Pharmasset Inc
Form 10-Q
May 11, 2009
Table of Contents

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 MARCH 31, 2009

or

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

Commission File Number: 1-33428

Pharmasset, Inc.

(Exact name of registrant as specified in its charter)

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

303-A College Road East

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

(609) 613-4100

(Telephone number, including area code)

N/A

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

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

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

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

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

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

The number of shares of the registrant s common stock, $0.001 par value, outstanding as of April 30, 2009 was 28,111,991.

Table of Contents

PHARMASSET, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2009

INDEX

Table of Contents

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 R7128 and PSI-7851 for the treatment of hepatitis C virus (HCV), and the development of Racivir® for use in combination with other approved human immunodeficiency virus (HIV) drugs:
- the termination of the clevudine registration studies.
- the initiation, termination, completion, or success of preclinical studies and clinical trials;
- clinical trial initiation and completion dates, anticipated regulatory filing dates, and regulatory approval for our product candidates;
- the commercialization of our product candidates;
- our collaboration agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche), including potential milestone and royalty payments thereunder;
- our intentions regarding the establishment of collaborations or the licensing of product candidates or intellectual property;
- our intentions to expand our capabilities and hire additional employees;
- anticipated operating losses, future revenues, research and development expenses, and the need for additional financing; and
- our financial performance.

Forward-looking statements reflect our current views with respect to future events and are subject to risks and uncertainties. We discuss many of the risks and uncertainties associated with our business in greater detail in our Annual Report on Form 10-K for the fiscal year ended September 30, 2008 under the heading Risk Factors. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. All forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in it completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this Quarterly Report on Form 10-Q is accurate as of the date on the front cover of this Quarterly Report on Form 10-Q only. Our business, financial condition, results of operations, and prospects may change. We may not update these forward-looking statements, even though our situation may change in

the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. The forward-looking statements contained in this Quarterly Report on Form 10-Q are subject to the safe-harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act).

Table of Contents

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PHARMASSET, INC.

CONDENSED BALANCE SHEETS

	As of March 31, 2009 (unaudited)	As of September 30, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 79,289,134	$ 63,073,103
Short-term investments		497,310
Amounts due from collaboration partner	638,926	1,169,690
Prepaid expenses and other assets	865,731	1,008,083
Total current assets	80,793,791	65,748,186
EQUIPMENT AND LEASEHOLD IMPROVEMENTS:		
Laboratory, office furniture and equipment	3,554,153	3,362,846
Leasehold improvements	1,836,553	1,836,553
	5,390,706	5,199,399
Less accumulated depreciation and amortization	(2,926,654)	(2,432,325)
Total equipment and leasehold improvements, net	2,464,052	2,767,074
OTHER ASSETS	424,400	466,809
TOTAL	$ 83,682,243	$ 68,982,069
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 5,774,058	$ 2,651,592
Current portion of capital lease obligation		41,641
Accounts payable	1,339,109	2,466,052
Accrued expenses	7,417,493	6,182,417
Deferred rent	124,463	124,463
Deferred revenue	1,857,136	1,857,136
Total current liabilities	16,512,259	13,323,301
DEFERRED RENT	17,732	79,793
DEFERRED REVENUE	2,940,382	3,868,965
LONG-TERM DEBT, net	16,291,594	16,522,665
Total liabilities	35,761,967	33,794,724
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		

Common Stock, $0.001 par value, 100,000,000 shares authorized, 28,111,991 and 23,340,498 shares issued and outstanding at March 31, 2009 (unaudited) and September 30, 2008, respectively	28,112	23,340
Warrants to purchase 127,248 and 116,183 shares of common stock for $12.05 per share, as of March 31, 2009, (unaudited) and September 30, 2008, respectively	1,229,767	1,140,114
Additional paid-in capital	192,201,947	145,818,439
Accumulated other comprehensive (loss) income		(2,604)
Accumulated deficit	(145,539,550)	(111,791,944)
Total stockholders equity	47,920,276	35,187,345
TOTAL	$ 83,682,243	$ 68,982,069

See notes to financial statements.

Table of Contents

PHARMASSET, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE NET LOSS

(UNAUDITED)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009	2008	2009	2008
REVENUES	$ 1,902,679	$ 464,292	$ 2,366,970	$ 928,583
COSTS AND EXPENSES:				
Research and development	13,694,247	8,990,469	27,717,177	19,540,840
General and administrative	2,893,504	3,809,073	6,962,874	6,428,818
Total costs and expenses	16,587,751	12,799,542	34,680,051	25,969,658
OPERATING LOSS	(14,685,072)	(12,335,250)	(32,313,081)	(25,041,075)
INVESTMENT INCOME	57,685	585,048	167,209	1,481,450
INTEREST EXPENSE	(844,822)	(386,161)	(1,601,734)	(749,337)
LOSS BEFORE INCOME TAXES	(15,472,209)	(12,136,363)	(33,747,606)	(24,308,962)
PROVISION FOR INCOME TAXES				
NET LOSS	$ (15,472,209)	$ (12,136,363)	$ (33,747,606)	$ (24,308,962)
COMPREHENSIVE NET LOSS:				
NET LOSS	$ (15,472,209)	$ (12,136,363)	$ (33,747,606)	$ (24,308,962)
UNREALIZED GAIN (LOSS) ON AVAILABLE-FOR-SALE INVESTMENTS		(29,572)		(29,572)
COMPREHENSIVE NET LOSS	$ (15,472,209)	$ (12,165,935)	$ (33,747,606)	$ (24,338,534)
NET LOSS PER SHARE				
BASIC	$ (0.59)	$ (0.57)	$ (1.36)	$ (1.14)
DILUTED	$ (0.59)	$ (0.57)	$ (1.36)	$ (1.14)
WEIGHTED AVERAGE SHARES OUTSTANDING:				
BASIC	26,262,090	21,379,638	24,799,895	21,321,336
DILUTED	26,262,090	21,379,638	24,799,895	21,321,336

See notes to financial statements.

Table of Contents

PHARMASSET, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ended March 31,	
	2009	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (33,747,606)	$ (24,308,962)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	494,329	487,580
Non-cash stock compensation	2,474,576	1,653,247
Non-cash interest expense	276,852	143,182
Changes in operating assets and liabilities:		
Amounts due from collaboration partner, prepaid expenses and other assets	664,141	(456,018)
Accounts payable	(1,126,943)	(1,572,488)
Accrued expenses	1,235,076	(1,500,374)
Deferred rent	(62,061)	(62,062)
Deferred revenue	(928,583)	(928,583)
Net cash used in operating activities	(30,720,219)	(26,544,478)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturity of short-term investments	500,000	
Purchase of equipment and leasehold improvements	(191,307)	(611,963)
Net cash (used in) provided by investing activities	308,693	(611,963)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowings of long-term debt	3,333,333	20,000,000
Proceeds from exercise of stock options	441,750	1,451,057
Principal payments on long-term debt	(577,839)	
Principal payments on capital lease obligations	(41,641)	(78,319)
Proceeds from issuance of common stock, net of issuance costs of $2,044,986	43,471,954	
Net cash provided by financing activities	46,627,557	21,372,738
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	16,216,031	(5,783,703)
CASH AND CASH EQUIVALENTS Beginning of period	63,073,103	68,745,694
CASH AND CASH EQUIVALENTS End of period	$ 79,289,134	$ 62,961,991
SUPPLEMENTAL DISCLOSURES:		
Cash paid during the period for:		
Interest	$ 1,324,882	$ 606,155
Noncash transactions:		
Unrealized (loss) gain on available-for-sale investments	$	$ (29,572)
Warrants granted in connection with debt financing	$ 89,653	$ 613,394

See notes to financial statements.

Table of Contents

Pharmasset, Inc.

Notes to Financial Statements (Unaudited)

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Description of Business-Pharmasset, Inc. (Pharmasset or the Company) is a clinical-stage pharmaceutical company committed to discovering, developing, and commercializing novel drugs to treat viral infections. The Company s primary focus is on the discovery and development of nucleos(t)ide analogs as oral therapeutics for the treatment of hepatitis C virus (HCV) and, secondarily, on the development of Racivir® for the treatment of human immunodeficiency virus (HIV). The Company currently has three clinical-stage product candidates: R7128, for the treatment of HCV, which has initiated a Phase 2b clinical trial through a collaboration with F. Hoffmann-La Roche Ltd and Hoffmann- La Roche Inc. (collectively, Roche); PSI-7851, our next generation HCV product candidate, which began dosing in a Phase 1 clinical trial to study safety and pharmacokinetics in healthy volunteer subjects on March 30, 2009; and Racivir, for the treatment of HIV, which is being developed for the treatment of HIV in combination with other approved HIV drugs and has completed a Phase 2 clinical trial. We are continuing to research a series of nucleotide analogs (both pyrimidines and purines) with the intention of identifying product candidates that can potentially be used in combination with our current nucleos(t)ides, R7128 or PSI-7851, or in combination with other classes of direct acting antivirals for the treatment of HCV. On April 20, 2009, the Company voluntarily terminated its Phase 3 registration studies of clevudine for the treatment of hepatitis B infection (see *Note 10. Subsequent Events* herein for additional information).

The Company s research and development efforts focus on nucleos(t)ide analogs, a class of compounds which act to inhibit viral replication. The Company is applying its expertise in nucleoside chemistry to the discovery and development of additional antiviral therapeutics for HCV. The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, risks and uncertainties relating to product development, protection of proprietary intellectual property, compliance with government regulations, dependence on key personnel, the need to obtain additional financing, uncertainty of market acceptance of products, and product liability. (See *Part II, Item 1A. Risk Factors* for additional information.)

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

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.

Table of Contents

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

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

Intangible Assets Intangible assets consist of a technology license which gives the Company the right to sublicense certain technology to contract manufacturing organizations for the purpose of manufacturing an active pharmaceutical ingredient on behalf of the Company. The technology license is being amortized on a straight-line basis over an estimated useful life of five years. The estimated useful life of five years was determined based on the consideration of several factors including the nature of the asset, its expected use, length of the agreement and the period over which benefits are expected to be received from the use of the asset. Intangible assets are included in Other assets on the Balance Sheets.

Impairment of Long-Lived Assets The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful lives of long-lived assets may require revision or that the carrying value of these assets may be impaired. To determine whether assets have been impaired, the estimated undiscounted future cash flows for the estimated remaining useful life of the respective assets are compared to the carrying value. To the extent that the undiscounted future cash flows are less than the carrying value, a new fair value of the asset is required to be determined. If such fair value is less than the current carrying value, the asset is written down to its estimated fair value.

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

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

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

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

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

Table of Contents

As of March 31, 2009, the Company did not have any Level 2 or 3 financial assets and the Company s Level 1 financial assets were as follows:

	Level 1 (in thousands)
Money Market Funds	$ 37,619
Mutual Funds (invested in short-term U.S. Treasury Obligations)	41,670
Total	$ 79,289

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

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

For the three and six months ended March 31, 2009 and 2008, the Company derived all of its revenues from one customer (see Note 4).

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

The Company s revenues are primarily related to its collaboration agreement with Roche. This agreement provides for various types of payments to the Company, including non-refundable upfront license fees, research and/or development payments, and milestone payments.

Where the Company has continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as revenues as the related activities are performed. The period over which these activities are to be performed is based upon management s estimate of the development period. Changes in management s estimate could change the period over which revenues are recognized. Research and/or development payments are recognized as revenues as the related research and/or development activities are performed and when the Company has no continuing performance obligations related to the research and development payment received.

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

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

Table of Contents

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

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

In accordance with EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3), nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Stock-Based Compensation The Company accounts for share-based payment(s) in accordance with SFAS No. 123R, *Share-Based Payment* (SFAS 123R). SFAS 123R requires companies to recognize stock compensation expense for awards of equity instruments to employees based on grant-date fair value of those awards (with limited exceptions). The Company adopted SFAS 123R on October 1, 2006, using the modified prospective method, which results in recognition of compensation expense for all share-based awards granted or modified after October 1, 2006 as well as all unvested awards outstanding at the date of adoption. Stock options granted to consultants are periodically valued as they vest in accordance with EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a Black-Scholes option pricing model.

Stock-based compensation expense is included in both research and development expenses and in general and administrative expenses in the statements of operations and comprehensive net (loss) income. Since the Company s stock was not publicly traded prior to April 27, 2007, the expected volatility was calculated for each date of grant prior to having a publicly traded stock based on the peer method. The Company identified companies that trade publicly within the pharmaceutical industry that have similar SIC codes, employee count and revenues. The Company had chosen the weekly high price volatility for these companies for a period of five years. Effective October 1, 2006 the Company has used the weekly high price for these companies for a period of six years to coordinate with the expected term calculated pursuant to SAB No. 107 (SAB 107), relating to share-based payment, issued by the SEC.

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

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

The following table provides each of the inputs to the calculations of basic and diluted net loss per share for the three and six months ended March 31, 2009 and 2008.

Table of Contents

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009	2008	2009	2008
	(In thousands, except per share amounts)			
Numerator:				
Net loss	$ (15,472)	$ (12,136)	$ (33,748)	$ (24,309)
Denominator:				
Weighted average common shares outstanding used in calculation of basic net loss per share	26,262	21,380	24,800	21,321
Effect of dilutive securities:				
Common stock options				
Common stock warrants				
Weighted average common shares outstanding used in calculation of diluted net loss per share	26,262	21,380	24,800	21,321
Net loss per share:				
Basic	$ (0.59)	$ (0.57)	$ (1.36)	$ (1.14)
Diluted	$ (0.59)	$ (0.57)	$ (1.36)	$ (1.14)

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009	2008	2009	2008
	(In thousands)			
Common stock warrants	127	116	127	116
Options to purchase common stock	2,728	2,540	2,728	2,540
Total	2,855	2,656	2,855	2,656

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

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

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

Recently Issued Accounting Pronouncements In December 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature would be presented. Companies

are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1

Table of Contents

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 adoption of SFAS 141R is not expected to have a material impact on the Company.

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

3. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of March 31, 2009	As of September 30, 2008
	(In thousands)	
Accrued compensation	$ 830	$ 1,161
Accrued legal fees	1,098	984
Accrued license fees	108	
Accrued clinical trial expenses	4,931	3,367
Other accrued expenses	450	670
	$ 7,417	$ 6,182

4. CONTRACT REVENUE AGREEMENTS

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Cash received/receivable	$ 1,438	$	$ 1,438	$
Deferred				
Amortization	465	464	929	929

Revenues	$ 1,903	$ 464	$ 2,367	$ 929

Table of Contents

The Company recorded revenues from the collaboration agreement with Roche comprising 100.0% of total revenues during the three and six months ended March 31, 2009 and 2008. The $1.9 million of revenues during the three months ended March 31, 2009 reflect amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue of $0.5 million and $1.4 million of research and development payments from Roche for activities related to holding the Investigational New Drug (IND) application for R7128, for which we have no continuing performance obligations related to this payment.

Roche In October 2004, the Company entered into a collaboration and license agreement with Roche to develop PSI-6130 and PSI-6130 pro-drugs (including R7128) for treating chronic hepatitis C infection, and to discover chemically related nucleoside polymerase inhibitors pursuant to a research collaboration which ended in December 2006. The Company granted Roche worldwide rights, excluding Latin America and Korea, to PSI-6130 and its pro-drugs. Roche paid the Company an up-front payment of $8.0 million and has agreed to pay future research and development costs. The up-front payment has been recorded as deferred revenue and is being amortized over the estimated development period. During the three months ended March 31, 2009, Roche also made research and development payments to the Company totaling $1.4 million for activities related to holding the IND application for R7128, all of which was recorded as revenue since there were no continuing performance obligations related to this payment. Roche is also required to make certain payments to the Company for R7128, a pro-drug of PSI-6130, 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 March 31, 2009 and September 30, 2008 was $4.8 million and $5.7 million, respectively.

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

The Company retained certain co-promotion rights in the United States. The Company will be required to pay Roche royalties on net product sales, if any, in Korea and Latin America, the territories the Company has retained. Prior to the transfer of the IND for R7128 to Roche, which occurred during December 2008, Roche funded and the Company was responsible for preclinical work, the IND filing, and the initial clinical trial, while Roche managed other preclinical studies and clinical development. Roche reimbursed the Company $0.5 million and $0.7 million during the three months ended March 31, 2009 and 2008, and $1.1 million and $2.8 million during the six months ended March 31, 2009 and 2008, respectively. Roche will continue to fund all of the expenses of, and be responsible for, other preclinical studies and future clinical development of R7128 in the territories licensed to Roche. Roche and Pharmasset will continue to jointly oversee all development and marketing activities of R7128 in the territories licensed to 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, and preclinical and clinical data related to this collaboration.

5. STOCK COMPENSATION

The Company s 1998 Stock Plan (the 1998 Plan), as amended, was originally adopted by its board of directors during 1998 and subsequently amended in 2000, 2004 and 2006. A maximum of 3,517,015 shares of the Company s common stock were authorized for issuance under the 1998 Plan. The purpose of the 1998 Plan is to provide an incentive to officers, directors, employees, independent contractors and to other persons who provide significant services to the Company. Upon the closing of its IPO, which occurred on May 2, 2007, the Company adopted the 2007 Equity Incentive Plan (the 2007 Plan). Upon the adoption of the 2007 Plan, no additional awards were granted under the 1998 Plan and the shares remaining for future grant under the 1998 Plan were transferred to the 2007 Plan. As of March 31, 2009, 201,106 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 incentive stock options, as defined under Section 422 of the Internal Revenue Code of 1986 or nonstatutory stock options. Options granted under the 2007 Plan have been at per share exercise prices equal to the fair market value of our common stock based on the publicly traded price as reported by The NASDAQ Stock Market LLC (NASDAQ) on the date of grant. The 2007 Plan will terminate in fiscal 2017 unless it is extended or terminated earlier pursuant to its terms. The assumptions used and weighted-average information for employee and director grants for the three and six months ended March 31, 2009 and 2008 are as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009(1)	2008	2009	2008
Risk free interest rate		2.92%	3.19%	4.16%

Expected dividend yield	0.0%	0.0%	0.0%
Expected lives (years)	5.79	5.98	6.05
Expected volatility	53.60%	54.39%	57.05%
Weighted-average fair value of options granted	$ 9.16	$ 9.97	$ 8.05

(1) No stock options were granted during the three months ended March 31, 2009.

Table of Contents

Generally, stock options granted under these plans have a contractual life of 10 years and vest pro rata over a four year term. A summary of the Company s stock option activity during the six months ended March 31, 2009 is as follows:

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

The range of exercise prices of stock options outstanding at March 31, 2009 was $3.00 to $32.00. The weighted average remaining contractual life of stock options outstanding at March 31, 2009 was 7.75 years. The total intrinsic value of options exercised during the six months ended March 31, 2009 was $804,245. As a result of applying the requirements of SFAS 123R, the Company recognized compensation expense of $833,764 and $681,421 during the three months ended March 31, 2009 and 2008, and $1,969,525 and $1,321,375 during the six months ended March 31, 2009 and 2008, respectively, related to stock options issued to employees and non-employees. At March 31, 2009 and September 30, 2008, $8,979,650 (including $8,431,646 resulting from the application of SFAS 123R) and $6,821,109 (including $5,981,822 resulting from the application of SFAS 123R), respectively, of deferred stock-based compensation expense related to employee and non-employee stock options remained unamortized. The unamortized amount of $8,431,646 as of March 31, 2009 has a weighted-average period of approximately 1.54 years to be recognized.

Outstanding as of March 31, 2009				Exercisable as of March 31, 2009	
Number of Options	Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
1,185,711	$ 3.00 - $4.49	6.46	$ 3.46	959,137	$ 3.34
35,251	4.50 - 5.99	7.93	5.47	22,532	5.46
48,602	6.00 - 7.49	2.98	6.46	48,602	6.46
99,666	7.50 -10.49	8.03	8.99	81,541	8.97
720,850	10.50 -15.00	8.59	13.68	208,938	13.63
636,981	15.01 - 29.99	9.49	18.65	73,875	18.74
1,000	30.00 - 45.00	8.81	32.00	250	32.00

Table of Contents

As of March 31, 2009, there were options to purchase 2,604,761 shares of the Company s common stock outstanding that were either vested or expected to vest in the future, of which options to purchase 1,394,875 shares were currently exercisable, with weighted average exercise prices of $9.81 and $6.18 per share, aggregate intrinsic values of $7,930,881 and $6,533,131 and weighted average remaining contractual terms of 7.75 and 6.75 years, respectively.

Restricted Stock During the fiscal year ended September 30, 2008, the Company issued a total of 40,666 shares of restricted stock to its non-employee directors and to a consultant. The restricted stock issued to each non-employee director vests on July 16, 2009, as long as the director continues to serve on the Company s board of directors on that date, unless the failure to be so engaged is due solely to the fact that the director is nominated but not re-elected to serve as a director. The restricted stock issued to the consultant vests quarterly over a four year period. On March 24, 2009, the Company issued a total of 14,000 shares of restricted stock to its non-employee directors. The restricted stock issued to each non-employee director vests on March 24, 2010, as long as the director continues to serve on the Company s board of directors on that date, unless the failure to be so engaged is due solely to the fact that the director is nominated but not re-elected to serve as a director. As of March 31, 2009, holders were vested in 24,229 of the 54,666 restricted shares outstanding, leaving a total of 30,437 restricted shares unvested as of March 31, 2009.

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

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

The Company recognized compensation expense of $213,768 during the six months ended March 31, 2009 related to restricted stock issued to its non-employee directors and to a consultant. Unrecognized compensation expense for the restricted shares granted to the non-employee directors was $223,753 at March 31, 2009. This amount will be recognized over the remaining vesting period of the restricted shares.

6. INCOME TAXES

Income tax expense was $0 during the three and six months ended March 31, 2009 and 2008. The Company s effective tax rate for the three and six months ended March 31, 2009 and 2008 was 0%, as the Company expects to have a loss for the full tax year. The net deferred tax asset as of March 31, 2009 remains fully offset by a valuation allowance since it is more likely than not that such tax benefits will not be realized.

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

As of March 31, 2009, the Company s unrecognized tax benefits have not significantly changed. The Company does not expect any significant changes to the unrecognized tax benefits within 12 months of the reporting date.

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

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

Table of Contents

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, the Company has not formally assessed whether there have been one or more changes in control since the Company s formation. In light of the completion of the registered direct offering of 4,678,000 shares of the Company s common stock on February 5, 2009, the Company is reconsidering the need to complete a formal assessment of whether there have 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 AND CONTINGENCIES

On May 23, 2005, the Company entered into an operating lease for office and laboratory space through May 22, 2010, in Princeton, New Jersey. Monthly lease payments began May 23, 2005. The Company also leases office space in Durham, North Carolina. Monthly lease payments began May 1, 2007 and, after amending the lease term on February 2, 2009, end on April 1, 2011.

As of March 31, 2009, future minimum payments under non-cancelable operating leases (including the amended lease noted above) are as follows:

	March 31, 2009 (In thousands)
Fiscal 2009	$ 463
Fiscal 2010	624
Fiscal 2011	49
Total minimum payments required	$ 1,136

We may pay up to an aggregate of $4.5 million in milestone payments and certain cost reimbursements if we reach milestones related to development and regulatory events under our license agreement with RFS Pharma LLC. We also agreed to pay Emory University up to an aggregate of $1.0 million in future marketing milestone payments under our license agreement for DFC. Under our collaboration and license agreement with Bukwang, up to an aggregate of $23.0 million in milestone payments are payable in the future if certain development, regulatory, and commercialization events occur. 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. None of these potential future payments are included in our financial statements, as the payments are contingent on the achievement of milestones, which we have not yet achieved.

8. DEBT

On September 30, 2007, the Company entered into a Loan Agreement that allowed the Company to borrow up to $30.0 million in $10.0 million increments (Loan Agreement). The Company borrowed the first and second $10.0 million increments by signing two Secured Promissory Notes (Notes A and B) on October 5, 2007 and March 28, 2008. Notes A and B bear interest at 12%. On December 12, 2008, the Company amended the Loan Agreement and borrowed $3.3 million by signing a Secured Promissory Note (Note C). Note C bears interest at 12.5%. Notes A, B, and C are to be repaid over a 45-month period with the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. The principal monthly repayments on each of the notes begin and end as follows:

Note	Begin	End
Note A	March 1, 2009	August 1, 2011
Note B	August 1, 2009	January 1, 2012

Note C	May 1, 2010	October 1, 2012

Table of Contents

Prepayment of the loans made pursuant to the Loan Agreement is subject to penalty and substantially all of our tangible and intangible assets (except for intellectual property) are collateral for the Loan Agreement. Total principal repayments of the three Notes amount to $2.7 million in fiscal 2009, $8.1 million in fiscal 2010, $9.4 million in fiscal 2011, $3.0 million in fiscal 2012, and $0.1 million in fiscal 2013. There are no additional borrowings available under the Loan Agreement.

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

In conjunction with entering into the Loan Agreement, the Company granted warrants to the lender to purchase shares of the Company s common stock (See Note 9). Since these warrants were granted in conjunction with entering into the Loan Agreement and with the intention of executing promissory notes, the relative fair value of the warrant was recorded as equity and deferred interest as the warrants became exercisable and the deferred financing costs and debt discount are being amortized over the term of the notes using the effective interest method.

9. STOCKHOLDERS EQUITY

Common Stock As of March 31, 2009, the Company had 100,000,000 shares of common stock authorized with a par value of $0.001, and the Company has reserved 2,728,061 and 127,248 shares of common stock for issuance upon the exercise of outstanding common stock options and outstanding warrants, respectively. Also, 201,106 shares of the Company s common stock were reserved for future grants of stock options (or other similar equity instruments) under the Company s 2007 Equity Incentive Plan as of March 31, 2009.

On May 2, 2007, the Company completed an IPO of 5,050,000 shares of its common stock at a public offering price of $9.00 per share. Net cash proceeds from the IPO were $40.7 million after deducting offering costs paid in fiscal 2007 and $39.1 million after deducting additional offering costs paid in fiscal 2006.

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

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

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

Table of Contents

10. SUBSEQUENT EVENTS

On April 20, 2009, the Company voluntarily terminated its Phase 3 registration studies of clevudine for the treatment of chronic hepatitis B infection after becoming aware of a number of spontaneous Serious Adverse Event reports and Events of Special Interest in patients receiving clevudine as prescribed therapy for hepatitis B in South Korea, where the drug is marketed by Bukwang under the trade name Levovir, and in Hong Kong, in clinical studies conducted in collaboration with investigators there and under sponsorships of Bukwang. The Company is in the process of determining if it will incur any non-recurring expenses or impairment charges from the termination of these studies and expects to record such expenses, if any, during the three months ended June 30, 2009.

On April 24, 2009, Roche initiated a Phase 2b study as part of its collaboration agreement with the Company for the development of R7128 for the treatment of HCV. Roche triggered a $10.0 million milestone payment to the Company upon initiating this study. The Company expects to receive this $10.0 million payment and immediately recognize it as revenue during the three months ended June 30, 2009.

Table of Contents

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 C virus (HCV) and, secondarily, on the development of Racivir® for the treatment of human immunodeficiency virus (HIV). Our research and development efforts focus on nucleos(t)ide analogs, a class of compounds which act to inhibit the enzymes required for viral replication. We currently have three clinical-stage product candidates, two of which we are developing ourselves and one of which we are developing with a strategic partner. We are also advancing a series of preclinical candidates in preparation for clinical development. Our three clinical stage product candidates are:

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

We are continuing to research a series of nucleotide analogs (both pyrimidines and purines) with the intention of identifying product candidates that can potentially be used in combination with our current nucleos(t)ides, R7128 or PSI-7851, or in combination with other classes of direct acting antivirals for the treatment of HCV.

Our research and development efforts focus on nucleoside and nucleotide analogs, compounds which act to inhibit viral replication. We are applying our expertise in nucleoside chemistry to the discovery and development of additional antiviral therapeutics for HCV. For example, we have identified a new series of proprietary nucleotide prodrugs that are referred to as phosphate prodrugs 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 goal of these efforts is to identify compounds with improved potency, safety, convenience, and oral bioavailability, and increased intrahepatic nucleoside triphosphate levels. Certain of these compounds have demonstrated exceptional *in vitro* anti-HCV activity with EC_{90} values up to 100 times lower than PSI-6130. Early studies in animals indicate that several of these compounds can achieve concentrations of the active triphosphate form in the liver up to 1000 times higher than PSI-6130 at equivalent doses.

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

Table of Contents

HCV Background

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

At least six major genotypes of HCV have been identified, each with multiple subtypes. Genotypes are designated with numbers (genotypes 1-6) and subtypes with letters. HCV genotypes 1, 2, and 3 appear to have a worldwide distribution, but their prevalence varies from one geographic area to another. Genotype 1 and its subtypes (1a and 1b) are the most common genotype globally, accounting for approximately 70% of infections. Patients with genotype 2 or 3 represent approximately 25% of the worldwide chronically infected HCV population and the remaining 5% is comprised of genotypes 3 through 6. Worldwide sales of HCV drugs in 2005 were approximately $2.2 billion and are forecasted to reach more than $4.0 billion by 2010 and more than $8.0 billion in 2015. Historical sales of HCV drugs increased as new therapies were introduced that improved the sustained viral response, or SVR, defined as a virus that is undetectable by a standard test utilizing polymerase chain reaction, or PCR, six months after discontinuation of therapy.

Certain Limitations of Current HCV Infection Therapy

Globally, the current standard of care is a combination of pegylated interferon plus a nucleoside analog, ribavirin. Pegylated interferon is a modified version of alpha interferon, a protein that occurs naturally in the human body and boosts the immune system s ability to fight viral infections. Roche, our collaboration partner in the development of R7128, is the market leader in sales of pegylated interferon and ribavirin under the brand names Pegasys® and Copegus® , respectively.

The standard of care, however, has substantial side effects that, in many patients, render treatment intolerable. For example, interferon and ribavirin patients report fatigue, bone marrow suppression, anemia, and neuropsychiatric effects. In addition, genotype 1 patients typically receive 48 weeks of pegylated interferon and ribavirin and achieve an SVR rate of less than 50%, which many physicians and patients believe is a low rate of success. Genotype 2 and 3 patients, treated for 24 weeks, achieve an SVR of between 60% to 80%. Despite current therapy, an estimated 400,000 patients globally are unable to obtain a sustained viral response. This illustrates the unmet medical need with regard to the currently available standard of care.

Nucleos(t)ide Analogs and Other Direct Acting Antivirals for HCV Therapy

The hepatitis C virus has several enzymes that are essential for its replication. To stop viral growth, many drug developers have focused on two enzyme-based targets: the protease (NS3) and the polymerase of HCV (NS5b). Their goal is to identify and develop molecules that have both a high affinity for these enzymes and which inhibit their activity, thus not allowing the virus to spread within the infected individual. These treatment approaches are referred to as protease inhibitors and polymerase inhibitors.

Pharmasset s efforts focus on nucleos(t)ide analog inhibitors of NS5b, which could lead to establishing a new standard of care for HCV. A nucleoside is a basic building block of the nucleic acids, DNA and RNA, the genetic material of all living cells and viruses. Nucleosides consist of a molecule of sugar linked to a nitrogen-containing organic ring compound. In the most important naturally occurring nucleosides, the sugar is either ribose (used to construct RNA) or deoxyribose (used to construct DNA), and the nitrogen-containing compound, referred to as the base, is either a pyrimidine (cytosine, thymine, or uracil) or a purine (adenine or guanine). A nucleoside combined with a phosphate group becomes a nucleotide. In biological systems, nucleotides are linked by enzymes, including the polymerase, in a specific order to make long, chainlike polynucleotides (DNA or RNA) of defined sequence to pass along genetic information for a specific protein, a gene, or an entire organism, a genome. A nucleoside analog is a synthetic molecule that resembles a naturally occurring nucleoside. Chemical modifications in either the sugar portion or the base portion allow these compounds to inhibit or disrupt the activity of the polymerase. When a nucleoside analog is incorporated into viral DNA or RNA during replication, the nucleoside analog acts to prevent production of new virus by blocking the complete synthesis of the new viral DNA or RNA genome.

In vitro experiments conducted by Pharmasset and others have shown that nucleos(t)ide analogs have consistent antiviral activity across all HCV genotypes. Recent clinical studies of R7128, as more fully described below, show comparable anti-HCV activity across genotypes 1, 2, and 3. Other non-nucleoside classes of anti-HCV drugs tested clinically have shown diminished antiviral activity outside of genotype 1.

Table of Contents

In monotherapy studies with three nucleoside analogs (including R7128) over 14 days, viral breakthrough or viral rebound while on therapy did not occur. In studies of non-nucleoside polymerase and protease inhibitors in humans infected with HCV, viral breakthrough or viral rebound was seen as early as 3 to 4 days into the 14-day treatment period. The relative rapidity of the rebound suggests that these patients may have harbored virus that was not susceptible to therapy. With longer exposure to any HCV therapy, drug resistant virus will likely be selected over time. The rapidity with which this occurs will likely have significant consequences for patients.

Summary of Nucleoside Analogs and Their Use as Future Therapy

Nucleoside analogs have long been considered the backbone of therapy for human immunodeficiency virus, or HIV. Recent experience with HCV suggests that combinations of antivirals with different modes of action will continue to be used in the treatment of HCV. The combinations may not include the current standard of care, pegylated interferon and ribavirin. In consultation with experts in the field and our advisors, we believe the combination of nucleos(t)ide analogs with, for example, protease inhibitors or non-nucleoside polymerase inhibitors, presents a potentially useful therapeutic regimen. These different classes of direct acting antivirals (DAAs) are metabolized via different routes of elimination and use different and complementary mechanisms of action, suggesting that they will not adversely affect or antagonize the antiviral activity of the other compound. In addition, nucleoside inhibitors have demonstrated *in vitro* the ability to suppress the resistant variants that emerge with partially-suppressive concentrations of protease inhibitors. Clinical use of a combination of DAAs may provide improved antiviral activity across HCV genotypes and may avoid the adverse side effects that are often found with the current standard of care.

We describe below our nucleos(t)ide research and development programs.

R7128

In October 2004, we entered into a collaboration with Roche for the development and commercialization of PSI-6130 (an oral cytidine neucleoside analog inhibitor we discovered) and its pro-drugs, including R7128, for the treatment of HCV. A pro-drug is a chemically modified form of a molecule designed to enhance the absorption, distribution and metabolic properties of that molecule. Roche and we initiated an adaptive Phase 1 clinical trial with R7128 in October 2006 under an IND filing. On October 12, 2007, we were informed by the FDA that R7128 received fast track designation. During September 2008, we completed the clinical activities of this clinical trial. Following is a review of the composition and results of this trial.

This adaptive Phase 1 clinical trial of R7128 was 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 subjects and in patients chronically infected with HCV genotypes 1, 2, or 3. This trial provided antiviral potency data over 14 and 28 days in patients chronically-infected with genotype 1 HCV and following 28 days of treatment in patients chronically-infected with HCV genotypes 2 or 3 who had not responded to earlier standard of care therapy. This study comprised three parts:

Part 1 was a single ascending dose study conducted in 46 healthy subjects. The primary objective of Part 1 was to assess the safety, tolerability, and pharmacokinetics of 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 subjects in five sequential dose groups (500 mg, 1500 mg, 4500 mg, 6000 mg, and 9000 mg) and one food effect group (1500 mg). Results from the single ascending dose portion of the study indicated:

All doses of 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 other safety laboratory abnormalities of clinical significance were noted.

No maximum tolerated dose was identified.

Part 2 was a multiple ascending dose study conducted in 40 patients chronically infected with HCV genotype 1 who had previously failed interferon therapy. The primary objective of Part 2 was to assess the safety, tolerability, and pharmacokinetics of 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

Table of Contents

monotherapy. The maximum decrease in HCV RNA from baseline was 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. Based on the mean data, 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 1500 mg BID of R7128, a value below the level of detection, which was less than 15 International Units per milliliter (15 IU/ml).

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

R7128 was generally safe and well tolerated over 14 days of treatment of patients chronically infected with HCV genotype 1 who had previously failed interferon therapy. There were no serious adverse events, no adverse events requiring dose modification, and no dose-related gastrointestinal adverse events.

Part 3 was a 4-week study of 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 genotype 1 HCV and, additionally, in 25 prior treatment non-responders, or patients who did not achieve an SVR with previous interferon-based therapy, who were chronically infected with HCV genotypes 2 or 3. The primary objective of this study was to assess the safety, tolerability, and pharmacokinetics of R7128 in the clinically relevant setting of combination therapy with the current standard of care for chronic HCV infection. The secondary objective of Part 3 was to evaluate the short-term change in HCV RNA. The study included 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 cohort 4) in patients chronically infected with HCV genotypes 2 or 3. All four dose regimens were administered twice-daily with Pegasys plus Copegus for 4 weeks. Dose cohorts 1, 2, and 4 enrolled 25 patients, with 20 patients randomized to receive R7128 and five patients randomized to receive placebo. Cohort 3 enrolled 31 patients, with 25 patients randomized to receive R7128 and six patients randomized to receive placebo. After completing 4 weeks of the triple combination regimen and a follow-up period of four weeks of Pegasys plus Copegus, all patients went on to receive up to 16-40 weeks of open-label standard of care dosing under a separate protocol, for a total of 24 to 48 weeks of SOC therapy.

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

Following 4 weeks of treatment with R7128 500mg BID with Pegasys plus Copegus (cohort 1), patients achieved a mean 3.8 $\log_{10}$ IU/mL decrease in HCV RNA and 30% (6 of 20) achieved undetectable levels of HCV RNA (<15 IU/ml), or rapid virologic response (RVR).

Following 4 weeks of treatment with R7128 1500mg BID with Pegasys plus Copegus (cohort 2), patients achieved a mean 5.1 $\log_{10}$ IU/mL decrease in HCV RNA and 85% (17 of 20) achieved RVR.

Following 4 weeks of treatment with R7128 1000mg BID with Pegasys plus Copegus (cohort 3), preliminary results indicated patients achieved a mean 5.1 $\log_{10}$ IU/mL decrease in HCV RNA and 88% (22 of 25) patients achieved RVR.

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

For cohorts 1, 2 and 3 in treatment-naïve genotype 1 patients, 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 periods of triple therapy, and most of the adverse events reported were of mild to moderate intensity. Headache and fatigue were the most frequently reported adverse events in patients who received

active R7128 plus Pegasys plus Copegus, with an overall frequency of 66% and 42% reporting at least one of these events, respectively. These events were also the most frequently reported adverse events in patients who received placebo with Pegasys and Copegus. In general, the adverse events reported were consistent with the clinical safety profile for Pegasys and Copegus,

Table of Contents

including the frequency and severity of these adverse events, as well as any general body system observations. Grade 3/4 neutropenia was observed in 31% of the placebo patients and in 12% to 30% of the R7128 patients in each active dosing cohort. Grade 3 changes in hemoglobin were observed in 19% of the placebo patients and in 31% of the R7128 patients. There were no clinically significant changes in hepatic, renal, or other safety laboratory parameters, vital signs, or electrocardiograms. Overall, there was no clinical evidence of any major organ toxicities related to 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 Pegasus plus Copegus in patients with HCV genotype 1.

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

Following 4 weeks of treatment with R7128 1500mg BID with Pegasys plus Copegus (cohort 4), preliminary results indicated patients achieved a mean 5.0 $\log_{10}$ IU/mL decrease in HCV RNA and 90% (18 of 20) patients achieved RVR.

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

Safety and tolerability during the 4-week treatment period were similar for 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. One subject discontinued R7128, Pegasys and Copegus due to protocol specified stopping criteria (not treatment-emergent), and ECG changes. Adverse events reported in cohort 4 were similar to those reported in Cohorts 1-3. Grade 3/4 neutropenia was observed in 0% of the 5 placebo patients and in 20% of the 20 R7128 patients in the active dosing cohort. Grade 3 changes in hemoglobin were observed in 20% of the placebo patients and in 25% of the R7128 patients. There were no clinically significant changes in hepatic, renal, or other safety laboratory parameters, vital signs, or electrocardiograms. As seen in the patients infected with HCV genotype 1, there was no clinical evidence of any major organ toxicities related to R7128. R7128 was generally safe and well-tolerated when administered for 4 weeks in combination with Pegasus plus Copegus in patients with HCV genotypes 2 and 3.

On April 24, 2009, Roche and we began dosing in a Phase 2b study with R7128. The Phase 2b trial is anticipated to enroll about 400 treatment-naive, genotype-1 or genotype-4 HCV-infected patients. The trial will evaluate the dose and duration of treatment of R7128 in combination with Pegasys plus Copegus. The primary efficacy endpoint of the trial will be the proportion of patients that achieve an SVR. Patients are expected to be enrolled into one of 5 arms:

24 weeks of total treatment, with R7128 500mg BID in combination with Pegasys plus Copegus for 12 weeks, followed by 12 weeks of Pegasys plus Copegus

24 weeks of total treatment, with R7128 1000mg BID in combination with Pegasys plus Copegus for 12 weeks, followed by 12 weeks of Pegasys plus Copegus

24 weeks of total treatment, with R7128 1000mg BID in combination with Pegasys plus Copegus for 8 weeks, followed by a further 16 weeks of Pegasys plus Copegus

48 weeks of total treatment, with R7128 1000mg BID in combination with Pegasys plus Copegus for 12 weeks, followed by a further 36 weeks of Pegasys plus Copegus.

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

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

Table of Contents

On April 25, 2009, Roche, InterMune, Inc., and we announced the first results from our initial study of an interferon-free regimen for the treatment of patients chronically infected with HCV. This study, INFORM-1, combined for the first time in patients, two oral, direct acting antiviral drugs, R7128 and R7227, which is being developed by InterMune, Inc., in collaboration with Roche. INFORM-1 is a randomized, double-blind, ascending dose Phase I trial. Patients receiving the combination of R7227 and R7128 for 14 days, without pegylated interferon or ribavirin, experienced a median reduction in HCV RNA of -4.8 to -5.2 $\log_{10}$ IU/mL in the highest doses tested to date. The addition of R7128 to R7227 resulted in sustained HCV RNA reductions over the dosing period, with approximately 63% of patients having levels of virus in their blood below the limit of the quantification of the diagnostic assay (less than 40 IU/mL). Furthermore, 25% of patients in the highest dosage groups were below the limit of detection of the virus in their blood (less than 15 IU/mL) on the 14th day of dosing.

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

The companies are now exploring combinations of R7128 dosed twice-daily at 1000mg with R7227 dosed twice-daily at 600mg and 900mg. In this expanded study, the companies also plan to explore this combination in treatment-experienced patients with HCV, or those who did not achieve SVR with a previous interferon-based treatment.

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

PSI-7851

PSI-7851 is a pro-drug of a nucleotide analog currently in development for the treatment of chronic HCV infection. PSI-7851 has demonstrated *in vitro* anti-HCV activity with EC_{50} values of approximately 90 +/- 60 nM, which is approximately 15- to 20- fold more potent than the active metabolite of our first generation nucleoside polymerase inhibitor, PSI-6130. The half-life of the triphosphate in primary human hepatocytes is approximately 38 hours, which suggests the possibility for once-daily dosing. Like R7128, PSI-7851 has demonstrated *in vitro* activity against all of the most common HCV genotypes.

We filed an IND for PSI-7851 with the FDA on January 30, 2009 and on March 30, 2009, dosing started in a Phase 1, single ascending dose (SAD) study in healthy subjects. This study is a double-blind (subject and investigator blinded), randomized, parallel, placebo-controlled, single ascending dose, first-time-in-human study of PSI-7851. The primary objective is to investigate the safety, tolerability, and pharmacokinetics of PSI-7851 and metabolites following single oral administration in healthy subjects. We anticipate presenting preliminary results from this study at a scientific conference later in the year.

HCV Purine Nucleos(t)ide Research

We are researching third generation nucleos(t)ides utilizing a purine base, focusing on the generation of novel product candidates that have comparable antiviral activity to PSI-7851 and a resistance profile that is complementary to both R7128 and PSI-7851. One objective of this program is to identify and develop a proprietary combination treatment regimen, potentially consisting of the third generation product candidate and either R7128 or PSI-7851. We believe such a combination may have the potential to eliminate or reduce the use of interferon for the treatment of HCV. We have identified a series of purine molecules with the above characteristics and are presently evaluating their pharmacokinetics in order to select clinical candidates.

Racivir

Racivir is an oral, once-daily deoxycytidine nucleoside analog that we are developing as an HIV therapy for use in combination with other approved HIV drugs. In a completed Phase 2 clinical trial, for the subset of patients carrying the M184V mutation and less than three thymidine analog mutations, replacing lamivudine with Racivir in their existing

Table of Contents

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.

Financial History

We have incurred substantial operating losses since our inception because we have devoted substantially all of our resources to our research and development activities and have not generated any revenues from the sale of approved drugs. As of March 31, 2009, we had an accumulated deficit of $145.5 million. We expect our operating losses to continue for at least the next several years as we pursue the clinical development of PSI-7851, Racivir and our other product and development candidates, and as we expand our discovery and development pipeline.

We have funded our operations primarily through the sale of equity securities, payments received under collaboration agreements, borrowings under our Loan Agreement, government grants and interest earned on investments. We expect to continue to fund our operations over the next several years through the net proceeds of our completed public offerings, our existing cash resources, borrowing under our Loan Agreement, potential future milestone payments that we expect to receive from Roche if certain conditions are satisfied, interest earned on our investments and additional capital to be raised through partnerships with pharmaceutical companies, public or private equity offerings, or debt financings. We will require additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. As of March 31, 2009, we had approximately $79.3 million of cash and cash equivalents.

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 and its pro-drugs. We entered into our collaboration agreement with Roche in October 2004. Roche subsequently paid us an up-front payment of $8.0 million. Pursuant to the terms of our collaboration agreement with Roche, we received $20.0 million in milestone payments during the year ended September 30, 2007. As of March 31, 2009, we had received an aggregate of $34.4 million in payments under the Roche collaboration agreement, including research and development payments, as well as up-front license and milestone payments.

Under the current terms of the Roche collaboration agreement, if we succeed in obtaining all of the regulatory approvals specified in the agreement for PSI-6130 or a pro-drug of PSI-6130, including R7128, as of March 31, 2009, the maximum future development and commercialization milestone payments payable to us are $115.0 million. On April 24, 2009, Roche initiated a Phase 2b study as part of its collaboration with us and triggered a $10.0 million milestone payment to us. We expect to receive the $10.0 million milestone payment during the quarter ended June 30, 2009. Receipt of any additional milestone payments depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments.

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

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Our research activities are primarily focused on discovering and developing novel drugs to treat HCV. Our development activities are primarily focused on the development of R7128 (in collaboration with Roche) and PSI-7851 for the treatment of HCV, and secondarily, on the development of Racivir for the treatment of HIV. We are responsible for all

25

Table of Contents

costs incurred in the clinical development of PSI-7851 and Racivir, as well as the research costs associated with our other internal research programs. On April 20, 2009, we voluntarily terminated our Phase 3 registration studies of clevudine for the treatment of hepatitis B virus (see *Part 1. - Item 1. Notes to Financial Statements Note 10. Subsequent Events* herein for additional information).

Under our collaboration with Roche, Roche will fund the clinical development and commercialization of R7128. Under this collaboration, Roche reimbursed us for all of the external expenses associated with, and we were responsible for, certain preclinical work, the IND filing, and the proof-of-concept clinical trial. During December 2008, we transferred the IND application for R7128 to Roche. Roche will continue to fund all of the expenses of, and be responsible for, other preclinical studies and future clinical development of R7128 in the territories licensed to Roche. We and Roche will continue to jointly oversee all development and marketing activities of R7128 in the territories licensed to Roche. Roche received a license only to PSI-6130 and its pro-drugs, including R7128.

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

The following table summarizes our research and development expenses for our current development projects, as well as clevudine, for the three and six months ended March 31, 2009 and 2008.

	Three Months Ended March 31,		Six Months Ended March 31,		Cumulative Project Costs
	2009	2008	2009	2008	
	(In thousands)				
Expenses attributed to projects:					
Clevudine Studies	$ 7,380	$ 4,932	$ 16,314	$ 11,987	$ 61,210
Phase 1 PSI-7851 Studies	1,126		1,308		1,308
Phase 2 Racivir Studies	24	95	33	153	4,238
Total attributed expenses	8,530	5,027	17,655	12,140	
Unattributed expenses					
Salaries and related personnel expenses	2,116	1,654	4,051	2,748	
Non-cash stock compensation expense	585	498	1,365	969	
Legal expenses associated with patents	497	406	910	637	
Preclinical studies and new drug discovery services	1,121	606	2,156	1,382	
Drug and laboratory supplies	273	243	486	728	
Consulting expense	78	134	51	217	
Facility and other expenses	494	422	1,043	720	
Total unattributed expenses	5,164	3,963	10,062	7,401	
Total research and development expenses	$ 13,694	$ 8,990	$ 27,717	$ 19,541	

We will continue to make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis. These determinations will be made in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate s commercial potential. We do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization for any of our product candidates, as there are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Product candidates that may appear promising at early stages of development may not reach the market for a number of reasons. For example, product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals, or may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality. The lengthy

process of seeking FDA and other regulatory agency approvals requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining regulatory approvals

Table of Contents

could materially adversely affect our product development effort and financial condition. Because of these and other risks and uncertainties, we cannot predict when or whether we will successfully complete the development of any of our product candidates or the ultimate product development cost or whether we will obtain any approval required by the FDA or other regulatory agencies on a timely basis, if at all.

As we obtain results from clinical trials, we may elect to discontinue or delay preliminary studies or clinical trials for a product candidate or development program in order to focus our resources on more promising product candidates or programs. We expect our research and development expenses to decrease after we complete the termination of the registration studies of clevudine.

General and Administrative Expenses

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

Results of Operations

Three and Six Months Ended March 31, 2009 and 2008

Revenues. Revenues increased to $1.9 million during the quarter ended March 31, 2009 from $0.5 million during the quarter ended March 31, 2008. Revenues during each period reflect amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue. Revenues during the quarter ended March 31, 2009 also include $1.4 million of research and development payments from Roche for activities related to holding the IND application for R7128, for which we have no continuing performance obligations.

Revenues increased to $2.4 million during the six months ended March 31, 2009 from $0.9 million during the six months ended March 31, 2008. Revenues during each period reflect amortization of up-front and subsequent collaborative and license payments received from Roche previously recorded as deferred revenue. Revenues during the six months ended March 31, 2009 also include $1.4 million of research and development payments from Roche for activities related to holding the IND application for R7128, for which we have no continuing performance obligations.

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Cash received/receivable	$ 1,438	$	$ 1,438	$
Deferred				
Amortization	464	464	929	929
Revenues	$ 1,902	$ 464	$ 2,367	$ 929

Research and Development Expenses. Research and development expenses increased to $13.7 million during the quarter ended March 31, 2009 from $9.0 million in the quarter ended March 31, 2008. This increase of $4.7 million consists primarily of a $2.4 million increase in Phase 3 registration clinical trial expenses for clevudine, an increase of $1.6 million for preclinical and clinical trial costs for our next generation HCV product candidate, PSI-7851, an increase in compensation expenses of $0.6 million ($0.1 million of which was non-cash stock compensation expense) resulting from an increase in headcount, and an increase of $0.1 million for preclinical costs for purine research. On April 20, 2009, we voluntarily terminated our Phase 3 registration studies of clevudine for the treatment of hepatitis B virus (see *Part 1. - Item 1. Notes to Financial Statements Note 10. Subsequent Events* herein for additional information).

Research and development expenses increased to $27.7 million during the six months ended March 31, 2009 from $19.5 million in the six months ended March 31, 2008. This increase of $8.2 million consists primarily of a $4.3 million increase in Phase 3 registration clinical trial

expenses for clevudine, an increase of $2.2 million for preclinical and clinical trial costs for our next generation HCV product candidate, PSI-7851, an increase in compensation expenses of $1.6 million ($0.4 million of which was non-cash stock compensation expense) resulting from an increase in headcount, and an increase of $0.1 million for preclinical costs for purine research.

Table of Contents

General and Administrative Expenses. General and Administrative expenses were $2.9 million during the quarter ended March 31, 2009, a decrease of $0.9 million from $3.8 million in the quarter ended March 31, 2008. The net decrease of $0.9 million was due primarily to decreases in legal fees of $0.5 million, insurance expenses of $0.2 million, audit and related expenses of $0.2 million, marketing expenses of $0.1 million, and miscellaneous administrative expenses of $0.2 million. Partially offsetting these decreases was an increase in compensation expense of $0.3 million ($0.1 million of which was non-cash stock compensation expense).

General and Administrative expenses were $6.9 million during the six months ended March 31, 2009, an increase of $0.5 million from $6.4 million in the six months ended March 31, 2008. The net increase of $0.5 million was due primarily to increases in compensation expense of $1.1 million ($0.4 million of which was non-cash stock compensation expense) and marketing expense of $0.4 million, that were partially offset by decreases in legal fees of $0.4 million, insurance expenses of $0.2 million, audit and related expenses of $0.2 million, and miscellaneous administrative expenses of $0.2 million.

Investment Income. Investment income decreased to $0.1 million during the quarter ended March 31, 2009 from $0.6 million in the quarter ended March 31, 2008, and decreased to $0.2 million during the six months ended March 31, 2009 from $1.5 million in the six months ended March 31, 2008. The decreases were due to lower rates of return on the average invested cash balances.

Interest Expense. Interest expense increased to $0.8 million during the quarter ended March 31, 2009 from $0.4 million in the quarter ended March 31, 2008, and increased to $1.6 million during the six months ended March 31, 2009 from $0.7 million in the six months ending March 31, 2008. The increases in interest expense were due to additional interest on borrowings of long-term debt of $13.3 million ($10.0 million on March 28, 2008 and $3.3 million on December 12, 2008).

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our collaboration agreements, borrowings under our Loan Agreement, and government grants. Since our inception, we have raised approximately $173.5 million in net proceeds from sales of our equity securities, including $43.5 million from our common stock offering completed on February 5, 2009. During the six months ended March 31, 2009, we borrowed $3.3 million in addition to the previously borrowed $20.0 million under our Loan Agreement entered into on September 30, 2007. At March 31, 2009, we held approximately $79.3 million in cash and cash equivalents and have invested substantially all of our available cash and cash equivalents in a mutual fund, which invests in short-term U.S. Treasury and Agency Obligations, or in a money fund account.

Net cash used in operating activities was $30.7 million during the six months ended March 31, 2009 compared to $26.5 million during the six months ended March 31, 2008. The $4.2 million increase in net cash used in operating activities during the six months ended March 31, 2009, as compared to the same period a year ago was due primarily to an increase in cash outflows for operations of $8.5 million that was partially offset by a reduction in cash outflows associated with changes in operating assets and liabilities of $4.3 million.

Net cash provided by investing activities of $0.3 million during the six months ended March 31, 2009 resulted from the maturity of $0.5 million of short-term investments that was partially offset by $0.2 million purchase of equipment and leasehold improvements. Net cash used in investing activities of $0.6 million during the six months ended March 31, 2008 was entirely for the purchase of equipment and leasehold improvements.

Net cash provided by financing activities was $46.6 million during the six months ended March 31, 2009, compared to $21.4 million during the six months ended March 31, 2008. The net cash provided by financing activities during the six months ended March 31, 2009 includes $43.5 million in net proceeds from the issuance of common stock completed on February 5, 2009, borrowings of long-term debt of $3.3 million, and proceeds from the exercise of stock options of $0.4 million, that were partially offset by principal payments on long-term debt and capital lease obligations of $0.6 million. The net cash provided by financing activities during the six months ended March 31, 2008 includes borrowings of long-term debt of $20.0 million, along with proceeds from the exercise of stock options of $1.5 million, that were partially offset by principal payments on capital lease obligations of $0.1 million.

Table of Contents

On September 30, 2007, we entered into a Loan Agreement that allowed us to borrow up to $30.0 million in $10.0 million increments (Loan Agreement). We borrowed the first and second $10.0 million increments by signing two Secured Promissory Notes (Notes A and B) on October 5, 2007 and March 28, 2008. Notes A and B bear interest at 12%. On December 12, 2008, we amended the Loan Agreement and borrowed $3.3 million by signing a Secured Promissory Note (Note C). Note C bears interest at 12.5%. Notes A, B, and C are to be repaid over a 45-month period with the first 15 monthly payments representing interest only followed by 30 equal monthly payments of principal and interest. The principal monthly repayments on each of the notes begin and end as follows:

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

Prepayment of the loans made pursuant to the Loan Agreement is subject to penalty and substantially all of our tangible and intangible assets (except for intellectual property) are collateral for the Loan Agreement. Total principal repayments of the three Notes amount to $2.7 million in fiscal 2009, $8.1 million in fiscal 2010, $9.4 million in fiscal 2011, $3.0 million in fiscal 2012, and $0.1 million in fiscal 2013. There are no additional borrowings available under the Loan Agreement.

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

Developing drugs, conducting clinical trials, and commercializing products is expensive and we will need to raise additional funds to achieve our strategic objectives. Although we believe our existing cash resources as of March 31, 2009 together with anticipated payments under our existing collaboration agreement will be sufficient to fund our projected cash requirements for the next 18 months, we will require additional financing in the future to complete our clinical trials for PSI-7851, to fund our portion, if any, of the cost of clinical trials for R7128 completed outside of the territories licensed by Roche, and to fund our other operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials, and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration agreements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our product candidates;
- the ability of our collaborators to achieve development milestones, marketing approval, and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;

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

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

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

the magnitude of our general and administrative expenses; and

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

Table of Contents

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

Contractual Obligations and Commitments

In May 2005, we entered into an operating lease for office and laboratory space through May 22, 2010, in Princeton, New Jersey. In April 2007, we entered into a lease for office space in Durham, North Carolina that, after amending the lease on February 2, 2009, ends on April 30, 2011. We executed three secured promissory notes totaling $23.3 million; $10.0 million in October 2007 and March 2008, and $3.3 million in December 2008. The secured promissory notes require payments of interest only for the first 15 months followed by 30 equal monthly payments of principal and interest. As of March 31, 2009, future payments under the Loan Agreement, minimum future payments under non-cancellable operating leases (including the lease extension noted above) are as follows:

	Payments Due By Period				
	Total	Less than 1 year	1-3 Years	4-5 Years	After 5 Years
			(In thousands)		
Debt obligations					
Debt maturities	$ 22,756	$ 5,774	$ 16,109	$ 873	$
Contractual interest	4,565	2,502	2,026	37	
Capital lease obligations					
Debt maturities					
Contractual interest					
Operating leases	1,136	927	209		
Purchase obligations					
Total contractual obligations	$ 28,457	$ 9,203	$ 18,344	$ 910	$

The above contractual obligations table does not include amounts for milestone payments related to development, regulatory or commercialization events to licensors or collaboration partners, as the payments are contingent on the achievement of these milestones, which we have not achieved. Under our collaboration and license agreement with Bukwang for clevudine, up to an aggregate of $23.0 million in milestone payments are payable in the future if certain development, regulatory and commercialization events occur. 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). 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. 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 dexelvucitabine (DFC).

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.

30

Table of Contents

Revenue Recognition

We recognize revenues in accordance with the Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB No. 104). SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. For agreements containing multiple elements, we follow the guidance in Financial Accounting Standards Board s (FASB) Emerging Issue Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF No. 00-21). In accordance with SAB No. 104 and EITF No. 00-21, the elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator and whether there is objective and reliable evidence of the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units either on the basis of each unit s fair value or using the residual method and the applicable revenue recognition criteria is applied to each of the separate units.

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

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as revenues as the related activities are performed. The period over which these activities are to be performed is based upon management s estimate of the development period. Changes in management s estimate could change the period over which revenues are recognized. Research and/or development payments are recognized as revenues as the related research and/or development activities are performed and when we have no continuing performance obligations related to the research and development payment received.

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

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

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

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves estimating the level of service performed on our behalf and the associated cost incurred in instances where we have not been invoiced or otherwise notified of actual costs. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, clinical trials, and manufacturing of clinical materials. We account for expenses associated with these external services by determining the total cost of a given study based on the terms of the related contract. We accrue for costs incurred as the services are being provided by monitoring the status of the trials and the invoices received from our external service providers. In the case of clinical trials, the estimated cost normally relates to the projected costs of treating the patients in our trials, which we recognize over the estimated term of the trial according to the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, the number of clinical trials and related research service agreements has been relatively limited and our estimates have not differed significantly from the actual costs incurred. We expect, however, as clinical trials for PSI-7851 advance, our estimated accruals for clinical and research services will be more material to our operations in future periods.

Table of Contents

Stock-based Compensation

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2009(1)	2008	2009	2008
Risk free interest rate		2.92%	3.19%	4.16%
Expected dividend yield		0.0%	0.0%	0.0%
Expected lives (years)		5.79	5.98	6.05
Expected volatility		53.60%	54.39%	57.05%
Weighted-average fair value of options granted		$ 9.16	$ 9.97	$ 8.05

(1) No stock options were granted during the three months ended March 31, 2009.

Recently Issued Accounting Standards

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. The adoption of SFAS 141R is not expected to have a material impact on us.

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

the presentation and disclosure requirements, which are to be applied retrospectively to all periods presented. The adoption of SFAS 160 is not expected to have a material impact on us.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Regarding our exposure to interest rate risk, there have been no material changes to the information in our Annual Report on Form 10-K filed with the SEC on December 11, 2008. In summary, we invest our excess cash in high quality, interest-bearing securities. The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we invest in highly liquid mutual and money market funds, and high quality marketable debt instruments of corporations, government agencies and financial institutions with maturities of less than two years. In addition, the $20.0 million we borrowed during fiscal 2008 has a fixed interest rate of 12% and the $3.3 million we borrowed during the six months ended March 31, 2009 has a fixed interest rate of 12.5%.

Foreign Currency Exchange Rate Risk

Regarding our exposure to foreign currency exchange rate risk, there have been no material changes to the information in our Annual Report on Form 10-K filed with the SEC on December 11, 2008. In summary, we have entered into some agreements denominated, wholly or partly, in foreign currencies, and, in the future, we may enter into additional agreements denominated in foreign currencies. If the values of these currencies increase against the United States dollar, our costs would increase. To date, we have not entered into any contracts to reduce the risk of fluctuations in currency exchange rates. In the future, depending upon the amounts payable under any such agreements, we may enter into forward foreign exchange contracts to reduce the risk of unpredictable changes in our costs. However, due to the variability of timing and amount of payments under any such agreements, foreign exchange contracts may not mitigate the potential adverse impact on our financial results.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (Exchange Act), as of March 31, 2009. Based on that evaluation, management concluded that these controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported as specified in SEC rules and forms.

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

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended March 31, 2009 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

Table of Contents

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, 2008 (Form 10-K). You should carefully consider the risks described in our Form 10-K, which could materially affect our business, financial condition or future results. The risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, and/or operating results. If any of the risks actually occur, our business, financial condition, and/or results of operations could be negatively affected.

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

Our Annual Meeting of Stockholders was held on March 24, 2009. There were present at the Annual Meeting in person or by proxy stockholders holding an aggregate of 20,571,419 shares of common stock. The results of the vote taken at the Annual Meeting with respect to the election of the nominees to be Class II Directors were as follows:

Class II Director Nominees	For	Withheld
G. Steven Burrill	19,587,611	983,808
Elliot F. Hahn	17,759,950	2,811,469
Robert F. Williamson	19,976,007	595,412

The terms of office of the following directors who were not up for re-election continued after the Annual Meeting: William J. Carney, Herbert J. Conrad, Michael K. Inouye, Fredric D. Price, and P. Schaefer Price.

A vote of the stockholders was taken at the Annual Meeting with respect to the proposal for the approval of the amendment of Pharmasset s 2007 Equity Incentive Plan to increase the number of shares issuable thereunder from 4,683,396 to 5,183,396. This vote resulted in 6,401,267 shares voted in favor of this proposal, 8,383,129 shares voted against this proposal, 113,111 shares abstained from voting, and 5,663,912 shares represented broker non-votes.

In addition, a vote of stockholders was taken at the Annual Meeting with respect to the proposal to ratify the selection by the Audit Committee of Grant Thornton LLP as our independent registered public accounting firm for the fiscal year ending September 30, 2009. This vote resulted in 20,455,645 shares voted in favor of this proposal, no shares voted against this proposal, and 115,774 shares abstained from voting.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1(1)	Second Amended and Restated Bylaws, as amended, of Pharmasset, Inc.
10.1(2)	Amendment No. 1 to License Agreement dated January 30, 2009 by and between Pharmasset, Inc. and Bukwang Pharm. Co., Ltd.

10.2(3)	Placement Agency Agreement dated January 29, 2009, by and between Pharmasset, Inc. and Leerink Swann LLC
10.3(3)	Form of Subscription Agreement
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.

Table of Contents

(1) Incorporated by reference to the Current Report on Form 8-K filed on January 21, 2009

(2) Incorporated by reference to the Current Report on Form 8-K filed on February 5, 2009

(3) Incorporated by reference to the Current Report on Form 8-K filed on January 30, 2009

Table of Contents

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: May 11, 2009

By: /s/ Kurt Leutzinger
Kurt Leutzinger

Chief Financial Officer

(duly authorized officer and principal financial officer)

Table of Contents

EXHIBIT INDEX

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