** — Material has been omitted and filed separately with the Commission

“Intellectual Property HIV Asset” means all of Borrower’s right, title and interest in and to Intellectual Property related to any molecule or compound used in, or in development for, now or in the future, the treatment of human immunodeficiency virus (“HIV”).

“Investment” means the purchase or acquisition of any capital stock, equity interest, or any obligations or other securities of, or any interest in, any Person, or the extension of any advance, loan, extension of credit or capital contribution to, or any other investment in, or deposit with, any Person.

“Landlord Agreement” means an agreement substantially in the form provided by Lender to Borrower or such other form as Lender may agree to accept.

“Lender” means the Lender as set forth on the cover page of this Agreement, and the several banks and other financial institutions or entities which may from time to time become participating parties to this Agreement.

“Lender’s Expenses” means all reasonable costs or expenses (including reasonable attorneys’ fees and expenses) incurred in connection with the preparation, negotiation, documentation, administration and funding of the Loan Documents; and Lender’s reasonable attorneys’ fees, costs and expenses incurred in amending, modifying, enforcing or defending the Loan Documents (including fees and expenses of appeal or review), including the exercise of any rights or remedies afforded hereunder or under applicable law, whether or not suit is brought, whether before or after bankruptcy or insolvency, including without limitation all fees and costs incurred by Lender in connection with Lender’s enforcement of its rights in a bankruptcy or insolvency proceeding filed by or against Borrower or its Property.

“Lien” means any voluntary or involuntary security interest, pledge, bailment, lease, mortgage, hypothecation, conditional sales and title retention agreement, encumbrance or other lien with respect to any Property in favor of any Person.

“Loan” means each advance of credit to Borrower made under this Agreement, and “Loans” means, collectively, all such advances of credit.

“Loan A” means the first advance of credit to Borrower under this Agreement in the Commitment Amount Loan A.

“Loan B” means the advance of credit to Borrower under this Agreement, if any, in the Commitment Amount Loan B.

“Loan C” means the advance of credit to Borrower under this Agreement, if any, in the Commitment Amount Loan C.

“Loan Documents” means, collectively, this Agreement, the Notes, the Warrant, any Landlord Agreement, any Account Control Agreement, any Participation Agreement and all other documents, instruments and agreements entered into in connection with this Agreement, all as amended or extended from time to time.

***** — Material has been omitted and filed separately with the Commission

“Loan Rate” means, with respect to each Loan, the per annum rate of interest (based on a year of twelve 30-day months) equal to the greater of (a) 12% or (b) 12% plus the difference between (i) the one month LIBOR Rate (rounded to the nearest one hundredth percent), as reported in the Wall Street Journal, on the date which is five (5) Business Days before the Funding Date for such Loan (or, if the Wall Street Journal is not published on such date, the next earlier date on which it is published) and (ii) 5.32%.

“Market Capitalization” means an amount determined by multiplying the number of shares of all of Borrower’s common stock outstanding on the applicable date, including, but not limited to all shares issued to or for the benefit of any Affiliate, officer, director, employee of Borrower and each of their respective family members and controlled entities on a fully diluted basis (assuming the conversion of all outstanding convertible securities and the exercise of all outstanding options and warrants), by the then current market price of the Borrower’s common stock on the NASDAQ Global National Market as reported on the Internet website “www.nasdaq.com” or if such website is unavailable, as reported in The Wall Street Journal as of such date.

“Material Agreement” means any agreement attached to any of the filings made by the Borrower with the U.S. Securities and Exchange Commission (the “SEC”).

“Maturity Date” means, with respect to each Loan, the date which is forty-five (45) months after the first day of the month following the month in which any Loan is made, or if earlier, the date of acceleration of any Loan following an Event of Default or the date of prepayment, whichever is applicable.

“Note” means each promissory note executed in connection with a Loan in substantially the form of Exhibit C attached hereto, and, collectively, “Notes” means all such promissory notes.

“Obligations” means all debt, principal, interest, fees, charges, expenses and attorneys’ fees and costs and other amounts, obligations, covenants, and duties owing by Borrower to Lender of any kind and description evidenced by the Loan Documents (other than the Warrant), whether direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, including all Lender’s Expenses.

“Officer’s Certificate” means a certificate executed by a Responsible Officer substantially in the form of Exhibit E or such other form as Lender may agree to accept.

“Participation Agreement” means that certain Participation Agreement entered into by each Lender, substantially in the form of Exhibit F attached hereto.

“Payment Date” has the meaning given such term in Section 2.2(a) of this Agreement.

“Permitted Indebtedness” means and includes:

- (a) Indebtedness of Borrower to Lender;

***** — Material has been omitted and filed separately with the Commission

(b) Indebtedness of Borrower secured by Liens permitted under clause (e) of the definition of Permitted Liens;

(c) Indebtedness and trade debt arising in the ordinary course of business; and

(d) Indebtedness existing on the date hereof and set forth on the Disclosure Schedule.

“ Permitted Investments ” means and includes any investments permitted to be entered into pursuant to the Investment Policy approved by the Board of Directors of the Borrower as may be amended from time to time. A current copy of such Investment Policy is attached hereto as Exhibit G .

“ Permitted Liens ” means and includes:

(a) the Lien created by this Agreement;

(b) Liens for fees, taxes, levies, imposts, duties or other governmental charges of any kind which are not yet delinquent or which are being contested in good faith by appropriate proceedings which suspend the collection thereof (provided that such appropriate proceedings do not involve any substantial danger of the sale, forfeiture or loss of any material item of Collateral which in the aggregate is material to Borrower and that Borrower has adequately bonded such Lien or reserves sufficient to discharge such Lien have been provided on the books of Borrower);

(c) Liens identified on the Disclosure Schedule;

(d) carriers', warehousemen's, mechanics', materialmen's, repairmen's or other similar Liens arising in the ordinary course of business and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings (provided that such appropriate proceedings do not involve any substantial danger of the sale, forfeiture or loss of any material item of Collateral or Collateral which in the aggregate is material to Borrower and that Borrower has adequately bonded such Lien or reserves sufficient to discharge such Lien have been provided on the books of Borrower); and

(e) Liens upon any equipment or other personal property acquired by Borrower after the date hereof to secure (i) the purchase price of such equipment or other personal property, or (ii) lease obligations or indebtedness incurred solely for the purpose of financing the acquisition of such equipment or other personal property; provided that (A) that such Liens shall be created substantially simultaneously with the acquisition of such equipment or personal property, (B) such Liens are confined solely to the equipment or other personal property so acquired and the amount secured does not exceed the acquisition price thereof, and (C) no such Lien shall be created, incurred, assumed or suffered to exist in favor of Borrower's officers, directors or shareholders holding five percent (5%) or more of Borrower's Equity Securities.

***** — Material has been omitted and filed separately with the Commission

“Person” means and includes any individual, any partnership, any corporation, any business trust, any joint stock company, any limited liability company, any unincorporated association or any other entity and any domestic or foreign national, state or local government, any political subdivision thereof, and any department, agency, authority or bureau of any of the foregoing.

“Property” means any interest in any kind of property or asset, whether real, personal or mixed, whether tangible or intangible.

“Responsible Officer” has the meaning given such term in Section 6.3 of this Agreement.

“Scheduled Payments” has the meaning given such term in Section 2.2(a) of this Agreement.

“Solvent” has the meaning given such term in Section 5.11 of this Agreement.

“Subsidiary” means any corporation or other entity of which a majority of the outstanding Equity Securities entitled to vote for the election of directors or other governing body (otherwise than as the result of a default) is owned by Borrower directly or indirectly through Subsidiaries and “Subsidiaries” means, collectively, each and every Subsidiary.

“Third Party Equipment” has the meaning given such term in Section 4.8 of this Agreement.

“Transfer” has the meaning given such term in Section 7.4 of this Agreement.

“Warrant” means the separate warrant or warrants dated on or about the date hereof in favor of the Lender or its designees to purchase securities of Borrower.

1.2 Construction. References in this Agreement to “Articles,” “Sections,” “Exhibits,” “Schedules” and “Annexes” are to recitals, articles, sections, exhibits, schedules and annexes herein and hereto unless otherwise indicated. References in this Agreement and each of the other Loan Documents to any document, instrument or agreement shall include (a) all exhibits, schedules, annexes and other attachments thereto, (b) all documents, instruments or agreements issued or executed in replacement thereof, and (c) such document, instrument or agreement, or replacement or predecessor thereto, as amended, modified and supplemented from time to time and in effect at any given time. The words “hereof,” “herein” and “hereunder” and words of similar import when used in this Agreement or any other Loan Document shall refer to this Agreement or such other Loan Document, as the case may be, as a whole and not to any particular provision of this Agreement or such other Loan Document, as the case may be. The words “include” and “including” and words of similar import when used in this Agreement or any other Loan Document shall not be construed to be limiting or exclusive. Unless otherwise indicated in this Agreement or any other Loan Document, all accounting terms used in this Agreement or any other Loan Document shall be construed, and all accounting and financial

***** — Material has been omitted and filed separately with the Commission

computations hereunder or thereunder shall be computed, in accordance with GAAP, and all terms describing Collateral shall be construed in accordance with the Code. The terms and information set forth on the cover page of this Agreement are incorporated into this Agreement.

2. Loans; Repayment.

2.1 Commitment.

(a) The Commitment Amount. Subject to the terms and conditions of this Agreement and relying upon the representations and warranties herein set forth as and when made or deemed to be made, Lender agrees to lend to Borrower within five (5) Business Days following the Closing Date, Loan A in the principal amount of Commitment Amount Loan A. Subject to the terms and conditions of this Agreement, including, without limitation, Section 3.3 below, and relying upon the representations and warranties herein set forth as and when made or deemed to be made, Lender agrees to lend to Borrower prior to the (i) Commitment Termination Date Loan B, Loan B in the principal amount of Commitment Amount Loan B and (ii) Commitment Termination Date Loan C, Loan C in the principal amount of Commitment Amount Loan C. Notwithstanding, anything contained herein to the contrary, Horizon Technology Funding Company V LLC (“Horizon”) shall have no obligation to fund more than Twenty Million Dollars (\$20,000,000) (“Horizon Total Commitment Amount”) in the aggregate at any one time.

(b) The Loans and the Notes. The obligation of Borrower to repay the unpaid principal amount of and interest on each Loan shall be evidenced by a Note issued to Lender.

(c) Use of Proceeds. The proceeds of each Loan shall be used solely for working capital or general corporate purposes of Borrower.

(d) Termination of Commitment to Lend. Notwithstanding anything in the Loan Documents, Lender’s obligation to lend the undisbursed portion of the Commitment Amount to Borrower hereunder shall terminate on the earlier of (i) at Lender’s sole election, the occurrence of any Default or Event of Default hereunder, or (ii) the Commitment Termination Date. Notwithstanding the foregoing, Lender’s obligation to lend the undisbursed portion of the Commitment Amount to Borrower shall terminate if, in Lender’s sole judgment, there has been a material adverse change in the general affairs, management, results of operations, condition (financial or otherwise) or prospects of Borrower, whether or not arising from transactions in the ordinary course of business, but such material adverse change shall not be considered to be an Event of Default.

2.2 Payments.

(a) Scheduled Payments. Borrower shall make payments of accrued interest only on the outstanding principal amounts of Loan A, Loan B and Loan C on the first fifteen (15) Payment Dates specified in the Note applicable to such Loan. Thereafter, Borrower shall make thirty (30) equal payments of principal plus accrued interest on the outstanding

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principal amount of each Loan on each subsequent Payment Date as set forth in the Note applicable to such Loan (collectively, the “Scheduled Payments”). Borrower shall make such Scheduled Payments commencing on the date set forth in the Note applicable to such Loan and continuing thereafter on the first Business Day of each calendar month (each a “Payment Date”) through the Maturity Date. In any event, all unpaid principal and accrued interest shall be due and payable in full on the Maturity Date.

(b) Interim Payment. Unless the Funding Date for a Loan is the first day of a calendar month, Borrower shall pay the per diem interest (accruing at the Loan Rate from the Funding Date through the last day of that month) payable with respect to such Loan on the first Business Day of the next calendar month.

(c) Payment of Interest. Borrower shall pay interest on each Loan at a per annum rate of interest equal to the Loan Rate. All computations of interest (including interest at the Default Rate, if applicable) shall be based on a year of twelve 30-day months. Notwithstanding any other provision hereof, the amount of interest payable hereunder shall not in any event exceed the maximum amount permitted by the law applicable to interest charged on commercial loans.

(d) Application of Payments. All payments received by Lender prior to an Event of Default shall be applied as follows: (1) first, to Lender’s Expenses then due and owing; and (2) second to all Scheduled Payments then due and owing (provided, however, if such payments are not sufficient to pay the whole amount then due, such payments shall be applied first to unpaid interest at the Loan Rate, then to the remaining amount then due). After an Event of Default, all payments and application of proceeds shall be made as set forth in Section 9.7.

(e) Late Payment Fee. Borrower shall pay to Lender a late payment fee equal to six percent (6%) of any Scheduled Payment not paid when due.

(f) Default Rate. Borrower shall pay interest at a per annum rate equal to the Default Rate on any amounts required to be paid by Borrower under this Agreement or the other Loan Documents (including Scheduled Payments), payable with respect to any Loan, accrued and unpaid interest, and any fees or other amounts which remain unpaid after such amounts are due. If an Event of Default has occurred and the Obligations have been accelerated (whether automatically or by Lender’s election), Borrower shall pay interest on the aggregate, outstanding accelerated balance hereunder from the date of the Event of Default until all Events of Default are cured, at a per annum rate equal to the Default Rate.

2.3 Prepayments.

(a) Mandatory Prepayment Upon an Acceleration. If the Loans are accelerated following the occurrence of an Event of Default pursuant to Section 9.1(a) hereof, then Borrower, in addition to any other amounts which may be due and owing hereunder, shall immediately pay to Lender the amount set forth in Section 2.3(b) below, as if the Borrower had opted to prepay on the date of such acceleration.

***** — Material has been omitted and filed separately with the Commission

(b) Upon ten (10) Business Days' prior written notice to Lender, Borrower may, at its option, at any time, prepay all of the Loans by paying to Lender an amount equal to (i) any accrued and unpaid interest on the outstanding principal balance of the Loans; (ii) for each Loan an amount equal to (A) if the Loan is prepaid within fifteen (15) months from the Funding Date thereof, four (4%) percent of the then outstanding principal balance of the Loan, (B) if the Loan is prepaid more than fifteen (15) months from the Funding Date thereof but less than thirty (30) months from the Funding Date, three (3%) percent of the then outstanding principal balance of the Loan, or (C) if the Loan is prepaid more than thirty (30) months from the Funding Date thereof, two (2%) percent of the then outstanding principal balance of the Loan; (iii) the outstanding principal balance of the Loan and (iv) all other sums, if any, that shall have become due and payable hereunder.

2.4 Other Payment Terms .

(a) Place and Manner . Borrower shall make all payments due to Lender in lawful money of the United States. All payments of principal, interest, fees and other amounts payable by Borrower hereunder shall be made, in immediately available funds, not later than 10:00 a.m. Connecticut time, on the date on which such payment is due. Borrower shall make such payments to Lender via wire transfer as follows:

<u>Payment via wire transfer:</u>	Horizon Technology Funding Company V
Credit:	LLC
Bank Name:	ABN Amro/LaSalle Bank NA CDO Trust Services
Bank Address:	135 South LaSalle Street, Suite 1625 Chicago, Illinois 60603 Attn: Greg Meyers, 312-904-0283
Account No.:	2090067 – Trust GL
FFCT-Reference Account Number	721771.1
ABA Routing No.:	071000505
Reference:	Pharmasset Invoice # _____

(b) Date . Whenever any payment is due hereunder on a day other than a Business Day, such payment shall be made on the next succeeding Business Day, and such extension of time shall be included in the computation of interest or fees, as the case may be.

2.5 Procedure for Making the Loans .

(a) Notice . Borrower shall notify Lender of the date on which Borrower desires Lender to make any Loan at least five (5) Business Days in advance of the desired Funding Date, unless Lender elects at its sole discretion to allow the Funding Date to be within five (5) Business Days of Borrower's notice. Borrower's execution and delivery to Lender of a Note shall be Borrower's agreement to the terms and calculations thereunder with respect to the Loan. Lender's obligation to make any Loan shall be expressly subject to the satisfaction of the conditions set forth in Section 3 .

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(b) Loan Rate Calculation . Prior to each Funding Date, Lender shall establish the Loan Rate with respect to such Loan, which shall be set forth in the Note to be executed by Borrower with respect to such Loan and shall be conclusive in the absence of a manifest error.

(c) Disbursement . Lender shall disburse the proceeds of each Loan by wire transfer to Borrower at the account specified in the Funding Certificate for the Loan.

2.6 Good Faith Deposit; Legal and Closing Expenses; and Commitment Fee .

(a) Good Faith Deposit . Borrower has delivered to Lender a good faith deposit in the amount of Seventy-Five Thousand Dollars (\$75,000) (the “ Good Faith Deposit ”). The Good Faith Deposit will be utilized to pay any amount due Lender under Section 2.6(b) below and the balance will be applied to the Commitment Fee.

(b) Legal, Due Diligence and Documentation Expenses . Upon the earlier of funding Loan A or within five (5) Business Days of the execution and delivery of this Agreement, Borrower shall pay to Lender all of Lender’s legal, due diligence and documentation expenses in connection with the negotiation and documentation of this Agreement and the Loan Documents in an amount not to exceed Fifty Thousand Dollars (\$50,000).

(c) Commitment Fee . Borrower shall pay Lender upon the earlier of funding Loan A or within five (5) Business Days of the execution and delivery of this Agreement a one-time commitment fee in the amount of One Hundred Fifty Thousand (\$150,000) (the “ Commitment Fee ”). The Commitment Fee shall be retained by Lender and be deemed fully earned upon receipt.

3. Conditions of Loan.

3.1 Conditions Precedent to Closing . At the time of the execution and delivery of this Agreement, Lender shall have received, in form and substance reasonably satisfactory to Lender, all of the following (unless Lender has agreed to waive such condition or document, in which case such condition or document shall be a condition precedent to the making of any Loan and shall be deemed added to Section 3.2):

(a) Loan Agreement . This Agreement duly executed by Borrower and Lender.

(b) Warrant . The Warrant duly executed by Borrower.

(c) Secretary’s Certificate . A certificate of the secretary or assistant secretary of Borrower with copies of the following documents attached: (i) the articles, certificate of incorporation and bylaws of Borrower certified by Borrower as being complete and in full force and effect on the date thereof, (ii) incumbency and representative signatures, and (iii) resolutions authorizing the execution and delivery of this Agreement and each of the other Loan Documents.

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(d) Good Standing Certificates. A good standing certificate from Borrower's state of incorporation and the state in which Borrower's principal place of business is located, each dated as of a recent date.

(e) Consents. All necessary consents of shareholders and other third parties with respect to the execution, delivery and performance of this Agreement, the Warrant and the other Loan Documents.

(f) Legal Opinion. A legal opinion of Borrower's counsel covering the matters set forth in Exhibit D hereto.

(g) Other Documents. Such other documents and completion of such other matters, as Lender may reasonably deem necessary or appropriate.

3.2 Conditions Precedent to Making a Loan. The obligation of Lender to make each Loan is further subject to the following conditions:

(a) No Default. No Default or Event of Default shall have occurred and be continuing.

(b) Note. Borrower shall have duly executed and delivered to Lender a Note in the amount of the Loan.

(c) UCC Financing Statements. Lender shall have received such documents, instruments and agreements, including UCC financing statements or amendments to UCC financing statements, as Lender shall reasonably request to evidence the perfection and priority of the security interests granted to Lender pursuant to Section 4. Borrower authorizes Lender to file any UCC financing statements, continuations of or amendments to UCC financing statements it deems necessary to perfect its security interest in the Collateral.

(d) Funding Certificate. Borrower shall have duly executed and delivered to Lender a Funding Certificate for such Loan.

(e) Participation Agreements. The Participation Agreement duly executed by each Lender, if applicable.

(f) Certificate of Insurance. Evidence of the insurance coverage required by Section 6.8 of this Agreement.

(g) Account Control Agreements. Account Control Agreements for all of Borrower's deposit accounts and accounts holding securities duly executed by all of the parties thereto, in the forms provided by Lender or otherwise in form and substance satisfactory to Lender.

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(h) Landlord Agreements. Borrower shall have provided Lender with a Landlord Agreement for each location where Borrower's books and records and the Collateral is located (unless Borrower is the fee owner thereof).

(i) Legal Opinion. A legal opinion of Borrower's counsel covering the matters set forth in Exhibit D hereto and certain other opinions as reasonably requested by Lender.

(j) Other Documents. Such other documents and completion of such other matters, as Lender may reasonably deem necessary or appropriate.

3.3 Condition Precedent to Making Loan B and Loan C. Borrower shall not request and Lender shall have no obligation to make (a) Loan B until, in addition to all of the other terms and conditions contained herein, Borrower provides Lender with ***** and (b) Loan C until, in addition to all of the other terms and conditions contained herein, within 30 days of the receipt by Lender *****.

3.4 Covenant to Deliver. Borrower agrees (not as a condition but as a covenant) to deliver to Lender each item required to be delivered to Lender as a condition to each Loan, if such Loan is advanced. Borrower expressly agrees that the extension of such Loan prior to the receipt by Lender of any such item shall not constitute a waiver by Lender of Borrower's obligation to deliver such item, and any such extension in the absence of a required item shall be in Lender's sole discretion.

4. Creation of Security Interest.

4.1 Grant of Security Interest. Borrower grants to Lender a valid, first priority, continuing security interest in all presently existing and hereafter acquired or arising Collateral in order to secure prompt, full and complete payment of any and all Obligations and in order to secure prompt, full and complete performance by Borrower of each of its covenants and duties under each of the Loan Documents (other than the Warrant). The "Collateral" shall mean and include all right, title, interest, claims and demands of Borrower in and to all personal property of Borrower, including without limitation, all of the following:

(a) All goods (and embedded computer programs and supporting information included within the definition of "goods" under the Code) and equipment now owned or hereafter acquired, including, without limitation, all laboratory equipment, computer equipment, office equipment, machinery, fixtures, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing, and all attachments, accessories, accessions, replacements, substitutions, additions, and improvements to any of the foregoing, wherever located;

(b) All inventory now owned or hereafter acquired, including, without limitation, all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products including such inventory as is temporarily out of Borrower's custody or possession or in transit and including any returns upon any accounts or other

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proceeds, including insurance proceeds, resulting from the sale or disposition of any of the foregoing and any documents of title representing any of the above, and Borrower's books relating to any of the foregoing;

(c) All contract rights and general intangibles (except to the extent included within the definition of Intellectual Property), now owned or hereafter acquired, including, without limitation, goodwill, license agreements, franchise agreements, blueprints, drawings, purchase orders, customer lists, route lists, infringements, claims, software, computer programs, computer disks, computer tapes, literature, reports, catalogs, design rights, income tax refunds, payment intangibles, commercial tort claims, payments of insurance and rights to payment of any kind;

(d) All now existing and hereafter arising accounts, contract rights, royalties, license rights, license fees and all other forms of obligations owing to Borrower arising out of the sale or lease of goods, the licensing of technology or the rendering of services by Borrower (subject, in each case, to the contractual rights of third parties to require funds received by Borrower to be expended in a particular manner), whether or not earned by performance, and any and all credit insurance, guaranties, and other security therefor, as well as all merchandise returned to or reclaimed by Borrower and Borrower's books relating to any of the foregoing;

(e) All documents, cash, deposit accounts, letters of credit (whether or not the letter of credit is evidenced by a writing), certificates of deposit, instruments, promissory notes, chattel paper (whether tangible or electronic) and investment property, including, without limitation, all securities, whether certificated or uncertificated, security entitlements, securities accounts, commodity contracts and commodity accounts, and all financial assets held in any securities account or otherwise, wherever located, now owned or hereafter acquired and Borrower's books relating to the foregoing;

(f) Any and all claims, rights and interests in any of the above and all substitutions for, additions and accessions to and proceeds thereof, including, without limitation, insurance, condemnation, requisition or similar payments and proceeds of the sale or licensing of Intellectual Property to the extent such proceeds no longer constitute Intellectual Property; but

(g) Notwithstanding the foregoing: the Collateral shall not include (i) any Intellectual Property or Intellectual Property HIV Asset; provided, however, that the Collateral shall include all accounts receivables, accounts, and general intangibles that consist of rights to payment and proceeds from the sale, licensing or disposition of all or any part, or rights in, the foregoing (the "Rights to Payment") (ii) the specific equipment and property listed on Schedule 4.1(g) attached hereto and (iii) any of the property of the Borrower listed in Section 4.1(a) of this Agreement which becomes property of the landlord by virtue of being fixed to the Landlord's property. Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of the date hereof, include the Intellectual Property to the extent necessary to permit perfection of Lender's security interest in the Rights to Payment.

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4.2 After-Acquired Property. If Borrower shall at any time acquire a commercial tort claim, as defined in the Code, Borrower shall immediately notify Lender in writing signed by Borrower of the brief details thereof and grant to Lender in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance satisfactory to Lender.

4.3 Duration of Security Interest. Lender's security interest in the Collateral shall continue until the payment in full and the satisfaction of all Obligations and termination of Lender's commitment to fund the Loans, whereupon such security interest shall terminate. Lender shall, at Borrower's sole cost and expense, execute such further documents and take such further actions as may be reasonably necessary to make effective the release contemplated by this Section 4.3, including duly executing and delivering termination statements for filing in all relevant jurisdictions under the Code.

4.4 Location and Possession of Collateral. The Collateral (other than Borrower's deposit accounts and/or accounts holding securities, which shall at all times be subject to one or more Account Control Agreements) is and shall remain in the possession of Borrower at its location listed on the cover page hereof or as set forth in the Disclosure Schedule, provided, that certain (a) goods and equipment of Borrower used by Borrower in the ordinary course of business for its clinical study programs may be located at the premises for such programs and (b) personal property of Borrower used in its ordinary course of business having a value not to exceed One Hundred Thousand Dollars (\$100,000) in the aggregate at any one time may be removed from the location listed on the cover page hereof from time to time. Borrower shall remain in full possession, enjoyment and control of the Collateral (except only as may be otherwise required by Lender for perfection of its security interest therein) and so long as no Event of Default has occurred, shall be entitled to manage, operate and use the same and each part thereof with the rights and franchises appertaining thereto; provided that the possession, enjoyment, control and use of the Collateral shall at all time be subject to the observance and performance of the terms of this Agreement.

4.5 Delivery of Additional Documentation Required. Borrower shall from time to time execute and deliver to Lender, at the request of Lender, all financing statements and other documents Lender may reasonably request, in form satisfactory to Lender, to perfect and continue Lender's perfected security interests in the Collateral and in order to consummate fully all of the transactions contemplated under the Loan Documents.

4.6 Right to Inspect. Lender (through any of its officers, employees, or agents) shall have the right, upon reasonable prior notice, from time to time during Borrower's usual business hours, to inspect Borrower's books and records and to make copies thereof and to inspect, test, and appraise the Collateral in order to verify Borrower's financial condition or the amount, condition of, or any other matter relating to, the Collateral.

4.7 Protection of Intellectual Property. Borrower shall (i) protect, defend and maintain the validity and enforceability of its Intellectual Property and promptly advise Lender in writing of material infringements, and (ii) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Lender's written consent.

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4.8 Lien Subordination . Lender agrees that the Liens granted to it hereunder in Third Party Equipment shall be subordinate to the Liens of future lenders providing equipment financing and equipment lessors for equipment and other personal property acquired by Borrower after the date hereof (“ Third Party Equipment ”); provided that such Liens are confined solely to the equipment so financed and the proceeds thereof and are Permitted Liens. Notwithstanding the foregoing, the Obligations hereunder shall not be subordinate in right of payment to any obligations to other equipment lenders or equipment lessors and Lender’s rights and remedies hereunder shall not in any way be subordinate to the rights and remedies of any such lenders or equipment lessors. So long as no Event of Default has occurred, Lender agrees to execute and deliver such agreements and documents as may be reasonably requested by Borrower from time to time which set forth the lien subordination described in this Section 4.8 and are reasonably acceptable to Lender. Lender shall have no obligation to execute any agreement or document which would impose obligations, restrictions or lien priority on Lender which are less favorable to Lender than those described in this Section 4.8 .

5. Representations and Warranties . Except as set forth in the Disclosure Schedule, Borrower represents and warrants as follows:

5.1 Organization and Qualification . Borrower and each Subsidiary is a corporation duly organized and validly existing under the laws of its state of incorporation and qualified and licensed to do business in, and is in good standing in, any state in which the conduct of its business or its ownership of Property requires that it be so qualified or in which the Collateral is located, except for such states as to which any failure to so qualify would not have a material adverse effect on Borrower.

5.2 Authority . Borrower and each Subsidiary has all necessary power and authority to execute, deliver, and perform in accordance with the terms thereof, the Loan Documents to which it is a party. Borrower and each Subsidiary has all requisite power and authority to own and operate its Property and to carry on its businesses as now conducted.

5.3 Conflict with Other Instruments, etc. . Neither the execution and delivery of any Loan Document to which Borrower or any Subsidiary is a party nor the consummation of the transactions therein contemplated nor compliance with the terms, conditions and provisions thereof will conflict with or result in a breach of any of the terms, conditions or provisions of the articles, certificate of incorporation, the by-laws, or any other organizational documents of Borrower or any Subsidiary or any law or any regulation, order, writ, injunction or decree of any court or governmental instrumentality or any Material Agreement or instrument to which Borrower or any Subsidiary is a party or by which they or any of their Property is bound or to which they or any of their Property is subject, or constitute a default thereunder or result in the creation or imposition of any Lien, other than Permitted Liens.

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5.4 Authorization; Enforceability. The execution and delivery of this Agreement, the granting of the security interest in the Collateral, the incurring of the Loans, the execution and delivery of the other Loan Documents to which Borrower or any Subsidiary is a party and the consummation of the transactions herein and therein contemplated have each been duly authorized by all necessary action on the part of Borrower or such Subsidiary, as applicable. No authorization, consent, approval, license or exemption of, and no registration, qualification, designation, declaration or filing with, or notice to, any Person is, was or will be necessary to (i) the valid execution and delivery of any Loan Document to which Borrower or any Subsidiary is a party, (ii) the performance of Borrower's and each Subsidiaries' obligations under any Loan Document, or (iii) the granting of the security interest in the Collateral, except for filings in connection with the perfection of the security interest in any of the Collateral or the issuance of the Warrant. The Loan Documents have been duly executed and delivered and constitute legal, valid and binding obligations of Borrower, enforceable in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application relating to or affecting the enforcement of creditors' rights or by general principles of equity.

5.5 No Prior Encumbrances. Borrower has good and marketable title to the Collateral, free and clear of Liens except for Permitted Liens. Borrower has good title and ownership of, or is licensed under, all of Borrower's current Intellectual Property. Borrower has not received any communications alleging that Borrower has violated, or by conducting its business as proposed, would violate any proprietary rights of any other Person. Borrower has no knowledge of any infringement or violation by it of the intellectual property rights of any third party and has no knowledge of any violation or infringement by a third party of any of its Intellectual Property. The Collateral and the Intellectual Property constitute substantially all of the assets and property of Borrower.

5.6 Name; Location of Chief Executive Office, Principal Place of Business and Collateral. Borrower has not done business under any name other than that specified on the signature page hereof. Borrower's jurisdiction of incorporation, chief executive office, principal place of business, and the place where Borrower maintains its records concerning the Collateral are presently located in the state and at the address set forth on the cover page of this Agreement. The Collateral is presently located at the address set forth on the cover page hereof or as set forth in the Disclosure Schedule.

5.7 Litigation. There are no actions or proceedings pending by or against Borrower or any Subsidiary before any court or administrative agency in which an adverse decision could have a material adverse effect on Borrower or the aggregate value of the Collateral. Borrower does not have knowledge of any such pending or threatened actions or proceedings.

5.8 Financial Statements. All financial statements relating to Borrower or any Affiliate that have been or may hereafter be delivered by Borrower to Lender present fairly in all material respects Borrower's combined financial condition as of the date thereof and Borrower's combined results of operations for the period then ended.

5.9 No Material Adverse Effect. No event has occurred and no condition exists which could reasonably be expected to have a material adverse effect on the financial condition, business or operations of Borrower and its Subsidiaries since June 30, 2007 that has not been disclosed in documents filed with or furnished to the SEC by the Borrower.

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5.10 Full Disclosure. No representation, warranty or other statement made by Borrower in any Loan Document (including the Disclosure Schedule), certificate or written statement furnished to Lender contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained in such certificates or statements not misleading. There is no fact known to Borrower which materially adversely affects, or which could in the future be reasonably expected to materially adversely affect, its ability to perform its obligations under this Agreement.

5.11 Solvency, Etc. Borrower is Solvent (as defined below) and, after the execution and delivery of the Loan Documents and the consummation of the transactions contemplated thereby, Borrower will be Solvent. “Solvent” means, with respect to any Person on any date, that on such date (a) the fair value of the property of such Person is greater than the fair value of the liabilities (including, without limitation, contingent liabilities) of such Person, (b) the present fair saleable value of the assets of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (c) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person’s ability to pay as such debts and liabilities mature and (d) such Person is not engaged in business or a transaction, and is not about to engage in business or a transaction, for which such Person’s property would constitute an unreasonably small capital.

5.12 Subsidiaries. Borrower has no Subsidiaries.

5.13 Catastrophic Events; Labor Disputes. Neither Borrower nor its properties is or has been affected by any fire, explosion, accident, strike, lockout or other labor dispute, drought, storm, hail, earthquake, embargo, act of God or other casualty that could reasonably be expected to have a material adverse effect on the financial condition, business or operations of Borrower. There are no disputes presently subject to grievance procedure, arbitration or litigation under any of the collective bargaining agreements, employment contracts or employee welfare or incentive plans to which Borrower is a party, and there are no strikes, lockouts, work stoppages or slowdowns, or, to the knowledge of Borrower, jurisdictional disputes or organizing activity occurring or threatened which could reasonably be expected to have a material adverse effect on the financial condition, business or operations of Borrower.

5.14 Certain Agreements of Officers, Employees and Consultants.

(a) No Violation. To the knowledge of Borrower, no officer, employee or consultant of Borrower is, or is now expected to be, in violation of any term of any employment contract, proprietary information agreement, nondisclosure agreement, noncompetition agreement or any other material contract or agreement or any restrictive covenant relating to the right of any such officer, employee or consultant to be employed by Borrower because of the nature of the business conducted or to be conducted by Borrower or relating to the use of trade secrets or proprietary information of others, and to Borrower’s knowledge, the continued employment of Borrower’s officers, employees and consultants does not subject Borrower to any material liability for any claim or claims arising out of or in connection with any such contract, agreement, or covenant.

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(b) No Present Intention to Terminate. To the knowledge of Borrower, no officer of Borrower, and no employee or consultant of Borrower whose termination, either individually or in the aggregate, could reasonably be expected to have a material adverse effect on the financial condition, business or operations of Borrower, has any present intention of terminating his or her employment or consulting relationship with Borrower.

6. Affirmative Covenants. Borrower, until the full and complete payment of the Obligations, covenants and agrees that:

6.1 Good Standing. Borrower shall maintain its corporate existence and its good standing in its jurisdiction of incorporation and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a material adverse effect on the financial condition, operations or business of Borrower. Borrower and each Subsidiary shall maintain in force all licenses, approvals and agreements, the loss of which could reasonably be expected to have a material adverse effect on its financial condition, operations or business.

6.2 Government Compliance. Borrower and its Subsidiaries shall comply with all statutes, laws, ordinances and government rules and regulations to which it is subject, noncompliance with which could reasonably be expected to materially adversely affect the financial condition, operations or business of Borrower.

6.3 Financial Statements, Reports, Certificates. Borrower shall deliver to Lender: (a) as soon as available, but in any event within thirty (30) days after the end of each month, a company prepared balance sheet, income statement and cash flow statement covering Borrower's and Subsidiaries' operations during such period, certified by Borrower's president, treasurer or chief financial officer (each, a "Responsible Officer"); (b) as soon as available, but in any event within one hundred twenty (120) days after the end of Borrower's fiscal year, if Borrower ceases to be a reporting company for purposes of the Securities Exchange Act of 1934, as amended, or ceases to file financial statements with the SEC, audited combined financial statements of Borrower prepared in accordance with GAAP, together with an unqualified opinion on such financial statements of a nationally recognized or other independent public accounting firm reasonably acceptable to Lender; (c) as soon as available, but in any event within ninety (90) days after the end of Borrower's fiscal year or the date of Borrower's board of directors' adoption, Borrower's operating budget and plan for the next fiscal year; (d) promptly as they are available and in any event (x) at the time of filing of Borrower's Form 10-K with the Securities and Exchange Commission after the end of each fiscal year of Borrower, the financial statements of Borrower filed with such Form 10-K; and (y) at the time of filing of Borrower's Form 10-Q with the Securities and Exchange Commission after the end of each of the first three fiscal quarters of Borrower, the financial statements of Borrower filed with such Form 10-Q. and (e) such other financial information as Lender may reasonably request from time to time. In addition, Borrower shall deliver to Lender (i) promptly upon becoming available, copies of all statements, reports and notices sent or made available generally by Borrower to its security holders; and (ii) immediately upon receipt of notice thereof, a report of any material legal actions

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pending or threatened against Borrower or any Subsidiary or the commencement of any action, proceeding or governmental investigation involving Borrower or any Subsidiary is commenced that is reasonably expected to result in damages or costs to Borrower or any Subsidiary of One Hundred Fifty Thousand Dollars (\$150,000).

6.4 Certificates of Compliance. Each time financial statements are furnished pursuant to Section 6.3 above, Borrower shall deliver to Lender an Officer's Certificate signed by a Responsible Officer in the form of, and certifying to the matters set forth in Exhibit E hereto.

6.5 Notice of Defaults. As soon as possible, and in any event within five (5) days after the discovery of a Default or an Event of Default, Borrower shall provide Lender with an Officer's Certificate setting forth the facts relating to or giving rise to such Default or Event of Default and the action which Borrower proposes to take with respect thereto.

6.6 Taxes. Borrower shall make due and timely payment or deposit of all federal, state, and local taxes, assessments, or contributions required of it by law or imposed upon any Property belonging to it, and will execute and deliver to Lender, on demand, appropriate certificates attesting to the payment or deposit thereof; and Borrower will make timely payment or deposit of all tax payments and withholding taxes required of it by applicable laws, including those laws concerning F.I.C.A., F.U.T.A., state disability, and local, state, and federal income taxes, and will, upon request, furnish Lender with proof satisfactory to Lender indicating that Borrower has made such payments or deposits; provided that Borrower need not make any payment if the amount or validity of such payment is contested in good faith by appropriate proceedings which suspend the collection thereof (provided that such proceedings do not involve any substantial danger of the sale, forfeiture or loss of any material item of Collateral or Collateral which in the aggregate is material to Borrower and that Borrower has adequately bonded such amounts or reserves sufficient to discharge such amounts have been provided on the books of Borrower).

6.7 Use; Maintenance. Borrower shall, consistent with its prior practice, keep and maintain all items of equipment and other similar types of personal property that form any significant portion or portions of the Collateral in operating condition and repair and shall, consistent with its prior practice, make all necessary replacements thereof and renewals thereto so that the value and operating efficiency thereof shall at all times be maintained and preserved. Borrower shall not permit any such material item of Collateral to become a fixture to real estate or an accession to other personal property, without the prior written consent of Lender. Borrower shall not permit any such material item of Collateral to be operated or maintained in violation of any applicable law, statute, rule or regulation. With respect to items of leased equipment (to the extent Lender has any security interest in any residual Borrower's interest in such equipment under the lease), Borrower shall keep, maintain, repair, replace and operate such leased equipment in accordance with the terms of the applicable lease.

6.8 Insurance. Borrower shall keep its business and the Collateral insured for risks and in amounts, and as Lender may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are satisfactory to Lender. All property policies shall

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have a lender's loss payable endorsement showing Lender as an additional loss payee and all liability policies shall show Lender as an additional insured and all policies shall provide that the insurer must give Lender at least thirty (30) days notice before canceling its policy. At Lender's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Lender's option, be payable to Lender on account of the Obligations. Notwithstanding the foregoing, so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy, toward the replacement or repair of destroyed or damaged property; provided that (i) any such replaced or repaired property (a) shall be of equal or like value as the replaced or repaired Collateral and (b) shall be deemed Collateral in which Lender has been granted a first priority security interest and (ii) after the occurrence and during the continuation of an Event of Default all proceeds payable under such casualty policy shall, at the option of Lender, be payable to Lender, on account of the Obligations. If Borrower fails to obtain insurance as required under Section 6.8 or to pay any amount or furnish any required proof of payment to third persons and Lender, Lender may make all or part of such payment or obtain such insurance policies required in Section 6.8, and take any action under the policies Lender deems prudent. On or prior to the first Funding Date and prior to each policy renewal, Borrower shall furnish to Lender certificates of insurance or other evidence satisfactory to Lender that insurance complying with all of the above requirements is in effect.

6.9 Security Interest . Assuming the proper filing of one or more financing statement(s) identifying the Collateral with the proper state and/or local authorities, the security interests in the Collateral granted to Lender pursuant to this Agreement (i) constitute and will continue to constitute first priority security interests (except to the extent any Permitted Liens may have a superior priority to Lender's Lien under this Agreement) and (ii) are and will continue to be superior and prior to the rights of all other creditors of Borrower (except to the extent of such Permitted Liens).

6.10 Market Capitalization . If any time during the term of this Agreement, Borrower's Market Capitalization is

(a) less than Ninety Million Dollars (\$90,000,000) and remains less than Ninety Million Dollars (\$90,000,000) for fifteen (15) consecutive days in which the NASDAQ is open for trading to the public, then Borrower will be required to repay, in immediately available funds, fifty percent (50%) of the then outstanding principal balance of all Loans without prepayment penalty or premiums; and

(b) less than Forty Million Dollars (\$40,000,000) and remains less than Forty Million Dollars (\$40,000,000) for fifteen (15) consecutive days in which the NASDAQ is open for trading to the public, then Borrower will be required to repay in immediately available funds all accrued and unpaid interest on the Loans, the outstanding principal balance of all Loans and all outstanding Obligations owed to Lender without prepayment penalty or premiums.

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6.11 Further Assurances. At any time and from time to time Borrower shall execute and deliver such further instruments and take such further action as may reasonably be requested by Lender to make effective the purposes of this Agreement, including without limitation, the continued perfection and priority of Lender's security interest in the Collateral.

7. Negative Covenants. Borrower, until the full and complete payment of the Obligations, covenants and agrees that Borrower and each Subsidiary shall not:

7.1 Chief Executive Office. Change its name, jurisdiction of incorporation, chief executive office, principal place of business or any of the items set forth in Section 1 of the Disclosure Schedule without thirty (30) days prior written notice to Lender.

7.2 Collateral Control. Subject to its rights under Sections 4.4 and 7.4, remove any items of Collateral from Borrower's facility located at the address set forth on the cover page hereof or as set forth on the Disclosure Schedule.

7.3 Liens. Create, incur, assume or suffer to exist any Lien of any kind upon any of Borrower's Property or any Subsidiary's Property, whether now owned or hereafter acquired, except Permitted Liens.

7.4 Other Dispositions of Collateral. Convey, sell, lease or otherwise dispose of all or any part of the Collateral to any Person (collectively, a "Transfer"), except for Transfers of worn-out or obsolete equipment.

7.5 Distributions. (i) Pay any dividends or make any distributions on its Equity Securities; (ii) purchase, redeem, retire, defease or otherwise acquire for value any of its Equity Securities (other than repurchases pursuant to the terms of employee stock option plans, employee stock purchase plans, employee restricted stock agreements or similar arrangements provided that at the time of such repurchases and after giving effect thereto no Default or Event of Default has occurred and is continuing); (iii) return any capital to any holder of its Equity Securities as such; (iv) make any distribution of assets, Equity Securities, obligations or securities to any holder of its Equity Securities as such; or (v) set apart any sum for any such purpose; provided, however, Borrower may pay dividends payable solely in common stock.

7.6 Mergers or Acquisitions. Merge or consolidate with or into any other Person or acquire all or substantially all of the capital stock or assets of another Person without the consent of Lender; provided, that if Lender does not consent to any of the foregoing transactions, Borrower may prepay all of the Loans without prepayment penalty or premium.

7.7 Change in Ownership. Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower or reasonably related thereto or at any time that the Borrower's stock ceases to be traded on a public national exchange or stock market, have a material change in its ownership of greater than twenty five percent (25%) (other than by the sale by Borrower of Borrower's Equity Securities in a public offering or to venture capital investors so long as Borrower identifies to Lender the venture capital investors prior to the closing of the investment).

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7.8 Transactions With Affiliates. Enter into any contractual obligation with any Affiliate or engage in any other transaction with any Affiliate except upon terms at least as favorable to Borrower as an arms-length transaction with Persons who are not Affiliates of Borrower.

7.9 Indebtedness Payments. (i) Prepay, redeem, purchase, defease or otherwise satisfy in any manner prior to the scheduled repayment thereof any Indebtedness for borrowed money (other than amounts due or permitted to be prepaid under this Agreement) or lease obligations, (ii) amend, modify or otherwise change the terms of any Indebtedness for borrowed money or lease obligations so as to accelerate the scheduled repayment thereof or (iii) repay any notes to officers, directors or shareholders.

7.10 Indebtedness. Create, incur, assume or permit to exist any Indebtedness except Permitted Indebtedness.

7.11 Investments. Make any Investment except for Permitted Investments.

7.12 Compliance. Become an “investment company” or a company controlled by an “investment company” under the Investment Company Act of 1940 or undertake as one of its important activities extending credit to purchase or carry margin stock, or use the proceeds of any Loan for that purpose; fail to meet the minimum funding requirements of the Employment Retirement Income Security Act of 1974, and its regulations, as amended from time to time (“ERISA”), permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a material adverse effect on Borrower’s business or operations or could reasonably be expected to cause a material adverse change, or permit any of its Subsidiaries to do so.

7.13 Maintenance of Accounts. (i) Maintain any deposit account or account holding securities owned by Borrower except accounts with respect to which Lender is able to take such actions as it deems necessary to obtain a perfected security interest in such accounts through one or more Account Control Agreements; or (ii) grant or allow any other Person (other than Lender) to perfect a security interest in, or enter into any agreements with any Persons (other than Lender) accomplishing perfection via control as to, any of its deposit accounts or accounts holding securities.

7.14 Negative Pledge Regarding Intellectual Property. Create, incur, assume or suffer to exist any Lien of any kind upon any Intellectual Property, Intellectual Property HIV Asset, or Transfer any Intellectual Property or Intellectual Property HIV Asset, whether now owned or hereafter acquired, other than non-exclusive licenses of Intellectual Property entered into in the ordinary course of business. Notwithstanding the foregoing, Lender agrees that it will release Borrower’s Intellectual Property HIV Asset from the limitations set forth in this Section in conjunction with any financing or strategic transaction which has been approved by Borrower’s Board of Directors, including, without limitation, any transaction where such Intellectual Property HIV Asset is transferred in whole or in part to an Affiliate of Borrower, provided, that Borrower at all times retains an exclusive right to repurchase the Intellectual Property HIV Assets and no Event of Default has occurred and is continuing at such time.

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8. Events of Default. Any one or more of the following events shall constitute an “Event of Default” by Borrower under this Agreement:

8.1 Failure to Pay. If Borrower fails to pay when due and payable or when declared due and payable in accordance with the Loan Documents: (i) any Scheduled Payment on the relevant Payment Date or on the relevant Maturity Date, or (ii) any other portion of the Obligations within five (5) days after receipt of written notice from Lender that such payment is due.

8.2 Certain Covenant Defaults. If Borrower fails to perform any obligation under Section 6.8 or Section 6.10 or violates any of the covenants contained in Section 7 of this Agreement.

8.3 Other Covenant Defaults. If Borrower fails or neglects to perform, keep, or observe any other material term, provision, condition, covenant, or agreement contained in this Agreement (other than as set forth in Sections 8.1, 8.2 or 8.4 through 8.13), in any of the other Loan Documents and Borrower has failed to cure such default within thirty (30) days of the earlier of Borrower’s knowledge or written notice from Lender of such default, unless the nature of the failure is such that (a) it cannot be cured within thirty (30) day period, (b) the Borrower institutes corrective action within the thirty (30) day period, and (c) the Borrower completes the cure within a period of an additional thirty (30) days. During this thirty (30) day period, the failure to cure the default is not an Event of Default (but no Loan will be made during the cure period).

8.4 Intentionally Omitted.

8.5 Seizure of Assets, Etc. If any material portion of Borrower’s assets is attached, seized, subjected to a writ or distress warrant, or is levied upon, or comes into the possession of any trustee, receiver or Person acting in a similar capacity and such attachment, seizure, writ or distress warrant or levy has not been removed, discharged or rescinded within ten (10) days, or if Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs, or if a judgment or other claim in excess of One Hundred Fifty Thousand Dollars (\$150,000) becomes a lien or encumbrance upon any material portion of Borrower’s assets, or if a notice of lien, levy, or assessment in excess of One Hundred Fifty Thousand Dollars (\$150,000) is filed of record with respect to any of Borrower’s assets by the United States Government, or any department, agency, or instrumentality thereof, or by any state, county, municipal, or governmental agency, and the same is not paid within ten (10) days after Borrower receives notice thereof; provided that none of the foregoing shall constitute an Event of Default where such action or event is stayed or an adequate bond has been posted pending a good faith contest by Borrower.

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8.6 Service of Process . The service of process upon Lender seeking to attach by a trustee or other process any funds of the Borrower on deposit or otherwise held by Lender, or the delivery upon Lender of a notice of foreclosure by any Person seeking to attach or foreclose on any funds of the Borrower on deposit or otherwise held by Lender, or the delivery of a notice of foreclosure or exclusive control to any entity holding or maintaining Borrower's deposit accounts or accounts holding securities by any Person (other than Lender) seeking to foreclose or attach any such accounts or securities.

8.7 Default on Indebtedness . One or more defaults shall exist under any agreement with any third party or parties which consists of the failure to pay any Indebtedness at maturity or which results in a right by such third party or parties, whether or not exercised, to accelerate the maturity of Indebtedness in an aggregate amount in excess of One Hundred Fifty Thousand Dollars (\$150,000) or a default after the expiration of any applicable notice and/or cure periods) shall exist under any financing agreement with Lender or any of Lender's Affiliates.

8.8 Judgments . If a judgment or judgments for the payment of money in an amount, individually or in the aggregate, of at least One Hundred Fifty Thousand Dollars (\$150,000) shall be rendered against Borrower or any Subsidiary and shall remain unsatisfied and unstayed for a period of twenty (20) days or more.

8.9 Misrepresentations . If any material misrepresentation or material misstatement exists now or hereafter in any warranty, representation, statement, certification, or report made to Lender by Borrower or any officer, employee, agent, or director of Borrower.

8.10 Breach of Warrant . If Borrower shall breach any material term of the Warrant.

8.11 Unenforceable Loan Document . If any Loan Document shall in any material respect cease to be, or Borrower shall assert that any Loan Document is not, a legal, valid and binding obligation of Borrower enforceable in accordance with its terms.

8.12 Involuntary Insolvency Proceeding . If a proceeding shall have been instituted in a court having jurisdiction in the premises seeking a decree or order for relief in respect of Borrower in an involuntary case under any applicable bankruptcy, insolvency or other similar law now or hereafter in effect, or for the appointment of a receiver, liquidator, assignee, custodian, trustee (or similar official) of Borrower or for any substantial part of its Property, or for the winding-up or liquidation of its affairs, and such proceeding shall remain undismissed or unstayed and in effect for a period of thirty (30) consecutive days or such court shall enter a decree or order granting the relief sought in such proceeding.

8.13 Voluntary Insolvency Proceeding . If Borrower shall commence a voluntary case under any applicable bankruptcy, insolvency or other similar law now or hereafter in effect, shall consent to the entry of an order for relief in an involuntary case under any such law, or shall consent to the appointment of or taking possession by a receiver, liquidator, assignee, trustee, custodian (or other similar official) of Borrower or for any substantial part of its Property, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any corporate action in furtherance of any of the foregoing.

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9. Lender's Rights and Remedies.

9.1 Rights and Remedies. Upon the occurrence of any Default or Event of Default, Lender shall not have any further obligation to advance money or extend credit to or for the benefit of Borrower. In addition, upon the occurrence of an Event of Default, Lender shall have the rights, options, duties and remedies of a secured party as permitted by law and, in addition to and without limitation of the foregoing, Lender may, at its election, without notice of election and without demand, do any one or more of the following, all of which are authorized by Borrower:

(a) Acceleration of Obligations. Declare all Obligations, whether evidenced by this Agreement, by any of the other Loan Documents, or otherwise, including (i) any accrued and unpaid interest, (ii) the amounts which would have otherwise come due under Section 2.3(b)(ii) if the Loans had been voluntarily prepaid, (iii) the unpaid principal balance of the Loans and (iv) all other sums, if any, that shall have become due and payable hereunder, immediately due and payable (provided that upon the occurrence of an Event of Default described in Section 8.12 or 8.13 all Obligations shall become immediately due and payable without any action by Lender);

(b) Protection of Collateral. Make such payments and do such acts as Lender considers necessary or reasonable to protect Lender's security interest in the Collateral. Borrower agrees to assemble the Collateral if Lender so requires and to make the Collateral available to Lender as Lender may designate. Borrower authorizes Lender and its designees and agents to enter the premises where the Collateral is located, to take and maintain possession of the Collateral, or any part of it, and to pay, purchase, contest, or compromise any Lien which in Lender's determination appears or is claimed to be prior or superior to its security interest and to pay all expenses incurred in connection therewith. With respect to any of Borrower's owned premises, Borrower hereby grants Lender a license to enter into possession of such premises and to occupy the same, without charge, for up to one hundred twenty (120) days in order to exercise any of Lender's rights or remedies provided herein, at law, in equity, or otherwise;

(c) Preparation of Collateral for Sale. Ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell (in the manner provided for herein) the Collateral;

(d) Sale of Collateral. Sell the Collateral at either a public or private sale, or both, by way of one or more contracts or transactions, for cash or on terms, in such manner and at such places (including Borrower's premises) as Lender determines are commercially reasonable; and

(e) Purchase of Collateral. Credit bid and purchase all or any portion of the Collateral at any public sale.

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Any deficiency that exists after disposition of the Collateral as provided above will be paid immediately by Borrower.

9.2 Set Off Right . Lender may set off and apply to the Obligations any and all indebtedness at any time owing to or for the credit or the account of Borrower or any other assets of Borrower in Lender's possession or control.

9.3 Effect of Sale . Upon the occurrence of an Event of Default, to the extent permitted by law, Borrower covenants that it will not at any time insist upon or plead, or in any manner whatsoever claim or take any benefit or advantage of, any stay or extension law now or at any time hereafter in force, nor claim, take nor insist upon any benefit or advantage of or from any law now or hereafter in force providing for the valuation or appraisal of the Collateral or any part thereof prior to any sale or sales thereof to be made pursuant to any provision herein contained, or to the decree, judgment or order of any court of competent jurisdiction; nor, after such sale or sales, claim or exercise any right under any statute now or hereafter made or enacted by any state or otherwise to redeem the property so sold or any part thereof, and, to the full extent legally permitted, except as to rights expressly provided herein, hereby expressly waives for itself and on behalf of each and every Person, except decree or judgment creditors of Borrower, acquiring any interest in or title to the Collateral or any part thereof subsequent to the date of this Agreement, all benefit and advantage of any such law or laws, and covenants that it will not invoke or utilize any such law or laws or otherwise hinder, delay or impede the execution of any power herein granted and delegated to Lender, but will suffer and permit the execution of every such power as though no such power, law or laws had been made or enacted. Any sale, whether under any power of sale hereby given or by virtue of judicial proceedings, shall operate to divest all right, title, interest, claim and demand whatsoever, either at law or in equity, of Borrower in and to the Property sold, and shall be a perpetual bar, both at law and in equity, against Borrower, its successors and assigns, and against any and all Persons claiming the Property sold or any part thereof under, by or through Borrower, its successors or assigns.

9.4 Power of Attorney in Respect of the Collateral . Borrower does hereby irrevocably appoint Lender (which appointment is coupled with an interest), the true and lawful attorney in fact of Borrower with full power of substitution, for it and in its name to file any notices of security interests, financing statements and continuations and amendments thereof pursuant to the Code or federal law, as may be necessary to perfect, or to continue the perfection of Lender's security interests in the Collateral. Borrower does hereby irrevocably appoint Lender (which appointment is coupled with an interest) on the occurrence of an Event of Default, the true and lawful attorney in fact of Borrower with full power of substitution, for it and in its name: (a) to ask, demand, collect, receive, receipt for, sue for, compound and give acquittance for any and all rents, issues, profits, avails, distributions, income, payment draws and other sums in which a security interest is granted under Section 4 with full power to settle, adjust or compromise any claim thereunder as fully as if Lender were Borrower itself; (b) to receive payment of and to endorse the name of Borrower to any items of Collateral (including checks, drafts and other orders for the payment of money) that come into Lender's possession or under Lender's control; (c) to make all demands, consents and waivers, or take any other action with respect to, the Collateral; (d) in Lender's discretion to file any claim or take any other action or proceedings, either in its own name or in the name of Borrower or otherwise, which Lender may

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reasonably deem necessary or appropriate to protect and preserve the right, title and interest of Lender in and to the Collateral; (e) endorse Borrower's name on any checks or other forms of payment or security; (f) sign Borrower's name on any invoice or bill of lading for any account or drafts against account debtors; (g) make, settle, and adjust all claims under Borrower's insurance policies; (h) settle and adjust disputes and claims about the accounts directly with account debtors, for amounts and on terms Lender determines reasonable; (i) transfer the Collateral into the name of Lender or a third party as the Code permits; and (j) to otherwise act with respect thereto as though Lender were the outright owner of the Collateral.

9.5 Lender's Expenses. If Borrower fails to pay any amounts or furnish any required proof of payment due to third persons or entities, as required under the terms of this Agreement, then Lender may do any or all of the following: (a) make payment of the same or any part thereof; or (b) obtain and maintain insurance policies of the type discussed in Section 6.8 of this Agreement, and take any action with respect to such policies as Lender deems prudent. Any amounts paid or deposited by Lender shall constitute Lender's Expenses, shall be immediately due and payable, shall bear interest at the Default Rate and shall be secured by the Collateral. Any payments made by Lender shall not constitute an agreement by Lender to make similar payments in the future or a waiver by Lender of any Event of Default under this Agreement. Borrower shall pay all reasonable fees and expenses, including without limitation, Lender's Expenses, incurred by Lender in the enforcement or attempt to enforce any of the Obligations hereunder not performed when due.

9.6 Remedies Cumulative. Lender's rights and remedies under this Agreement, the Loan Documents, and all other agreements shall be cumulative. Lender shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Lender of one right or remedy shall be deemed an election, and no waiver by Lender of any Event of Default on Borrower's part shall be deemed a continuing waiver. No delay by Lender shall constitute a waiver, election, or acquiescence by it.

9.7 Application of Collateral Proceeds. The proceeds and/or avails of the Collateral, or any part thereof, and the proceeds and the avails of any remedy hereunder (as well as any other amounts of any kind held by Lender, at the time of or received by Lender after the occurrence of an Event of Default hereunder) shall be paid to and applied as follows:

(a) First, to the payment of out-of-pocket costs and expenses, including all amounts expended to preserve the value of the Collateral, of foreclosure or suit, if any, and of such sale and the exercise of any other rights or remedies, and of all proper fees, expenses, liability and advances, including reasonable legal expenses and attorneys' fees, incurred or made hereunder by Lender, including, without limitation, Lender's Expenses;

(b) Second, to the payment to Lender of the amount then owing or unpaid on the Loans for any accrued and unpaid interest, the amounts which would have otherwise come due under Section 2.3(b)(ii), if the Loans had been voluntarily prepaid, the principal balance of the Loans, and all other Obligations with respect to the Loans (provided, however, if such proceeds shall be insufficient to pay in full the whole amount so due, owing or unpaid upon the Loans, then to the unpaid interest thereon, then to the amounts which would

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have otherwise come due under Section 2.3(b)(ii), if the Loans had been voluntarily prepaid, then to the principal balance of the Loans, and then to the payment of other amounts then payable to Lender under any of the Loan Documents); and

(c) Third, to the payment of the surplus, if any, to Borrower, its successors and assigns, or to the Person lawfully entitled to receive the same.

9.8 Reinstatement of Rights. If Lender shall have proceeded to enforce any right under this Agreement or any other Loan Document by foreclosure, sale, entry or otherwise, and such proceedings shall have been discontinued or abandoned for any reason or shall have been determined adversely, then and in every such case (unless otherwise ordered by a court of competent jurisdiction), Lender shall be restored to its former position and rights hereunder with respect to the Property subject to the security interest created under this Agreement.

10. Waivers; Indemnification.

10.1 Demand; Protest. Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Borrower may in any way be liable.

10.2 Lender's Liability for Collateral. So long as Lender complies with its obligations, if any, under the Code, Lender shall not in any way or manner be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage thereto occurring or arising in any manner or fashion from any cause other than Lender's gross negligence or willful misconduct; (c) any diminution in the value thereof; or (d) any act or default of any carrier, warehouseman, bailee, forwarding agency, or other Person whomsoever. All risk of loss, damage or destruction of the Collateral shall be borne by Borrower.

10.3 Indemnification and Waiver. Whether or not the transactions contemplated hereby shall be consummated:

(a) General Indemnity. Borrower agrees upon demand to pay or reimburse Lender for all liabilities, obligations and out-of-pocket expenses, including Lender's Expenses and reasonable fees and expenses of counsel for Lender from time to time arising in connection with the enforcement or collection of sums due under the Loan Documents, and in connection with any amendment or modification of the Loan Documents or any "work-out" in connection with the Loan Documents. Borrower shall indemnify, reimburse and hold Lender, and each of its respective successors, assigns, agents, attorneys, officers, directors, shareholders, servants, agents and employees (each an "Indemnified Person") harmless from and against all liabilities, losses, damages, actions, suits, demands, claims of any kind and nature (including claims relating to environmental discharge, cleanup or compliance), all costs and expenses whatsoever to the extent they may be incurred or suffered by such Indemnified Person in connection therewith (including reasonable attorneys' fees and expenses), fines, penalties (and other charges of any applicable Governmental Authority), licensing fees relating to any item of

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Collateral, damage to or loss of use of property (including consequential or special damages to third parties or damages to Borrower's property), or bodily injury to or death of any person (including any agent or employee of Borrower) (each, a "Claim"), directly or indirectly relating to or arising out of the use of the proceeds of the Loans or otherwise, the falsity of any representation or warranty of Borrower or Borrower's failure to comply with the terms of this Agreement or any other Loan Document. The foregoing indemnity shall cover, without limitation, (i) any Claim in connection with a design or other defect (latent or patent) in any item of equipment or product included in the Collateral, (ii) any Claim for infringement of any patent, copyright, trademark or other intellectual property right, (iii) any Claim resulting from the presence on or under or the escape, seepage, leakage, spillage, discharge, emission or release of any Hazardous Materials on the premises owned, occupied or leased by Borrower, including any Claims asserted or arising under any Environmental Law, (iv) any Claim for negligence or strict or absolute liability in tort, or (v) any Claim asserted as to or arising under any Account Control Agreement or any Landlord Agreement; provided, however, Borrower shall not indemnify Lender for any liability incurred by Lender as a direct and sole result of Lender's gross negligence or willful misconduct. Such indemnities shall continue in full force and effect, notwithstanding the expiration or termination of this Agreement. Upon Lender's written demand, Borrower shall assume and diligently conduct, at its sole cost and expense, the entire defense of Lender, each of its partners, and each of their respective, agents, employees, directors, officers, shareholders, successors and assigns against any indemnified Claim described in this Section 10.3(a). Borrower shall not settle or compromise any Claim against or involving Lender without first obtaining Lender's written consent thereto, which consent shall not be unreasonably withheld.

(b) Waiver. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT OR ANYWHERE ELSE, BORROWER AGREES THAT IT SHALL NOT SEEK FROM LENDER UNDER ANY THEORY OF LIABILITY (INCLUDING ANY THEORY IN TORTS), ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES.

(c) Survival; Defense. The obligations in this Section 10.3 shall survive payment of all other Obligations pursuant to Section 12.8. At the election of any Indemnified Person, Borrower shall defend such Indemnified Person using legal counsel satisfactory to such Indemnified Person in such Person's reasonable discretion, at the sole cost and expense of Borrower. All amounts owing under this Section 10.3 shall be paid within thirty (30) days after written demand.

11. Notices. Unless otherwise provided in this Agreement, all notices or demands by any party relating to this Agreement or any other agreement entered into in connection herewith shall be in writing and (except for financial statements and other informational documents which may be sent by first-class mail, postage prepaid) shall be personally delivered or sent by certified mail, postage prepaid, return receipt requested, by prepaid nationally recognized overnight courier, or by prepaid facsimile to Borrower or to Lender, as the case may be, at their respective addresses set forth below:

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If to Borrower: Pharmasset, Inc.
303A College Road East
Princeton, New Jersey 08540
Attention:
Fax:
Ph:

If to Lender: Horizon Technology Funding Company V LLC
76 Batterson Park Road
Farmington, CT 06032
Attention: Legal Department
Fax: (860) 676-8655
Ph: (860) 676-8654

The parties hereto may change the address at which they are to receive notices hereunder, by notice in writing in the foregoing manner given to the other.

12. General Provisions.

12.1 Successors and Assigns. This Agreement and the Loan Documents shall bind and inure to the benefit of the respective successors and permitted assigns of each of the parties; provided, however, neither this Agreement nor any rights hereunder may be assigned by Borrower without Lender's prior written consent, which consent may be granted or withheld in Lender's sole discretion. Lender shall have the right without the consent of or notice to Borrower to sell, transfer, assign, negotiate, or grant participations in all or any part of, or any interest in Lender's rights and benefits hereunder. Lender may disclose the Loan Documents and any other financial or other information relating to Borrower or any Subsidiary to any potential participant or assignee of any of the Loans, provided that such participant or assignee agrees to protect the confidentiality of such documents and information using the same measures that it uses to protect its own confidential information, and provided, further, such participant or assignee shall execute and deliver to the other Lender a Participation Agreement, whereupon such party shall become a "Lender" for all purposes and to the same extent as if originally a party hereto and shall be bound by and entitled to the benefits of this Agreement.

12.2 Time of Essence. Time is of the essence for the performance of all obligations set forth in this Agreement.

12.3 Severability of Provisions. Each provision of this Agreement shall be several from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

12.4 Entire Agreement; Construction; Amendments and Waivers.

(a) Entire Agreement. This Agreement and each of the other Loan Documents dated as of the date hereof, taken together, constitute and contain the entire agreement between Borrower and Lender and supersede any and all prior agreements,

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negotiations, correspondence, understandings and communications between the parties, whether written or oral, respecting the subject matter hereof. Borrower acknowledges that it is not relying on any representation or agreement made by Lender or any employee, attorney or agent thereof, other than the specific agreements set forth in this Agreement and the Loan Documents.

(b) Construction. This Agreement is the result of negotiations between and has been reviewed by each of Borrower and Lender executing this Agreement as of the date hereof and their respective counsel; accordingly, this Agreement shall be deemed to be the product of the parties hereto, and no ambiguity shall be construed in favor of or against Borrower or Lender. Borrower and Lender agree that they intend the literal words of this Agreement and the other Loan Documents and that no parol evidence shall be necessary or appropriate to establish Borrower's or Lender's actual intentions.

(c) Amendments and Waivers. Any and all discharges or waivers of, or consents to any departures from any provision of this Agreement or of any of the other Loan Documents shall not be effective without the written consent of Lender. Any and all amendments and modifications of this Agreement or of any of the other Loan Documents shall not be effective without the written consent of Lender and Borrower. Any waiver or consent with respect to any provision of the Loan Documents shall be effective only in the specific instance and for the specific purpose for which it was given. No notice to or demand on Borrower in any case shall entitle Borrower to any other or further notice or demand in similar or other circumstances. Any amendment, modification, waiver or consent affected in accordance with this Section 12.4 shall be binding upon Lender and on Borrower.

12.5 Reliance by Lender. All covenants, agreements, representations and warranties made herein by Borrower shall be deemed to be material to and to have been relied upon by Lender, notwithstanding any investigation by Lender.

12.6 No Set-Offs by Borrower. All sums payable by Borrower pursuant to this Agreement or any of the other Loan Documents shall be payable without notice or demand and shall be payable in United States Dollars without set-off or reduction of any manner whatsoever.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement shall continue in full force and effect so long as any Obligations or commitment to fund remain outstanding. The obligations of Borrower to indemnify Lender with respect to the expenses, damages, losses, costs and liabilities described in Section 10.3 shall survive until all applicable statute of limitations periods with respect to actions that may be brought against Lender have run.

***** — Material has been omitted and filed separately with the Commission

13. **Relationship of Parties.** Borrower and Lender acknowledge, understand and agree that the relationship between Borrower, on the one hand, and Lender, on the other, is, and at all time shall remain solely that of a borrower and lender. Lender shall not under any circumstances be construed to be a partner or a joint venturer of Borrower or any of its Affiliates; nor shall Lender under any circumstances be deemed to be in a relationship of confidence or trust or a fiduciary relationship with Borrower or any of its Affiliates, or to owe any fiduciary duty to Borrower or any of its Affiliates. Lender does not undertake or assume any responsibility or duty to Borrower or any of its Affiliates to select, review, inspect, supervise, pass judgment upon or otherwise inform Borrower or any of its Affiliates of any matter in connection with its or their Property, any Collateral held by Lender or the operations of Borrower or any of its Affiliates. Borrower and each of its Affiliates shall rely entirely on their own judgment with respect to such matters, and any review, inspection, supervision, exercise of judgment or supply of information undertaken or assumed by Lender in connection with such matters is solely for the protection of Lender and neither Borrower nor any Affiliate is entitled to rely thereon.

14. **Confidentiality.** All information (other than periodic reports filed by Borrower with the Securities and Exchange Commission) disclosed by Borrower to Lender in writing or through inspection pursuant to this Agreement that is marked confidential shall be considered confidential. Lender agrees to use the same degree of care to safeguard and prevent disclosure of such confidential information as Lender uses with its own confidential information, but in any event no less than a reasonable degree of care. Lender shall not disclose such information to any third party (other than to Lender's partners, attorneys, governmental regulators, or auditors, or to Lender's subsidiaries and affiliates and prospective transferees and purchasers of the Loans, all subject to the same confidentiality obligation set forth herein or as required by law, regulation, subpoena or other order to be disclosed) and shall use such information only for purposes of evaluation of its investment in Borrower and the exercise of Lender's rights and the enforcement of its remedies under this Agreement and the other Loan Documents. The obligations of confidentiality shall not apply to any information that (a) was known to the public prior to disclosure by Borrower under this Agreement, (b) becomes known to the public through no fault of Lender, (c) is disclosed to Lender by a third party having a legal right to make such disclosure, or (d) is independently developed by Lender. Notwithstanding the foregoing, Lender's agreement of confidentiality shall not apply if Lender has acquired indefeasible title to any Collateral or in connection with any enforcement or exercise of Lender's rights and remedies under this Agreement following an Event of Default, including the enforcement of Lender's security interest in the Collateral.

15. **CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER.** THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF CONNECTICUT, WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW. EACH OF BORROWER AND LENDER HEREBY SUBMITS TO THE NON-EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS LOCATED IN THE STATE OF CONNECTICUT. BORROWER AND LENDER HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF ANY OF THE LOAN DOCUMENTS OR ANY OF THE TRANSACTIONS CONTEMPLATED THEREIN, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW OR STATUTORY CLAIMS.

***** — Material has been omitted and filed separately with the Commission

[Remainder of page intentionally left blank.]

***** — Material has been omitted and filed separately with the Commission

IN WITNESS WHEREOF, the parties hereto have caused this Venture Loan & Security Agreement to be executed as of the date first above written.

BORROWER:

PHARMASSET, INC.

By: /s/ KURT LEUTZINGER

Name: Kurt Leutzinger

Title: Chief Financial Officer

LENDER:

HORIZON TECHNOLOGY FUNDING COMPANY V
LLC

By: Horizon Technology Finance, LLC, its agent

By: /s/ ROBERT D. POMEROY, JR.

Robert D. Pomeroy, Jr., Managing Member

***** — Material has been omitted and filed separately with the Commission

LIST OF EXHIBITS AND SCHEDULES

Exhibit A	Disclosure Schedule
Exhibit B	Funding Certificate
Exhibit C	Form of Note
Exhibit D	Form of Legal Opinion
Exhibit E	Form of Officer's Certificate
Exhibit F	Form of Participation Agreement
Exhibit G	Investment Policy

***** — Material has been omitted and filed separately with the Commission

EXHIBIT A

DISCLOSURE SCHEDULE

Borrower hereby certifies the following information to Lender:

Section 1. Information For UCC Financing Statements and Searches and Deposit Accounts and Accounts Holding Securities.

- (a) The exact corporate name of Borrower as it appears in its Articles of Incorporation, as amended to date is: Pharmasset, Inc.
- (b) Borrower's state of incorporation is: Delaware.
- (c) The organizational ID number of Borrower from its jurisdiction of incorporation is 3796672.
- (d) Borrower's taxpayer identification number is 98-0406340.
- (e) The following is a list of all corporate names, dba or trade names used by Borrower in the past five years: Pharmasset, Inc. and Pharmasset, Ltd.
- (f) The following is a list of all Subsidiaries of Borrower: N/A.
- (g) The address of Borrower's headquarters and chief executive office is: 303A College Road East, Princeton, New Jersey 08540.
The following is a list of all States where Borrower's headquarters and chief executive office has been located in the past five years: New Jersey and Georgia.
- (h) The following is a list of all States where Borrower's property and assets have been located in the past five years: New Jersey, Georgia, and North Carolina.
- (i) The following is a list of all of Borrower's deposit accounts (bank name, address and account names and numbers): Account No. 373-49855-12-500. Citigroup Global Markets, 3455 Peachtree Road North East, Suite 1400, Atlanta GA 30326.
- (j) The following is a list of all of Borrower's accounts holding securities (broker/bank name, address and account names and numbers): Account No. 373-91554-18-500. Citigroup Global Markets, 3455 Peachtree Road North East, Suite 1400, Atlanta GA 30326.

Section 2. Liens to be included in the definition of Permitted Liens

***** — Material has been omitted and filed separately with the Commission

Capital Lease by and between Pharmasset, Inc. and Commerce Capital Leasing, LLC dated October 15, 2006 for the various and sundry laboratory equipment listed on the schedules thereto.

Section 3. Additional Disclosures

- In addition to the items leased by the Capital Lease referred to in Section 2 hereof, the following items in Borrower's possession, at its location at 303A College Road East, Princeton, New Jersey 08540, are not owned by the Borrower and do not represent Collateral under the Agreement.:

Item	Value (\$)
1. Leasehold Improvements	1,836,552.90
2. Telephone Equipment	35,257.37
3. Boiler	34,900.00

***** — Material has been omitted and filed separately with the Commission

EXHIBIT B

FUNDING CERTIFICATE

The undersigned, being the duly elected and acting _____ of PHARMASSET, INC., a Delaware corporation (“Borrower”), does hereby certify to HORIZON TECHNOLOGY FUNDING COMPANY V LLC (the “Lender”) in connection with that certain Venture Loan and Security Agreement dated as of September 30, 2007 by and between Borrower and Lender (the “Loan Agreement”); with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct as of the date hereof.
2. No event or condition has occurred that would constitute a Default or an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied.
5. No material adverse change in the general affairs, management, results of operations, condition (financial or otherwise) or prospects of Borrower, whether or not arising from transactions in the ordinary course of business, has occurred.
6. The proceeds for Loan [] should be disbursed as follows:

Disbursement from Lender:	
Loan Amount	\$
Less:	
Legal Fees	\$
Balance of Commitment Fee	\$
Net Proceeds due from Lender:	\$

***** — Material has been omitted and filed separately with the Commission

7. The aggregate net proceeds of Loan [] in the amount of \$_____ shall be transferred to Borrower's account as follows:

Account Name:
Bank Name:
Bank Address:
Attention:
Telephone:
Account Number:
ABA Number:

Dated: _____, 2007

BORROWER:

PHARMASSET, INC.

By: _____

Name:

Title:

***** — Material has been omitted and filed separately with the Commission

EXHIBIT C

SECURED PROMISSORY NOTE

\$ _____

[September] __, 2007

FOR VALUE RECEIVED, the undersigned, PHARMASSET, INC., a Delaware corporation ("Borrower"), HEREBY PROMISES TO PAY to the order of HORIZON TECHNOLOGY FUNDING COMPANY V LLC, a Delaware limited liability company ("Lender") the principal amount of _____ Dollars (\$ _____) or such lesser amount as shall equal the outstanding principal balance of the Loan [____] (the "Loan") made to Borrower by Lender pursuant to the Loan Agreement (as defined below), and to pay all other amounts due with respect to the Loan on the dates and in the amounts set forth in the Loan Agreement.

Interest on the principal amount of this Note from the date of this Note shall accrue at the Loan Rate or, if applicable, the Default Rate. The Loan Rate for this Note is _____ percent (__%) per annum based on a year of twelve 30-day months. If the Funding Date is not the first (1st) day of the month, interim interest accruing from the Funding Date through the last day of that month shall be paid on the first (1st) calendar day of the next calendar month. Commencing _____, 2007, through and including _____, 200 __, on the first (1st) day of each month (each an "Interest Payment Date") Borrower shall make payments of accrued interest only on the outstanding principal amount of the Loan. Commencing on _____, 200 __, and continuing on the first (1st) day of each month thereafter (each a "Principal and Interest Payment Date" and, collectively with each Interest Payment Date, each a "Payment Date"), Borrower shall make to Lender thirty (30) equal payments of principal and accrued interest on the then outstanding principal amount due hereunder of _____ Dollars (\$ _____). If not sooner paid, all outstanding amounts hereunder and under the Loan Agreement shall become due and payable on _____.

Principal, interest and all other amounts due with respect to the Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement. The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

This Note is referred to in, and is entitled to the benefits of, the Venture Loan and Security Agreement dated as of [September] __, 2007 by and between Borrower and Lender (the "Loan Agreement"). The Loan Agreement, among other things, (a) provides for the making of a secured Loan to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid, except as set forth in Section 2.3 of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Loan, interest on the Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due. This Note shall be governed by, and construed and interpreted in accordance with, the laws of the State of Connecticut.

[Remainder of This Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

PHARMASSET, INC.

By: _____

Name:

Title:

***** — Material has been omitted and filed separately with the Commission

EXHIBIT D

ITEMS TO BE COVERED BY OPINION OF BORROWER'S COUNSEL

1. Borrower is a corporation, duly organized, validly existing and in good standing under the laws of the State of Delaware, and is duly qualified and authorized to do business in the State of New Jersey.
2. Borrower has the full corporate power, authority and legal right, and has obtained all necessary approvals, consents and given all notices to execute and deliver the Loan Documents and perform the terms thereof.
3. The Loan Documents have been duly authorized, executed and delivered by Borrower and constitute valid, legal and binding agreements, and are enforceable in accordance with their terms.
4. To our knowledge, there is no action, suit, audit, investigation, proceeding or patent claim pending or threatened against Borrower in any court or before any governmental commission, agency, board or authority which might have a material adverse effect on the business, condition or operations of Borrower or the ability of Borrower to perform its obligations under the Loan Documents.
5. The Shares (as defined in the Warrant) issuable pursuant to exercise or conversion of the Warrant have been duly authorized and reserved for issuance by Borrower and, when issued in accordance with the terms thereof, will be validly issued, fully paid and nonassessable.
6. The execution and delivery of the Loan Documents are not, and the issuance of the Shares upon exercise of the Warrant in accordance with the terms thereof will not be, inconsistent with Borrower's Articles of Incorporation, as amended, or Bylaws, do not and will not contravene any law, governmental rule or regulation, judgment or order applicable to Borrower, and do not and will not conflict with or contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other agreement or instrument of which Borrower is a party or by which it is bound or require the consent or approval of, the giving of notice to, the registration or filing with or the taking of any action in respect of or by, any federal, state or local government authority or agency or other person, except for the filing of notices pursuant to federal and state securities laws, which filings will be effected by the time required thereby.

***** — Material has been omitted and filed separately with the Commission

EXHIBIT E

FORM OF OFFICER'S CERTIFICATE

TO: HORIZON TECHNOLOGY FUNDING COMPANY V LLC

Reference is made to the Venture Loan and Security Agreement dated as of September 30, 2007 (as it may be amended from time to time, the "Loan Agreement") by and between PHARMASSET, INC. ("Borrower") and HORIZON TECHNOLOGY FUNDING COMPANY V LLC ("Lender"). Unless otherwise defined herein, capitalized terms have the meanings given such terms in the Loan Agreement.

The undersigned Responsible Officer of Borrower hereby certifies to Lender that:

1. No Event of Default or Default has occurred under the Loan Agreement. (If a Default or Event of Default has occurred, specify the nature and extent thereof and the action Borrower proposes to take with respect thereto.)
2. The information provided in Section 1 of the Disclosure Schedule is currently true and accurate, except as noted below.
3. Borrower is in compliance with the provisions of Sections 4, 6 and 7 of the Loan Agreement, except as noted below.
4. Attached herewith are the [monthly financial statements pursuant to Section 6.3(a) of the Loan Agreement/annual audited financial statements pursuant to Section 6.3(b) of the Loan Agreement]. These have been prepared in accordance with GAAP and are consistent from one period to the next except as noted below.

NOTES TO ABOVE CERTIFICATIONS:

BORROWER:

PHARMASSET, INC.

By: _____

Name:

Title:

***** — Material has been omitted and filed separately with the Commission

EXHIBIT F

FORM OF PARTICIPATION AGREEMENT

***** — Material has been omitted and filed separately with the Commission

EXHIBIT G
INVESTMENT POLICY
OF
PHARMASSET, INC.

The securities investments of Pharmasset, Inc. (the “Company”) should be made in accordance with this Investment Policy.

It is the Company’s policy to make investments for the purpose of conserving capital and liquidity until the funds are used in the Company’s primary business, which is to research and develop drugs to treat viral infections. The Company’s capital preservation investments should be liquid so that they can be readily sold to support the Company’s research and development activities as necessary and present limited credit risk. This Investment Policy emphasizes principal preservation, so it requires strong issuer credit ratings and limits the amount of credit exposure. No investment can be speculative or present a significant lack of liquidity or significant credit risk.

The Company’s management is permitted to invest its funds in the following securities:

ACCEPTABLE INVESTMENTS

U.S. Treasury Securities	Asset-Backed Securities
Federal Agency Securities (GSE’s)	Floating Rate Notes
Repurchase Agreements	Corporate Notes/Bonds
Commercial Paper (foreign and domestic issues)	
Time Deposits	
Certificates of Deposit	
Yankee Certificates of Deposit	
Euro Certificates of Deposit	
Money Market Funds/Sweep Vehicle	
Bankers’ Acceptances	

BENCHMARK

Merrill Lynch 6-Month U.S. Treasury Bill Index

***** — Material has been omitted and filed separately with the Commission

MATURITY PARAMETERS

Maximum Maturity/Demand Feature/Average Life: 2 years
Maximum Average Maturity for Portfolio 1 year

CONCENTRATION AND DIVERSIFICATION

No more than 5% in any single issue/issuer except U.S. Treasury/Agency Securities at time of purchase.

MINIMUM ACCEPTABLE CREDIT QUALITY

The obligor must be rated in the rating category as indicated below by at least two of the Nationally Recognized Statistical Rating Organizations (NRSRO's).

	5. <u>S & P</u>	6. <u>Moody's</u>	7. <u>Fitch IBCA</u>
Short Term Rating	A-1	P-1	F-1
Long Term Rating	A-	A3	A-

Investments in equity securities generally are not allowed. Investments related to licensing contracts and equity holdings in any licensor, licensee or collaborative partner are treated as "other investments" and are allowed only to the extent permitted by Rule 3a-8 of the U.S. Investment Company Act of 1940, as amended.

***** — Material has been omitted and filed separately with the Commission

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-142630 on Form S-8 of our report dated May 5, 2006 (January 4, 2007, as to the effects of the restatement discussed in Note 18, and April 19, 2007, as to the effect of the reverse stock split, discussed in Note 17), as it relates to the financial statements for the nine months ended September 30, 2005 of Pharmasset, Inc. appearing in this Annual Report on Form 10-K of Pharmasset, Inc. for the year ended September 30, 2007

/s/ Deloitte & Touche LLP
Parsippany, New Jersey
December 24, 2007

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated December 24, 2007 (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the adoption of Statement of Financial Accounting Standards No. 123R, Share-Based Payment, on October 1, 2006), accompanying the financial statements included in the Annual Report of Pharmasset, Inc. on Form 10-K for the year ended September 30, 2007. We hereby consent to the incorporation by reference of said report in the Registration Statement of Pharmasset, Inc. on Form S-8 (File No. 333-142630, effective May 4, 2007).

/s/ Grant Thornton LLP
Philadelphia, Pennsylvania
December 24, 2007

CERTIFICATION

I, P. Schaefer Price, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pharmasset, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 31, 2007

/s/ P. S CHAEFER P RICE

P. Schaefer Price
President and Chief Executive Officer

CERTIFICATION

I, Kurt Leutzinger, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pharmasset, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 31, 2007

/s/ **KURT LEUTZINGER**

Kurt Leutzinger
Executive Vice President
and Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report on Form 10-K of Pharmasset, Inc. (the "Company") for the period ended September 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, P. Schaefer Price, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350 as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 31, 2007

/s/ P. S CHAEFER P RICE

**P. Schaefer Price
President and Chief Executive Officer**

A signed original of this written statement required by Section 906 has been provided to Pharmasset, Inc. and will be retained by Pharmasset, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report on Form 10-K of Pharmasset, Inc. (the "Company") for the period ended September 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Kurt Leutzinger, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350 as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 31, 2007

/s/ KURT LEUTZINGER

Kurt Leutzinger
Executive Vice President
and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to Pharmasset, Inc. and will be retained by Pharmasset, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.