

Pharmasset Inc
Form 10-Q
August 14, 2008

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, 2008**

or

**“ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____**

Commission File Number: 1-33428

Pharmasset, Inc.

(Exact name of registrant as specified in its charter)

Edgar Filing: Pharmasset Inc - Form 10-Q

DELAWARE (State or other jurisdiction of incorporation or organization)	98-0406340 (IRS Employer Identification No.)
303-A College Road East Princeton, New Jersey (Address of registrant's principal executive offices)	08540 (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. ☒ 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 ☐

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 ☒

The number of shares of the registrant's common stock, \$0.001 par value, outstanding as of July 31, 2008 was 23,229,669.

PHARMASSET, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2008

INDEX

	Page
PART 1. <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	4
<u>Condensed Balance Sheets as of June 30, 2008 (Unaudited) and September 30, 2007</u>	4
<u>Condensed Statements of Operations and Comprehensive Net Loss for the Three and Nine Months Ended June 30, 2008 (Unaudited) and 2007 (Unaudited)</u>	5
<u>Condensed Statements of Cash Flows for the Nine Months Ended June 30, 2008 (Unaudited) and 2007 (Unaudited)</u>	6
<u>Notes to Financial Statements (Unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
Item 4. <u>Controls and Procedures</u>	32
PART II. <u>OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	33
Item 1A. <u>Risk Factors</u>	33
Item 6. <u>Exhibits</u>	33
<u>SIGNATURES</u>	34

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, in particular with respect to the clinical trial results and regulatory approval of clevedine, Racivir®, and R7128;

the initiation, completion or success of preclinical studies and clinical trials;

clinical trial initiation and completion dates, anticipated regulatory filing dates and regulatory approval for our product candidates;

the commercialization of our product candidates;

our collaboration agreement with F. Hoffmann-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;

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, 2007 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.

PART 1. FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****PHARMASSET, INC.****CONDENSED BALANCE SHEETS**

	As of June 30, 2008 (unaudited)	As of September 30, 2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 51,048,837	\$ 68,745,694
Short-term investments	987,126	1,252,113
Amounts due under collaborative agreements	1,863,843	919,110
Prepaid expenses and other assets	1,189,002	783,311
Total current assets	55,088,808	71,700,228
EQUIPMENT AND LEASEHOLD IMPROVEMENTS:		
Laboratory, office furniture and equipment	3,240,023	2,462,647
Leasehold improvements	1,836,553	1,836,553
	5,076,576	4,299,200
Less accumulated depreciation and amortization	(2,185,498)	(1,437,080)
Total equipment and leasehold improvements, net	2,891,078	2,862,120
OTHER ASSETS	249,875	1,282,051
TOTAL	\$ 58,229,761	\$ 75,844,399
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 1,167,289	\$
Current portion of capital lease obligation	82,558	159,440
Accounts payable	1,314,299	3,281,600
Accrued expenses	6,538,180	5,513,407
Deferred rent	124,462	124,462
Deferred revenue	1,857,136	1,857,136
Total current liabilities	11,083,924	10,936,045
DEFERRED RENT	111,164	204,256
NON CURRENT PORTION OF CAPITAL LEASE OBLIGATION		41,641
DEFERRED REVENUE	4,333,257	5,726,131
LONG-TERM DEBT, net	17,899,100	
Total liabilities	33,427,445	16,908,073
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Common Stock, \$0.001 par value, 100,000,000 shares authorized, 21,751,503 and 21,232,991 shares issued and outstanding at June 30, 2008 (unaudited) and September 30, 2007, respectively	21,752	21,233

Edgar Filing: Pharmasset Inc - Form 10-Q

Warrants to purchase 116,183 shares of common stock for \$12.05 per share, with 66,390 exercisable starting September 30, 2007, and 49,793 shares exercisable starting March 28, 2008 (unaudited)	1,140,114	526,720
Additional paid-in capital	120,124,752	115,518,201
Accumulated other comprehensive (loss) income	(12,664)	4,405
Accumulated deficit	(96,471,638)	(57,134,233)
Total stockholders' equity	24,802,316	58,936,326
TOTAL	\$ 58,229,761	\$ 75,844,399

See notes to financial statements.

PHARMASSET, INC.**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE NET LOSS****(UNAUDITED)**

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2008	2007	2008	2007
REVENUES:	\$ 464,291	\$ 464,291	\$ 1,392,874	\$ 14,045,167
COSTS AND EXPENSES:				
Research and development	11,499,843	4,426,252	31,040,683	12,096,962
General and administrative	3,473,635	2,640,655	9,902,453	6,892,707
Total costs and expenses	14,973,478	7,066,907	40,943,136	18,989,669
OPERATING LOSS	(14,509,187)	(6,602,616)	(39,550,262)	(4,944,502)
INVESTMENT INCOME	216,287	744,938	1,697,737	1,544,018
INTEREST EXPENSE	(735,543)	(4,435)	(1,484,880)	(11,369)
LOSS BEFORE INCOME TAXES	(15,028,443)	(5,862,113)	(39,337,405)	(3,411,853)
PROVISION FOR INCOME TAXES				
NET LOSS	(15,028,443)	(5,862,113)	(39,337,405)	(3,411,853)
REDEEMABLE PREFERRED STOCK ACCRETION		1,204,653		1,775,684
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (15,028,443)	\$ (7,066,766)	\$ (39,337,405)	\$ (5,187,537)
COMPREHENSIVE NET LOSS:				
NET LOSS	\$ (15,028,443)	\$ (5,862,113)	\$ (39,337,405)	\$ (3,411,853)
UNREALIZED GAIN (LOSS) ON AVAILABLE-FOR-SALE INVESTMENTS	12,503		(17,069)	2,425
COMPREHENSIVE NET LOSS	\$ (15,015,940)	\$ (5,862,113)	\$ (39,354,474)	\$ (3,409,428)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER SHARE:				
BASIC	\$ (0.69)	\$ (0.40)	\$ (1.84)	\$ (0.40)
DILUTED	\$ (0.69)	\$ (0.40)	\$ (1.84)	\$ (0.40)
WEIGHTED AVERAGE SHARES OUTSTANDING:				
BASIC	21,635,205	17,558,466	21,425,577	12,919,580
DILUTED	21,635,205	17,558,466	21,425,577	12,919,580

See notes to financial statements.

PHARMASSET, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended June 30,	
	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (39,337,405)	\$ (3,411,853)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	748,418	662,109
Non-cash stock compensation	2,398,198	1,931,010
Non-cash interest expense	273,701	
Changes in operating assets and liabilities:		
Amounts due under collaborative agreements, prepaid expenses and other assets	(1,081,949)	(1,390,580)
Accounts payable	(1,967,301)	(216,834)
Accrued expenses	1,192,474	1,130,877
Deferred rent	(93,092)	(93,091)
Deferred revenue	(1,392,874)	(1,120,553)
Net cash used in operating activities	(39,259,830)	(2,508,915)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturity of short-term investment	250,000	
Purchase of equipment and leasehold improvements	(777,376)	(287,110)
Net cash used in investing activities	(527,376)	(287,110)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowings of long-term debt	20,000,000	
Proceeds from exercise of stock options	2,208,872	981,833
Net proceeds from initial public offering		40,962,382
Principal payments on capital lease obligations	(118,523)	(74,298)
Net cash provided by financing activities	22,090,349	41,869,917
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(17,696,857)	39,073,892
CASH AND CASH EQUIVALENTS Beginning of period	68,745,694	26,182,316
CASH AND CASH EQUIVALENTS End of period	\$ 51,048,837	\$ 65,256,208
SUPPLEMENTAL DISCLOSURES:		
Cash paid during the period for:		
Interest	\$ 1,211,179	\$ 11,369
Noncash transactions:		
Accretion of redeemable convertible preferred stock to redemption value	\$	\$ 1,775,684
Accretion of redeemable common stock to redemption value	\$	\$ 729,509
Fixed assets purchased on account	\$	\$ 8,682
Offering costs unpaid at end of period	\$	\$ 316,407
Unrealized (loss) gain on available-for-sale investments	\$ (17,069)	\$ 2,425
	\$	\$ 21,325,000

Edgar Filing: Pharmasset Inc - Form 10-Q

Conversion of redeemable convertible preferred stock, redeemable common stock, and convertible preferred stock into common stock

Exercise and conversion of Series D-1 warrants into common stock	\$	\$ 5,411,932
Capital lease obligations incurred	\$	\$ 313,520
Dividends paid on the Series D preferred stock in the form of common stock	\$	\$ 1,186,871
Warrants granted in connection with debt financing	\$ 613,394	\$
See notes to financial statements.		

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 development of oral therapeutics for the treatment of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). The Company currently has three product candidates: clevudine, in Phase 3 registration clinical trials for the treatment of HBV; R7128, a pro-drug of PSI-6130, in a 4-week Phase 1 clinical trial for the treatment of HCV through a collaboration with F. Hoffmann-La Roche Ltd and Hoffmann- La Roche Inc. (collectively, Roche); and Racivir, which has completed a Phase 2 clinical trial for the treatment of HIV. The Company is also continuing to evaluate the status of dextelvucitabine, or DFC, for the treatment of HIV following the completion of a Phase 2b clinical trial. The Company has also identified proprietary, next generation HCV development candidates that are being evaluated for advancement into clinical development. One of these compounds, PSI-7851, was recently nominated as a lead candidate and is being advanced into Good Laboratory Practices (GLP) toxicity studies required for submission of an IND application with the FDA or an equivalent foreign regulatory filing. The Company's research and development efforts focus on a class of compounds known as nucleoside analogs, which act to inhibit the natural enzymes required for viral replication. The Company is applying its expertise in nucleoside chemistry to the discovery and development of additional antiviral therapeutics. The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, product development risks, protection of proprietary intellectual property, compliance with government regulations, dependence on key personnel, the need to obtain additional financing, uncertainty of market acceptance of products, and product liability. (See Part II, Item 1A. Risk Factors for additional information).

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

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, 2007 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on December 31, 2007.

Other than the adoption of the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* (FIN 48) during the three months ended December 31, 2007, there have been no significant changes in the Company's accounting policies during the nine months ended June 30, 2008 as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended September 30, 2007.

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 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 over 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.

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 The carrying amounts of cash and cash equivalents, amounts due under collaborative agreements, accounts payable, and accrued expenses approximate fair value because of their short-term nature. Investments at June 30, 2008 and September 30, 2007 are classified as available-for-sale securities and carried at fair market value. The fair value of the Company's debt as of June 30, 2008 approximates the carrying value. The fair value is based on management's estimate of current rates available to the Company for similar debt with the same remaining maturity.

Concentrations of Credit Risk, Suppliers and Revenues The Company's financial instruments that potentially subject it to concentrations of credit risk are cash and cash equivalents, and investments. The Company invests cash that is not currently being used in operations in accordance with its investment policy. The policy allows for the purchase of low-risk, investment grade debt securities issued by the United States government and very highly-rated banks and corporations, subject to certain concentration limits. The policy allows for maturities that are not longer than two years for individual securities and an average of one year for the portfolio as a whole.

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

For the nine months ended June 30, 2007 the Company derived substantially all of its revenues from one customer, and during the three months ended June 30, 2008 and 2007, and nine months ended June 30, 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 No. 104, Revenue Recognition, or SAB 104. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectibility is reasonably assured. For agreements containing multiple elements, the company follows the guidance in Financial Accounting Standards Board, or FASB, Emerging Issue Task Force, or EITF, Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, or 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 are applied to each of the separate units.

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

Where the Company has continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as 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. Payments for research funding are recognized as revenues as the related research activities are performed.

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. 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.

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 costs of intangibles that are purchased from others for use in research and development activities, such as in-licensed product candidates, that have no alternative future uses. Research and development expenses are included in operating expenses when incurred. Reimbursements received from the Company's collaborators for third-party research and development expenses incurred by the Company on their behalf are recorded as a contra-expense. Amounts due from collaborators for reimbursement of research and development expenses are recorded on the balance sheets as Amounts due under collaborative agreements.

Stock-Based Compensation On October 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS 123R). This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and its related implementation guidance. SFAS 123R requires companies to recognize stock compensation expense for awards of equity instruments to employees based on grant-date fair value of those awards (with limited exceptions). The Company adopted SFAS 123R using the modified prospective method, which results in recognition of compensation expense for all share-based awards granted or modified after October 1, 2006 as well as all unvested awards outstanding at the date of adoption. 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, relating to share-based payment, (SAB 107) issued by the SEC. The volatility of the stock prices of these

companies have increased in the aggregate over the periods presented, therefore the expected volatility calculated for the Company has increased. The assumptions used and weighted-average information for employee and director grants for the three and nine months ended June 30, 2008 and 2007, are as follows:

Employee and Director Grants:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2008	2007	2008	2007
Risk free interest rate	3.27%	4.60%	4.09%	4.55%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected lives (years)	6.11	5.31	6.05	5.93
Expected volatility	54.26%	55.07%	57.25%	54.33%
Weighted-average fair value of options granted	\$ 7.81	\$ 4.65	\$ 8.03	\$ 2.73

During the quarter ended June 30, 2008, the Company granted 61,000 stock options at fair values ranging from \$7.71 to \$10.23 per share, risk free interest rates ranging from 3.25% to 3.54%, an expected volatility of the market price of the Company's common stock ranging from 53.06% to 54.30%, a dividend yield of 0%, an expected life of 6.11 years, and forfeiture rates of 11.03% for employees.

As a result of applying the requirements of SFAS 123R, the Company recorded non-cash stock-based compensation expense of \$581,291, or \$0.03 per share, and \$607,885, or \$0.03 per share, during the three months ended June 30, 2008 and 2007, respectively, and \$1,902,665, or \$0.09 per share, and \$1,374,845, or \$0.11 per (diluted) share, during the nine months ended June 30, 2008 and 2007, respectively. As of June 30, 2008, total unrecognized stock-based compensation expense resulting from the adoption of SFAS 123R was approximately \$5,708,320, which has a weighted-average period of approximately 1.63 years to be recognized.

Preferred Stock Accretion Prior to the conversion of all of the Company's redeemable convertible preferred stock into common stock on May 2, 2007 when the Company completed an initial public offering (IPO) of its common stock, the Company used the effective interest method to increase the carrying amount of its redeemable convertible preferred stock on each balance sheet date, so that the carrying amount, initially the fair value of the security on the date of issue, would equal the redemption amount at the earliest redemption date. These periodic increases to the carrying amount also used the effective interest method to include amounts representing dividends not currently declared or paid, but which would have been payable under the redemption features had they been still accrued and unpaid at the redemption date.

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) attributable to common stockholders 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) attributable to common stockholders by the weighted average number of common shares and other dilutive securities outstanding during the period. Dilutive potential common shares resulting from the assumed exercise of outstanding stock options and warrants are determined based on the treasury stock method.

Edgar Filing: Pharmasset Inc - Form 10-Q

The following table provides each of the inputs to the calculations of basic and diluted net loss attributable to common stockholders per share for the three and nine months ended June 30, 2008 and 2007.

	Three Months Ended June 30, 2008		Nine Months Ended June 30, 2007	
(In thousands, except per share amounts)				
Numerator:				
Net loss attributable to common stockholders	\$ (15,028)	\$ (7,067)	\$ (39,337)	\$ (5,188)
Denominator:				
Weighted average common shares outstanding used in calculation of basic net loss per share	21,635	17,558	21,426	12,920
Effect of dilutive securities:				
Common stock options				
Common stock warrants				
Preferred stock				
Preferred stock warrants				
Weighted average common shares outstanding used in calculation of diluted net loss per share	21,635	17,558	21,426	12,920
Net loss attributable to common stockholders per share:				
Basic	\$ (0.69)	\$ (0.40)	\$ (1.84)	\$ (0.40)
Diluted	\$ (0.69)	\$ (0.40)	\$ (1.84)	\$ (0.40)

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 attributable to common stockholders per share, as their effect would have been anti-dilutive.

	Three and Nine Months Ended June 30, 2008		2007
	(In thousands)		
Preferred stock			
Preferred stock warrants			
Common stock warrants		116	
Options to purchase common stock		2,366	2,442
Total		2,482	2,442

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

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

On February 15, 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and

Edgar Filing: Pharmasset Inc - Form 10-Q

liabilities. SFAS 159 will be effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact this standard would have on its financial statements.

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

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 Company is currently evaluating the requirements of EITF 07-1; however it does not believe that its adoption will have a significant impact on its financial statements.

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 Company has not yet determined the impact SFAS 141R may have on its results of operations or financial position.

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 Company has not yet determined the impact SFAS 160 may have on its results of operations or financial position.

3. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of June 30, 2008	As of September 30, 2007
	(In thousands)	
Accrued compensation	\$ 894	\$ 790
Accrued accounting fees	45	69
Accrued legal fees	899	700
Accrued license fees		1,195
Accrued clinical trial expenses	4,120	2,309
Other accrued expenses	580	450
	\$ 6,538	\$ 5,513

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, 2008		Nine Months Ended June 30, 2008	
	2008	2007	2008	2007
	(In thousands)			
Cash received/receivable	\$	\$	\$	\$ 12,925
Deferred				(375)
Amortization	464	464	1,393	1,495
Revenues	\$ 464	\$ 464	\$ 1,393	\$ 14,045

The Company recorded revenues from the collaboration agreement with Roche comprising 100.0% of total revenues during the three months ended June 30, 2008 and 2007, and the nine months ended June 30, 2008. During the nine months ended June 30, 2007, Roche represented 99.7% of total revenues. No other customer accounted for 10% or more of the Company's total revenues in the periods presented herein.

Roche In October 2004, the Company entered into a collaboration and license agreement with Roche to develop PSI-6130, PSI-6130 pro-drugs (including R7128) and chemically related nucleoside polymerase inhibitors for all indications, including the treatment of chronic HCV infections. Roche paid the Company an up-front payment of \$8.0 million and has agreed to pay future research and development costs. The up-front payment has been recorded as deferred revenue and is being amortized over the estimated development period. Roche is also required to make certain payments to the Company for PSI-6130 and its pro-drugs, the lead nucleoside compound of the collaboration, 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, 2008 and September 30, 2007 was \$6.2 million and \$7.6 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 granted Roche worldwide rights, excluding Latin America and Korea, to PSI-6130 and its related compounds. The Company retained certain co-promotion rights in the United States. The Company will be required to pay Roche royalties on net product sales, if any, in the territories the Company has retained. Roche will fund research related to the collaboration. Roche will fund and the Company will be responsible for preclinical work, the Investigational New Drug (IND) filing, and the initial clinical trial, while Roche will manage other preclinical studies and clinical development. Roche has reimbursed the Company \$1.6 million and \$1.5 million during the three months ended June 30, 2008 and 2007, and \$4.5 million and \$2.7 million during the nine months ended June 30, 2008 and 2007, respectively. Upon the completion of the ongoing Phase 1 study, the Company expects to transfer the IND application for R7128 to Roche and Roche will continue to

Edgar Filing: Pharmasset Inc - Form 10-Q

fund all of the expenses of, and be responsible for, other preclinical studies and future clinical development of R7128. We will continue to jointly oversee all development activities with Roche.

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

5. STOCK PLANS

The Company's 1998 Stock Plan (the "1998 Plan") 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, 2008, 795,961 shares of the Company's common stock were 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 either incentive stock options, as defined under Section 422 of the Internal Revenue Code of 1986 or nonstatutory stock options. To date, options granted under the 2007 Plan have been at per share exercise prices equal to the fair market value of our common stock based on the publicly traded price as reported by the NASDAQ Stock Market on the date of grant. The 2007 Plan will terminate in fiscal 2017 unless it is extended or terminated earlier pursuant to its terms. Generally, options granted under these plans have a contractual life of 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, 2008 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding - September 30, 2007	2,101,273	\$ 4.01
Granted (unaudited)	682,600	\$ 13.65
Exercised (unaudited)	(55,625)	\$ 5.49
Forfeited (unaudited)	(1,166)	\$ 3.50
Outstanding - December 31, 2007 (unaudited)	2,727,082	\$ 6.39
Granted (unaudited)	56,500	\$ 17.50
Exercised (unaudited)	(243,367)	\$ 4.71
Forfeited (unaudited)		
Outstanding - March 31, 2008 (unaudited)	2,540,215	\$ 6.80
Granted (unaudited)	61,000	\$ 14.30
Exercised (unaudited)	(219,524)	\$ 3.45
Forfeited (unaudited)	(16,000)	\$ 9.22
Outstanding - June 30, 2008 (unaudited)	2,365,691	\$ 7.28
Exercisable - September 30, 2007	1,096,430	\$ 4.16
Exercisable - December 31, 2007 (unaudited)	1,223,414	\$ 4.12
Exercisable - March 31, 2008 (unaudited)	1,150,094	\$ 4.07
Exercisable - June 30, 2008 (unaudited)	1,066,197	\$ 4.15

The range of exercise prices of options outstanding at June 30, 2008 was \$1.50 to \$32.00. The weighted average remaining contractual life of options outstanding at June 30, 2008 was 7.63 years. The total intrinsic value of options exercised during the nine months ended June 30, 2008 was \$7,004,428. At June 30, 2008 and September 30, 2007, \$6,696,529 (including \$5,708,662 resulting from the adoption of SFAS 123R) and \$3,500,662 (including \$1,977,912 resulting from the adoption of SFAS 123R), respectively, of deferred stock-based compensation expense

related to employee stock options remained unamortized.

Outstanding as of June 30, 2008				Exercisable as of June 30, 2008	
Number of Options	Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
85,001	\$ 1.50 - \$2.99	0.92	\$ 1.50	85,001	\$ 1.50
1,267,739	3.00 - 4.49	7.14	\$ 3.45	779,970	\$ 3.31
37,167	4.50 - 5.99	8.56	\$ 5.46	17,292	\$ 5.44
65,935	6.00 - 7.49	3.90	\$ 6.47	65,935	\$ 6.47
119,749	7.50 - 10.49	7.89	\$ 8.85	92,999	\$ 8.78
739,600	10.50 - 14.99	9.34	\$ 13.69	15,000	\$ 13.67
49,500	15.00 - 29.99	9.73	\$ 17.88	10,000	\$ 17.55
1,000	30.00 - 45.00	9.56	\$ 32.00		\$

As of June 30, 2008, there were options to purchase 2,238,262 shares of the Company's common stock outstanding that were either vested or expected to vest in the future, of which options to purchase 1,066,197 shares were currently exercisable, with weighted average exercise prices of \$7.12 and \$4.15 per share, aggregate intrinsic values of \$26,349,774 and \$15,706,540 and weighted average remaining contractual terms of 7.56 and 6.28 years, respectively.

6. INCOME TAXES

Income tax expense was \$0 during the three and nine months ended June 30, 2008 and 2007. The Company's effective tax rate for the three and nine months ended June 30, 2008 and 2007 was 0%, as the Company expects to have a loss for the full tax year. The net deferred tax asset as of June 30, 2008 remains fully offset by a valuation allowance since it is more likely than not that such tax benefits will not be realized.

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 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.

As a result of 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, 2008, 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 IRS 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 2004-2007 from federal and state jurisdictions, and from 1998 - 2004 for foreign jurisdictions.

As of September 30, 2007, the Company has United States federal net operating loss carryforwards (NOLs) of approximately \$25.1 million and gross (and net) deferred tax assets of approximately \$17.0 million. The Company maintains a full valuation allowance against its deferred tax assets and liabilities since it is more likely than not that such tax benefits will not be realized.

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. These ownership changes may limit the amount of NOL and research and development tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382. Due to the significant complexity and cost associated with a change in control study, and because there could be additional changes in control in the future, the Company has not formally assessed whether there has been one or more changes in control since the Company's formation. If the Company has experienced a change of control at any time since Company 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

On May 23, 2005, the Company entered into an operating lease for office and laboratory space through May 22, 2010, in Princeton, New Jersey. Monthly lease payments began May 23, 2005. The Company also leases office space in Durham, North Carolina. Monthly lease payments began May 1, 2007 and end on April 1, 2009. In December 2006, the Company entered into a capital lease for lab equipment with principal and interest payments of \$14,044 due monthly beginning in January 2007 through December 2008.

As of June 30, 2008, future payments under capital leases and minimum payments under non-cancelable operating leases are as follows:

	June 30, 2008	
	Capital Lease	Operating Leases
	(In thousands)	
Fiscal 2008	\$ 43	\$ 227
Fiscal 2009	42	873
Fiscal 2010		530
 Total minimum payments required	 85	 \$ 1,630
 Less: Amounts representing interest	 (2)	
 Minimum future payments of principal	 83	
Less: Current portion	(83)	
 Long-term portion	 \$	

8. DEBT

On September 30, 2007, the Company entered into a Loan Agreement that allows 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") on October 5, 2007 and March 28, 2008, respectively. The Notes bear interest at 12% and 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 the first \$10.0 million begin on March 1, 2009 and end on August 1, 2011. The principal monthly repayments on the second \$10.0 million begin on August 1, 2009 and end on January 1, 2012. Total principal repayments of the two Notes amount to \$2.7 million in fiscal 2009, \$7.6 million in fiscal 2010, \$8.2 million in fiscal 2011, and \$1.5 million in fiscal 2012.

The third \$10.0 million increment is subject to ordinary and customary closing procedures as noted in the Loan Agreement, including the execution of a promissory note. It is also subject to the achievement of certain product development milestones and has a commitment termination date of November 30, 2008. The interest rate on the third \$10.0 million increment will be equal to the greater of 12% or 12% plus the difference between the one month LIBOR rate five days before the funding date for such loan and 5.32%. Any future loan under this agreement will be repaid over a 45-month period with

the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. Prepayment of all 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.

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 a warrant to the lender to purchase up to 149,377 shares of the Company's common stock (See Note 9). Since these warrants were granted in conjunction with entering into the Loan Agreement and with the intention of executing promissory notes, the fair value of the warrant was recorded as equity and deferred interest as the warrants became exercisable and the deferred interest is being amortized over the term of the promissory note using the effective interest method.

9. STOCKHOLDERS' EQUITY

Common Stock As of June 30, 2008, the Company had 100,000,000 shares of common stock authorized with a par value of \$0.001. As of June 30, 2008, the Company has reserved under the 2007 Plan 3,161,652 shares of common stock for issuance upon the exercise of 2,365,691 outstanding common stock options and the remaining 795,961 shares of the Company's common stock are reserved for future grants of stock options (or other similar equity instruments).

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.

Warrants On September 30, 2007, in conjunction with entering into the Loan Agreement (See Note 8), the Company granted a warrant to the lender to purchase up to 149,377 shares of the Company's common stock at a price of \$12.05. The warrant was immediately exercisable for 66,390 shares of common stock. On March 28, 2008, the Company executed a second promissory note with the lender in the amount of \$10.0 million, increasing the amount of exercisable shares of common stock under this warrant by 49,793 to 116,183. The remaining 33,194 shares under this warrant would become exercisable if the Company elects to enter into a third \$10.0 million promissory note with the lender and satisfies certain other borrowing conditions. The warrant expires seven years from the date of grant or upon a change of control as defined in the Loan Agreement. The fair value of the warrant was calculated using the Black-Scholes warrant-pricing methodology and was recorded as equity and deferred interest as the warrants became exercisable.

10. 12-MONTH EARNINGS STATEMENT

Pursuant to section 11(A) of the Securities Act of 1933 and Rule 158 promulgated thereunder, the following is an unaudited quarterly and 12-month earnings statement covering the period from July 1, 2007 through June 30, 2008.

	Three Months Ended March 31,			Twelve Months Ended	
	September 30, 2007	December 31, 2007	2008	June 30, 2008	June 30, 2008
REVENUES:	\$ 7,964,291	\$ 464,291	\$ 464,292	\$ 464,291	\$ 9,357,165
COSTS AND EXPENSES:					
Research and development	8,221,948	10,550,371	8,990,469	11,499,843	39,262,631
General and administrative	2,317,916	2,619,745	3,809,073	3,473,635	12,220,369
Total costs and expenses	10,539,864	13,170,116	12,799,542	14,973,478	51,483,000
OPERATING LOSS	(2,575,573)	(12,705,825)	(12,335,250)	(14,509,187)	(42,125,835)
INVESTMENT INCOME	926,545	896,402	585,048	216,287	2,624,282
INTEREST EXPENSE	(3,767)	(363,176)	(386,161)	(735,543)	(1,488,647)
LOSS BEFORE INCOME TAXES	(1,652,795)	(12,172,599)	(12,136,363)	(15,028,443)	(40,990,200)
PROVISION FOR INCOME TAXES					
NET LOSS	\$ (1,652,795)	\$ (12,172,599)	\$ (12,136,363)	\$ (15,028,443)	\$ (40,990,200)

11. SUBSEQUENT EVENT

Registered Direct Public Offering 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 \$24.2 million in net proceeds after deducting placement agent fees 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.

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 development of oral therapeutics for the treatment of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Our research and development efforts focus on a class of compounds known as nucleoside analogs, which act to inhibit the enzymes required for viral replication. We are currently developing three product candidates, two of which we are developing ourselves and one of which we are developing with a strategic partner:

Clevudine, for the treatment of chronic HBV infection, is enrolling Phase 3 registration clinical trials;

R7128, a pro-drug of PSI-6130 for the treatment of HCV, is in a 4-week Phase 1 clinical trial through a collaboration with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche); and

Racivir, for the treatment of HIV, which has completed a Phase 2 clinical trial.

Additionally, we are continuing to evaluate the status of dextelvucitabine, or DFC, for the treatment of HIV following the completion of a Phase 2b clinical trial. The Company has also identified proprietary, next generation HCV development candidates that are being evaluated for advancement into clinical development. One of these compounds, PSI-7851, was recently nominated as a lead candidate and is being advanced into Good Laboratory Practice (GLP) toxicity studies required for submission of an IND application with the FDA or an equivalent foreign regulatory filing.

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

We initiated two Phase 3 clinical trials of clevidine for registration in North, Central and South America and Europe during the third calendar quarter of 2007. The clevidine registration studies include two 48-week Phase 3 clinical trials designed to test the superiority of once-daily doses of Clevidine 30mg over Hepsera 10mg (adefovir) on predetermined primary and secondary endpoints. Study 305 will be conducted in approximately 376 e-antigen positive patients, and Study 306 will be conducted in approximately 480 e-antigen negative patients. The primary endpoint of these registration studies is a composite measurement of the percentage of patients with undetectable HBV DNA (less than 300 copies/ml) and the normalization of liver enzyme levels at 48 weeks on therapy. We plan to continue the clevidine Phase 3 studies from week 48 to week 96 to gather additional safety and efficacy data, as well as assess clevidine's SVR rate for HBV.

In October 2006, Roche and we initiated oral dosing of R7128 in a Phase 1 clinical trial under an IND filing. We were subsequently informed by the FDA that R7128 received fast track designation. The Phase 1 trial is a multiple center, observer-blinded, randomized and placebo-controlled study designed to investigate the pharmacokinetics, pharmacodynamics, safety, tolerability and food effect of R7128 in healthy volunteers and in patients chronically infected with HCV

genotypes 1, 2 or 3. The trial will also provide antiviral potency data following 14 and 28 days of treatment in patients chronically-infected with HCV genotype 1 and following 28 days of treatment in patients chronically-infected with HCV genotypes 2 or 3. This adaptive Phase 1 study is comprised of three parts:

Part 1 was a single ascending dose study conducted in 46 healthy volunteers. The primary objective of Part 1 was to assess the safety, tolerability and pharmacokinetics of R7128 following single ascending doses under fasting conditions. The secondary objective of Part 1 was to explore the effect of food on the pharmacokinetics of R7128. Single oral doses of R7128 were administered to 46 healthy volunteers in five sequential dose groups (500 mg, 1500 mg, 4500 mg, 6000 mg, and 9000 mg) and one food effect group (1500 mg). Results from the single ascending dose portion of the study indicated:

All doses of R7128 studied (500 mg to 9000 mg) were generally safe and well-tolerated.

All patients completed the study, and none experienced gastrointestinal adverse events or serious adverse events during the study.

No hematological or laboratory abnormalities of clinical significance were noted.

Part 2 was a multiple ascending dose study conducted in 40 patients chronically infected with HCV genotype 1 who had previously failed interferon therapy. The primary objective of Part 2 was to assess the safety, tolerability, and pharmacokinetics of R7128 after once-daily (QD) or twice-daily (BID) dosing for 14 days. The secondary objective was to assess antiviral efficacy by measuring the change in HCV RNA. Results from the multiple ascending dose portion of the study indicated:

R7128 demonstrated potent, dose-dependent antiviral activity in four patient cohorts (8 active, 2 placebo per cohort) receiving 750 mg or 1500 mg administered either QD or BID for 14 days as monotherapy. Both the greatest mean decrease and maximum decrease in HCV RNA from baseline were demonstrated in the patient cohort that received 1500 mg BID. R7128 demonstrated mean HCV RNA decreases of 0.9 log (87.4% reduction), 1.5 log (96.8% reduction), 2.1 log (99.2% reduction) and 2.7 log (99.8% reduction) in patients receiving 750mg QD, 1500mg QD, 750mg BID and 1500 mg BID, respectively. All four dose groups reached nadir values at Day 15. A maximum 4.2 log (99.9% reduction) HCV RNA decrease was demonstrated in a patient following 14 days of monotherapy with 1,500 mg BID of R7128, a value also below the level of detection, which was less than 15 International Units per milliliter (IU/ml).

There was no evidence of viral rebound in any dose cohort during the 14 days of dosing. In addition, R7128 was generally safe and well tolerated.

There were no serious adverse events, no adverse events requiring dose modification, no dose-related gastrointestinal adverse events and no clinically significant changes in hematologic or other laboratory parameters.

Part 3 is a 4-week study of R7128 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 HCV genotype 1, and additionally, in 25 prior treatment non-responders, or patients who did not achieve an SVR with previous interferon-based therapy, who are chronically infected with HCV genotypes 2 or 3. The primary objective of this study is to assess the safety, tolerability, and pharmacokinetics of R7128 in the clinically-relevant setting of combination therapy with the current standard of care for chronic HCV infection. The secondary objective is to evaluate the short-term change in HCV RNA. The study will include three oral dose regimens of R7128 (500 mg, 1000 mg and 1500 mg) in patients chronically infected with HCV genotype 1 and one oral dose regimen of R7128 (1500 mg) in patients chronically infected with HCV genotypes 2 or 3. All four dose regimens are being administered twice-daily with Pegasys plus Copegus for 4 weeks. Dose cohorts 1, 2 and 4 enrolled 25 patients, with 20 patients

Edgar Filing: Pharmasset Inc - Form 10-Q

randomized to receive R7128 and five patients randomized to receive placebo, and cohort 3 enrolled 31 patients, with 25 patients randomized to receive R7128 and six patients randomized to receive placebo, all administered in combination with the standard of care. After completing 4 weeks of the triple combination regimen and a follow-up period of four weeks of Pegasys plus Copegus, all patients will then receive up to 40 weeks of open-label standard of care dosing under a separate protocol. Results from the 500mg, 1500mg and 1000mg dose cohorts (cohorts 1, 2 and 3) in 81 treatment-naïve patients chronically infected with HCV genotype 1 indicated:

Following 4 weeks of treatment with R7128 1000mg BID with Pegasys plus Copegus, preliminary results indicated patients achieved a mean 5.0 log₁₀ IU/mL decrease in HCV RNA and 88% (22 of 25) patients achieved undetectable levels of HCV RNA (<15 IU/ml), or rapid virologic response (RVR).

Following 4 weeks of treatment with R7128 1500mg BID with Pegasys plus Copegus, patients achieved a mean 5.1 log₁₀ IU/mL decrease in HCV RNA and 85% (17 of 20) achieved undetectable levels of HCV RNA (<15 IU/ml), or RVR.

Following 4 weeks of treatment with R7128 500mg BID with Pegasys plus Copegus, patients achieved a mean 3.8 log10 IU/mL decrease in HCV RNA and 30% (6 of 20) achieved RVR.

Following 4 weeks of treatment with placebo with Pegasys plus Copegus, patients achieved a mean 2.9 log10 IU/mL decrease in HCV RNA and 18.75% (3 of 16) achieved RVR.

For cohorts 1 and 2, safety and tolerability for the 4-week treatment period were similar for R7128 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. The most common adverse events, reported in 15% or greater of patients in any treatment group during the 4-week treatment period, were headache, injection site reaction, myalgia, fatigue, chills, rash, nausea, diarrhea, arthralgia, pyrexia, dizziness, dyspepsia and pruritis. The frequency and severity of these adverse events, as well as any general body system observations, were generally similar to clinical experience with the standard of care for HCV, pegylated interferon plus ribavirin. Grade 3/4 neutropenia was observed in 30% of the placebo patients and in 10% to 15% of the R7128 patients in each active dosing cohort. Grade 3 changes in hemoglobin were observed in 10% of the placebo patients and in 15% of the R7128 patients. There were no clinically significant changes in other hepatic, renal, or other safety laboratory parameters, vital signs, or electrocardiograms. Overall, there was no clinical evidence of any major organ toxicities related to R7128. 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. R7128 was generally safe and well-tolerated when administered for 4 weeks in combinations with Pegasys plus Copegus in patients with HCV genotype 1.

For cohort 3, safety data has not yet been unblinded, however blinded safety and tolerability for the 4-week treatment period was similar to the safety profile observed during treatment with the standard of care alone (Pegasys plus Copegus).

Patients in the 1500 mg cohort (cohort 4) that will study R7128 in prior non-responders with HCV genotype 2 or 3 began dosing in May 2008. Preliminary safety and antiviral activity data from this 4-week combination study is anticipated during the latter half of the third calendar quarter of 2008. This cohort is being conducted in parallel with the global Phase 2b study preparation activities for R7128.

The timeline mutually-agreed upon by Pharmasset and Roche anticipates the submission of the draft Phase 2b protocol and supporting documentation to the FDA during November 2008. One of the doses of R7128 to be administered in the Phase 2b study is expected to be 1000mg BID, administered with standard doses of Pegasys plus Copegus, in treatment-naïve and/or treatment experienced HCV patients with genotypes 1, 2, 3 and/or 4. Other study details, including the number of patients and duration of both on-treatment and off-treatment periods, have not yet been finalized.

We cannot guarantee that the final results of this study or any future study of R7128 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.

We and Roche have performed and will continue to perform in vitro and animal studies to determine the preclinical pharmacokinetics and safety of PSI-6130 administered as its pro-drug, R7128. PSI-6130 did not cause genetic mutations or cellular damage in preclinical models. The goal of longer-term animal studies is to identify the potential target organs as the drug progresses in the clinic, as well as to identify the No Observed Adverse Effect Level (NOAEL) dose in animals. Finding a NOAEL dose in one rodent and one non-rodent species over the same treatment period to be applied to humans may provide guidance in the choice of doses to be studied in humans; however, since animals metabolize PSI-6130 differently than do humans, the exposures found to be safe or toxic in animals may not directly correspond to human drug exposures. For example, in monkeys, approximately 30-70% of PSI-6130 is converted into a uridine metabolite, PSI-6206, which appears in the blood, whereas, in humans, approximately 10% is converted to this metabolite. Rats and dogs convert less than 1% of PSI-6130 to this metabolite. Because of these differences between species, no fixed relationship between NOAEL doses in animals and doses in humans has been established.

Oral administration of R7128 at doses of 200, 600 and 2000 mg/kg/day over 28 days in monkeys, dogs and rats established the NOAEL dose of 600 mg/kg/day in monkeys and 2000 mg/kg/day in dogs and rats.

Oral administration of R7128 at doses of 200, 600 and 2000 mg/kg/day in monkeys, in a study designed to be six months but stopped at 13 weeks, did not establish a NOAEL dose. A thorough examination of the monkeys' tissues in every organ system determined that the only significant treatment-related pathology changes were confined to a single organ. We believe these changes were dose-related, appearing in all members of the high and middle dose groups and one member of the low dose group, in which changes appeared in a much milder form. No scarring was observed, so changes were considered likely to be reversible. This particular type of injury, if present, is likely to be detectable in both monkeys and humans with standard assays.

A second long-term R7128 safety study in monkeys began in April 2008 at doses of 10, 40, 100, and 600 mg/kg/day, to be administered for 13 weeks in preparation for the start of a Phase 2b study in which humans are expected to receive R7128 for 13 weeks. The drug-treatment portion of this study has recently concluded after being conducted for the full scheduled 13 weeks without a repeat of the outward clinical signs in the monkeys that caused the early termination of the previous safety study. Histopathology data is currently being gathered and analyzed. In this study, we expect to establish a NOAEL dose in monkeys over 13 weeks below 600 mg/kg/day, and we hope to repeat the changes observed at the 600 mg/kg/day in the previous study in order to assess the monitorability of these changes, as well as their reversibility upon discontinuation of R7128.

In January 2008, Roche completed the dosing portion of a six month safety study of R7128 in rats. The histopathology results of this study revealed no toxicities at any dose level tested, which were 200, 600 and 2000 mg/kg/day. Thus, at the highest dose tested in rats, exposure of the rats to PSI-6130 exceeds the exposure of humans at the 1500 BID doses without causing toxicity over six months.

Species-specific differences in drug metabolism and excretion that may render the monkey more susceptible to the pathology changes observed with R7128 than the rat or humans continue to be under review.

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 (80% reduction) in the second week of treatment. Twenty-eight percent of these patients achieved an undetectable level of virus (less than 400 copies per milliliter) and 64% of these patients achieved at least a 0.5 log decrease (68% reduction) in plasma HIV RNA.

Our research and development efforts focus on a class of compounds known as nucleoside analogs, which act to inhibit the enzymes required for viral replication. We are applying our expertise in nucleoside chemistry to the discovery and development of additional antiviral therapeutics for HCV and HIV. For example, we have identified a new series of proprietary nucleoside pro-drugs that are referred to as phosphate pro-drugs because they have the ability to deliver into infected cells the monophosphate forms of the compounds, thus bypassing a rate limiting step in the metabolic pathway to the active triphosphate form of the drug. The goals of these efforts are to identify compounds with improved potency, equivalent or improved safety and oral bioavailability, and increased intrahepatic triphosphate levels. These compounds have demonstrated exceptional in vitro anti-HCV activity with EC90 values up to 100 times lower than PSI-6130. Early studies in animals indicate that several of these compounds can achieve concentrations of active triphosphate in the liver up to 1000 times higher than PSI-6130 at equivalent doses. We continue to conduct additional in vivo studies to select preclinical development candidates from several lead compounds.

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, 2008, we had an accumulated deficit of \$96.5 million. We expect our operating losses to increase for at least the next several years as we continue to pursue the clinical development of clevudine, Racivir, PSI-7851 and our other product and development candidates, and as we expand our discovery and development pipeline. We expect our compensation expense to increase in the future as we implement our planned increase in the number of our employees.

We have funded our operations primarily through the sale of equity securities, payments received under collaboration agreements, government grants and interest earned on investments. We expect to continue to fund our operations over the next several years using the net proceeds from our common stock public offering completed on July 21, 2008, our existing

cash resources, borrowings under our existing Loan Agreement, potential future milestone payments that we expect to receive from Roche if certain conditions are satisfied, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. We will require significant additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. As of June 30, 2008, we had approximately \$51.0 million of cash and cash equivalents and approximately \$1.0 million of short-term investments.

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, research funding and grants. We currently have one collaboration agreement with Roche for the development of PSI-6130, its pro-drugs and related compounds. We entered into our collaboration agreement with Roche in October 2004. Roche subsequently paid us an up-front payment of \$8.0 million. Pursuant to the terms of our collaboration agreement with Roche, we received \$20.0 million in milestone payments during the year ended September 30, 2007. As of June 30, 2008, we had received an aggregate of \$33.0 million in payments under the Roche collaboration agreement, including research funding and related fees as well as up-front and milestone payments.

Under the current terms of the Roche collaboration agreement, if we succeed in obtaining all of the regulatory approvals specified in the agreement for PSI-6130 or a pro-drug of PSI-6130, including R7128, as of June 30, 2008 the maximum future development and commercialization milestone payments payable to us are \$115.0 million. Receipt of any additional milestone payments depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments.

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

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. Our development activities are primarily focused on the clinical development of clevudine, Racivir and R7128, as well as the preclinical development of PSI-7851. We are responsible for all costs incurred in the future in the clinical development of clevudine for registration in the Americas, Europe and certain other territories, where we have the rights to develop and commercialize clevudine, which we in-licensed from Bukwang. We are responsible for all costs incurred in the clinical development of Racivir, as well as the research costs associated with our other internal research programs. Under our collaboration with Roche, Roche will fund the clinical development and commercialization of PSI-6130 and its pro-drugs, including R7128. Under this collaboration, Roche reimbursed us for all of the external expenses associated with, and we were responsible for, certain preclinical work, the IND filing, and the proof-of-concept clinical trials. Going forward, Roche will reimburse us for all external expenses associated with, and we will be responsible for, the conduct of the two additional cohorts of Part 3 of the Phase 1 study of R7128. Upon the successful completion of Part 3 of this study, we plan to transfer the IND application for R7128 to Roche and Roche will fund all of the expenses of, and be responsible for, other non-clinical studies and future clinical development of R7128. We will continue to jointly oversee all future development activities with Roche. We will continue to develop and retain worldwide rights to ongoing and future HCV programs unrelated to the PSI-6130 series of nucleoside polymerase inhibitors licensed to Roche.

We are currently focused on the development of clevudine, Racivir, R7128 (in collaboration with Roche) and PSI-7851. We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis. These determinations will be made in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential. Clevudine is in Phase 3 registration clinical trials which commenced dosing during the third calendar quarter of 2007. We currently estimate it will cost approximately \$78.0 million, excluding the internal personnel costs associated with conducting these two

registration trials, to progress clevudine's currently planned clinical program from September 30, 2007 to completion. We do not believe, however, that it is possible at this time to accurately project total program-specific expenses through commercialization for clevudine or any of our other product candidates, as there are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Product candidates that may appear promising at early stages of development may not reach the market for a number of reasons. Product candidates may be found ineffective or cause harmful side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals and may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality. The lengthy process of seeking FDA approvals requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining regulatory approvals could materially adversely affect our product development efforts. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost or whether we will obtain any approval required by the FDA on a timely basis, if at all.

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

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, business development, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs and professional fees for outside accounting and legal services, travel, insurance premiums and depreciation. We expect general and administrative costs to increase significantly in connection with our planned growth.

Results of Operations

Three and Nine Months Ended June 30, 2008 and 2007

Revenues. Revenues were \$0.5 million during each of the quarters ended June 30, 2008 and 2007. Revenues during each period reflect amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue.

Revenues were \$1.4 million and \$14.0 million during the nine months ended June 30, 2008 and 2007, respectively. Revenues during the nine months ended June 30, 2008 and 2007 reflect amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue of \$1.4 million and \$1.5 million, respectively, and the revenues from the year ago nine month period include milestone payments totaling \$12.5 million received pursuant to our Roche collaboration.

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

	Three Months Ended June 30, 2008		Nine Months Ended June 30, 2008	
	2008	2007	2008	2007
	(In thousands)			
Cash received/receivable	\$	\$	\$	\$ 12,925
Deferred				(375)
Amortization	464	464	1,393	1,495
Revenues	\$ 464	\$ 464	\$ 1,393	\$ 14,045

Research and Development Expenses. Research and development expenses increased to \$11.5 million during the quarter ended June 30, 2008 from \$4.4 million in the quarter ended June 30, 2007. This net increase of \$7.1 million consists primarily of a \$5.8 million increase in Phase 3 registration clinical trial expenses for clevudine, an increase in compensation expenses of \$0.9 million resulting from an increase in headcount, and a \$0.4 million increase in new drug discovery expenses.

Research and development expenses increased to \$31.0 million during the nine months ended June 30, 2008 from \$12.1 million in the nine months ended June 30, 2007. This net increase of \$18.9 million consists primarily of a \$15.6 million increase in Phase 3 registration clinical trial expenses for clevudine, an increase in compensation expenses of \$2.6 million (\$0.5 million of which was non-cash stock compensation expense) resulting from an increase in headcount, and a \$1.2 million increase in new drug discovery expenses. Partially offsetting these increases was a \$0.5 million reduction in Phase 2 clinical trial expenses for Racivir during the nine months ended June 30, 2008, compared to the same period in 2007.

General and Administrative Expenses. General and Administrative expenses were \$3.5 million during the quarter ended June 30, 2008, an increase of \$0.8 million from \$2.6 million in the quarter ended June 30, 2007. The increase of \$0.8 million was due primarily to increases in marketing expenses of \$0.2 million, compensation expenses of \$0.1 million, audit and related fees (including consulting fees in support of our compliance with Section 404 of the Sarbanes-Oxley Act of 2002) of \$0.1 million, insurance expense of \$0.1 million, travel and related expenses of \$0.1 million, and miscellaneous administrative expenses of \$0.2 million.

General and Administrative expenses were \$9.9 million during the nine months ended June 30, 2008, an increase of \$3.0 million from \$6.9 million in the nine months ended June 30, 2007. The increase of \$3.0 million was due primarily to increases in legal fees of \$0.6 million, insurance expense of \$0.6 million, audit and related fees (including consulting fees in support of our compliance with Section 404 of the Sarbanes-Oxley Act of 2002) of \$0.6 million, marketing expenses of \$0.4 million, compensation expenses of \$0.2 million, travel and related expenses of \$0.2 million, and miscellaneous administrative expenses of \$0.4 million.

Investment Income. Investment income decreased to \$0.2 million during the quarter ended June 30, 2008 from \$0.7 million in the quarter ended June 30, 2007, and increased to \$1.7 million during the nine months ended June 30, 2008 from \$1.5 million in the nine months ended June 30, 2007. The decrease from the quarter ending June 30, 2007 to the quarter ending June 30, 2008 of \$0.5 million was due to lower rates of return on the average invested cash balances, while the increase for the nine months ending June 30, 2008 compared to the same period during 2007 of \$0.2 million was primarily due to higher average invested cash balances that were mostly offset by lower rates of return on the average invested cash balances.

Interest Expense. Interest expense increased to \$0.7 million during the quarter ended June 30, 2008 from \$0.0 million in the quarter ended June 30, 2007, and increased to \$1.5 million during the nine months ended June 30, 2008 from \$0.0 million in the nine months ended June 30, 2007. The increases were due to interest on the \$20.0 million of long-term debt we incurred during October 2007 and March 2008.

Redeemable Preferred Stock Accretion. Redeemable preferred stock accretion was \$1.2 million and \$1.8 million during the three and nine months ended June 30, 2007, respectively. There has been no redeemable preferred stock accretion subsequent to May 2, 2007 (when the Company completed its IPO) because all of the redeemable preferred stock outstanding was converted into common stock upon completion of the IPO.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily with the proceeds from our IPO, which was completed on May 2, 2007, private placements of our equity securities, payments received under our collaboration agreements, government grants, and more recently with borrowings under our Loan Agreement. Since our inception, we have raised approximately \$129.2 million in net proceeds from sales of our equity securities, including \$24.2 million from our common stock public offering completed on July 21, 2008 (See *Part I. Item 1. Notes to Financial Statements Note 11. Subsequent Event*

herein for additional information) and \$40.7 million from our IPO after deducting offering costs paid during fiscal 2007 (\$39.1 million after deducting additional offering costs paid in fiscal 2006). At June 30, 2008, we held approximately \$51.0 million in cash and cash equivalents and approximately \$1.0 million of short-term investments. We have invested a substantial portion of our available cash funds in mutual and money market funds, as well as investment securities consisting of investment grade, marketable debt instruments of corporations, government agencies and financial institutions. We presently do not have any auction rate securities.

Net cash used in operating activities was \$39.3 million during the nine months ended June 30, 2008 compared to \$2.5 million during the nine months ended June 30, 2007. The \$36.8 million increase in net cash used in operating activities during the nine months ended June 30, 2008, as compared to the same year ago period was due primarily to reductions in cash revenues and net investment income, of \$12.7 million and \$1.3 million, respectively, an increase in cash outflows for operating expenses of \$21.1 million primarily resulting from our phase 3 clinical trials for clevudine, and an increase of \$1.7 million of cash outflows associated with changes in operating assets and liabilities.

Net cash used in investing activities was \$0.5 million and \$0.3 million during the nine months ended June 30, 2008 and 2007, respectively. Included in the net cash used in investing activities of \$0.5 million during the nine months ended June 30, 2008 were purchases of equipment, furniture and fixtures for our lab and office space of \$0.8 million. Partially offsetting these cash outflows were proceeds from the maturity of short-term investments of \$0.3 million. All of the \$0.3 million of cash used in investing activities during the nine months ended June 30, 2007 were for purchases of equipment, furniture and fixtures for our lab and office space.

Net cash provided by financing activities was \$22.1 million during the nine months ended June 30, 2008, compared to \$41.9 million during the nine months ended June 30, 2007. 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 under the Loan Agreement we entered into during September 2007, along with proceeds from the exercise of stock options of \$2.2 million. The net cash provided by financing activities during the nine months ended June 30, 2007 includes net proceeds from our IPO of \$41.0 million, along with \$0.9 million of proceeds from the exercise of stock options.

On September 30, 2007, we entered into a Loan Agreement that allows 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") on October 5, 2007 and March 28, 2008, respectively. The Notes bear interest at 12% and 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 the first \$10.0 million begin on March 1, 2009 and end on August 1, 2011. The principal monthly repayments on the second \$10.0 million begin on August 1, 2009 and end on January 1, 2012. Total principal repayments of the two Notes amount to \$2.7 million in fiscal 2009, \$7.6 million in fiscal 2010, \$8.2 million in fiscal 2011, and \$1.5 million in fiscal 2012.

The third \$10.0 million increment is subject to ordinary and customary closing procedures as noted in the Loan Agreement, including the execution of a promissory note. It is also subject to the achievement of certain product development milestones and has a commitment termination date of November 30, 2008. The interest rate on the third increment would be equal to the greater of 12% or 12% plus the difference between the one month LIBOR rate five days before the funding date for such loan and 5.32%. Any future loan will be repaid over a 45-month period with the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. Prepayment of any 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.

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 product candidates, conducting clinical trials and commercializing product candidates are expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash resources as of June 30, 2008, together with the \$24.2 million of net proceeds from our common stock public offering completed on July 21, 2008 (See *Part I. Item 1. Notes to Financial Statements - Note 11. Subsequent Event* herein for additional information), remaining borrowings available under our Loan Agreement and anticipated payments under our

existing collaboration agreement, will be sufficient to fund our projected cash requirements for the next 24 months, we will require additional financing in the future to complete our clinical trials for clevudine and fund our other operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

the progress and costs of our preclinical studies, clinical trials and other research and development activities;

the scope, prioritization and number of our clinical trials and other research and development programs;

the amount of revenues we receive under our collaboration agreements;

the costs of the development and expansion of our operational infrastructure;

the costs and timing of obtaining regulatory approval of our product candidates;

the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;

the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

the costs and timing of securing manufacturing arrangements for clinical or commercial production;

the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;

the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;

the magnitude of our general and administrative expenses; and

any costs that we may incur under current and future licensing arrangements relating to our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

Contractual Obligations and Commitments

In May 2005, we entered into an operating lease for office and laboratory space through May 22, 2010, in Princeton, New Jersey. In April 2007, we entered into a lease for office space in Durham, North Carolina. In December 2006, we entered into a capital lease for lab equipment with monthly payments beginning in January 2007 through December 2008. In October 2007 and March 2008, we executed two secured promissory notes totaling \$20.0 million. Pursuant to the terms of the secured promissory notes, we are required to make payments of interest only for the first 15 months followed by 30 equal monthly payments of principal and interest. As of June 30, 2008, future payments under the Loan Agreement, capital leases and minimum future payments under non-cancellable operating leases are as follows:

Edgar Filing: Pharmasset Inc - Form 10-Q

	Payments Due By Period				
	Total	Less than 1 year	1-3 Years	4-5 Years	After 5 Years
(In thousands)					
Debt obligations					
Debt maturities	\$ 20,000	\$ 1,167	\$ 15,462	\$ 3,371	\$
Contractual interest	\$ 5,349	2,383	2,849	117	
Capital lease obligations					
Debt maturities	\$ 83	83			
Contractual interest	\$ 2	2			
Operating leases	\$ 1,630	893	737		
Purchase obligations	\$				
Total contractual obligations	\$ 27,064	\$ 4,528	\$ 19,048	\$ 3,488	\$

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

Off-Balance Sheet Transactions

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with 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 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, the company follows the guidance in FASB, Emerging Issue Task Force, or 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 are 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 development payments, and milestone payments.

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as 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. Payments for research funding are recognized as revenues as the related research activities are performed.

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. 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 clevudine, Racivir and R7128 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 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. Prior to October 1, 2006, we accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and related interpretations and had adopted the pro forma disclosure option for stock-based employee compensation under SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123). Stock options granted to consultants are periodically valued as they vest in accordance with EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a

Black-Scholes option pricing model. The fair value of our employee and director options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2008	2007	2008	2007
Risk free interest rate	3.27%	4.60%	4.09%	4.55%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected lives (years)	6.11	5.31	6.05	5.93
Expected volatility	54.26%	55.07%	57.25%	54.33%
Weighted-average fair value of options granted	\$ 7.81	\$ 4.65	\$ 8.03	\$ 2.73

Recently Issued Accounting Standards

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

On February 15, 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact this standard would have on our financial statements.

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

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. We are currently evaluating the requirements of EITF 07-1; however we do not believe that its adoption will have a significant impact on our financial statements.

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. We have not yet determined the impact SFAS 141R may have on our results of operations or financial position.

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. We have not yet determined the impact SFAS 160 may have on our results of operations or financial position.

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 31, 2007. 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 the nine months ended June 30, 2008 has a fixed interest rate of 12%.

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 31, 2007. 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

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2008. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2008, our management, with the participation of our chief executive officer and chief financial officer, concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

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, 2008 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

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, 2007 (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 conditions or results of operations could be negatively affected.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1*	Form of Indemnity Agreement for Directors and Officers
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.

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 14, 2008

By: /s/ Kurt Leutzinger
Kurt Leutzinger

Chief Financial Officer

*(duly authorized officer and principal financial
officer)*

EXHIBIT INDEX

Exhibit

Number	Description
10.1	Form of Indemnity Agreement for Directors and Officers
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32	Section 1350 Certifications