AVANIR PHARMACEUTICALS, INC.
Form 10-Q
February 02, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended December 31, 2009

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from _____ to _____.

Commission File No. 1-15803

AVANIR PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0314804**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
101 Enterprise Suite 300, Aliso Viejo, California	**92656**
(Address of principal executive offices)	(Zip Code)

(949) 389-6700

(Registrant s telephone number, including area code)

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 and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
YES þ NO o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES o NO o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company þ

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

As of January 31, 2010, the registrant had 83,383,455 shares of common stock issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

AVANIR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2009 (unaudited)	September 30, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,116,320	$ 31,486,012
Inventories	114,098	114,098
Prepaid expenses	678,349	397,100
Other current assets	934,938	331,717
Current portion of restricted investments in marketable securities	66,925	200,775
Total current assets	26,910,630	32,529,702
Restricted investments in marketable securities, net of current portion	401,550	267,700
Property and equipment, net	290,082	310,677
Non-current inventories	710,531	710,531
Other assets	256,933	249,462
TOTAL ASSETS	$ 28,569,726	$ 34,068,072
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 919,369	$ 1,214,117
Accrued expenses and other liabilities	1,238,908	1,001,599
Accrued compensation and payroll taxes	530,422	1,345,859
Current portion of deferred revenues	2,392,893	2,282,560
Total current liabilities	5,081,592	5,844,135
Accrued expenses and other liabilities, net of current portion	571,232	652,395
Deferred revenues, net of current portion	6,920,867	7,629,807
Total liabilities	12,573,691	14,126,337
Commitments and contingencies		
Stockholders equity:		
Preferred stock $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2009 (unaudited) and September 30, 2009		
Common stock $0.0001 par value, 200,000,000 shares authorized; 83,178,113 and 83,084,182 shares issued and outstanding as of December 31, 2009 (unaudited) and September 30, 2009, respectively	8,318	8,308
Additional paid-in capital	298,801,162	297,923,915
Accumulated deficit	(282,813,445)	(277,990,488)

Total stockholders equity	15,996,035	19,941,735
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 28,569,726	$ 34,068,072

The accompanying notes to condensed consolidated financial statements are an integral part of this statement.

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AVANIR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended December 31,	
	2009	**2008**
REVENUES AND COST OF RESEARCH SERVICES AND OTHER		
Revenue from royalties and royalty rights	$ 1,484,934	$ 1,696,796
Revenues from license agreements		57,265
Revenues from research services and other	1,484,934	1,754,061
Cost of research and development services		8,051
Research services and other gross profit	1,484,934	1,746,010
OPERATING EXPENSES		
Research and development	3,446,890	4,724,914
General and administrative	2,866,478	2,314,312
Total operating expenses	6,313,368	7,039,226
Loss from operations	(4,828,434)	(5,293,216)
OTHER INCOME (EXPENSES)		
Interest income	5,804	135,696
Interest expense		(480)
Other, net	(327)	(17,516)
Loss before provision for income taxes	(4,822,957)	(5,175,516)
Provision for income taxes		3,200
Net loss	$ (4,822,957)	$ (5,178,716)
Basic and diluted net loss per share	$ (0.06)	$ (0.07)
Basic and diluted weighted average number of common shares outstanding	83,159,376	78,225,041

The accompanying notes to condensed consolidated financial statements are an integral part of this statement.

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AVANIR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three Months Ended December 31,	
	2009	**2008**
OPERATING ACTIVITIES:		
Net loss	$ (4,822,957)	$ (5,178,716)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	52,181	81,177
Share-based compensation expense	699,072	386,134
Loss on disposal of assets		4,792
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(891,941)	(618,992)
Accounts payable	(294,748)	1,611,758
Accrued expenses and other liabilities	156,146	(474,199)
Accrued compensation and payroll taxes	(815,437)	(778,065)
Deferred revenues	(598,607)	(754,969)
Net cash used in operating activities	(6,516,291)	(5,721,080)
INVESTING ACTIVITIES:		
Purchase of property and equipment	(31,586)	(19,171)
Proceeds from disposal of assets		1,950
Net cash used in investing activities	(31,586)	(17,221)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock, net of commissions	183,044	
Tax withholding payments reimbursed by restricted stock payments on debt	(4,859)	
Payments on notes and capital lease obligations		(21,622)
Net cash provided by (used in) financing activities	178,185	(21,622)
Net decrease in cash and cash equivalents	(6,369,692)	(5,759,923)
Cash and cash equivalents at beginning of period	31,486,012	41,383,930
Cash and cash equivalents at the end of the period	$ 25,116,320	$ 35,624,007
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$	$ 480
Income taxes paid	$ 3,200	$ 4,313

The accompanying notes to condensed consolidated financial statements are an integral part of this statement.

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AVANIR PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of Avanir Pharmaceuticals, Inc. (Avanir , we , or the Company) have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC) for interim reporting including the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. These condensed consolidated financial statements do not include all disclosures for annual audited financial statements required by accounting principles generally accepted in the United States of America (U.S. GAAP) and should be read in conjunction with the Company s audited consolidated financial statements and related notes included in the Company s Annual Report on Form 10-K for the year ended September 30, 2009. The Company believes these condensed consolidated financial statements reflect all adjustments (consisting only of normal, recurring adjustments) that are necessary for a fair presentation of the financial position and results of operations for the periods presented. Results of operations for the interim periods presented are not necessarily indicative of results to be expected for the year.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts and the disclosures of commitments and contingencies in the financial statements and accompanying notes. Actual results could differ from those estimates.

2. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Avanir is a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. The Company s lead product candidate, Zenvia (dextromethorphan hydrobromide/quinidine sulfate), has successfully completed three Phase III clinical trials for the treatment of pseudobulbar affect (PBA) and has successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain (DPN pain). In addition to the Company s focus on products for the central nervous system, the Company also has partnered programs in other therapeutic areas which may generate future income. The Company s first commercialized product, docosanol 10% cream, (sold in the United States and Canada as Abreva® by its marketing partner GlaxoSmithKline Consumer Healthcare) is the only over-the-counter treatment for cold sores that has been approved by the U.S. Food and Drug Administration (FDA). In 2008, the Company out-licensed its monoclonal antibody program and remains eligible to receive milestone payments and royalties related to the sale of these assets. Avanir was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009.

The Company s operations are subject to certain risks and uncertainties frequently encountered by companies in the early stages of operations, particularly in the evolving market for small biotech and specialty pharmaceuticals companies. Such risks and uncertainties include, but are not limited to, timing and uncertainty of achieving milestones in clinical trials and in obtaining approvals by the FDA and regulatory agencies in other countries. The Company s ability to generate revenues in the future will depend on license arrangements, the timing and success of reaching development milestones, and obtaining regulatory approvals and ultimately market acceptance of Zenvia for the treatment of PBA, assuming the FDA approves the Company s new drug application. The Company s operating expenses depend substantially on the level of expenditures for clinical development activities for Zenvia for the treatment of PBA and the rate of progress being made on such programs.

Significant Accounting Policies

The following represents an update for the three months ended December 31, 2009 to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended September 30, 2009.

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Concentrations

As of December 31, 2009, $24.5 million of the Company s cash and cash equivalents were maintained in six separate money market mutual funds, and approximately $572,000 of the Company s cash and cash equivalents were maintained at two major financial institutions in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (FDIC), which provides deposit coverage with limits up to $250,000 per owner through January 1, 2014. At December 31, 2009, such uninsured deposits totaled $24.8 million. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear minimal risk.

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents. The Company s cash and cash equivalents are placed in various money market mutual funds and at financial institutions of high credit standing.

The Company performs ongoing credit evaluations of its customers financial condition and would limit the amount of credit extended if necessary; however the Company has usually required no collateral.

Fair value of financial instruments

At December 31, 2009 and September 30, 2009, the Company s financial instruments included cash and cash equivalents, restricted investments in marketable securities, accounts payable, accrued expenses and other liabilities, and accrued compensation and payroll taxes. The carrying amount of cash and cash equivalents, accounts payable, accrued expenses and other liabilities, and accrued compensation and payroll taxes approximates fair value due to the short-term maturities of these instruments. The Company s short-term and long-term restricted investments in marketable securities are carried at fair value based on quoted market prices.

Revenue Recognition

The Company has historically generated revenues from product sales, collaborative research and development arrangements, and other commercial arrangements such as royalties, the sale of royalty rights and sales of technology rights. Payments received under such arrangements may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, royalties on sales of products resulting from collaborative arrangements, and payments for the sale of rights to future royalties.

The Company recognizes revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the Company s price to the buyer is fixed and determinable; and (4) collectability is reasonably assured. Certain product sales are subject to rights of return. For products sold where the buyer has the right to return the product, the Company recognizes revenue at the time of sale only if (1) the Company s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the Company, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer s obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes such product revenues when either it has met all the above criteria, including the ability to reasonably estimate future returns, when it can reasonably estimate that the return privilege has substantially expired, or when the return privilege has substantially expired, whichever occurs first.

Product Sales Active Pharmaceutical Ingredient docosanol (docosanol). Revenue from sales of the Company s docosanol is recorded when title and risk of loss have passed to the buyer and provided the criteria for revenue recognition are met. The Company sells the docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than three times a year. The Company s contracts for sales of the docosanol include buyer acceptance provisions that give the Company s buyers the right of replacement if the delivered product does not meet specified criteria. That right requires that they give the Company notice within 30 days after receipt of the product. The Company has the option to refund or replace any such defective materials; however, it has historically demonstrated that the materials shipped from the same pre-inspected lot have

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consistently met the specified criteria and no buyer has rejected any of the Company s shipments from the same pre-inspected lot to date. Therefore, the Company recognizes revenue at the time of delivery without providing any returns reserve.

Multiple Element Arrangements

The Company has arrangements whereby it delivers to the customer multiple elements including technology and/or services. Such arrangements have generally included some combination of the following: antibody generation services; licensed rights to technology, patented products, compounds, data and other intellectual property; and research and development services. The Company analyzes its multiple element arrangements to determine whether the elements can be separated. The Company performs its analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables will be accounted for as a single unit of accounting.

A delivered element can be separated from other elements when it meets all of the following criteria: (1) the delivered item has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item; and (3) if the arrangement includes a general right of return relative to the delivered item, delivery, or performance of the undelivered item is considered probable and substantially in the Company s control. If an element can be separated the Company allocates amounts based upon the relative fair values of each element. The Company determines the fair value of a separate deliverable using the price it charges other customers when it sells that product or service separately; however, if the Company does not sell the product or service separately, it uses third-party evidence of fair value. The Company considers licensed rights or technology to have standalone value to its customers if it or others have sold such rights or technology separately or its customers can sell such rights or technology separately without the need for the Company s continuing involvement.

License Arrangements. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive licensed rights to patented or patent pending compounds, technology access fees, various performance or sales milestones. These arrangements are often multiple element arrangements.

Non-refundable, up-front fees that are not contingent on any future performance by the Company, and require no consequential continuing involvement on its part, are recognized as revenue when the license term commences and the licensed data, technology and/or compound is delivered. Such deliverables may include physical quantities of compounds, design of the compounds and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patents pending for such compounds. The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of the Company s performance under the other elements of the arrangement. In addition, if the Company has required continuing involvement through research and development services that are related to its proprietary know-how and expertise of the delivered technology, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenues upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.

Research Services Arrangements. Revenues from research services are recognized during the period in which the services are performed and are based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed-upon direct costs including direct materials and outsourced services, or subcontracted, pre-clinical studies are classified as revenues and recognized in the period the reimbursable expenses are incurred. Payments received in advance are deferred until the research services are performed or costs are incurred. These arrangements are often multiple element arrangements.

Royalty Arrangements. The Company recognizes royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales amounts generally required to be used for calculating

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royalties include deductions for returned product, pricing allowances, cash discounts, freight and warehousing. These arrangements are often multiple element arrangements.

Certain royalty arrangements require that royalties are earned only if a sales threshold is exceeded. Under these types of arrangements, the threshold is typically based on annual sales. For royalty revenue generated from the license agreement with GlaxoSmithKline, the Company recognizes royalty revenue in the period in which the threshold is exceeded. For royalty revenue generated from the license agreement with Azur Pharma, the Company recognizes revenue when it has confirmed that the threshold has been exceeded.

When the Company sells its rights to future royalties under license agreements and also maintains continuing involvement in earning such royalties, it defers recognition of any upfront payments and recognizes them as revenues over the life of the license agreement. The Company recognizes revenues for the sale of an undivided interest of its Abreva® license agreement to Drug Royalty USA under the units-of-revenue method. Under this method, the amount of deferred revenues to be recognized in each period is calculated by multiplying the ratio of the royalty payments due to Drug Royalty USA by GlaxoSmithKline for the period to the total remaining royalties the Company expects GlaxoSmithKline will pay Drug Royalty USA over the remaining term of the agreement by the unamortized deferred revenues.

Government Research Grant Revenues. The Company recognizes revenues from federal research grants during the period in which the related expenditures are incurred.

Cost of Revenues

Cost of revenues includes direct and indirect costs to manufacture product sold, including the write-off of obsolete inventory, and to provide research and development services.

Recognition of Expenses in Outsourced Contracts

Pursuant to management s assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management s judgment. Several of the Company s contracts, including subsequent amendments, extend across multiple reporting periods.

Share-Based Compensation

The Company grants options, restricted stock units and restricted stock awards to purchase its common stock to its employees, directors and consultants under its stock option plans. The benefits provided under these plans are share-based payments that the Company accounts for using the fair value method.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model (Black-Scholes model) that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the Company s expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on historical volatility of the Company s common stock and other factors. The expected terms of options granted are based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since the Company does not expect to pay dividends on its common stock in the foreseeable future, the Company estimated the dividend yield to be 0%.

Share-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest amortized under the straight-line attribution method. As share-based compensation expense recognized in the consolidated statements of operations for periods in fiscal 2010 and 2009 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The fair value

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method requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on its historical experience.

Total compensation expense related to all of the Company s share-based awards for the three month periods ended December 31, 2009 and 2008 was comprised of the following:

	For the three months ended December 31,	
	2009	2008
Share-based compensation classified as:		
General and administrative expense	$ 516,912	$ 305,999
Research and development expense	182,160	80,135
Total	$ 699,072	$ 386,134

	For the three months ended December 31,	
	2009	2008
Share-based compensation expense from:		
Stock options	$ 238,950	$ 178,789
Restricted stock units	460,122	207,345
Total	$ 699,072	$ 386,134

Since the Company has a net operating loss carryforward as of December 31, 2009, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in the three month periods ended December 31, 2009 and 2008 that would have resulted in a reclassification to reduce net cash used in operating activities with an offsetting increase in net cash provided by (used in) financing activities. (See Note 10, Employee Equity Incentive Plans.)

Income Taxes

The Company accounts for income taxes and the related accounts under the liability method. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company recognizes any uncertain income tax positions on the income tax returns at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The total amount of unrecognized tax benefits as of the date of adoption was $3.0 million. At December 31, 2009, the total unrecognized tax benefit resulting in a decrease in deferred tax assets, and corresponding decrease in the valuation allowance is $3.3 million. There are no unrecognized tax benefits included in the consolidated balance sheet that would, if recognized, affect the effective tax rate.

The Company s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had $0 accrued for interest and penalties on the Company s condensed consolidated balance sheets at December 31, 2009 and September 30, 2009.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company s tax years for 1992 and forward are subject to examination by the U.S. and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

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The Company does not foresee material changes to its gross uncertain income tax liability within the next twelve months.

Recent Authoritative Guidance

Multiple-Deliverable Revenue Arrangements. In September 2009, the FASB issued authoritative guidance regarding multiple-deliverable revenue arrangements. This guidance addresses how to measure and allocate consideration to one or more units of accounting. Specifically, the guidance requires that consideration be allocated among multiple deliverables based on relative selling prices. The guidance establishes a selling price hierarchy of (1) vendor-specific objective evidence, (2) third-party evidence and (3) estimated selling price. This guidance is effective for annual periods beginning on or after June 15, 2010 but may be early adopted as of the beginning of an annual period. The Company is currently evaluating the effect that this guidance will have on its consolidated financial position, results of operations and cash flows.

Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity s Own Stock. In June 2008, the FASB issued authoritative guidance on determining whether an instrument (or an embedded feature) is indexed to an entity s own stock. This guidance provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument s contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. The Company adopted this guidance effective October 1, 2009. The adoption of this guidance did not have a material impact on its consolidated financial position, results of operations and cash flows.

Noncontrolling Interests in Consolidated Financial Statements. In December 2007, the FASB issued authoritative guidance on noncontrolling interests in consolidated financial statements, which is intended to improve the relevance, comparability and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing certain required accounting and reporting standards. This guidance is effective for fiscal years beginning on or after December 15, 2008. The Company adopted this guidance effective October 1, 2009. The adoption of this guidance did not have a material impact on its consolidated financial position, results of operations and cash flows.

Fair Value Measurements. In September 2006, the FASB issued authoritative guidance on fair value measurements, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This guidance was effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB delayed the effective date of this guidance for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those years. The Company adopted certain provisions of this guidance effective October 1, 2008 and the delayed provisions of this guidance effective October 1, 2009. The adoption of this guidance did not have a material impact on its consolidated financial position, results of operations and cash flows.

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company measures the fair value of certain of its financial assets on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1-Quoted prices in active markets for identical assets and liabilities.

Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets and liabilities, quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3-Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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As of December 31, 2009, the Company s cash equivalents of approximately $24.5 million are all valued using quoted prices generated by market transactions involving identical assets, or Level 1, as defined by the fair value hierarchy.

4. RESTRICTED INVESTMENTS IN MARKETABLE SECURITIES

Restricted investments in marketable securities at December 31, 2009 and September 30, 2009 consist of certificates of deposits, which are classified as held-to-maturity. At December 31, 2009 and September 30, 2009, the fair value of these investments approximated their cost basis. At December 31, 2009, restricted investments in marketable securities totaling $66,925 and $401,550 are recorded as current and non-current assets, respectively, in the condensed consolidated balance sheet. Of these investments, $66,925 will mature in 2010 and $401,550 will mature throughout 2011 and 2013. At September 30, 2009, restricted investments in marketable securities totaling $200,775 and $267,700 were recorded as current and non-current assets, respectively, in the consolidated balance sheet.

5. INVENTORIES

Inventories relate to the active pharmaceutical ingredient docosanol and the active pharmaceutical ingredients of Zenvia, dextromethorphan and quinidine.

The composition of inventories is as follows:

	December 31, 2009	September 30, 2009
Raw materials	$ 824,629	$ 824,629
Less: current portion	(114,098)	(114,098)
Non-current portion	$ 710,531	$ 710,531

The amount classified as non-current inventories is comprised of docosanol and the raw material components for Zenvia, dextromethorphan and quinidine, which will be used in the manufacture of Zenvia capsules in the future.

6. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities are as follows:

	December 31, 2009	September 30, 2009
Accrued research and development expenses	$ 270,866	$ 372,494
Accrued general and administrative expenses	650,598	270,401
Deferred rent	18,410	19,516
Lease restructuring liability (1)	870,266	991,583
Total accrued expenses and other liabilities	1,810,140	1,653,994
Less: current portion	(1,238,908)	(1,001,599)
Accrued expenses and other liabilities, non-current portion	$ 571,232	$ 652,395

(1) In fiscal 2006, the Company relocated all operations other than research

and development from San Diego, California to Aliso Viejo, California. In fiscal 2007, the Company subleased a total of approximately 49,000 square feet of laboratory and office space in San Diego and relocated remaining personnel and clinical trial support functions to the Company s offices in Aliso Viejo, California. Restructuring expenses included recognition of the estimated loss due to the exit of the Company s leases of approximately $2.1 million. No further costs were incurred related to these restructuring events in fiscal 2008. In April 2009,

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the Company entered into a sublease for office space in San Diego, California. Sublease rental payments commenced in September 2009 pursuant to this sublease.

The following table presents the restructuring activities in fiscal 2010:

	Balance at September 30, 2009	Payments/ Reductions	Balance at December 31, 2009
Accrued Restructuring			
Total lease restructuring liability	$ 991,583	$ (121,317)	$ 870,266
Less current portion	(358,704)		(317,444)
Non-current portion	$ 632,879		$ 552,822

7. DEFERRED REVENUES

The following table sets forth as of December 31, 2009 the deferred revenue balances for the Company s sale of future Abreva® royalty rights to Drug Royalty USA:

	Total
Net deferred revenues as of October 1, 2009	$ 9,912,367
Changes during the period:	
Recognized as revenues during period	(598,607)
Net deferred revenues as of December 31, 2009	$ 9,313,760
Classified and reported as:	
Current portion of deferred revenues	$ 2,392,893
Deferred revenues, net of current portion	6,920,867
Total deferred revenues	$ 9,313,760

8. COMPUTATION OF NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period plus additional weighted average common equivalent shares outstanding during the period. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the

proceeds of which are then presumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In loss periods, certain of the common equivalent shares have been excluded from the computation of diluted net loss per share, because their effect would have been anti-dilutive.

For the three-month periods ended December 31, 2009 and 2008, the following options and warrants to purchase shares of common stock and restricted stock units were excluded from the computation of diluted net loss per share, as the inclusion of such shares would be anti-dilutive:

	2009	**2008**
Stock options	5,834,106	4,065,627
Stock warrants	12,240,437	12,509,742
Restricted stock units (1)	2,714,433	2,419,362

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(1) Includes 848,023 and 198,714 shares of restricted stock at December 31, 2009 and 2008, respectively, awarded to directors that have vested but are still restricted until the directors resign.

9. STOCKHOLDERS EQUITY

On July 30, 2009, the Company entered into a Controlled Equity Offering Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), providing for the sale of up to 12,500,000 shares of common stock from time to time into the open market at prevailing prices. Pursuant to the Sales Agreement, sales of common stock will be made in such quantities and on such minimum price terms as the Company may set from time to time. During the three month period ended December 31, 2009, the Company issued 85,600 shares of common stock under the Sales Agreement raising gross proceeds of approximately $189,000 ($183,000 after commissions). As of December 31, 2009, a total of 4,698,950 shares of common stock have been issued under the Sales Agreement at an average price of $2.34 per share raising gross proceeds of approximately $11.0 million ($10.4 million after offering expenses, including commissions).

During the three-month period ended December 31, 2009, the Company issued 11,001 shares of common stock in connection with the vesting of restricted stock units. In connection with the vesting, two officers elected to pay for minimum required withholding taxes associated with the vesting of restricted stock by surrendering 2,670 shares of common stock at a market price of $1.82 per share.

As of December 31, 2009, warrants to purchase 12,240,437 shares of the Company s common stock at a weighted-average exercise price per share of $1.43 remained outstanding, all of which are exercisable.

10. EMPLOYEE EQUITY INCENTIVE PLANS

The Company currently has five equity incentive plans under which awards are outstanding (the Plans), two of which are currently in active use as described below. The Plans are: the 2005 Equity Incentive Plan (the 2005 Plan), the 2003 Equity Incentive Plan (the 2003 Plan), the 2000 Stock Option Plan (the 2000 Plan), the 1998 Stock Option Plan (the 1998 Plan) and the 1994 Stock Option Plan (the 1994 Plan), which are described in the Company s Annual Report on Form 10-K for the year ended September 30, 2009. All of the Plans were approved by the stockholders, except for the 2003 Equity Incentive Plan, which was approved solely by the Board of Directors. Share-based awards are subject to terms and conditions established by the Compensation Committee of the Company s Board of Directors. The Company s policy is to issue new common shares upon the exercise of stock options, conversion of share units/RSUs or purchase of restricted stock.

During the three-month periods ended December 31, 2009 and 2008, the Company granted share-based awards under the 2003 Plan. Under the 2003 Plan and 2005 Plan, options to purchase shares, restricted stock units, restricted stock and other share-based awards may be granted to the Company s directors, employees and consultants. Under the Plans, as of December 31, 2009, the Company had an aggregate of 11,487,492 shares of its common stock reserved for future issuance. Of those shares, 8,548,539 were subject to outstanding options and other awards and 3,038,953 shares were available for future grants of share-based awards. As of December 31, 2009, 120,000 restricted stock units were outstanding to consultants. The Company may also, from time to time, issue share-based awards outside of the

Plans to the extent permitted by NASDAQ rules. As of December 31, 2009, there were no options to purchase shares of the Company s common stock that were issued outside of the Plans (inducement option grants) outstanding. None of the share-based awards are classified as a liability as of December 31, 2009.

Stock Options. Stock options are granted with an exercise price equal to the current market price of the Company s common stock at the grant date and have 10-year contractual terms. For option grants to employees in general, 25% of the option shares vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the option shares vest and become exercisable quarterly in equal installments thereafter over three years; for option grants to non-employee directors, one-third of the option shares vest and become exercisable on the first anniversary of the grant date and the remaining two-thirds of the option shares vest and become exercisable daily or quarterly in equal installments thereafter over two years; and for certain option grants to non-employee directors, options have been granted as fully vested and exercisable at the date of grant. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans). During fiscal 2008, the Company granted performance stock options to purchase 2,048,000 shares of common stock from the 2003 Equity Incentive Plan at a grant price of $0.88 per share. The grant price represents the market price of the Company s common stock on the date of grant. During fiscal 2009, 2,031,218 shares of performance stock options granted in fiscal 2008 were met and vesting began. The performance stock options are included in the equity compensation tables below.

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Summaries of stock options outstanding and changes during the three-month period ended December 31, 2009 are presented below.

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding October 1, 2009	4,217,156	$ 1.55		
Granted	1,616,950	$ 1.75		
Outstanding December 31, 2009	5,834,106	$ 1.60	8.8	$4,613,924
Vested and expected to vest in the future, December 31, 2009	4,875,857	$ 1.69	8.8	$3,907,984
Exercisable, December 31, 2009	1,029,845	$ 3.71	7.8	$ 869,412

The weighted average grant-date fair value of options granted during the three-month periods ended December 31, 2009 and 2008 was $1.40 and $0.40 per share, respectively. There were no options exercised in the three month periods ended December 31, 2009 and 2008. As of December 31, 2009, the total unrecognized compensation cost related to unvested options was approximately $3,905,000 which is expected to be recognized over the weighted-average period of 3.2 years, based on the vesting schedules.

The fair value of each option award is estimated on the date of grant using the Black-Scholes model, which uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company s common stock and other factors. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant.

Assumptions used in the Black-Scholes model for options granted during the three-month period ended December 31, 2009 were as follows:

Expected volatility	105%
Expected term in years	5.6
Risk-fee interest rate (zero coupon U.S. Treasury Note)	2.5%
Expected dividend yield	0%

The following table summarizes information concerning outstanding and exercisable stock options as of December 31, 2009:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.47-$0.79	1,605,010	9.0	$ 0.53	357,253	$ 0.53
$0.88	2,031,218	8.6	$ 0.88	363,248	$ 0.88

$1.20-$1.74	1,722,910	9.7	$ 1.70	13,750	$ 1.20
$2.08-$9.92	253,031	7.4	$ 3.82	76,000	$ 6.68
$10.24-$19.38	221,937	5.3	$12.72	219,594	$12.68
	5,834,106	8.8	$ 1.60	1,029,845	$ 3.71

Restricted stock units service-based (RSU). RSUs granted to employees generally vest based on three years of continuous service. RSUs granted to non-employee directors generally either vest over one year from the grant date or vest one-third of the options shares on the first anniversary of the grant date and the remaining two-thirds of the option shares vest in equal monthly installments thereafter or the option shares vest in equal monthly

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installments over one year. The following table summarizes the RSU activities for the three-months ended December 31, 2009:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2009	1,812,986	$ 1.83
Granted	240,000	$ 2.08
Vested	(166,576)	$ 0.87
Forfeited	(20,000)	$ 2.08
Unvested, December 31, 2009	1,866,410	$ 1.93

The grant-date fair value of RSUs granted during the three month period ended December 31, 2009 was $499,200. As of December 31, 2009, the total unrecognized compensation cost related to unvested shares was approximately $1,223,000 which is expected to be recognized over a weighted-average period of 0.8 years, based on the vesting schedules. The Company received no cash from restricted stock awards under all share-based payment arrangements during the three-month periods ended December 31, 2009 and 2008. No tax benefit was realized for the tax deductions from option exercise of the share-base payment arrangements in the three month periods ended December 31, 2009 and 2008.

At December 31, 2009, there were 848,023 shares of restricted stock with a weighted-average grant date fair value of $1.65 per share awarded to directors that have vested but are still restricted until the directors resign.

During the three-month period ended December 31, 2009, the Company awarded 120,000 shares of restricted stock units to a non-employee. The grant date fair value of this award was $2.08 per share and it is exercisable at a purchase price of $0.0001 per share. The restricted stock units vest on the earlier of October 15, 2011 or the completion of a performance target, and it is re-measured at each balance sheet date until vested. There were no restricted stock units granted during the three-month period ended December 31, 2008.

In November 2009, the Company s compensation committee approved a modification to the vesting schedule of RSUs originally granted on December 4, 2007 (Modified Awards). The Modified Awards originally were to vest 50% upon the earlier of the completion of a Company milestone or December 4, 2010, and the remaining 50% on December 4, 2010. The awards vesting was modified to vest equally over two specified dates, March 15, 2010 and December 4, 2010. The Modified Awards are for an aggregate of 480,785 RSUs held by eight employees, including officers. The modification did not change the probability of vesting and did not result in any incremental share-based compensation. At the date of modification, no RSUs were vested and the remaining unamortized share-based compensation expense will be amortized over the remaining vesting periods of the Modified Awards.

Restricted stock units performance-based (Performance RSU). During the three-month period ended December 31, 2009, the Company awarded a Performance RSU to an employee to purchase up to 120,000 shares of the Company s common stock. The grant date fair value of this award was $2.08 per share and it is exercisable at a price of $0.0001 per share. The RSU has a performance goal that determines when vesting begins and the actual number of shares to be awarded up to 120,000 shares. For every quarter that the performance goal is not achieved, 20,000 RSU shares are forfeited. For the three months ended December 31, 2009, 20,000 performance RSU shares were forfeited. Vesting is over 3.75 years beginning on the date the performance goal is achieved (Achievement Date), with 6.25% vesting on the Achievement Date and 6.25% quarterly from the Achievement Date for the following fifteen quarters. At December 31, 2009, the performance goal has not been achieved. As of December 31, 2009, the total unrecognized compensation cost related to the unvested performance RSU was approximately $202,000, which is expected to be recognized over the weighted-average period of 4.0 years, based on the vesting schedules and Company estimates regarding the likelihood of meeting the performance criterion.

11. COMMITMENTS AND CONTINGENCIES

Center for Neurologic Study (CNS) The Company holds the exclusive worldwide marketing rights to Zenvia for certain indications pursuant to an exclusive license agreement with CNS. The Company will be obligated

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to pay CNS up to $400,000 in the aggregate in milestones to continue to develop Zenvia for both PBA and DPN pain, assuming they are both approved for marketing by the FDA. The Company is not currently developing, nor does it have an obligation to develop, any other indications under the CNS license agreement. In fiscal 2005, the Company paid $75,000 to CNS under the CNS license agreement, and will need to pay an additional $75,000 milestone if the FDA approves Zenvia for the treatment of PBA. In addition, the Company is obligated to pay CNS a royalty on commercial sales of Zenvia with respect to each indication, if and when the drug is approved by the FDA for commercialization. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if it sublicenses Zenvia to a third party. Under the agreement with CNS, the Company is required to make payments on achievements of up to a maximum of ten milestones, based upon five specific medical indications. Maximum payments for these milestone payments could total approximately $2.1 million if the Company pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that the Company currently plans to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 for each accepted new drug application (NDA) and a similar amount for each approved NDA. In addition, the Company is obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues.

Contingencies In the ordinary course of business, the Company may face various claims brought by third parties and it may, from time to time, make claims or take legal actions to assert the Company s rights, including intellectual property rights as well as claims relating to employment and the safety or efficacy of its products. Any of these claims could subject the Company to costly litigation and, while the Company generally believes that it has adequate insurance to cover many different types of liabilities, the Company s insurance carriers may deny coverage or the Company s policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the Company s operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage the Company s reputation and business. Management believes the outcomes of currently pending claims and lawsuits are not likely to have a material effect on the Company s operations or financial position.

In addition, it is possible that the Company could incur termination fees and penalties if it elected to terminate contracts with certain vendors, including clinical research organizations.

Guarantees and Indemnities The Company indemnifies its directors and officers to the maximum extent permitted under the laws of the State of Delaware, and various lessors in connection with facility leases for certain claims arising from such facilities or leases. Additionally, the Company periodically enters into contracts that contain indemnification obligations, including contracts for the purchase and sale of assets, clinical trials, pre-clinical development work and securities offerings. These indemnification obligations provide the contracting parties with the contractual right to have Avanir pay for the costs associated with the defense and settlement of claims, typically in circumstances where Avanir has failed to meet its contractual performance obligations in some fashion.

The maximum amount of potential future payments under such indemnifications is not determinable. The Company has not incurred significant costs related to these guarantees and indemnifications, and no liability has been recorded in the condensed consolidated financial statements for guarantees and indemnifications as of December 31, 2009.

12. SEGMENT INFORMATION

The Company operates its business on the basis of a single reportable segment, which is the business of discovery, development and commercialization of novel therapeutics for chronic diseases. The Company s chief operating decision-maker is the Chief Executive Officer, who evaluates the Company as a single operating segment.

The Company categorizes revenues by geographic area based on selling location. All the Company s operations are currently located in the United States; therefore, total revenues for the three-month periods ended December 31, 2009 and 2008 are attributed to the United States. All long-lived assets at December 31, 2009 and September 30, 2009 are located in the United States.

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For the three-month periods ended December 31, 2009 and 2008, the revenues from prior sale of rights to royalties under the GlaxoSmithKline (GSK) license agreement were 100% and 97% of total net revenues, respectively.

13. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the filing date of this Form 10-Q, and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosure in the notes thereto other than as discussed in the accompanying notes.

From January 1, 2010 through January 31, 2010, approximately 205,342 shares of common stock were issued pursuant to the vesting of restricted stock units.

Item 2.

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning future events and performance of the Company. When used in this report, the words intend, estimate, anticipate, believe, plan or and similar expressions are included to identify forward-looking statements. These forward-looking statements are based on our current expectations and assumptions and many factors could cause our actual results to differ materially from those indicated in these forward-looking statements. You should review carefully the factors identified in this report in Part II, Item 1A, Risk Factors and in our most recent Annual Report on Form 10-K filed with the SEC. We disclaim any intent to update or announce revisions to any forward-looking statements to reflect actual events or developments. Except as otherwise indicated herein, all dates referred to in this report represent periods or dates fixed with reference to the calendar year, rather than our fiscal year ending September 30. The three-month period ended December 31, 2009 is also referred to as the first quarter of fiscal 2010.

EXECUTIVE OVERVIEW

We are a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. Our lead product candidate, Zenvia (dextromethorphan hydrobromide/quinidine sulfate), has successfully completed three Phase III clinical trials for the treatment of pseudobulbar affect (PBA) and has successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain (DPN pain). In addition to our focus on products for the central nervous system, we also have partnered programs in other therapeutic areas which may generate future income for us. Our first commercialized product, docosanol 10% cream; (sold in the United States and Canada as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare), is the only over-the-counter treatment for cold sores that has been approved by the U.S. Food and Drug Administration (FDA). In 2008, we out-licensed our monoclonal antibody program and we remain eligible to receive milestone payments and royalties related to the sale of these assets.

Zenvia for the treatment of PBA

Zenvia has successfully completed three Phase III clinical trials in the treatment of patients with PBA, also known as emotional lability, and has successfully completed a Phase III trial for the treatment of patients with DPN pain.

In August 2009, we reported top line safety and efficacy data from the STAR trial. The STAR trial (Safety, Tolerability and Efficacy Results of AVP-923 in PBA) is a confirmatory Phase III trial of Zenvia in patients with PBA, which was a confirmatory Phase III trial of Zenvia in patients with PBA testing two doses (20/10 mg and 30/10 mg) that what had been previously tested. The study results demonstrated that both doses of Zenvia met the primary efficacy endpoint in the treatment of PBA and were generally safe and well tolerated. Both doses of Zenvia provided a statistically significant reduction in episode rates over the course of the study when compared to placebo

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(p<0.0001). In an additional analysis of the primary endpoint, at week twelve (end of study), patients in the Zenvia 30/10 mg group reported a statistically significant mean reduction of 88% from baseline in PBA episode rates (p=0.01).

In November 2009, we reported safety and efficacy and tolerability data from the 12-week open-label extension phase of the STAR trial. The study results demonstrated that patients maintained on Zenvia 30/10 mg demonstrated statistically significant incremental improvement in their CNS-LS scores over the additional 12-week treatment period of the open-label study (p<0.0001). In addition, patients who were titrated from Zenvia 20/10 mg to Zenvia 30/10 mg demonstrated statistically significant improvement in their CNS-LS scores (p<0.0001) and patients originally on placebo who initiated Zenvia 30/10 mg demonstrated statistically significant improvement in their CNS-LS scores as well.

The STAR trial was conducted as a result of an approvable letter we received from the FDA for Zenvia in October 2006. The approvable letter raised certain safety and efficacy concerns that have required additional clinical development to resolve. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concern relating to the original dose formulation that was tested in our earlier trials. However, to address the remaining safety concerns, we agreed to re-formulate Zenvia at a lower dose and and conduct one additional confirmatory Phase III clinical trial using lower quinidine dose formulations. The goal of this study was to demonstrate improved safety while maintaining significant efficacy at a lower quinidine exposure.

In October 2007, we reached agreement with the FDA under the Special Protocol Assessment (SPA) process on the design of the STAR trial. We enrolled our first patient in the STAR trial in December 2007 and in March 2009, we completed enrollment with a total of 326 patients.

In addition to conducting the STAR trial, we have conducted various pre-clinical and clinical safety studies to enhance our complete response to the 2006 approvable letter and to assist with planned label discussions with the FDA. We expect that the FDA s approval decision for Zenvia will depend on the agency s overall assessment of benefits versus potential risks. (See additional information included in this report in Part II, Item 1A, Risk Factors.)

After completion of the STAR trial and pre-clinical and clinical safety studies, we engaged in constructive written communication with the FDA. Based on the feedback we received, we expect to proceed with filing the full response with existing Zenvia data as planned, early in second calendar quarter of 2010.

Zenvia for the treatment of neuropathic pain

In April 2007, we announced positive top-line data from our first Phase III clinical trial of Zenvia for DPN pain. Before discussing a second Phase III trial with the FDA, we made the decision to conduct a formal pharmacokinetic (PK) study to identify a lower quinidine dose formulation that may have similar efficacy to the doses tested in the Phase III study, anticipating that some of the concerns with the quinidine component that were raised in the PBA approvable letter could affect the clinical development of this indication as well.

In May 2008, we reported a positive outcome of the formal PK study and announced that we identified alternative lower quinidine dose formulations of Zenvia for the next DPN pain phase III clinical trial. The new dose is intended to deliver similar efficacy and improved safety/tolerability versus the formulations previously tested in DPN pain.

In September 2008, we submitted our Phase III protocol and related program questions for Zenvia in the treatment of patients with DPN pain to the FDA under the SPA process. In recent communications regarding the continued development of Zenvia for DPN pain, the FDA has expressed that the safety concerns and questions raised in the PBA approvable letter would be expected to necessitate the testing of a lower quinidine dose formulation in the DPN pain indication, as we had expected. Additionally, based on feedback we have received from the FDA on the proposed continued development of Zenvia for DPN pain, it is possible that two large well controlled Phase III trials utilizing a new lower quinidine dose formulation would be needed to support a New Drug Application (NDA) filing for this indication. Due to our limited capital resources and current focus on gaining approval for the PBA indication, we do not expect that we will be able to initiate the trials needed for this indication

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without additional capital or a development partner for Zenvia. Accordingly, we are evaluating our options to fund this program, including the potential for a development partner.

In September 2009, we reported on secondary efficacy endpoints from the double-blind phase of the Zenvia STAR trail in PBA, including an endpoint measuring reduction of pain in patients with underlying multiple sclerosis (MS). Zenvia 30/10 mg demonstrated statistically significant relief of MS-related pain compared to placebo in the subset of MS patients with moderate-to-severe pain. Based on these data and the previous proof of concept pain data in MS patients with PBA, we are conducting a strategic assessment of the optimal clinical development path for Zenvia to obtain marketing approval for a pain indication.

Docosanol 10% Cream

Docosanol 10% cream is a topical treatment for cold sores. In 2000, we received FDA approval for marketing docosanol 10% cream as an over-the-counter product. Since that time, docosanol 10% cream has been approved by regulatory agencies in Canada, Denmark, Finland, Israel, Korea, Norway, Portugal, Spain, Poland, Greece and Sweden and is sold by our marketing partners in these territories. In 2000, we granted a subsidiary of GlaxoSmithKline, SB Pharmco Puerto Rico, Inc. GSK the exclusive rights to market docosanol 10% cream in North America. GSK markets the product under the name Abreva® in the United States and Canada. In fiscal 2003, we sold an undivided interest in our GSK license agreement for docosanol 10% cream to Drug Royalty USA, Inc. (Drug Royalty USA) for $24.1 million. We retained the right to receive 50% of all royalties (a net of 4%) under the GSK license agreement for annual net sales of Abreva in the U.S. and Canada in excess of $62 million. We also retained the rights to develop and license docosanol 10% cream outside the U.S. and Canada for the treatment of cold sores and other potential indications. We currently have several other collaborations for docosanol around the world. Two of these collaborations currently generate royalty revenue and the others may generate future royalty revenue for us depending on clinical and regulatory success outside of the United States.

Under the terms of our docosanol license agreements, our partners are generally responsible for all regulatory approvals, sales and marketing activities, and manufacturing and distribution of the product in the licensed territories. The terms of the license agreements typically provide for us to receive a data transfer fee, potential milestone payments and royalties on product sales. We purchase the active pharmaceutical ingredient docosanol, from a large supplier in Western Europe and sell the material to our licensees for commercialization. We currently store our docosanol in the United States. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales.

Xenerex Human Antibody Technology Anthrax/Other Infectious Diseases

In March 2008, we entered into an Asset Purchase and License Agreement with Emergent Biosolutions for the sale of our anthrax antibodies and license to use our proprietary Xenerex Technology platform, which was used to generate fully human antibodies to target antigens. Under the terms of the Agreement, we completed the remaining work under our NIH/NIAID grant (NIH grant) and transferred all materials to Emergent. Under the terms of the agreement, we are eligible to receive milestone payments and royalties on any product sales generated from this program. In connection with the sale of the anthrax antibody program, we also ceased all future research and development work related to other infectious diseases on June 30, 2008.

In September 2008, we entered into an Asset Purchase Agreement with a privately held San Diego based biotechnology company for the sale of our non-anthrax related antibodies as well as the remaining equipment and supplies associated with the Xenerex Technology platform. In connection with this sale, we received an upfront payment of $210,000 and are eligible to receive future royalties on potential product sales, if any.

General Information

Our principal executive offices are located at 101 Enterprise, Suite 300, Aliso Viejo, California 92656. Our telephone number is (949) 389-6700 and our e-mail address is *info@avanir.com*. Our Internet website address is *www.avanir.com*. We make our periodic and current reports available on our Internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. No portion of our website is incorporated by reference into this Quarterly Report on Form 10-Q. The public may read and copy the

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materials we file with the SEC at the SEC s Public Reference Room, located at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The public may also read and copy the materials we file with the SEC by visiting the SEC s website, www.sec.gov.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Significant estimates and assumptions are required in the determination of revenue recognition and allowances, certain royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of amounts recognized for inventories, income taxes, contingencies, and share-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are also reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions are made. Actual results may differ significantly from our estimates.

A summary of significant accounting policies and a description of accounting policies that are considered critical may be found in Part II, Item 7 of our Annual Report on Form 10-K for the year ended September 30, 2009 in the Critical Accounting Policies and Estimates section, as updated and amended in Note 2 of the Notes to our Condensed Consolidated Financial Statements included herein.

RESULTS OF OPERATIONS

COMPARISON OF THREE MONTHS ENDED DECEMBER 31, 2009 AND 2008

Revenues and Cost of Revenues

	Three months ended December 31,			
	2009	2008	$ Change	% Change
REVENUES AND COST OF RESEARCH SERVICES AND OTHER				
Revenues:				
Revenue from royalties and royalty rights	$ 1,484,934	$ 1,696,796	$ (211,862)	-12%
Revenues from license agreements		57,265	(57,265)	-100%
Revenues from research services and other	1,484,934	1,754,061	(269,127)	-15%
Costs:				
Cost of research and development services		8,051	(8,051)	-100%
Research services and other gross profit	$ 1,484,934	$ 1,746,010	$ (261,076)	-15%

Revenues

Revenues from research services and other were $1.5 million for the period ended December 31, 2009 compared to approximately $1.8 million for the period ended December 31, 2008. The decrease in revenues of approximately $269,000, or 15%, is attributed to an approximately $212,000 decrease in revenue related to both deferred revenue and annual royalty revenue from our license agreement with GSK as well as revenue of approximately $57,000 related to the license agreement with Kobayashi Pharmaceutical Co. Ltd. which was terminated in fiscal 2009.

Potential revenue-generating contracts that remained active as of December 31, 2009 include licensing revenue from our agreement with GSK, potential royalties from our agreements with Azur Pharma and Emergent

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Biosolutions, Inc. and modest revenue generated from various other licensing agreements. Partnering, licensing and research collaborations have been, and may continue to be, an important part of our business development strategy. We may continue to seek partnerships with pharmaceutical companies that can help fund our operations in exchange for sharing in the success of any licensed compounds or technologies.

Cost of Revenues

There were no cost of research services and grants for the first quarter of fiscal 2010 compared with approximately $8,000 or 0.5% of revenues from research services and other for the first quarter of fiscal 2009.

Operating Expenses

	Three months ended December 31,			
	2009	2008	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 3,446,890	$ 4,724,914	$ (1,278,024)	-27%
General and administrative	2,866,478	2,314,312	552,166	24%
Total operating expenses	$ 6,313,368	$ 7,039,226	$ (725,858)	-10%

Research and Development Expenses

Research and development expenses decreased by approximately $1.3 million from approximately $4.7 million in the first quarter of fiscal 2009 to approximately $3.4 million for the first quarter of fiscal 2010. The decrease is primarily due to the STAR trial which was completed in the fourth quarter of fiscal 2009. We expect these expenses to continue to decrease in fiscal 2010 after submission to the FDA of the full response to the Zenvia approvable letter which is anticipated to take place in the second calendar quarter of 2010.

General and Administrative Expenses

General and administrative expenses increased by approximately $550,000 from approximately $2.3 million for the first quarter of fiscal 2009 compared to approximately $2.8 million for the first quarter of fiscal 2010. The increase is primarily attributed to costs associated with preparation for commercial readiness as well as higher share-based compensation costs.

Share-Based Compensation

Total share-based compensation expense in the three month periods ended December 31, 2009 and 2008 was approximately $699,000 and $386,000, respectively. General and administrative expense in the three-month periods ended December 31, 2009 and 2008 include share-based compensation expense of approximately $517,000 and $306,000, respectively. Research and development expense in the three-month periods ended December 31, 2009 and 2008 include share-based compensation expense of approximately $182,000 and $80,000, respectively. As of December 31, 2009, approximately $5.3 million of total unrecognized compensation costs related to nonvested options and awards is expected to be recognized over a weighted average period of 2.1 years. See Note 10, Employee Equity Incentive Plans in the Notes to Condensed Consolidated Financial Statements (Unaudited) for further discussion.

Other Income (Expenses)

For the three-month period ended December 31, 2009, interest income decreased to approximately $6,000, compared to approximately $136,000 for the same period in the prior year. The decrease is due to approximately a 27% decrease in the average balance of cash, cash equivalents and investments in securities for the quarter ended December 31, 2009, compared to the same period in the prior year. In addition, our investment accounts earned a lower yield in the first quarter of 2010 as compared to the same period in the prior year.

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Net Loss

Net loss was approximately $4.8 million or $0.06 per share in the three month period ended December 31, 2009 compared to a net loss of approximately $5.2 million, or $0.07 per share, for the three month period ended December 31, 2008.

LIQUIDITY AND CAPITAL RESOURCES

We assess our liquidity by our ability to utilize existing cash and to generate additional cash to fund future operations. Key factors in the management of our liquidity are: cash required to fund operating activities including expected operating losses and the levels of inventories, accounts payable and capital expenditures; the timing and extent of cash received from milestone payments under license agreements; adequate credit facilities; and financial flexibility to attract long-term equity capital on favorable terms. Historically, cash required to fund on-going business operations has been provided by financing activities and used to fund operations, working capital requirements and investing activities.

Cash, cash equivalents and restricted investments, as well as net cash provided by or used in operating, investing and financing activities, are summarized in the table below.

	Three Months Ended December 31, 2009	Change Between Periods	Three Months Ended December 31, 2008
Net cash used in operating activities	$ (6,516,291)	$ (795,211)	$ (5,721,080)
Net cash used in investing activities	(31,586)	(14,365)	(17,221)
Net cash provided by (used in) financing activities	178,185	199,807	(21,622)
Net decrease in cash and cash equivalents	$ (6,369,692)	$ (609,769)	$ (5,759,923)

Operating activities. Net cash used in operating activities amounted to approximately $6.5 million in the first three months of fiscal 2010 compared to approximately $5.7 million used in the first three months of fiscal 2009. The increase is primarily due to the following: costs associated with conclusion of the confirmatory Phase III STAR trial for Zenvia, costs associated with the preparation for the full response to the approvable letter and commercial readiness expenses.

Investing activities. Net cash used in investing activities was approximately $32,000 in the first three months of fiscal 2010, compared to approximately $17,000 used in the first three months of fiscal 2009. The increase in cash used in investing activities is primarily related to capital equipment purchases.

Financing activities. Net cash provided by financing activities was approximately $178,000 in the first three months of fiscal 2010 compared to net cash used in financing activities of approximately $22,000 in the first three months of fiscal 2009. In the first quarter of fiscal 2010, we raised approximately $189,000 in gross proceeds (approximately $183,000 net of commissions) from our at-the-market offering facility.

In April 2009, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $35.0 million in common stock, preferred stock, debt securities and warrants. On May 6, 2009, the registration statement was declared effective. On July 30, 2009 we entered into a financing facility with Cantor Fitzgerald & Co., providing for the sale of up to 12,500,000 shares of our common stock from time to time into the open market at prevailing prices. As of January 31, 2010, 4.7 million shares of common stock had been sold under this facility for total gross proceeds of approximately $11.0 million. We may or may not sell additional shares under this facility, depending on the volume and price of our common stock, as well as our capital needs and potential alternative sources of capital, such as a development partner for Zenvia.

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In September 2009, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $75.0 million in common stock, preferred stock, debt securities and warrants. On September 23, 2009, the registration statement was declared effective. No offerings have been made pursuant to this registration statement to date.

As of December 31, 2009 we have contractual obligations for long-term debt and operating lease obligations, as summarized in the table that follows.

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations (1)	$ 4,206,767	$ 1,544,496	$ 2,616,249	$ 46,022	$
Purchase obligations (2)	859,583	859,583			
Total	$ 5,066,350	$ 2,404,079	$ 2,616,249	$ 46,022	$

(1) Operating leases obligations are exclusive of payments we expect to receive under subleases.

(2) Purchase obligations consist of the total of trade accounts payable and trade related accrued expenses at December 31, 2009 which approximates our contractual commitments for goods and services in the normal course of our business.

Zenvia License Milestone Payments. We hold the exclusive worldwide marketing rights to Zenvia for certain indications pursuant to an exclusive license agreement with the Center for Neurologic Study (CNS). We will be obligated to pay CNS up to $400,000 in the aggregate in milestones to continue to develop Zenvia for both PBA and DPN pain, assuming they are both approved for marketing by the FDA. We are not currently developing, nor do we have an obligation to develop, any other indications under the CNS license agreement. We will pay a $75,000 milestone if the FDA approves Zenvia for the treatment of PBA. In addition, we are obligated to pay CNS a royalty on

commercial sales of Zenvia with respect to each indication, if the drug is approved by the FDA for commercialization. Under certain circumstances, we may have the obligation to pay CNS a portion of net revenues received if we sublicense Zenvia to a third party. Under the agreement with CNS, we are required to make payments on achievements of up to a maximum of ten milestones, based upon five specific clinical indications. Maximum payments for these milestone payments could total approximately $2.1 million if we pursue the development of Zenvia for all of the licensed indications. Of the clinical indications that we currently plan to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 for each accepted new drug application (NDA) and a similar amount for each approved NDA. In addition, we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Management Outlook

We believe that cash and cash equivalents and restricted investments of approximately $25.6 million at December 31, 2009 will be sufficient to sustain our planned level of operations for at least the next twelve months and through the anticipated FDA approval decision for Zenvia for PBA. However, we cannot provide assurances that our plans will not change, or that changed circumstances or delays in clinical development will not result in the depletion of capital resources more rapidly than anticipated.

For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations, please see Part II, Item 1A, Risk Factors.

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Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As described below, we are exposed to market risks related to changes in interest rates. Because substantially all of our revenue, expenses and capital purchasing activities are transacted in U.S. dollars, our exposure to foreign currency exchange rates is immaterial. However, in the future we could face increasing exposure to foreign currency exchange rates as we expand international distribution of docosanol 10% cream and purchase additional services from outside the U.S. Until such time as we are faced with material amounts of foreign currency exchange rate risks, we do not plan to use derivative financial instruments, which can be used to hedge such risks. We will evaluate the use of derivative financial instruments to hedge our exposure as the needs and risks should arise.

Interest rate sensitivity

Our investment portfolio consists primarily of cash fixed income instruments invested in government money market funds. The primary objective of our investments in these securities is to preserve principal. We classify our restricted investments, which are primarily certificates of deposit, as of December 31, 2009 as held-to-maturity. These held to maturity securities are subject to interest rate risk. Based on the average duration of our investments as of December 31, 2009 and 2008, an increase of one percentage point in the interest rates would have resulted in an annual increase in interest income of approximately $273,000 and $353,000, respectively.

As of December 31, 2009, approximately $24.5 million of the Company s cash and cash equivalents were maintained in six separate money market mutual funds, and approximately $572,000 of the Company s cash and cash equivalents were maintained at two major financial institutions in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (FDIC), which provides deposit coverage limits up to $250,000 through January 1, 2014. At December 31, 2009, such uninsured deposits totaled approximately $24.8 million. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear minimal risk.

Financial instruments that potentially subject us to concentrations of credit risk consist of cash and cash equivalents. However, we seek to mitigate this risk by placing our cash and cash equivalents in various money market mutual funds and at financial institutions of high credit standing.

We perform ongoing credit evaluations of our customers financial condition and would limit the amount of credit extended if necessary; however, we have usually required no collateral.

Item 4T. 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 Chief Executive Officer and our Vice President, Finance, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report, pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended.

In connection with that evaluation, our CEO and Vice President, Finance concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms as of December 31, 2009. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that we file or submit is accumulated and communicated to management, including our principal executive officer, principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our fiscal quarter ended December 31, 2009, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may face various claims brought by third parties. Any of these claims could subject us to costly litigation. Management believes the outcome of currently identified claims and lawsuits will not have a material adverse effect on our financial condition or results of operations.

Item 1A. RISK FACTORS

Risks Relating to Our Business

There can be no assurance that the FDA will approve Zenvia for PBA or any other indication.

In October 2006, we received an approvable letter from the FDA for our NDA submission for Zenvia in the treatment of patients with PBA. The approvable letter raised certain safety and efficacy concerns. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concern of the original dose formulation that was tested in earlier clinical trials. However, the safety concerns require additional clinical development to resolve. To address the safety concerns, we re-formulated Zenvia and conducted one additional confirmatory Phase III clinical trial using new lower quinidine dose formulations. Although we believe that the data from the confirmatory trial, combined with additional clinical and pre-clinical data, should be sufficient to address the issues outlined in the FDA approvable letter, it is possible that the FDA will continue to have safety concerns that could prevent or delay approval. Accordingly, there can be no assurance that the FDA will approve Zenvia for commercialization.

Additionally, although we have a Special Protocol Assessment (SPA) from the FDA for our recently completed confirmatory Phase III trial for Zenvia in patients with PBA, there can be no assurance that the terms of the SPA will ultimately be binding on the FDA. An SPA is intended to serve as a binding agreement with the FDA on the adequacy of the planned design, conduct and analysis of a clinical trial. Even where an SPA has been granted, however, additional data may subsequently become available that causes the FDA to reconsider the previously agreed upon SPA and the FDA may have subsequent safety or efficacy concerns that override this agreement. As a result, even with positive data obtained under an SPA, we cannot be certain that the trial results will be found to be adequate to demonstrate a favorable risk/benefit profile required for product approval.

The FDA s safety concerns regarding Zenvia for the treatment of PBA extend to other clinical indications that we have been pursuing, including DPN pain. Due to these concerns, any future development of Zenvia for other indications is expected to use an alternative lower-dose quinidine formulation, which may negatively affect efficacy.

We have successfully completed a single Phase III trial for Zenvia in the treatment of DPN pain. In communications regarding the continued development of Zenvia for this indication, the FDA has expressed that the safety concerns and questions raised in the PBA approvable letter necessitate the testing of a low-dose quinidine formulation in the DPN pain indication as well. Additionally, based on feedback we have received from the FDA on the proposed continued development of Zenvia for this indication, it is possible that two large well-controlled Phase III trials would be needed to support an NDA filing for this indication. Due to our limited capital resources and current focus on gaining approval for the PBA indication, we do not expect that we will be able to conduct the trials needed for this indication without additional capital or a development partner for Zenvia. Moreover, although we achieved positive results in our initial Phase III trial, an alternative low-dose quinidine formulation may not yield the same levels of efficacy as seen in the earlier trials or as predicted based on our subsequent PK study. Any decrease in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo. Additionally, any alternative low-dose quinidine formulation that we develop may not sufficiently satisfy the FDA s safety concerns. If this were to happen, we may not be able to pursue the development of Zenvia for other

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indications or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays.

Even if Zenvia receives marketing approval from the FDA, the approval may not be on the terms that we seek and could limit the marketability of the drug.

Even if the FDA approves Zenvia for marketing in one or more indications, approval could be granted on terms less favorable than those we are seeking. This may, in turn, limit our ability to commercialize Zenvia and generate substantial revenues from its sales. In addition to the confirmatory Phase III trial in PBA, we recently completed additional pre-clinical and clinical cardiac safety studies designed to enhance our response to the FDA s approvable letter and to support planned label discussions with the FDA. Although we believe these studies showed an improvement in the margin of cardiac safety with the new lower dose of quinidine, it did show QTc prolongation of a duration that is above the FDA s threshold of concern (5 ms mean increase) in approving new drugs. As a result, we could face one or more of the following risks:

- regulatory authorities may require the addition of labeling statements, such as a black box warning, which is the strongest type of warning that the FDA can require for a drug and is generally reserved for warning prescribers about adverse drug reactions that can cause serious injury or death;
- regulatory authorities may withdraw approval of the product after its initial approval;
- product labeling may be amended to restrict use in certain populations;
- physicians may be required to conduct additional tests prior to dispensing product or monitor patients taking Zenvia;
- we may be required to conduct additional studies either post-marketing or before approval; and
- Zenvia may not be approved by the FDA for commercialization as the FDA may perceive that the benefit does not outweigh the potential risk.

Additionally, we experienced a total of seven deaths in the double-blind phase of the STAR trial, all among ALS patients. Although the overall mortality rate in the trial is consistent with published mortality rates, it is possible that these deaths may negatively affect the FDA decision on our PBA application. Any of these events could prevent us from achieving or maintaining market acceptance of our product, even if it receives marketing approval, or could substantially increase the cost of commercialization, which in turn could impair our ability to generate revenues from the product candidate.

We have limited capital resources and will need to raise additional funds to support our operations.

We have experienced significant operating losses in funding the research, development and clinical testing of our drug candidates, accumulating losses totaling approximately $282.8 million as of December 31, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future. As of December 31, 2009, we had approximately $25.6 million in cash and cash equivalents and restricted investments in marketable securities. Additionally, we currently do not have any meaningful sources of recurring revenue or cash flow from operations.

In light of our current capital resources, lack of near-term revenue opportunities and substantial long-term capital needs, we will need to raise additional capital in the future to finance our long-term operations, including the planned launch of Zenvia, until we expect to be able to generate meaningful amounts of revenue from product sales. Based on our current loss rate and existing capital resources as of the date of this filing, we estimate that we have sufficient funds to sustain our operations at their current levels through calendar 2010, which includes the anticipated timing of the FDA approval decision for Zenvia in PBA in the second half of calendar year 2010. Although we expect to be able to raise additional capital, there can be no assurance that we will be able to do so or that the available terms of any financing would be acceptable to us. If we are unable to raise additional capital to fund future operations, then we may be unable to fully execute our development plans for Zenvia. This may result in significant delays in the development of Zenvia and may force us to further curtail our operations.

Any transactions that we may engage in to raise capital could dilute our stockholders and diminish certain commercial prospects.

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Although we believe that we will have adequate capital reserves to fund operations beyond the anticipated timing of the FDA approval decision for Zenvia in PBA, we expect that we will need to raise additional capital in the future. We may do so through various financing alternatives, including licensing or sales of our technologies, drugs and/or drug candidates, selling shares of common or preferred stock, through the acquisition of other companies, or through the issuance of debt. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock. Any such financing will dilute our existing stockholders and, if our stock price is relatively depressed at the time of any such offering, the levels of dilution would be greater. In addition, debt financing, to the extent available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as making capital expenditures or entering into licensing transactions. If we seek to raise capital through licensing transactions or sales of one or more of our technologies, drugs or drug candidates, as we have previously done with certain investigational compounds and docosanol 10% cream, then we will likely need to share a significant portion of future revenues from these drug candidates with our licensees. Additionally, the development of any drug candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such relationships.

In July 2009, we entered into a financing facility with Cantor Fitzgerald & Co., providing for the sale of up to 12.5 million shares of our common stock from time to time into the open market at prevailing prices. As of January 31, 2010, we had sold a total of approximately 4.7 million shares under this facility. We may or may not sell additional shares under this facility, depending on the volume and price of our common stock, as well as our capital needs and potential alternative sources of capital, such as a development partner for Zenvia. If we actively sell shares under this facility, a significant number of shares of common stock could be issued in a short period of time, although we would attempt to structure the volume and price thresholds in a way that minimizes market impact. Notwithstanding these control efforts, these sales, or the perceived risk of dilution from potential sales of stock through this facility, may depress our stock price or cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. A decline in our stock price might impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities, and may cause our stockholders to lose part or all of the value of their investment in our stock.

We have licensed out or sold most of our non-core drug development programs and related assets and these and other possible future dispositions carry certain risks.

We have entered into agreements for the licensing out or sale of our non-core assets, including FazaClo, our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in major markets worldwide. From time to time, we have been and will continue to be engaged in discussions with potential licensing or development partners for Zenvia for PBA and/or other indications and we may choose to pursue a partnership or license involving Zenvia, if the terms are attractive. However, these transactions involve numerous risks, including:

- diversion of management s attention from normal daily operations of the business;
- disputes over earn-outs, working capital adjustments or contingent payment obligations;
- insufficient proceeds to offset expenses associated with the transactions; and
- the potential loss of key employees following such a transaction.

Transactions such as these may result in disputes regarding representations and warranties, indemnities, earn-outs, and other provisions in the transaction agreements. If disputes are resolved unfavorably, our financial condition and results of operations may be adversely affected and we may not realize the anticipated benefits from the transactions.

Disputes relating to these transactions can lead to expensive and time-consuming litigation and may subject us to unanticipated liabilities or risks, disrupt our operations, divert management s attention from day-to-day operations, and increase our operating expenses.

Our issued patents may be challenged and our patent applications may be denied. Either result would seriously jeopardize our ability to compete in the intended markets for our proposed products.

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We have invested in an extensive patent portfolio and we rely substantially on the protection of our intellectual property through our ownership or control of issued patents and patent applications. Because of the competitive nature of the biopharmaceutical industry, we cannot assure you that:

- the claims in any pending patent applications will be allowed or that patents will be granted;
- competitors will not develop similar or superior technologies independently, duplicate our technologies, or design around the patented aspects of our technologies;
- our technologies will not infringe on other patents or rights owned by others, including licenses that may not be available to us;
- any of our issued patents will provide us with significant competitive advantages;
- challenges will not be instituted against the validity or enforceability of any patent that we own or, if instituted, that these challenges will not be successful; or
- we will be able to secure additional worldwide intellectual property protection for our Zenvia patent portfolio.

Even if we successfully secure our intellectual property rights, third parties, including other biotechnology or pharmaceutical companies, may allege that our technology infringes on their rights or that our patents are invalid. Intellectual property litigation is costly, and even if we were to prevail in such a dispute, the cost of litigation could adversely affect our business, financial condition, and results of operations. Litigation is also time consuming and would divert management s attention and resources away from our operations and other activities. If we were to lose any litigation, in addition to any damages we would have to pay, we could be required to stop the infringing activity or obtain a license. Any required license might not be available to us on acceptable terms, or at all. Some licenses might be non-exclusive, and our competitors could have access to the same technology licensed to us. If we were to fail to obtain a required license or were unable to design around a competitor s patent, we would be unable to sell or continue to develop some of our products, which would have a material adverse effect on our business, financial condition and results of operations.

It is unclear whether we would be eligible for patent-term restoration in the U.S. under applicable law and we therefore do not know whether our patent-term can be extended.

Depending upon the timing, duration and specifics of FDA approval, if any, of Zenvia, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. If Zenvia is approved, the Hatch-Waxman Amendments may permit a patent restoration term of up to five years for one of our patents covering Zenvia as compensation for the patent term lost during product development and the regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. We intend to apply for patent term restoration. However, because Zenvia is not a new chemical entity, but is a combination of two previously approved products, it is uncertain whether Zenvia will be granted any patent term restoration under the U.S. Patent and Trademark Office guidelines. In addition, the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years after the product s approval date.

Market exclusivity provisions under the Federal Food, Drug and Cosmetic Act, or the FDCA, also may delay the submission or the approval of certain applications for competing product candidates. The FDCA provides three years of non-patent marketing exclusivity for an NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving abbreviated NDAs for drugs containing the original active agent.

Once the three-year FDCA exclusivity period has passed and after the patents (including the patent restoration term, if any) that cover Zenvia expire, generic drug companies would be able to introduce competing versions of the

drug. If we are unsuccessful in defending our patents against generic competition, our long-term revenues from Zenvia sales may be less than expected, we may have greater difficulty finding a development partner or licensee for Zenvia and the costs to defend the patents would be significant.

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If we fail to obtain regulatory approval in foreign jurisdictions, we would not be able to market our products abroad and our revenue prospects would be limited.

We may seek to have our products or product candidates marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval processes may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. For example, our development partner in Japan encountered significant difficulty in seeking approval of docosanol in that country and was forced to abandon efforts to seek approval in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

We face challenges retaining members of management and other key personnel.

The industry in which we compete has a high level of employee mobility and aggressive recruiting of skilled employees. This type of environment creates intense competition for qualified personnel, particularly in clinical and regulatory affairs, research and development and accounting and finance. Because we have a relatively small organization, the loss of any executive officers, including the Chief Executive Officer, key members of senior management or other key employees, could adversely affect our operations. For example, if we were to lose one or more of the senior members of our clinical and regulatory affairs team, the pace of clinical development for Zenvia could be slowed significantly.

Risks Relating to Our Industry

There are a number of difficulties and risks associated with clinical trials and our trials may not yield the expected results.

There are a number of difficulties and risks associated with conducting clinical trials. For instance, we may discover that a product candidate does not exhibit the expected therapeutic results, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved. It typically takes several years to complete a late-stage clinical trial and a clinical trial can fail at any stage of testing. If clinical trial difficulties or failures arise, our product candidates may never be approved for sale or become commercially viable.

In addition, the possibility exists that:

- the results from earlier clinical trials may not be predictive of results that will be obtained from subsequent clinical trials, particularly larger trials;

- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

- subjects may drop out of our clinical trials;

- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials;

- trial results derived from top-line data, which is based on a preliminary analysis of efficacy and safety data related to primary and secondary endpoints, may change following a more comprehensive review of the complete data set derived from a particular clinical trial or may change due to FDA requests to analyze the data

differently; and

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the cost of our clinical trials may be greater than we currently anticipate.

It is possible that earlier clinical and pre-clinical trial results may not be predictive of the results of subsequent clinical trials. If earlier clinical and/or pre-clinical trial results cannot be replicated or are inconsistent with subsequent results, our development programs may be cancelled or deferred. In addition, the results of these prior clinical trials may not be acceptable to the FDA or similar foreign regulatory authorities because the data may be incomplete, outdated or not otherwise acceptable for inclusion in our submissions for regulatory approval.

Additionally, the FDA has substantial discretion in the approval process and may reject our data or disagree with our interpretations of regulations or draw different conclusions from our clinical trial data or ask for additional information at any time during their review. For example, the use of different statistical methods to analyze the efficacy data from our Phase III trial of Zenvia in DPN pain results in significantly different conclusions about the efficacy of the drug. Although we believe we have legitimate reasons to use the methods that we have adopted as outlined in our SPA with the FDA, the FDA may not agree with these reasons and may disagree with our conclusions regarding the results of these trials.

Although we would work to be able to fully address any such FDA concerns, we may not be able to resolve all such matters favorably, if at all. Disputes that are not resolved favorably could result in one or more of the following:

delays in our ability to submit an NDA;

the refusal by the FDA to accept for filing any NDA we may submit;

requests for additional studies or data;

delays in obtaining an approval;

the rejection of an application; or

the approval of the drug, but with adverse labeling claims that could adversely affect the commercial market.

If we do not receive regulatory approval to sell our product candidates or cannot successfully commercialize our product candidates, we would not be able to generate meaningful levels of sustainable revenues.

The pharmaceutical industry is highly competitive and most of our competitors have larger operations and have greater resources. As a result, we face significant competitive hurdles.

The pharmaceutical and biotechnology industries are highly competitive and subject to significant and rapid technological change. We compete with hundreds of companies that develop and market products and technologies in areas similar to those in which we are performing our research. For example, we expect that Zenvia will face competition from antidepressants, atypical anti-psychotic agents and other agents in the treatment of PBA and from a variety of pain medications and narcotic agents for the treatment of DPN pain.

Our competitors may have specific expertise and development technologies that are better than ours and many of these companies, which include large pharmaceutical companies, either alone or together with their research partners, have substantially greater financial resources, larger research and development capabilities and substantially greater experience than we do. Accordingly, our competitors may successfully develop competing products. We are also competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

If we fail to comply with regulatory requirements, regulatory agencies may take action against us, which could significantly harm our business.

Marketed products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. Even if we receive regulatory approval for one of our product candidates, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

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In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to ongoing review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, current Good Manufacturing Practices (cGMP) regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements.

The cGMP regulations also include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. We rely on the compliance by our contract manufacturers with cGMP regulations and other regulatory requirements relating to the manufacture of products. We are also subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We may be slow to adapt or may not be able to adapt to these changes or new requirements.

We rely on insurance companies to mitigate our exposure for business activities, including developing and marketing pharmaceutical products for human use.

The conduct of our business, including the testing, marketing and sale of pharmaceutical products, involves the risk of liability claims by consumers, stockholders, and other third parties. Although we maintain various types of insurance, including product liability and director and officer liability, claims can be high and our insurance may not sufficiently cover our actual liabilities. If liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could materially and adversely affect our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us. Additionally, we are potentially at risk if our insurance carriers become insolvent. Although we have historically obtained coverage through highly rated and capitalized firms, the ongoing financial crisis may affect our ability to obtain coverage under existing policies or purchase insurance under new policies at reasonable rates.

Risks Related to Reliance on Third Parties

Because we depend on clinical research centers and other contractors for clinical testing and for certain research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

The nature of clinical trials and our business strategy of outsourcing a substantial portion of our research require that we rely on clinical research centers and other contractors to assist us with research and development, clinical testing activities, patient enrollment and regulatory submissions to the FDA. As a result, our success depends partially on the success of these third parties in performing their responsibilities. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, the current global economic slowdown may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed and our prospects could be adversely affected.

We depend on third parties to manufacture, package and distribute compounds for our drugs and drug candidates. The failure of these third parties to perform successfully could harm our business.

We have utilized, and intend to continue utilizing, third parties to manufacture, package and distribute Zenvia and the Active Pharmaceutical Ingredient (API) for docosanol 10% cream and to provide clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for the API for docosanol and Zenvia, and a sole manufacturer for the finished form of Zenvia. In addition, these materials are custom and available from only a limited number of sources. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales. We do not have any long-term agreements in place with our current docosanol supplier or Zenvia supplier. If we are required to change manufacturers, we may

experience delays associated with finding an alternate manufacturer that is properly

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qualified to produce supplies of our products and product candidates in accordance with FDA requirements and our specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing Zenvia could delay our clinical trials of this product candidate for DPN pain. The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities. Additionally, the ongoing economic crisis creates risk for us if any of these third parties suffer liquidity or operational problems. If a key third party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

We generally do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.

Under our typical license arrangement we have no direct control over the development of drug candidates and have only limited, if any, input on the direction of development efforts. These development efforts are made by our licensing partner, and if the results of their development efforts are negative or inconclusive, it is possible that our licensing partner could elect to defer or abandon further development of these programs. We similarly rely on licensing partners to obtain regulatory approval for docosanol in foreign jurisdictions. Because much of the potential value of these license arrangements is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of these licenses will depend on the efforts of licensing partners. If our licensing partners do not succeed in developing the licensed technology for whatever reason, or elect to discontinue the development of these programs, we may be unable to realize the potential value of these arrangements. If we were to license Zenvia to a third party or a development partner, it is likely that much of the long-term success of that drug will similarly depend on the efforts of the licensee.

We expect to rely entirely on third parties for international registration, sales and marketing efforts.

In the event that we attempt to enter into international markets, we expect to rely on collaborative partners to obtain regulatory approvals and to market and sell our product(s) in those markets. We have not yet entered into any collaborative arrangement with respect to marketing or selling Zenvia, with the exception of one such agreement relating to Israel. We may be unable to enter into any other arrangements on terms favorable to us, or at all, and even if we are able to enter into sales and marketing arrangements with collaborative partners, we cannot assure you that their sales and marketing efforts will be successful. If we are unable to enter into favorable collaborative arrangements with respect to marketing or selling Zenvia in international markets, or if our collaborators efforts are unsuccessful, our ability to generate revenues from international product sales will suffer.

Risks Relating to Our Stock

Our stock price has historically been volatile and we expect that this volatility will continue for the foreseeable future.

The market price of our common stock has been, and is likely to continue to be, highly volatile. This volatility can be attributed to many factors independent of our operating results, including the following:

comments made by securities analysts, including changes in their recommendations;

short selling activity by certain investors, including any failures to timely settle short sale transactions;

announcements by us of financing transactions and/or future sales of equity or debt securities;

sales of our common stock by our directors, officers or significant stockholders;

lack of volume of stock trading leading to low liquidity;

market and economic conditions; and

Announcements we may make regarding our compliance with continued listing standards on the NASDAQ Global Market.

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If a substantial number of shares are sold into the market at any given time, particularly following any significant announcements or large swings in our stock price (whether sales are through the financing facility with Cantor Fitzgerald & Co. or from an existing stockholder), there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

Additionally, our stock price has been volatile as a result of announcements of regulatory actions and decisions relating to our product candidates, including Zenvia, and periodic variations in our operating results. We expect that our operating results will continue to vary from quarter to quarter. Our operating results and prospects may also vary depending on the status of our partnering arrangements.

As a result of these factors, we expect that our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Additionally, any significant drops in our stock price, such as the one we experienced following the announcement of the Zenvia approvable letter, could give rise to stockholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved in favor of the Company. We have, from time to time, been a party to such suits and although none have been material to date, there can be no assurance that any such suit will not have an adverse effect on the Company.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibits

31.1 Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.

31.2 Certification of Principal Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.

32.1 Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350.

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SIGNATURES

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

Signature	Title	Date
/s/ *Keith A. Katkin*	President and Chief Executive Officer	February 2, 2010
Keith A. Katkin	(Principal Executive Officer)	
/s/ *Christine G. Ocampo*	Vice President, Finance	
Christine G. Ocampo	(Principal Financial and Accounting Officer)	February 2, 2010