Pharmasset Inc
Form 10-Q
August 10, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2009

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	**98-0406340**
(State or other jurisdiction	**(IRS Employer**
of incorporation or organization)	**Identification No.)**

303-A College Road East

Princeton, New Jersey	**08540**
(Address of registrant s principal executive offices)	**(Zip Code)**

(609) 613-4100

(Telephone number, including area code)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ¨ Yes ¨ No

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

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

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

The number of shares of the registrant s common stock, $0.001 par value, outstanding as of July 31, 2009 was 28,150,807.

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PHARMASSET, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2009

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. The forward-looking statements are principally contained in the section entitled 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, primarily with respect to the preclinical and clinical trial results and regulatory approval of RG7128 (formerly R7128), PSI-7851 and PSI-938 for the treatment of hepatitis C virus (HCV), and, secondarily, the development of Racivir™ for the treatment of human immunodeficiency virus (HIV) for use in combination with other approved HIV drugs;
- the termination of the clevudine registration studies;
- the initiation, termination, 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-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche), including potential milestone and royalty payments thereunder;
- our intentions regarding the establishment of collaborations or the licensing of product candidates or intellectual property;
- the scope and enforceability of the Company s intellectual property rights, including claims that the Company may infringe third party intellectual property rights or be otherwise required to pay license fees under such third party rights;
- 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 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2008 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 Quarterly Report on Form 10-Q.

You should read this Quarterly Report on Form 10-Q 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. You should assume that the information appearing in this Quarterly Report on Form 10-Q is accurate as of the date on the front cover of this Quarterly Report on Form 10-Q only. 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 Quarterly Report on Form 10-Q 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).

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PHARMASSET, INC.

CONDENSED BALANCE SHEETS

	As of June 30, 2009 (unaudited)	As of September 30, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 72,656,823	$ 63,073,103
Short-term investments		497,310
Amounts due from collaboration partner	594,403	1,169,690
Prepaid expenses and other assets	2,395,142	1,008,083
Total current assets	75,646,368	65,748,186
EQUIPMENT AND LEASEHOLD IMPROVEMENTS:		
Laboratory, office furniture and equipment	3,563,147	3,362,846
Leasehold improvements	1,836,553	1,836,553
	5,399,700	5,199,399
Less accumulated depreciation and amortization	(3,172,216)	(2,432,325)
Total equipment and leasehold improvements, net	2,227,484	2,767,074
OTHER ASSETS	186,463	466,809
TOTAL	$ 78,060,315	$ 68,982,069
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 7,011,558	$ 2,651,592
Current portion of capital lease obligation		41,641
Accounts payable	2,188,714	2,466,052
Accrued expenses	7,978,083	6,182,417
Deferred rent	111,164	124,463
Deferred revenue	1,857,136	1,857,136
Total current liabilities	19,146,655	13,323,301
DEFERRED RENT		79,793
DEFERRED REVENUE	2,476,091	3,868,965
LONG-TERM DEBT, net	14,277,488	16,522,665
Total liabilities	35,900,234	33,794,724

COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		
Common Stock, $0.001 par value, 100,000,000 shares authorized, 28,139,902 and 23,340,498 shares issued and outstanding at June 30, 2009 (unaudited) and September 30, 2008, respectively	28,140	23,340
Warrants to purchase 127,248 and 116,183 shares of common stock for $12.05 per share, as of June 30, 2009, (unaudited) and September 30, 2008, respectively	1,229,767	1,140,114
Additional paid-in capital	193,390,835	145,818,439
Accumulated other comprehensive (loss) income		(2,604)
Accumulated deficit	(152,488,661)	(111,791,944)
Total stockholders equity	42,160,081	35,187,345
TOTAL	$ 78,060,315	$ 68,982,069

See notes to financial statements.

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PHARMASSET, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE NET LOSS

(UNAUDITED)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2009	2008	2009	2008
REVENUES	$ 10,501,191	$ 464,291	$ 12,868,162	$ 1,392,874
COSTS AND EXPENSES:				
Research and development	13,676,701	11,499,843	41,393,878	31,040,683
General and administrative	2,995,566	3,473,635	9,958,441	9,902,453
Total costs and expenses	16,672,267	14,973,478	51,352,319	40,943,136
OPERATING LOSS	(6,171,076)	(14,509,187)	(38,484,157)	(39,550,262)
INVESTMENT INCOME	37,729	216,287	204,938	1,697,737
INTEREST EXPENSE	(815,764)	(735,543)	(2,417,498)	(1,484,880)
LOSS BEFORE INCOME TAXES	(6,949,111)	(15,028,443)	(40,696,717)	(39,337,405)
PROVISION FOR INCOME TAXES				
NET LOSS	$ (6,949,111)	$ (15,028,443)	$ (40,696,717)	$ (39,337,405)
COMPREHENSIVE NET LOSS:				
NET LOSS	$ (6,949,111)	$ (15,028,443)	$ (40,696,717)	$ (39,337,405)
UNREALIZED GAIN (LOSS) ON AVAILABLE-FOR-SALE INVESTMENTS		12,503		(17,069)
COMPREHENSIVE NET LOSS	$ (6,949,111)	$ (15,015,940)	$ (40,696,717)	$ (39,354,474)
NET LOSS PER SHARE				
BASIC	$ (0.25)	$ (0.69)	$ (1.57)	$ (1.84)
DILUTED	$ (0.25)	$ (0.69)	$ (1.57)	$ (1.84)
WEIGHTED AVERAGE SHARES OUTSTANDING:				
BASIC	28,121,400	21,635,205	25,907,063	21,425,577
DILUTED	28,121,400	21,635,205	25,907,063	21,425,577

See notes to financial statements.

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PHARMASSET, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended June 30,	
	2009	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (40,696,717)	$ (39,337,405)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	739,891	748,418
Non-cash stock compensation	3,570,531	2,398,198
Non-cash interest expense	414,607	273,701
Changes in operating assets and liabilities:		
Amounts due from collaboration partner, prepaid expenses and other assets	(608,567)	(1,081,949)
Accounts payable	(277,338)	(1,967,301)
Accrued expenses	1,795,666	1,192,474
Deferred rent	(93,092)	(93,092)
Deferred revenue	(1,392,874)	(1,392,874)
Net cash used in operating activities	(36,547,893)	(39,259,830)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturity of short-term investments	500,000	250,000
Purchase of equipment and leasehold improvements	(200,301)	(777,376)
Net cash (used in) provided by investing activities	299,699	(527,376)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowings of long-term debt	3,333,333	20,000,000
Proceeds from exercise of stock options	581,922	2,208,872
Principal payments on long-term debt	(1,466,443)	
Principal payments on capital lease obligations	(41,641)	(118,523)
Proceeds from issuance of common stock, net of issuance costs of $2,092,196	43,424,743	
Net cash provided by financing activities	45,831,914	22,090,349
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	9,583,720	(17,696,857)
CASH AND CASH EQUIVALENTS Beginning of period	63,073,103	68,745,694
CASH AND CASH EQUIVALENTS End of period	$ 72,656,823	$ 51,048,837
SUPPLEMENTAL DISCLOSURES:		
Cash paid during the period for:		
Interest	$ 2,002,891	$ 1,211,179
Noncash transactions:		
Unrealized (loss) gain on available-for-sale investments	$	$ (17,069)
Warrants granted in connection with debt financing	$ 89,653	$ 613,394

See notes to financial statements.

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Pharmasset, Inc.

Notes to Financial Statements (Unaudited)

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

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 discovery and development of nucleoside/tide analogs as oral therapeutics for the treatment of hepatitis C virus (HCV) and, secondarily, on the development of RaciVir™ for the treatment of human immunodeficiency virus (HIV). The Company currently has three clinical-stage product candidates: RG7128 (formerly R7128), for the treatment of HCV, which is in a Phase 2b clinical trial through a collaboration with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche); PSI-7851, the Company s next generation HCV product candidate, which is in a Phase 1 clinical trial; and Racivir, which is being developed for the treatment of HIV in combination with other approved HIV drugs and has completed a Phase 2 clinical trial. In addition, the Company recently nominated PSI-352938 (PSI-938) as a development candidate for the treatment of HCV and has begun studies required for the submission of an Investigational New Drug (IND) application with the FDA or equivalent regulatory application. The Company is also continuing to research nucleoside/tide analogs (both pyrimidines and purines) with the intention of identifying product candidates that can potentially be used in combination with the Company s current nucleosides/tides, RG7128 or PSI-7851, or in combination with other classes of direct acting antivirals for the treatment of HCV. On April 20, 2009, the Company voluntarily terminated its Phase 3 registration studies of clevudine for the treatment of chronic hepatitis B infection after becoming aware of a number of spontaneous Serious Adverse Event reports and Events of Special Interest in patients in South Korea, where clevudine is marketed by Bukwang Pharm. Co. Ltd. (Bukwang) under the trade name Levovir, and in Hong Kong, where clinical studies were being conducted under the sponsorship of Bukwang.

The Company s research and development focuses on nucleoside/tide analogs, a class of compounds which act as alternative substrates for the viral polymerase, thus inhibiting viral replication. The Company is applying its expertise in nucleoside/tide chemistry to the discovery and development of additional antiviral therapeutics for HCV. The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, risks and uncertainties relating to product development, 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, healthcare reform and related regulatory or healthcare industry developments in the United States and elsewhere, and product liability. (See *Part II, Item 1A. Risk Factors* for additional information.)

Basis of Presentation - The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required for complete financial statements. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company s interim financial information. The accompanying unaudited condensed financial statements and notes to the condensed financial statements should be read in conjunction with the audited financial statements for the fiscal year ended September 30, 2008 included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on December 11, 2008.

Management has evaluated subsequent events for disclosure or recognition in the accompanying unaudited condensed financial statements up to the filing of this Form 10-Q with the SEC on August 10, 2009.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 revenues 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 consist primarily of mutual and money market funds.

Investments - The Company invests available cash primarily in mutual and money market funds, bank certificates of deposit and investment-grade commercial paper, corporate notes, and government securities. All investments are classified as

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available-for-sale and are carried at fair market value with unrealized gains and losses recorded in accumulated other comprehensive (loss) income. For purpose of determining realized gains and losses, the cost of securities sold is based on specific identification.

Deferred Offering Costs - Costs incurred in connection with an equity offering are deferred and, upon completion of the equity offering, are 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) income.

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 the lesser of the estimated life of the asset and 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.

Intangible Assets - Intangible assets are recorded at cost and are amortized on a straight-line basis over the estimated useful life. The estimated useful life is determined based on the consideration of several factors including the nature of the asset, its expected use, length of related agreements and the period over which benefits are expected to be received from the use of the asset.

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.

Fair Value of Financial Instruments - On October 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines and establishes a framework for measuring fair value and expands disclosures about fair value instruments. In accordance with SFAS 157, the Company has categorized its financial assets, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. The Company does not have any financial liabilities that are required to be measured at fair value on a recurring basis. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial assets recorded on the balance sheets are categorized based on the inputs to the valuation techniques as follows:

Level 1 Financial assets whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date (examples include active exchange-traded equity securities and most U.S. Government and agency securities).

Level 2 Financial assets whose value are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.

Level 3 Financial assets whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management s own assumptions about the assumptions a market participant would use in pricing the asset.

As of June 30, 2009, the Company did not have any Level 2 or 3 financial assets and the Company s Level 1 financial assets were as follows:

	Level 1 (in thousands)
Money Market Funds	$ 30,986
Mutual Funds (invested in short-term U.S. Treasury Obligations)	41,671
Total	$ 72,657

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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. The Company invests cash that is not currently being used in operations in accordance with its investment policy. The policy allows for the purchase of low-risk, investment grade debt securities issued by the United States government and 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.

For the three and nine months ended June 30, 2009 and 2008, the Company derived all of its revenues from one customer (see Note 4).

Revenue Recognition - The Company recognizes revenues in accordance with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* (SAB 104). SAB No. 104 requires that four basic criteria 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 collectability is reasonably assured. For agreements containing multiple elements, the Company follows the guidance in the Financial Accounting Standards Board s (FASB) Emerging Issue Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF No. 00-21). In accordance with SAB No. 104 and EITF No. 00-21, the elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator and whether there is objective and reliable evidence of the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units either on the basis of each unit's fair value or using the residual method and the applicable revenue recognition criteria is applied to each of the separate units.

The Company s revenues are primarily related to its collaboration agreement with Roche. This agreement provides for various types of payments to the Company, including non-refundable upfront license fees, research and/or 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 revenues 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 revenues are recognized. Research and/or development payments are recognized as revenues as the related research and/or development activities are performed and when the Company has no continuing performance obligations related to the research and development payment received.

The Company recognizes revenues 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 related to the achievement of the milestone earned. 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 revenues as the Company completes its 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.

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

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 cost 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 from collaboration partner.

In accordance with EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3), nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then 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.

Stock-Based Compensation - The Company accounts for share-based payment(s) in accordance with SFAS No. 123R, *Share-Based Payment* (SFAS 123R). 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 on October 1, 2006, 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. 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) income. Since the Company s stock was not publicly traded prior to April 27, 2007, the expected volatility was calculated for each date of grant prior to having a publicly traded stock 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 SAB No. 107 (SAB 107), relating to share-based payment, issued by the SEC.

Comprehensive Net Income (Loss) - Components of comprehensive income (loss) include net income (loss) and unrealized gain (loss) on available-for-sale securities, net of tax. Comprehensive income (loss) is presented in the statements of operations and comprehensive net income (loss).

Net Income (Loss) Per Common Share - Basic net income (loss) per common share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is calculated by dividing net income (loss) 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.

The following table provides each of the inputs to the calculations of basic and diluted net loss per share for the three and nine months ended June 30, 2009 and 2008.

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	Three Months Ended June 30,		Nine Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands, except per share amounts)			
Numerator:				
Net loss	$ (6,949)	$ (15,028)	$ (40,697)	$ (39,337)
Denominator:				
Weighted average common shares outstanding used in calculation of basic net loss per share	28,121	21,635	25,907	21,426
Effect of dilutive securities:				
Common stock options				
Common stock warrants				
Weighted average common shares outstanding used in calculation of diluted net loss per share	28,121	21,635	25,907	21,426
Net loss per share:				
Basic	$ (0.25)	$ (0.69)	$ (1.57)	$ (1.84)
Diluted	$ (0.25)	$ (0.69)	$ (1.57)	$ (1.84)

The following table summarizes the securities outstanding as of the dates shown with the potential to become common stock that have been excluded from the computation of diluted net loss per share, as their effect would have been anti-dilutive.

	Three and Nine Months Ended June 30,	
	2009	2008
	(In thousands)	
Common stock warrants	127	116
Options to purchase common stock	2,689	2,366
Total	2,816	2,482

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 that focuses on developing nucleoside/tide analog drugs for the treatment of viral infections.

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.

On October 1, 2007, the Company adopted FASB Interpretation No. 48 (FIN 48). FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not to file a return in a particular jurisdiction). Under FIN 48, the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities full knowledge of the position and all relevant facts.

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Recently Adopted Accounting Pronouncements

In May 2009, the FASB issued Statement of Financial Accounting Standards No. 165, *Subsequent Events* (Statement 165). Statement 165 incorporates the accounting and disclosure requirements for subsequent events into U.S. generally accepted accounting principles. Statement 165 also introduces new terminology, defines a date through which management must evaluate subsequent events, and lists the circumstances under which an entity must recognize and disclose events or transactions occurring after the balance-sheet date. The Company adopted Statement 165 as of June 30, 2009, which was the required effective date, and its adoption did not affect the Company s financial statements, other than the disclosures required by it, which can be found in Note 1 Description of Business and Basis of Presentation.

Recently Issued Accounting Pronouncements

In December 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature, however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The adoption of EITF 07-1 is not expected to have a material impact on the Company.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, (SFAS 141R), which changes the accounting for business acquisitions. SFAS 141R requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard will, among other things, impact the determination of acquisition-date fair value of consideration paid in a business combination (including contingent consideration); exclude transaction costs from acquisition accounting; and change accounting practices for acquired contingencies, acquisition-related restructuring costs, in-process research and development, indemnification assets, and tax benefits. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of SFAS 141R is not expected to have a material impact on the Company.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* (SFAS 160), which establishes new standards governing the accounting for and reporting of noncontrolling interests (NCIs) in partially owned consolidated subsidiaries and the loss of control of subsidiaries. Certain provisions of this standard indicate, among other things, that NCIs (previously referred to as minority interests) be treated as a separate component of equity, not as a liability; that increases and decrease in the parent s ownership interest that leave control intact be treated as equity transactions, rather than as step acquisitions or dilution gains or losses; and that losses of a partially owned consolidated subsidiary be allocated to the NCI even when such allocation might result in a deficit balance. This standard also requires changes to certain presentation and disclosure requirements. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The provisions of the standard are to be applied to all NCIs prospectively, except for the presentation and disclosure requirements, which are to be applied retrospectively to all periods presented. The adoption of SFAS 160 is not expected to have a material impact on the Company.

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3. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of June 30, 2009	As of September 30, 2008
	(In thousands)	
Accrued compensation	$ 1,225	$ 1,161
Accrued accounting fees	45	
Accrued legal fees	768	984
Accrued license fees	54	
Accrued clinical trial expenses	5,335	3,367
Other accrued expenses	551	670
	$ 7,978	$ 6,182

4. CONTRACT REVENUE AGREEMENTS

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Cash received/receivable	$ 10,037	$	$ 11,475	$
Deferred				
Amortization	464	464	1,393	1,393
Revenues	$ 10,501	$ 464	$ 12,868	$ 1,393

The Company recorded revenues from the collaboration agreement with Roche comprising 100.0% of total revenues during the three and nine months ended June 30, 2009 and 2008. The $10.5 million of revenues during the three months ended June 30, 2009 include a $10.0 million milestone payment received from Roche for initiating a Phase 2b study of RG7128 and $0.5 million of amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue. The Company s performance obligations relating to the $10.0 million milestone payment consisted of successfully completing a Phase 1 study of RG7128, which led to the initiation of the Phase 2b study for RG7128 that triggered the milestone payment.

Roche - In October 2004, the Company entered into a collaboration and license agreement with Roche to develop PSI-6130 and PSI-6130 pro-drugs (including RG7128) for treating chronic hepatitis C infection, and to discover chemically related nucleoside polymerase inhibitors pursuant to a research collaboration which ended in December 2006. The Company granted Roche worldwide rights, excluding Latin America and Korea, to PSI-6130 and its pro-drugs. 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. During the nine months ended June 30, 2009, Roche paid the Company a $10.0 million milestone payment for initiation of a Phase 2b study for RG7128, as well as a $1.5 million payment for research and development activities related to holding the IND application for RG7128, all of which was recorded as revenue since there were no continuing performance obligations related to these payments. Roche is also required to make certain future payments to the Company for RG7128 upon the achievement of predefined development and marketing milestones in Roche s territories. The portion of the above payments recorded as deferred revenue on the Company s balance sheets as of June 30, 2009 and September 30, 2008 was $4.3 million and $5.7 million, respectively.

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

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 Korea and Latin America, the territories the Company has retained. Prior to the transfer of the IND for RG7128 to Roche, which occurred during December 2008, Roche funded and the Company was responsible for preclinical work, the IND filing, and the initial clinical trial, while Roche managed other preclinical studies and clinical development. Roche reimbursed the Company $0.3 million and $1.6 million during the three months ended June 30, 2009 and 2008, and $1.4 million and $4.5 million during the nine months ended June 30, 2009 and 2008, respectively. Roche will continue to fund all of the expenses of, and be responsible for, other preclinical studies and future clinical development of RG7128 in the territories licensed to Roche. Roche and Pharmasset will continue to jointly oversee all development and marketing activities of RG7128 in the territories licensed to Roche.

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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, and preclinical and clinical data related to this collaboration.

5. STOCK COMPENSATION

The Company s 1998 Stock Plan (the 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 were 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 its IPO, which occurred on May 2, 2007, the Company adopted the 2007 Equity Incentive Plan (the 2007 Plan). Upon the adoption of the 2007 Plan, no additional awards were granted under the 1998 Plan and the shares remaining for future grant under the 1998 Plan were transferred to the 2007 Plan. As of June 30, 2009, there were 212,294 shares of the Company s common stock reserved for future grants 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) under the 2007 Plan. Options granted under the 2007 Plan may be incentive stock options, as defined under Section 422 of the Internal Revenue Code of 1986 or nonstatutory stock options. Options granted under the 2007 Plan have been at per share exercise prices equal to the fair market value of the Company s common stock based on the publicly traded price as reported by The NASDAQ Stock Market LLC (NASDAQ) on the date of grant. The 2007 Plan will terminate in fiscal 2017 unless it is extended or terminated earlier pursuant to its terms.

Stock Options - The assumptions used and weighted-average information for employee and director grants for the three and nine months ended June 30, 2009 and 2008 are as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2009(1)	2008	2009	2008
Risk free interest rate		3.27%	3.19%	4.09%
Expected dividend yield		0.0%	0.0%	0.0%
Expected lives (years)		6.11	5.98	6.05
Expected volatility		54.26%	54.39%	57.25%
Weighted-average fair value of options granted		$ 7.81	$ 9.97	$ 8.03

(1) No stock options were granted during the three months ended June 30, 2009.

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Generally, stock options granted under these plans have a contractual life of 10 years and vest pro rata over a four year term. A summary of the Company s stock option activity during the nine months ended June 30, 2009 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding - September 30, 2008	2,371,861	$ 7.97
Granted (unaudited)	483,981	$ 18.43
Exercised (unaudited)	(50,364)	$ 7.56
Forfeited (unaudited)	(1,625)	$ 17.01
Outstanding - December 31, 2008 (unaudited)	2,803,853	$ 9.77
Granted (unaudited)		$
Exercised (unaudited)	(29,125)	$ 2.09
Forfeited (unaudited)	(46,667)	$ 1.50
Outstanding - March 31, 2009 (unaudited)	2,728,061	$ 10.00
Granted (unaudited)		$
Exercised (unaudited)	(27,916)	$ 5.02
Forfeited (unaudited)	(11,187)	$ 13.82
Outstanding - June 30, 2009 (unaudited)	2,688,958	$ 10.03
Exercisable - September 30, 2008	1,117,609	$ 4.31
Exercisable - December 31, 2008 (unaudited)	1,342,481	$ 5.70
Exercisable - March 31, 2009 (unaudited)	1,394,875	$ 6.18
Exercisable - June 30, 2009 (unaudited)	1,481,550	$ 6.44

The range of exercise prices of stock options outstanding at June 30, 2009 was $3.00 to $32.00. The weighted average remaining contractual life of stock options outstanding at June 30, 2009 was 7.49 years. The total intrinsic value of options exercised during the nine months ended June 30, 2009 was $1,088,480. As a result of applying the requirements of SFAS 123R, the Company recognized compensation expense of $822,756 and $581,291 during the three months ended June 30, 2009 and 2008, and $2,792,281 and $1,902,665 during the nine months ended June 30, 2009 and 2008, respectively, related to stock options issued to employees and non-employees. At June 30, 2009, and September 30, 2008, $7,931,881 (including $7,520,776 resulting from the application of SFAS 123R) and $6,821,109 (including $5,981,822 resulting from the application of SFAS 123R), respectively, of deferred stock-based compensation expense related to employee and non-employee stock options remained unamortized. The unamortized amount of $7,520,776 as of June 30, 2009 has a weighted-average period of approximately 1.43 years to be recognized.

Outstanding as of June 30, 2009				Exercisable as of June 30, 2009	
Number of Options	Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
1,179,461	$3.00 - $4.49	6.21	$ 3.46	1,002,336	$ 3.36
13,585	4.50 - 5.99	7.71	5.51	3,251	5.58
48,602	6.00 - 7.49	2.73	6.46	48,602	6.46
93,479	7.50 - 10.49	7.75	8.92	83,479	8.97
720,850	10.50 - 15.00	8.35	13.68	265,850	13.66
631,981	15.01 - 29.99	9.24	18.65	77,719	18.69

1,000	30.00 - 45.00	8.56	32.00	313	32.00

As of June 30, 2009, there were options to purchase 2,576,007 shares of the Company s common stock outstanding that were either vested or expected to vest in the future, of which options to purchase 1,481,550 shares were currently exercisable, with weighted average exercise prices of $9.85 and $6.44 per share, aggregate intrinsic values of $9,603,455 and $8,346,135 and weighted average remaining contractual terms of 7.44 and 6.59 years, respectively.

Restricted Stock - During the fiscal year ended September 30, 2008, the Company issued a total of 40,666 shares of restricted stock to its non-employee directors and to a consultant. The restricted stock issued to each non-employee director vested on July 16, 2009, as long as the director continued to serve on the Company s board of directors on that date, unless the failure to be so engaged is due solely to the fact that the director was nominated but not re-elected to serve as a director. The restricted stock issued to the consultant vests quarterly over a four year period. On March 24, 2009, the Company issued

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a total of 14,000 shares of restricted stock to its non-employee directors that vest one year from the date of grant, as long as the director continues to serve on the Company s board of directors on that date, unless the failure to be so engaged is due solely to the fact that the director is nominated but not re-elected to serve as a director. As of June 30, 2009, 16,666 of the 54,666 restricted shares outstanding were vested, leaving a total of 38,000 restricted shares unvested as of June 30, 2009.

With regard to the restricted stock granted to the non-employee directors, the fair value of the restricted stock issued was determined using the closing price of the Company s common stock as reported by NASDAQ on the date of grant and is recognized as stock-based compensation expense evenly over the vesting period. The weighted average fair value of the shares granted in 2008 and 2009 was $20.01 and $8.92, respectively, per share.

With regard to the restricted stock granted to the consultant, stock-based compensation expense equal to the fair value of the restricted shares that vest is recorded on a quarterly basis over the vesting period. The fair value of each of the restricted shares that vest is equal to the fair value of a share of the Company s common stock as of each vesting date.

The Company recognized compensation expense of $350,068 during the nine months ended June 30, 2009 related to restricted stock issued to its non-employee directors and to a consultant. Unrecognized compensation expense for the restricted shares granted to the non-employee directors was $106,202 at June 30, 2009. This amount will be recognized over the remaining vesting period of the restricted shares.

6. INCOME TAXES

Income tax expense was $0 during the three and nine months ended June 30, 2009 and 2008. The Company s effective tax rate for the three and nine months ended June 30, 2009 and 2008 was 0% due to uncertainties related to the realizability of the deferred tax assets as a result of the Company s history of operating losses. The net deferred tax asset as of June 30, 2009 remains fully offset by a valuation allowance since it is more likely than not that such tax benefits will not be realized.

As of September 30, 2008, the Company had United States federal net operating loss carryforwards (NOLs) of approximately $88.0 million and gross deferred tax assets of approximately $36.9 million. Of the federal NOLs, $8.8 million was generated from windfall tax benefit stock option deductions. The tax benefit of this portion of the NOL will be accounted for directly to equity as additional paid in capital as the stock option related losses are utilized.

Upon the adoption of FIN 48, there were no changes to the Company s deferred tax assets as of October 1, 2007. The total amount of unrecognized tax benefits at October 1, 2007 was $126,000, all of which would favorably impact the Company's effective tax rate if recognized. Since the unrecognized tax benefit has not been utilized on the Company s tax returns, there is no liability recorded on the balance sheet. The Company does not have any interest or penalties accrued related to tax positions at adoption of FIN 48. In the event the Company determines that accrual of interest or penalties are necessary in the future, the amount will be presented as a component of income taxes.

As of June 30, 2009, the Company's unrecognized tax benefits have not significantly changed. The Company does not expect any significant changes to the unrecognized tax benefits within 12 months of the reporting date.

The United States Internal Revenue Service could challenge tax positions taken by the Company for the periods for which there are open tax years. The Company is open to challenge for the periods of 2005-2007 from federal and state jurisdictions and from 1998-2004 for foreign jurisdictions.

Utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to changes in ownership of the Company that have occurred previously or that could occur in the future. The Company is in the process of assessing whether there have been one or more changes in control since the Company s formation and expects to disclose the results of this study in its Annual Report on Form 10-K for the fiscal year ended September 30, 2009. If the Company has experienced a change of control at any time since its formation, utilization of its NOL or research and development credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization which would reduce the Company s gross deferred tax assets.

7. 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. On June 2, 2009, the Company entered into an

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extension and modification of the lease, extending the term of the lease for an additional five years, from May 22, 2010 through May 22, 2015. The Company also leases office space in Durham, North Carolina. Monthly lease payments began May 1, 2007 and, after amending the lease term on February 2, 2009, end on April 1, 2011.

As of June 30, 2009, future minimum payments under non-cancelable operating leases (including the amendment and extension noted above) are as follows:

	June 30, 2009 (In thousands)
Fiscal 2009	$ 232
Fiscal 2010	714
Fiscal 2011	884
Fiscal 2012	835
Fiscal 2013	835
Thereafter	1,372
Total minimum payments required	$ 4,872

Under the Company s collaboration and license agreement with Bukwang, up to an aggregate of $23.0 million in milestone payments are payable in the future if certain development, regulatory, and commercialization events occur, and which are unlikely to occur due to the Company s termination of the registration studies of clevudine. Under the Company s 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. None of these potential future payments are included in the Company s financial statements, as the payments are contingent on the achievement of milestones, which the Company has not yet achieved.

8. DEBT

On September 30, 2007, the Company entered into a Loan Agreement that allowed the Company to borrow up to $30.0 million in $10.0 million increments (Loan Agreement). The Company borrowed the first and second $10.0 million increments by signing two Secured Promissory Notes (Notes A and B) on October 5, 2007 and March 28, 2008. Notes A and B bear interest at 12%. On December 12, 2008, the Company amended the Loan Agreement and borrowed $3.3 million by signing a Secured Promissory Note (Note C). Note C bears interest at 12.5%. Notes A, B, and C are to 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. The principal monthly repayments on each of the notes begin and end as follows:

Note	Begin	End
Note A	March 1, 2009	August 1, 2011
Note B	August 1, 2009	January 1, 2012
Note C	May 1, 2010	October 1, 2012

Prepayment of the loans made pursuant to the Loan Agreement 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. Future total principal repayments of the three Notes amount to $1.2 million in fiscal 2009, $8.1 million in fiscal 2010, $9.4 million in fiscal 2011, $3.0 million in fiscal 2012, and $0.1 million in fiscal 2013. There are no additional borrowings available under the Loan Agreement.

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

In conjunction with entering into the Loan Agreement, the Company granted warrants to the lender to purchase 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

promissory notes, the relative fair value of the warrant was recorded as equity and deferred interest as the warrants became exercisable and the deferred financing costs and debt discount are being amortized over the term of the notes using the effective interest method.

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9. STOCKHOLDERS EQUITY

Common Stock - As of June 30, 2009, the Company had 100,000,000 shares of common stock authorized with a par value of $0.001, and the Company has reserved 2,688,958 and 127,248 shares of common stock for issuance upon the exercise of outstanding common stock options and outstanding warrants, respectively. Also, 212,294 shares of the Company s common stock were reserved for future grants of stock options (or other similar equity instruments) under the Company s 2007 Equity Incentive Plan as of June 30, 2009.

On May 2, 2007, the Company completed an IPO of 5,050,000 shares of its common stock 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 in fiscal 2007 and $39.1 million after deducting additional offering costs paid in fiscal 2006.

On July 21, 2008, the Company completed a registered direct public offering of 1,450,000 shares of its common stock to a select group of institutional investors at a price of $17.85 per share, resulting in $24.1 million in net proceeds after deducting placement agent fees and offering expenses. The Company intends to use the net proceeds from the sale of the shares for general corporate purposes, which may include, but are not limited to, the acquisition of assets or businesses that are complementary to its existing business, the funding of clinical trials, and the funding of in-licensing agreements for product candidates, additional technologies, or other forms of intellectual property.

On February 5, 2009, the Company completed a registered direct public offering of 4,678,000 shares of its common stock to a select group of institutional investors at a price of $9.73 per share, resulting in $43.5 million in net proceeds after deducting the placement agent fee and estimated offering expenses. The Company intends to use the net proceeds from the sale of the shares for general corporate purposes, which may include, but are not limited to, the acquisition of assets or businesses that are complementary to its existing business, the funding of clinical trials, and the funding of in-licensing agreements for product candidates, additional technologies, or other forms of intellectual property.

Warrants - In conjunction with entering into a Loan Agreement and with executing three secured promissory notes (See Note 8), the Company granted warrants to the lender to purchase 127,248 shares of the Company s Common Stock. The warrants expire seven years from the date of grant (or upon a change of control as defined in the Loan Agreement) as follows: 66,390 expire on September 30, 2014, 49,793 expire on March 28, 2015, and 11,065 expire on December 12, 2015.

10. SUBSEQUENT EVENTS

On December 30, 1998, the Company entered into an exclusive license agreement with Emory University (Emory) to pursue the research, development and commercialization of a compound known as DFC (the DFC Agreement). On August 10, 2009, the Company informed Emory University that it was terminating the DFC Agreement (and all amendments thereto) in accordance with the termination provisions of the agreement, as it no longer wanted to pursue the development of this product candidate.

On 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 called DOT (the DOT Agreement). On August 10, 2009, the Company informed RFS Pharma LLC that it was terminating the DOT Agreement (and all amendments thereto) in accordance with the termination provisions of the license agreement, as it no longer wanted to pursue the development of this product candidate.

Dr. Raymond F. Schinazi, one of the Company's significant stockholders, is the founder and majority stockholder of RFS Pharma LLC and is a named inventor of the technology licensed under the DOT Agreement.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read together with our condensed financial statements and the related notes to those condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 discovery and development of nucleoside/tide analogs as oral therapeutics for the treatment of hepatitis C virus (HCV) and, secondarily, on the development of Racivir™ for the treatment of human immunodeficiency virus (HIV). Nucleoside/tide analogs are a class of compounds which act as alternative substrates for the viral polymerase, thus inhibiting viral replication. We currently have three clinical-stage product candidates, two of which we are developing ourselves and one of which we are developing with a strategic partner. We are also advancing a series of preclinical candidates in preparation for clinical development. Our three clinical stage product candidates are:

- RG7128 (formerly R7128), a pro-drug of PSI-6130 for the treatment of HCV, which is in a Phase 2b clinical trial in combination with Pegasys® plus Copegus® through a strategic collaboration with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche);
- PSI-7851, our next generation HCV development candidate, which is in a Phase 1 clinical trial; and
- Racivir, for the treatment of HIV, which has completed a Phase 2 clinical trial.

In addition, we recently nominated PSI-352938 (PSI-938) as a development candidate for the treatment of HCV, which could potentially be used in combination with our current nucleoside/tides RG7128 or PSI-7851. PSI-938 is a proprietary purine nucleotide analog inhibitor of HCV polymerase that is being advanced into studies required for submission of an Investigational New Drug (IND) application with the FDA or equivalent foreign regulatory application.

We are continuing to research nucleoside/tide analogs (both pyrimidines and purines) with the intention of identifying additional product candidates that can potentially be used in combination with our current nucleoside/tides, RG7128 or PSI-7851, or in combination with other classes of direct acting antivirals for the treatment of HCV. We have identified two series of proprietary nucleotide prodrugs that are referred to as phosphate prodrugs because they have the ability to deliver the monophosphate forms of the compounds into infected cells, thus bypassing a rate-limiting step in the metabolic pathway to the active triphosphate form of the drug. The goal of these efforts is to identify compounds with improved potency, safety, convenience, oral bioavailability, and intrahepatic nucleoside triphosphate levels. Certain of these compounds have demonstrated exceptional *in vitro* anti-HCV activity, with EC_{90} values up to 100 times lower than PSI-6130. Early studies in animals indicate that several of these compounds can achieve concentrations of the active triphosphate form in the liver up to 1000 times higher than PSI-6130 at equivalent doses.

Clevudine is an oral, once-daily pyrimidine nucleoside analog that we had been developing for the treatment of hepatitis B virus (HBV) pursuant to our license agreement with Bukwang Pharm. Co. Ltd., or Bukwang, a South Korean pharmaceutical company. On April 20, 2009, following consultations with our independent Data Safety Monitoring Board and the FDA, we voluntarily terminated our Phase 3 studies of clevudine after we became aware of a large number of spontaneous Serious Adverse Event reports and Events of Special Interest in patients receiving clevudine as prescribed therapy for HBV in South Korea, where the drug is marketed by Bukwang under the trade name Levovir, and in Hong Kong, where clinical studies were being conducted under the sponsorship of Bukwang. Though only a small number of cases of mild to moderate myopathy or muscle weakness associated with creatine kinase elevations were reported in our clinical studies, many of the patients in South Korea and Hong Kong had longer exposures to clevudine than patients in our studies and have reported more serious myopathy than patients in our clinical trials. Given the number and severity of cases observed in South Korea and Hong Kong, we determined it is in the best interest of patients to voluntarily terminate the studies.

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HCV Background

HCV is a leading cause of chronic liver disease and liver transplants. The World Health Organization, or WHO, estimates nearly 180 million people worldwide, or approximately 3% of the world s population, are infected with HCV. About 130 million of these individuals are chronic HCV carriers who are at an increased risk of developing liver cirrhosis or liver cancer, approximately 15 million of whom are in the United States, Europe, and Japan. The Center for Disease Control and Prevention, or CDC, has reported that 4.1 million people in the United States have been infected with HCV, of whom 3.2 million are chronically infected. Of those chronically infected, the majority are undiagnosed and unaware of their status. Separately, approximately 10% of diagnosed HCV patients in the United States are treated each year.

At least six major genotypes of HCV have been identified, each with multiple subtypes. Genotypes are designated with numbers (genotypes 1-6) and subtypes with letters. HCV genotypes 1, 2, and 3 appear to have a worldwide distribution, but their prevalence varies from one geographic area to another. Genotype 1 and its subtypes (1a and 1b) are the most common genotype globally, accounting for approximately 70% of infections. Patients with genotype 2 or 3 represent approximately 25% of the worldwide chronically infected HCV population and the remaining 5% is comprised of genotypes 4 through 6. Worldwide sales of HCV drugs in 2005 were approximately $2.2 billion and are forecasted to reach more than $8.0 billion in 2015. Historical sales of HCV drugs increased as new therapies were introduced that improved the sustained viral response, or SVR, defined as the inability to detect HCV RNA in a patient s blood six months after discontinuation of therapy, with a standard test utilizing polymerase chain reaction, or PCR.

Limitations of Current HCV Infection Therapy

Globally, the current standard of care is a combination of pegylated interferon plus 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. Roche, our collaboration partner in the development of RG7128, is the market leader in sales of pegylated interferon and branded ribavirin under the brand names Pegasys® and Copegus®, respectively.

The standard of care, however, has limitations that result in low sustained virologic response rates, such as substantial side effects that render treatment intolerable and weekly injections. For example, pegylated interferon and ribavirin treated patients can have difficulties with fatigue, bone marrow suppression, anemia, and neuropsychiatric effects. In addition, genotype 1 patients typically receive 48 weeks of pegylated interferon and ribavirin and achieve an SVR rate of less than 50%, which many physicians and patients consider a low rate of success. Genotype 2 and 3 patients, treated for 24 weeks, achieve an SVR of between 60% and 80%. Pegylated interferon is given as a weekly injection, along with daily ribavirin pills. The side effects combined with the treatment regimen results in many patients not completing therapy. This illustrates the unmet medical need with regard to the currently available standard of care.

Nucleoside/tide Analogs and Other Direct Acting Antivirals for HCV

The hepatitis C virus has several viral specific enzymes that are essential for its replication, thus providing opportunities for therapeutic intervention. Many drug developers have focused on two of these enzymes: the protease (NS3) and the polymerase (NS5b) of HCV. The goal of HCV drug development is to discover and develop molecules that have a high affinity for binding to these enzymes thereby inhibiting enzymatic activity. This, in turn, inhibits viral replication and does not allow the virus to spread within the infected individual. These compound classes are referred to as protease inhibitors and polymerase inhibitors. There are two types of polymerase inhibitors and they have different mechanisms of action. One type of inhibitor binds directly to the polymerase enzyme which causes a change in its shape. This conformational change inhibits its enzymatic activity. This type of inhibitor is called a non-nucleoside polymerase inhibitor. The second type of polymerase inhibitor works by acting as alternative substrates that block the synthesis of nucleic acids, which are essential for the production of proteins needed by the virus to replicate. This type of inhibitor is called a nucleoside polymerase inhibitor.

Our efforts focus on blocking HCV nucleic acid synthesis by discovering and developing nucleoside/tide analog polymerase inhibitors. A nucleoside is a basic building block of the nucleic acids, DNA and RNA, the genetic material of all living cells and viruses. Nucleosides consist of a molecule of sugar linked to a nitrogen-containing organic ring compound. In the most important naturally occurring nucleosides, the sugar is either ribose (used to construct RNA) or deoxyribose (used to construct DNA), and the nitrogen-containing compound, referred to as the base, is either a pyrimidine (cytosine, thymine, or uracil) or a purine (adenine or guanine). A nucleoside combined with a phosphate group becomes a nucleotide. In biological systems, nucleotides are linked by enzymes, including the polymerase, in a specific order to make long, chainlike polynucleotides (DNA or RNA) of defined sequence to pass along genetic information for a specific protein, a gene, or an entire organism, a genome. A nucleoside analog is a synthetic molecule that resembles a naturally occurring nucleoside. Chemical modifications in either the sugar portion or the base portion allow these compounds to inhibit or disrupt the activity of the polymerase. When a nucleotide analog is incorporated into viral DNA or RNA during replication, the nucleotide analog acts to prevent production of new virus by blocking the complete synthesis of the new viral DNA or RNA genome.

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Experiments *in vitro* conducted by us and others have shown that nucleoside/tide analogs have consistent antiviral activity across all HCV genotypes. This characteristic of the nucleoside polymerase inhibitor class relates to its unique mechanism of action. Recent clinical studies of RG7128, as more fully described below, show comparable anti-HCV activity across genotypes 1, 2, and 3. Other classes of anti-HCV drugs (i.e., protease inhibitors and non-nucleoside polymerase inhibitors) tested clinically have shown diminished antiviral activity outside of genotype 1.

In monotherapy studies with three nucleoside analogs (including RG7128) over 14 days, viral breakthrough while on therapy did not occur. In studies of non-nucleoside polymerase and protease inhibitors in humans infected with HCV, viral breakthrough or viral rebound was seen as early as 3 to 4 days into the 14-day treatment period. The relative rapidity of the breakthrough suggests that these patients may have harbored virus that was not susceptible to therapy. With longer exposure to any direct acting antiviral (DAA), drug resistant virus will likely be selected over time. The rapidity and frequency with which this occurs may have significant consequences for patients.

Summary of Nucleoside Analogs and Their Use as Future Therapy

Conventional combination therapy for human immunodeficiency virus, or HIV usually includes a nucleoside/tide analog. Therefore, nucleoside/tide analogs are often referred to as the backbone of HIV therapy. The frequency of emergence of resistance variants in HCV inhibitor monotherapy trials suggests that combinations of antivirals with different modes of action may be required in the treatment of HCV. The combinations may not include the current standard of care, pegylated interferon and ribavirin. In consultation with experts in the field and our advisors, we believe the combination of nucleoside/tide analogs with, for example, protease inhibitors or non-nucleoside polymerase inhibitors, presents a potentially useful therapeutic regimen. These different classes of DAAs use different and complementary mechanisms of action, suggesting that they will not adversely affect or antagonize the antiviral activity of the other compound. In addition, nucleoside inhibitors have demonstrated *in vitro* the ability to suppress the resistant variants that emerge with partially-suppressive concentrations of protease inhibitors or non-nucleoside polymerase inhibitors. Clinical use of a combination of DAAs may provide improved antiviral activity across HCV genotypes and may avoid the adverse side effects that are often found with the current standard of care.

Our nucleoside/tide research and development programs are described below.

RG7128

In October 2004, we entered into a collaboration with Roche for the development and commercialization of PSI-6130 (an oral cytidine nucleoside analog inhibitor which we discovered) and its pro-drugs, including RG7128, for the treatment of HCV. A pro-drug is a chemically modified form of a molecule designed to enhance the absorption, distribution, and metabolic properties of that molecule. Roche and we initiated an adaptive Phase 1 clinical trial with RG7128 in October 2006 under an IND filing. On October 12, 2007, we were informed by the FDA that RG7128 received fast track designation. During September 2008, we completed the clinical activities of this clinical trial. Following is a review of the composition and results of this trial.

This adaptive Phase 1 clinical trial of RG7128 was a multiple center, observer-blinded, randomized, and placebo-controlled study designed to investigate the pharmacokinetics, pharmacodynamics, safety, tolerability, and food effect of RG7128 in healthy subjects and in patients chronically infected with HCV genotypes 1, 2, or 3. This trial provided antiviral potency data over 14 and 28 days in patients chronically-infected with genotype 1 HCV and following 28 days of treatment in patients chronically-infected with HCV genotypes 2 or 3 who had not responded to earlier standard of care therapy. This study included three parts:

Part 1 was a single ascending dose study conducted in 46 healthy subjects. The primary objective of Part 1 was to assess the safety, tolerability, and pharmacokinetics of RG7128 following single ascending doses under fasting conditions. The secondary objective of Part 1 was to explore the effect of food on the pharmacokinetics of RG7128. Single oral doses of RG7128 were administered to 46 healthy subjects 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 RG7128 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 other safety laboratory abnormalities of clinical significance were noted.

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No maximum tolerated dose was identified.

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 RG7128 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:

RG7128 demonstrated potent, dose-dependent antiviral activity in four patient cohorts (8 active, 2 placebo per cohort) receiving 750 mg or 1500 mg administered either QD or BID for 14 days as monotherapy. The maximum decrease in HCV RNA from baseline was demonstrated in the patient cohort that received 1500 mg BID. RG7128 demonstrated mean HCV RNA decreases of 0.9 $\log_{10}$ (87.4% reduction), 1.5 $\log_{10}$ (96.8% reduction), 2.1 $\log_{10}$ (99.2% reduction), and 2.7 $\log_{10}$ (99.8% reduction) in patients receiving 750mg QD, 1500mg QD, 750mg BID, and 1500 mg BID, respectively. Based on the mean data, all four dose groups reached nadir values at Day 15. A maximum decrease in HCV RNA of 4.2 $\log_{10}$ (99.9% reduction) was demonstrated in a patient following 14 days of monotherapy with 1500 mg BID of RG7128, a value below the level of detection, which was less than 15 International Units per milliliter (15 IU/ml).

There was no evidence of drug resistance in any dose cohort during the 14 days of dosing.

RG7128 was generally safe and well tolerated over 14 days of treatment of patients chronically infected with HCV genotype 1 who had previously failed interferon therapy. There were no serious adverse events, no adverse events requiring dose modification, and no dose-related gastrointestinal adverse events.

Part 3 was a 4-week study of RG7128 in combination with the current standard of care for chronic HCV infection, Pegasys® (pegylated interferon) plus Copegus® (ribavirin), in 81 treatment-naïve patients chronically infected with genotype 1 HCV and, additionally, in 25 prior treatment non-responders, or patients who did not achieve an SVR with previous interferon-based therapy, who were chronically infected with HCV genotypes 2 or 3. The primary objective of this study was to assess the safety, tolerability, and pharmacokinetics of RG7128 in the clinically relevant setting of combination therapy with the current standard of care for chronic HCV infection. The secondary objective of Part 3 was to evaluate the short-term change in HCV RNA. The study included three oral dose regimens of RG7128 (500 mg, 1000 mg, and 1500 mg) in patients chronically infected with HCV genotype 1 and one oral dose regimen of RG7128 (1500 mg cohort 4) in patients chronically infected with HCV genotypes 2 or 3. All four dose regimens were administered twice-daily with Pegasys plus Copegus for 4 weeks. Dose cohorts 1, 2, and 4 enrolled 25 patients, with 20 patients randomized to receive RG7128 and five patients randomized to receive placebo. Cohort 3 enrolled 31 patients, with 25 patients randomized to receive RG7128 and six patients randomized to receive placebo. After completing 4 weeks of the triple combination regimen and a follow-up period of four weeks of Pegasys plus Copegus, all patients went on to receive up to 16-40 weeks of open-label standard of care dosing under a separate protocol, for a total of 24 to 48 weeks of standard of care therapy.

Results from cohorts 1, 2, and 3 in 81 treatment-naïve patients chronically infected with HCV genotype 1 indicated:

Following 4 weeks of treatment with RG7128 500mg BID with Pegasys plus Copegus (cohort 1), patients achieved a mean 3.8 $\log_{10}$ IU/mL decrease in HCV RNA and 30% (6 of 20) achieved undetectable levels of HCV RNA (<15 IU/ml), or rapid virologic response (RVR).

Following 4 weeks of treatment with RG7128 1500mg BID with Pegasys plus Copegus (cohort 2), patients achieved a mean 5.1 $\log_{10}$ IU/mL decrease in HCV RNA and 85% (17 of 20) achieved RVR.

Following 4 weeks of treatment with RG7128 1000mg BID with Pegasys plus Copegus (cohort 3), preliminary results indicated patients achieved a mean 5.1 $\log_{10}$ IU/mL decrease in HCV RNA and 88% (22 of 25) patients achieved RVR.

Following 4 weeks of treatment with placebo with Pegasys plus Copegus, patients achieved a mean 2.9 $\log_{10}$ IU/mL decrease in HCV RNA and 18.75% (3 of 16) achieved RVR.

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For cohorts 1, 2, and 3 in treatment-naïve genotype 1 patients, safety and tolerability for the 4-week treatment period were similar for RG7128 with Pegasys plus Copegus compared to placebo with Pegasys plus Copegus. There were no serious adverse events reported during the 4-week treatment periods of triple therapy, and most of the adverse events reported were of mild to moderate intensity. Headache and fatigue were the most frequently reported adverse events in patients who received active RG7128 plus Pegasys plus Copegus, with an overall frequency of 66% and 42% reporting at least one of these events, respectively. These events were also the most frequently reported adverse events in patients who received placebo with Pegasys and Copegus. In general, the adverse events reported were consistent with the clinical safety profile for Pegasys and Copegus, including the frequency and severity of these adverse events, as well as any general body system observations. Grade 3/4 neutropenia was observed in 31% of the placebo patients and in 12% to 30% of the RG7128 patients in each active dosing cohort. Grade 3 changes in hemoglobin were observed in 19% of the placebo patients and in 31% of the RG7128 patients. There were no clinically significant changes in hepatic, renal, or other safety laboratory parameters, vital signs, or electrocardiograms. Overall, there was no clinical evidence of any major organ toxicities related to RG7128. One patient in the active treatment group discontinued the study during the 4 week treatment period due to lower gastrointestinal adverse events. At the time of study discontinuation, this patient had undetectable HCV RNA. RG7128 was generally safe and well-tolerated when administered for 4 weeks in combinations with Pegasus plus Copegus in patients with HCV genotype 1.

Results from the 1500 mg dose cohort (cohort 4) in 25 prior treatment non-responders (patients who did not achieve an SVR with previous interferon-based therapy) who were chronically infected with HCV genotypes 2 or 3 indicated:

Following 4 weeks of treatment with RG7128 1500mg BID with Pegasys plus Copegus (cohort 4), preliminary results indicated patients achieved a mean 5.0 $\log_{10}$ IU/mL decrease in HCV RNA and 90% (18 of 20) patients achieved RVR.

Following 4 weeks of treatment with placebo with Pegasys plus Copegus, patients achieved a mean 3.7 $\log_{10}$ IU/mL decrease in HCV RNA and 60.0% (3 of 5) achieved RVR.

Safety and tolerability during the 4-week treatment period were similar for RG7128 with Pegasys plus Copegus compared to placebo with Pegasys plus Copegus. There were no serious adverse events reported during the 4-week treatment period, and most of the adverse events reported were of mild to moderate intensity. One subject discontinued RG7128, Pegasys and Copegus due to protocol specified stopping criteria (not treatment-emergent), and ECG changes. Adverse events reported in cohort 4 were similar to those reported in Cohorts 1-3. Grade 3/4 neutropenia was observed in 0% of the 5 placebo patients and in 20% of the 20 RG7128 patients in the active dosing cohort. Grade 3 changes in hemoglobin were observed in 20% of the placebo patients and in 25% of the RG7128 patients. There were no clinically significant changes in hepatic, renal, or other safety laboratory parameters, vital signs, or electrocardiograms. As seen in the patients infected with HCV genotype 1, there was no clinical evidence of any major organ toxicities related to RG7128. RG7128 was generally safe and well-tolerated when administered for 4 weeks in combination with Pegasus plus Copegus in patients with HCV genotypes 2 and 3.

On April 24, 2009, Roche and we began dosing in a Phase 2b study with RG7128. The Phase 2b trial is anticipated to enroll about 400 treatment-naive, genotype-1 or genotype-4 HCV-infected patients. The trial will evaluate the dose and duration of treatment of RG7128 in combination with Pegasys plus Copegus. The primary efficacy endpoint of the trial will be the proportion of patients that achieve an SVR. Patients are expected to be enrolled into one of 5 arms:

24 weeks of total treatment, with RG7128 500mg BID in combination with Pegasys plus Copegus for 12 weeks, followed by 12 weeks of Pegasys plus Copegus

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24 weeks of total treatment, with RG7128 1000mg BID in combination with Pegasys plus Copegus for 12 weeks, followed by 12 weeks of Pegasys plus Copegus

24 weeks of total treatment, with RG7128 1000mg BID in combination with Pegasys plus Copegus for 8 weeks, followed by a further 16 weeks of Pegasys plus Copegus

48 weeks of total treatment, with RG7128 1000mg BID in combination with Pegasys plus Copegus for 12 weeks, followed by a further 36 weeks of Pegasys plus Copegus.

A control arm with only Pegasys plus Copegus for 48 weeks.

Patients in the 24 week arms will discontinue treatment at week 24 if they achieved an RVR. Patients who do not achieve an RVR will continue on the standard of care, Pegasys plus Copegus, until week 48. Patients are expected to be enrolled as two cohorts, with randomization of the second cohort, of about 300 patients, being initiated based on 12 week safety data of the first 100 patient cohort.

On April 25, 2009, Roche, InterMune, Inc., and we announced the first results from our initial study of an interferon-free regimen for the treatment of patients chronically infected with HCV. This study, INFORM-1, combined for the first time in patients two oral, direct acting antiviral drugs, RG7128 and R7227, an inhibitor of the HCV NS3/4 protease, which is being developed by InterMune, Inc., in collaboration with Roche. INFORM-1 is a randomized, double-blind, ascending dose Phase I trial. Patients receiving the combination of R7227 and RG7128 for 14 days, without pegylated interferon or ribavirin, experienced a median reduction in HCV RNA of -4.8 to -5.2 $\log_{10}$ IU/mL in the highest doses tested to date. The addition of RG7128 to R7227 resulted in sustained HCV RNA reductions over the dosing period, with approximately 63% of patients having levels of virus in their blood below the limit of the quantification of the diagnostic assay (less than 40 IU/mL). Furthermore, 25% of patients in the highest dosage groups were below the limit of detection of the virus in their blood (less than 15 IU/mL) on the 14th day of dosing.

The combination was well tolerated over 14 days, with no treatment-related serious adverse events (SAEs), dose reductions or discontinuations. Pharmacokinetic analysis confirmed that there were no drug-drug interactions between the compounds.

The companies are now exploring combinations of RG7128 dosed twice-daily at 1000mg with R7227 dosed twice-daily at 600mg and 900mg. In this expanded study, the companies also plan to explore this combination in treatment-experienced patients with HCV, or those who did not achieve SVR with a previous interferon-based treatment.

We cannot guarantee that the final results of the above study or any future study of RG7128 will corroborate earlier results, and further testing will be required to provide enough evidence regarding safety and efficacy to support a New Drug Application (NDA) filing with the FDA in the future.

PSI-7851

PSI-7851 is a pro-drug of a nucleotide analog and is currently in development for the treatment of chronic HCV infection. PSI-7851 has demonstrated *in vitro* anti-HCV activity with EC50 values of approximately 90 +/- 60 nM, which is approximately 15- to 20- fold more potent than the active metabolite of our first generation nucleoside polymerase inhibitor, PSI-6130. The half-life of the triphosphate (the biologically active form of the molecule) in primary human hepatocytes is approximately 38 hours, which suggests the possibility for once-daily dosing. Like RG7128, PSI-7851 has demonstrated *in vitro* activity against HCV genotypes 1, 2, 3 and 4.

During March 2009, we initiated a Phase 1 study for PSI-7851. As part of the Phase 1 study, we completed a single ascending dose study that assessed the safety, tolerability and pharmacokinetics of PSI-7851 in healthy subjects at doses ranging from 25mg to 800mg. Preliminary results from this study indicated there were:

No serious adverse events or discontinuations;

No dose-related adverse events;

No grade III/ IV lab abnormalities; and

No clinically significant changes in vital signs or ECGs.

During June 2009, we initiated a Phase 1 multiple ascending dose study in HCV-infected patients. Subjects were enrolled at two U.S. centers and randomized to PSI-7851 (8 per cohort) or placebo (2 per cohort). The primary objective of this study was to assess the safety, tolerability, and pharmacokinetics of PSI-7851 after once-daily dosing for three days. The secondary objective of this study was to assess antiviral activity by measuring the change in HCV RNA. Three dose cohorts of PSI-7851 (50mg QD, 100mg QD, and 200mg QD) were evaluated. Preliminary results from this study indicated:

PSI-7851 was generally safe and well tolerated across all cohorts with no discontinuations, no serious adverse events, and no dose-related trends in adverse events or laboratory abnormalities.

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PSI-7851 demonstrated potent antiviral activity with a mean HCV RNA decrease of -0.49 $\log_{10}$ IU/mL, -0.61 $\log_{10}$ IU/mL, and -1.01 $\log_{10}$ IU/mL in patients receiving 50mg QD, 100mg QD, and 200mg QD, respectively.

PSI-938

PSI-938 is a purine nucleotide analog for the treatment of chronic HCV infection. PSI-938 has demonstrated *in vitro* anti-HCV activity with EC50 values of approximately 0.17 ± 0.06 μM. More importantly this compound has demonstrated equivalent potency against the S282T mutant which has reduced sensitivity to several nucleoside inhibitors including RG7128, PSI-7851, NM283 and IDX184. The half-life of the triphosphate in primary human hepatocytes is approximately 12 hours, which suggests the possibility for once-daily dosing. During July 2009, we nominated PSI-938 as a development candidate for the treatment of HCV, which could potentially be used in combination with our current pyrimidine nucleosides/tides RG7128 or PSI-7851. This proprietary nucleotide analog polymerase inhibitor of HCV is being advanced into studies required for submission of an IND application with the FDA or equivalent foreign regulatory application. Our current plan is to submit an IND, or its foreign equivalent, during the first calendar quarter of 2010.

HCV Purine Nucleotide Research

We are continuing to research nucleotide analogs utilizing a purine base, focusing on the generation of novel product candidates that have comparable antiviral activity to PSI-7851 and a resistance profile that is complementary to both RG7128 and PSI-7851. One objective of this program is to identify and develop a proprietary combination treatment regimen, potentially consisting of a purine nucleotide analog and either RG7128 or PSI-7851. We believe such a combination may have the potential to eliminate or reduce the use of interferon for the treatment of HCV. We have identified a series of purine molecules with the above characteristics and are presently evaluating their pharmacokinetics in order to select clinical candidates.

Racivir

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 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 $\log_{10}$ (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 $\log_{10}$ decrease (68% reduction) in plasma HIV RNA.

Financial History

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 revenues from the sale of approved drugs. As of June 30, 2009, we had an accumulated deficit of $152.5 million. We expect our operating losses to continue for at least the next several years as we pursue the clinical development of PSI-7851, PSI-938, Racivir and our other product and development candidates, and as we expand our discovery and development pipeline.

We have funded our operations primarily through the sale of equity securities, payments received under collaboration agreements, borrowings under our Loan Agreement, 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 completed public offerings, our existing cash resources, borrowing under our 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 partnerships with pharmaceutical companies, public or private equity offerings, or debt financings. We will require additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. As of June 30, 2009, we had $72.7 million of cash and cash equivalents.

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Revenue

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, and research funding. We currently have one collaboration agreement with Roche for the development of PSI-6130 and its pro-drugs. 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 a $10.0 million milestone payment during the quarter ended June 30, 2009. As of June 30, 2009, we had received an aggregate of $44.4 million in payments under the Roche collaboration agreement, including research and development payments, as well as up-front license 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 RG7128, as of June 30, 2009, the maximum future development and commercialization milestone payments payable to us are $105.0 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.

We expect our revenues for the next several years to be derived primarily from payments under our 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. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then 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.

Our research activities are primarily focused on discovering and developing novel drugs to treat HCV. Our development activities are primarily focused on the development of RG7128 (in collaboration with Roche), PSI-7851, and PSI-938 for the treatment of HCV, and secondarily, on the development of Racivir for the treatment of HIV. We are responsible for all costs incurred in the clinical development of PSI-7851, PSI-938, and Racivir, as well as the research costs associated with our other internal research programs. On April 20, 2009, we voluntarily terminated our Phase 3 registration studies of clevudine for the treatment of hepatitis B virus.

Under our Roche collaboration, Roche will fund the clinical development and commercialization of RG7128. Under this collaboration, Roche reimbursed us for all of the external expenses associated with RG7128 that we were responsible for, including certain preclinical work, the IND filing, and the proof-of-concept clinical trial. During December 2008, we transferred the IND application for RG7128 to Roche. Roche will continue to fund all of the expenses of, and be responsible for, other preclinical studies and future clinical development of RG7128 in the territories licensed to Roche. We and Roche will continue to jointly oversee all development and marketing activities of RG7128 in the territories licensed to Roche. Roche received a license only to PSI-6130 and its pro-drugs, including RG7128.

We use our internal research and development resources, including our employees and discovery infrastructure, across various projects. Our related internal expenses are not attributable to a specific project, but are directed to broadly applicable research activities. Accordingly, we do not account for our internal research and development expenses on a project basis. We use external service providers to manufacture our product candidates for clinical trials and for the substantial majority of our preclinical and clinical development work. We have tracked some of these external research and development expenses on a project basis. To the extent that expenses are not attributable to a specific project, they are included in one of the unattributed expenses in the table below.

The following table summarizes our research and development expenses for our current development projects, as well as clevudine, for the three and nine months ended June 30, 2009 and 2008.

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	Three Months Ended June 30,		Nine Months Ended June 30,		Cumulative Project Costs
	2009	2008	2009	2008	
	(In thousands)				
Expenses attributed to projects:					
Clevudine Studies	$ 7,098	$ 7,465	$ 23,437	$ 19,452	$ 68,333
Preclinical PSI-7851 Studies	279	124	1,122	124	1,246
Phase 1 PSI-7851 Studies	1,622		2,930		2,930
Phase 2 Racivir Studies	5	50	39	203	4,244
Total attributed expenses	9,004	7,639	27,528	19,779	
Unattributed expenses					
Salaries and related personnel expenses	2,043	1,734	6,094	4,609	
Non-cash stock compensation expense	580	436	1,945	1,405	
Legal expenses associated with patents	141	478	1,051	1,115	
Preclinical studies and new drug discovery services	901	463	1,889	1,341	
Drug and laboratory supplies	261	243	747	971	
Consulting expense	34	115	84	332	
Facility and other expenses	713	392	2,056	1,489	
Total unattributed expenses	4,673	3,861	13,866	11,262	
Total research and development expenses	$ 13,677	$ 11,500	$ 41,394	$ 31,041	

We will continue to 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. We do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization for any of our 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. For example, product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer than anticipated to progress through clinical trials, may fail to receive necessary regulatory approvals, or may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality. The lengthy process of seeking FDA and other regulatory agency 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 effort and financial condition. Because of these and other risks and uncertainties, we cannot predict when or whether we will successfully complete the development of any of our product candidates or the ultimate product development cost or whether we will obtain any approval required by the FDA or other regulatory agencies 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 are in the process of terminating our Phase 3 registration studies of clevudine and expect our level of expenses for these studies to be lower during the quarters ending September 30, 2009 and December 31, 2009 than the level of expenses during the quarter ended June 30, 2009. We anticipate having this termination process and the related expenses complete by the end of the quarter ending December 31, 2009.

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.

Results of Operations

Three and Nine Months Ended June 30, 2009 and 2008

Revenues. Revenues increased to $10.5 million during the quarter ended June 30, 2009 from $0.5 million during the quarter ended June 30, 2008. Revenues during the quarter ended June 30, 2009 include a $10.0 million milestone payment received from Roche for initiating a Phase 2b study of RG7128. Our performance obligations relating to the $10.0 million milestone payment consisted of successfully completing a Phase 1 study of RG7128, which led to the initiation of the Phase

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2b study for RG7128 that triggered the milestone payment. Also included in revenues during the three months ended June 30, 2009 and 2008 are $0.5 million of amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue.

Revenues increased to $12.9 million during the nine months ended June 30, 2009 from $1.4 million during the nine months ended June 30, 2008. Revenues during the nine months ended June 30, 2009 include a $10.0 million milestone payment from Roche for initiating a Phase 2b study of RG7128 and $1.4 million of research and development payments from Roche for activities related to holding the IND application for RG7128, for which we have no continuing performance obligations. Revenues during each period also include $1.4 million of amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Cash received/receivable	$ 10,037	$	$ 11,475	$
Deferred				
Amortization	464	464	1,393	1,393
Revenues	$ 10,501	$ 464	$ 12,868	$ 1,393

Research and Development Expenses. Research and development expenses increased to $13.7 million during the quarter ended June 30, 2009 from $11.5 million in the quarter ended June 30, 2008. This increase of $2.2 million consists primarily of a $1.8 million increase for preclinical and clinical trial costs for our HCV product candidate, PSI-7851, an increase in compensation expenses of $0.4 million ($0.1 million of which was non-cash stock compensation expense) resulting from an increase in headcount, and an increase of $0.3 million in preclinical study costs for our HCV product candidate, PSI-938. Partially offsetting these increases was a decrease of $0.3 million in Phase 3 registration clinical trial expenses for clevudine. On April 20, 2009, we voluntarily terminated our Phase 3 registration studies of clevudine for the treatment of hepatitis B virus. We expect our level of expenses for these terminated studies to be lower during the quarters ending September 30, 2009 and December 31, 2009 than the level of expenses during the quarter ended June 30, 2009. We anticipate having this termination process and the related expenses complete by the end of the quarter ending December 31, 2009.

Research and development expenses increased to $41.4 million during the nine months ended June 30, 2009 from $31.0 million in the nine months ended June 30, 2008. This increase of $10.4 million consists primarily of an increase of $4.0 million in Phase 3 registration clinical trial expenses for clevudine, a $3.9 million increase in preclinical and clinical trial costs for our HCV product candidate, PSI-7851, an increase in compensation expenses of $2.0 million ($0.5 million of which was non-cash stock compensation expense) resulting from an increase in headcount, an increase of $0.4 million in preclinical study costs for our HCV product candidate, PSI-938, and an increase of $0.1 million in miscellaneous research and development expenses.

General and Administrative Expenses. General and administrative expenses were $3.0 million during the quarter ended June 30, 2009, a decrease of $0.5 million from $3.5 million in the quarter ended June 30, 2008. The net decrease of $0.5 million was due primarily to decreases in audit and related fees of $0.2 million, travel expenses of $0.2 million, legal fees of $0.1 million, marketing expenses of $0.1 million, and miscellaneous administrative expenses of $0.2 million. Partially offsetting these decreases was an increase in compensation expense of $0.3 million ($0.2 million of which was non-cash stock compensation expense).

General and administrative expenses were $10.0 million during the nine months ended June 30, 2009, an increase of $0.1 million from $9.9 million in the nine months ended June 30, 2008. The net increase of $0.1 million was due primarily to increases in compensation expense of $1.5 million ($0.6 million of which was non-cash stock compensation expense) and marketing expense of $0.2 million, that were mostly offset by decreases in legal fees of $0.5 million, audit and related expenses of $0.4 million, travel expenses of $0.4 million, insurance expenses of $0.2 million, and miscellaneous administrative expenses of $0.1 million.

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Investment Income. Investment income decreased to $0.0 million during the quarter ended June 30, 2009 from $0.2 million in the quarter ended June 30, 2008, and decreased to $0.2 million during the nine months ended June 30, 2009 from $1.7 million in the nine months ended June 30, 2008. The decreases were due to lower rates of return on the average invested cash balances.

Interest Expense. Interest expense increased to $0.8 million during the quarter ended June 30, 2009 from $0.7 million in the quarter ended June 30, 2008, and increased to $2.4 million during the nine months ended June 30, 2009 from $1.5 million in the nine months ending June 30, 2008. The increases in interest expense were due to interest on additional borrowings of long-term debt of $13.3 million ($10.0 million on March 28, 2008 and $3.3 million on December 12, 2008).

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our collaboration agreements, and borrowings under our Loan Agreement. Since our inception, we have raised approximately $173.5 million in net proceeds from sales of our equity securities, including $43.5 million from our common stock offering completed on February 5, 2009. During the nine months ended June 30, 2009, we borrowed $3.3 million in addition to the previously borrowed $20.0 million under our Loan Agreement entered into on September 30, 2007. At June 30, 2009, we held $72.7 million in cash and cash equivalents and have invested substantially all of our available cash and cash equivalents in a mutual fund, which invests in short-term U.S. Treasury and Agency Obligations, or in a money fund account.

Net cash used in operating activities was $36.5 million during the nine months ended June 30, 2009 compared to $39.3 million during the nine months ended June 30, 2008. The $2.8 million decrease in net cash used in operating activities during the nine months ended June 30, 2009, as compared to the same period a year ago was due primarily to favorable changes in our working capital.

Net cash provided by investing activities of $0.3 million during the nine months ended June 30, 2009 resulted from the maturity of $0.5 million of short-term investments that was partially offset by $0.2 million of purchases of equipment and leasehold improvements. Net cash used in investing activities of $0.5 million during the nine months ended June 30, 2008 was comprised of $0.8 million for the purchase of equipment and leasehold improvements partially offset by $0.3 million resulting from the maturity of short-term investments.

Net cash provided by financing activities was $45.8 million during the nine months ended June 30, 2009, compared to $22.1 million during the nine months ended June 30, 2008. The net cash provided by financing activities during the nine months ended June 30, 2009 includes $43.4 million in net proceeds from the issuance of common stock completed on February 5, 2009, borrowings of long-term debt of $3.3 million, and proceeds from the exercise of stock options of $0.6 million, that were partially offset by principal payments on long-term debt and capital lease obligations of $1.5 million. The net cash provided by financing activities during the nine months ended June 30, 2008 includes borrowings of long-term debt of $20.0 million, along with proceeds from the exercise of stock options of $2.2 million that were partially offset by principal payments on capital lease obligations of $0.1 million.

On September 30, 2007, we entered into a Loan Agreement that allowed us to borrow up to $30.0 million in $10.0 million increments (Loan Agreement). We borrowed the first and second $10.0 million increments by signing two Secured Promissory Notes (Notes A and B) on October 5, 2007 and March 28, 2008. Notes A and B bear interest at 12%. On December 12, 2008, we amended the Loan Agreement and borrowed $3.3 million by signing a Secured Promissory Note (Note C). Note C bears interest at 12.5%. Notes A, B, and C are to 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. The principal monthly repayments on each of the notes begin and end as follows:

Note	Begin	End
Note A	March 1, 2009	August 1, 2011
Note B	August 1, 2009	January 1, 2012
Note C	May 1, 2010	October 1, 2012

Prepayment of the loans made pursuant to the Loan Agreement is subject to penalty and substantially all of our tangible and intangible assets (except for intellectual property) are collateral for the Loan Agreement. Future total principal repayments of the three Notes amount to $1.2 million in fiscal 2009, $8.1 million in fiscal 2010, $9.4 million in fiscal 2011, $3.0 million in fiscal 2012, and $0.1 million in fiscal 2013. There are no additional borrowings available under the Loan Agreement.

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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 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.

Developing drugs, conducting clinical trials, and commercializing products are expensive and we will need to raise additional funds to achieve our strategic objectives. Although we believe our existing cash resources as of June 30, 2009 together with anticipated payments under our existing collaboration agreement will be sufficient to fund our projected cash requirements for the next 12 months, we will require additional financing in the future to complete our clinical trials for PSI-7851 and PSI-938, to fund our portion, if any, of the cost of clinical trials for RG7128 completed outside of the territories licensed by Roche, and to 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 or intellectual property. We cannot be certain that additional funding will be available in sufficient amounts 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. On June 2, 2009, we entered into an extension and modification of the lease, extending the lease for five years, from May 22, 2010 through May 22, 2015. In April 2007, we entered into a lease for office space in Durham, North Carolina that, after amending the lease on February 2, 2009, ends on April 30, 2011. We executed three secured promissory notes totaling $23.3 million; $10.0 million in October 2007 and March 2008, and $3.3 million in December 2008. The secured promissory notes require payments of interest only for the first 15 months followed by 30 equal monthly payments of principal and interest. As of June 30, 2009, future payments under the Loan Agreement, minimum future payments under non-cancellable operating leases (including the lease extension noted above) are as follows:

		Payments Due By Period			
	Total	Less than 1 year	1-3 Years	4-5 Years	After 5 Years
			(In thousands)		
Debt obligations					
Debt maturities	$ 21,867	$ 7,012	$ 14,349	$ 506	$
Contractual interest	3,655	2,085	1,557	13	
Capital lease obligations					
Debt maturities					
Contractual interest					
Operating leases	4,872	855	2,436	1,581	
Purchase obligations					
Total contractual obligations	$ 30,394	$ 9,952	$ 18,342	$ 2,100	$

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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. Under our collaboration and license agreement with Bukwang for clevudine, up to an aggregate of $23.0 million in milestone payments are payable in the future if certain development, regulatory and commercialization events occur, and which are unlikely to occur due to our termination of the registration studies of clevudine. 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 generally accepted accounting principles 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 (unaudited) included in this Quarterly Report on Form 10-Q; 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 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 collectability is reasonably assured. For agreements containing multiple elements, we follow the guidance in the Financial Accounting Standards Board s (FASB) Emerging Issue Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF No. 00-21). In accordance with SAB No. 104 and EITF No. 00-21, the elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator and whether there is objective and reliable evidence of the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units either on the basis of each unit's fair value or using the residual method and the applicable revenue recognition criteria is applied to each of the separate units.

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/or development payments, and milestone payments.

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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 revenues 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 revenues are recognized. Research and/or development payments are recognized as revenues as the related research and/or development activities are performed and when we have no continuing performance obligations related to the research and development payment received.

We recognize revenues 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 related to the achievement of the milestone earned. 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 revenues 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 record 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 PSI-7851 advance, our estimated accruals for clinical and research services will be more material to our operations in future periods.

Stock-based Compensation

We account for stock-based employee compensation arrangements in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS 123R). 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). 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. 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:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2009(1)	2008	2009	2008
Risk free interest rate		3.27%	3.19%	4.09%
Expected dividend yield		0.0%	0.0%	0.0%

Expected lives (years)	6.11	5.98	6.05
Expected volatility	54.26%	54.39%	57.25%
Weighted-average fair value of options granted	$ 7.81	$ 9.97	$ 8.03

(1) No stock options were granted during the three months ended June 30, 2009.

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Recently Adopted Accounting Pronouncements

In May 2009, the FASB issued Statement of Financial Accounting Standards No. 165, *Subsequent Events* (Statement 165). Statement 165 incorporates the accounting and disclosure requirements for subsequent events into U.S. generally accepted accounting principles. Statement 165 also introduces new terminology, defines a date through which management must evaluate subsequent events, and lists the circumstances under which an entity must recognize and disclose events or transactions occurring after the balance-sheet date. We adopted Statement 165 as of June 30, 2009, which was the required effective date, and its adoption did not affect our financial statements, other than the disclosures required by it, which can be found in Note 1 Description of Business and Basis of Presentation.

Recently Issued Accounting Pronouncements

In December 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The adoption of EITF 07-1 is not expected to have a material impact on us.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations* (SFAS 141R), which changes the accounting for business acquisitions. SFAS 141R requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard will, among other things, impact the determination of acquisition-date fair value of consideration paid in a business combination (including contingent consideration); exclude transaction costs from acquisition accounting; and change accounting practices for acquired contingencies, acquisition-related restructuring costs, in-process research and development, indemnification assets, and tax benefits. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of SFAS 141R is not expected to have a material impact on us.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*, (SFAS 160), which establishes new standards governing the accounting for and reporting of noncontrolling interests (NCIs) in partially owned consolidated subsidiaries and the loss of control of subsidiaries. Certain provisions of this standard indicate, among other things, that NCIs (previously referred to as minority interests) be treated as a separate component of equity, not as a liability; that increases and decrease in the parent s ownership interest that leave control intact be treated as equity transactions, rather than as step acquisitions or dilution gains or losses; and that losses of a partially owned consolidated subsidiary be allocated to the NCI even when such allocation might result in a deficit balance. This standard also requires changes to certain presentation and disclosure requirements. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The provisions of the standard are to be applied to all NCIs prospectively, except for the presentation and disclosure requirements, which are to be applied retrospectively to all periods presented. The adoption of SFAS 160 is not expected to have a material impact on us.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Regarding our exposure to interest rate risk, there have been no material changes to the information in our Annual Report on Form 10-K filed with the SEC on December 11, 2008. In summary, 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 maximize yields without significantly increasing risk. To achieve this objective, we invest in highly liquid mutual and money market funds, and high quality marketable debt instruments of corporations, government agencies and financial institutions with maturities of less than two years. In addition, the $20.0 million we borrowed during fiscal 2008 has a fixed interest rate of 12% and the $3.3 million we borrowed during the nine months ended June 30, 2009 has a fixed interest rate of 12.5%.

Foreign Currency Exchange Rate Risk

Regarding our exposure to foreign currency exchange rate risk, there have been no material changes to the information in our Annual Report on Form 10-K filed with the SEC on December 11, 2008. In summary, 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 our 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 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure 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 Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (Exchange Act), as of June 30, 2009. Based on that evaluation, management 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.

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.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2009 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 28, 2009, Emory University and University of Georgia Research Foundation, Inc. (Claimants) filed a Demand for Arbitration and Relief (the Demand) with the American Arbitration Association in Atlanta, Georgia (the Emory Arbitration), claiming certain payments and seeking specific performance under the Company s January 8, 2004 license agreement with Claimants (the Emory License).

The Demand alleges that payments Pharmasset has received under the Roche collaboration agreement are subject to the Emory License and that Pharmasset has not paid fees to Claimants based on such payments. In addition, the Demand alleges that Pharmasset has not complied with certain terms and conditions of the Emory License and that other Pharmasset product candidates are, or will be, covered by the Emory License. The Demand requests, among other things, specific performance of the Emory License, including the payment of license fees related to past payments received by Pharmasset. The Company s response to the Demand is scheduled to be filed on August 14, 2009. The Company denies these allegations and intends to vigorously defend itself against the Demand.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors discussed in Part I, Item 1A. Risk Factors, in our Annual Report on Form 10-K for the year ended September 30, 2008 (Form 10-K). You should carefully consider the risks described in our Form 10-K, which could materially affect our business, financial condition or future results. The risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, and/or operating results. If any of the risks actually occur, our business, financial condition, and/or results of operations could be negatively affected.

ITEM 6. EXHIBITS

Exhibit

Number	**Description**
10.1(1)	First Extension and Modification of Lease by and between 300 CRA LLC and Pharmasset, Inc. dated June 2, 2009
31.1*	Rule 13a-14(a)/15d-14(a) Certification
31.2*	Rule 13a-14(a)/15d-14(a) Certification
32*	Section 1350 Certifications

* - Filed herewith.

(1) Incorporated by reference to the Current Report on Form 8-K filed on June 17, 2009

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SIGNATURES

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

PHARMASSET, INC.

Date: August 10, 2009

By: /s/ Kurt Leutzinger
Kurt Leutzinger
Chief Financial Officer
(duly authorized officer and principal financial officer)

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EXHIBIT INDEX

Exhibit Number	Description
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32	Section 1350 Certifications