AVANIR PHARMACEUTICALS
Form 10-Q
February 17, 2009

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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, 2008

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

(Exact name of registrant as specified in its charter)

California	**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 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, 2009, the registrant had 78,227,041 shares of common stock issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

AVANIR PHARMACEUTICALS
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2008 (unaudited)	September 30, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,624,007	$ 41,383,930
Inventories	17,000	17,000
Prepaid expenses	753,107	1,030,630
Other current assets	1,141,520	237,334
Current portion of restricted investments in marketable securities	388,122	388,122
Total current assets	37,923,756	43,057,016
Restricted investments in marketable securities, net of current portion	468,475	468,475
Property and equipment, net	738,161	806,909
Non-current inventories	1,316,277	1,316,277
Other assets	249,813	257,484
TOTAL ASSETS	$ 40,696,482	$ 45,906,161
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,063,604	$ 451,846
Accrued expenses and other liabilities	1,516,152	1,881,401
Accrued compensation and payroll taxes	414,392	1,192,457
Current portion of deferred revenues	2,509,129	2,333,932
Notes payable	4,122	25,744
Total current liabilities	6,507,399	5,885,380
Accrued expenses and other liabilities, net of current portion	759,567	868,517
Deferred revenues, net of current portion	9,221,934	10,152,100
Total liabilities	16,488,900	16,905,997
Commitments and contingencies		
Shareholders equity:		
Preferred stock no par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2008 (unaudited) and September 30, 2008		
Class A Common stock no par value, 200,000,000 shares authorized; 78,227,041 and 78,213,986 shares issued and outstanding as of December 31, 2008 (unaudited) and September 30, 2008, respectively	285,380,770	284,994,636

Accumulated deficit	(261,173,188)	(255,994,472)
Total shareholders equity	24,207,582	29,000,164
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 40,696,482	$ 45,906,161

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

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AVANIR PHARMACEUTICALS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended December 31,	
	2008	**2007**
REVENUES FROM PRODUCT SALES		
Net revenues	$	$ 36,000
Cost of revenues		6,204
Product gross margin		29,796
REVENUES AND COST OF RESEARCH SERVICES AND OTHER		
Revenue from royalties and royalty rights	1,696,796	1,837,853
Revenues from license agreements	57,265	57,265
Revenues from government research grant services		167,647
Revenues from research services and other	1,754,061	2,062,765
Cost of research and development services	(8,051)	(49,991)
Cost of government research grant services		(125,587)
Research services and other gross margin	1,746,010	1,887,187
Total gross margin	1,746,010	1,916,983
OPERATING EXPENSES		
Research and development	4,724,914	3,426,259
General and administrative	2,314,312	3,128,120
Total operating expenses	7,039,226	6,554,379
Loss from continuing operations	(5,293,216)	(4,637,396)
OTHER INCOME (EXPENSES)		
Interest income	135,696	427,162
Interest expense	(480)	(234,001)
Other, net	(17,516)	(704)
Loss from continuing operations before provision for income taxes	(5,175,516)	(4,444,939)
Provision for income taxes	(3,200)	
Loss before discontinued operations	(5,178,716)	(4,444,939)

Loss from discontinued operations		(1,073,695)
Net loss	$ (5,178,716)	$ (5,518,634)
BASIC AND DILUTED NET LOSS PER SHARE:		
Loss before discontinued operations	$ (0.07)	$ (0.10)
Loss from discontinued operations		(0.03)
Net loss	$ (0.07)	$ (0.13)
Basic and diluted weighted average number of common shares outstanding	78,225,041	43,106,369

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

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AVANIR PHARMACEUTICALS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three Months Ended December 31,	
	2008	**2007**
OPERATING ACTIVITIES:		
Net loss	$ (5,178,716)	$ (5,518,634)
Loss from discontinued operations		1,073,695
Adjustments to reconcile net loss before discontinued operations to net cash used in operating activities:		
Depreciation and amortization	81,177	137,480
Share-based compensation expense	386,134	443,909
Amortization of debt discount		34,917
Loss on disposal of assets	4,792	3,464
Changes in operating assets and liabilities (net of effects of acquisition/disposition of business):		
Receivables		(36,000)
Inventories		6,204
Prepaid and other assets	(618,992)	(127,268)
Accounts payable	1,611,758	828,560
Accrued expenses and other liabilities	(474,199)	502,047
Accrued compensation and payroll taxes	(778,065)	(531,705)
Deferred revenue	(754,969)	(916,279)
Net cash used in operating activities	(5,721,080)	(4,099,610)
INVESTING ACTIVITIES:		
Proceeds from sales and maturities of investments in securities		2,050,841
Purchase of property and equipment	(19,171)	(13,804)
Proceeds from disposal of assets	1,950	
Net cash (used in) provided by investing activities	(17,221)	2,037,037
FINANCING ACTIVITIES:		
Tax withholding payments reimbursed by restricted stock payments on debt		(17,092)
Payments on notes and capital lease obligations	(21,622)	(92,837)
Net cash used in financing activities	(21,622)	(109,929)
Net decrease in cash and cash equivalents	(5,759,923)	(2,172,502)
Cash and cash equivalents at beginning of period	41,383,930	30,487,962
Cash and cash equivalents at the end of the period	$ 35,624,007	$ 28,315,460

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:				
Interest paid	$	480	$	199,084
Income taxes paid	$	4,313	$	15,050
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:				
Accrued liabilities of discontinued operations in connection with the Working Capital Adjustment	$		$	867,000

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

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AVANIR PHARMACEUTICALS
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of Avanir Pharmaceuticals (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 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, 2008. 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. Certain prior period amounts have been reclassified to conform to the current period presentation.

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. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company adopted FAS No. 157, *Fair Value Measurements* (FAS 157), as of October 1, 2008 to measure the fair value of certain of its financial assets required to be measured on a recurring basis. Under FAS 157 based on the observability of the inputs used in the valuation techniques, the Company is required to provide the following information according to the fair value hierarchy. The fair value hierarchy ranks 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.

As of December 31, 2008, the Company s cash equivalents of $35.1 million are all valued using quoted prices generated by market transactions involving identical assets, or Level 1 assets as defined under FAS No. 157.

3. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

Avanir Pharmaceuticals, a California corporation incorporated in August 1988, is a pharmaceutical company focused on developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. The Company s product candidates address therapeutic markets that include the central nervous system and inflammatory diseases. The Company s lead product candidate, Zenvia (dextromethorphan hydrobromide/quinidine sulfate), is currently in Phase III clinical development for the treatment of pseudobulbar affect (PBA) and diabetic peripheral neuropathic pain (DPN pain). The Company s 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

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approved by the U.S. Food and Drug Administration (FDA). The Company s inflammatory disease program, which targets macrophage migration inhibitory factor (MIF), is currently partnered with Novartis. The Company s infectious disease program has historically been focused primarily on monoclonal antibodies. In 2008, the Company sold its rights to substantially all of these antibodies to two biotechnology companies. As of June 30, 2008, we ceased all future research and development work related to the infectious disease program and we remain eligible to receive milestone payments and royalties related to that program.

The Company s operations are subject to certain risks and uncertainties frequently encountered by companies in similar 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 our 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.

Concentrations

As of December 31, 2008, $35.1 million of our cash and cash equivalents were maintained in three separate money market mutual funds, and approximately $500,000 of our cash and cash equivalents were maintained at a major financial institution in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk. Effective October 3, 2008, the Emergency Economic Stabilization Act of 2008 raised the Federal Deposit Insurance Corporation deposit coverage limits to $250,000 per owner from $100,000 per owner. This program is currently available through December 31, 2009.

Effective September 19, 2008, the U.S. Treasury commenced its Temporary Guarantee Program for Money Market Mutual Funds. This program, which is offered to all money market mutual funds that are regulated under Rule 2A-7 of the Investment Company Act of 1940, guarantees the share price of any publicly offered eligible money market fund that applies for and pays a fee to participate in the program. As of December 31, 2008, one of the money market mutual funds in which we had invested approximately 60% of our cash and cash equivalents was participating in the U.S. Treasury program. The current termination date for this program is April 30, 2009.

After giving effect to the increased FDIC insurance and the Temporary Guarantee Program, at December 31, 2008, our uninsured cash totaled approximately $13.6 million. This uninsured balance will increase to $34.9 million if the Temporary Guarantee Program is not extended beyond April 30, 2009.

Other financial instruments that potentially subject us to concentrations of credit risk consist of accounts receivable. We perform ongoing credit evaluations of our customers financial condition and would limit the amount of credit extended if necessary but usually we have required no collateral.

Income Taxes

We account 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.

On July 13, 2006, the Financial Accounting Standards Board (FASB) issued Financial Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109.* FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FAS No. 109, *Accounting for Income Taxes,* and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN No. 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax

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position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN No. 48 provides guidance on recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted the provisions of FIN No. 48 on October 1, 2007.

The total amount of unrecognized tax benefits as of the date of adoption was $3.0 million. The total unrecognized tax benefit resulting in a decrease in deferred tax assets, and corresponding decrease in the valuation allowance, at December 31, 2008 is $3.2 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, 2008 and September 30, 2008.

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.

The Company does not foresee material changes to its gross FIN No. 48 liability within the next twelve months.

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 in accordance with the SEC s Staff Accounting Bulletin (SAB) Topic 13 (Topic 13), *Revenue Recognition.* Revenue is recognized 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 seller s price to the buyer is fixed and determinable; and (4) collectability is reasonably assured. Certain product sales are subject to rights of return. In accordance with Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists* (FAS 48), the Company recognizes such product revenues at the time of sale only if it has met all the criteria of FAS 48, including the ability to reasonably estimate future returns. FAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, 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 seller 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 seller 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 criteria of FAS 48, including that 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.

Certain sales transactions include multiple deliverables. The Company allocates amounts to separate elements in multiple element arrangements in accordance with Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables.* Revenues are allocated to a delivered product or service when all of the following criteria are met: (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. The Company uses the relative fair values of the separate deliverables to allocate revenue. For arrangements with multiple elements that are separated, the Company recognizes revenues in accordance with Topic 13.

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Product Sales

Active Pharmaceutical Ingredient Docosanol (API Docosanol). Revenue from sales of the Company s API Docosanol is recorded when title and risk of loss have passed to the buyer and provided the criteria in SAB Topic 13 are met. The Company sells the API Docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than five times a year. The Company s contracts for sales of the API 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 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. In accordance with EITF 00-21, 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.

When a delivered element meets the criteria for separation in accordance with EITF 00-21, 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.

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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 in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent,* 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 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. The Company recognizes royalty revenue in the period in which the threshold is 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 that is expected GlaxoSmithKline will pay Drug Royalty USA over the remaining term of the agreement by the unamortized deferred revenues.

In 2000, the Company 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, the Company 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. The company 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. The Company 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. The Company currently has 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 the Company depending on clinical and regulatory success outside of the United States.

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, including its largest contract, representing a $7.1 million Phase III clinical trial contract that was entered into in the first fiscal quarter of 2008. A 3% variance in the Company s estimate of the work completed in its largest contract could increase or decrease its quarterly operating expenses by approximately $213,000.

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Share-Based Compensation

We grant options, restricted stock units and restricted stock awards to purchase our common stock to our employees, directors and consultants under our stock option plans. The benefits provided under these plans are share-based payments subject to the provisions of revised FAS No. 123, *Share-Based Payment* (FAS 123R), including the provisions of the SEC s Staff Accounting Bulletin No. 107 (SAB 107), that require the fair value method to account for share-based payments.

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, our 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 our 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 we do not expect to pay dividends on our common stock in the foreseeable future, we 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 fiscal 2009 and 2008 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate forfeitures based on our historical experience.

Total compensation expense related to all of our share-based awards, recognized under FAS 123R, for the three months ended December 31, 2008 and 2007 was comprised of the following:

	For the three months ended December 31,	
	2008	**2007**
From Continuing Operations:		
General and administrative expense	$ 305,999	$ 297,620
Research and development expense	80,135	146,289
Total	$ 386,134	$ 443,909

	For the three months ended December 31,	
	2008	**2007**
Share-based compensation expense from:		
Stock options	$ 178,789	$ 214,124
Restricted stock units	207,345	217,670
Restricted stock awards		12,115
Total	$ 386,134	$ 443,909

Since the Company has a net operating loss carryforward as of December 31, 2008, 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, 2008 and 2007 that would have resulted in a reclassification to reduce net cash used in operating activities with an offsetting increase in net cash provided by financing activities. (See Note 13 Employee Equity Incentive Plans.)

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Recently Issued Accounting Pronouncements

EITF Issue No. 07-5. In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity s Own Stock* (EITF 07-5). EITF 07-5 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. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. Therefore, we will be required to adopt EITF 07-5 for the fiscal year beginning October 1, 2009. We are currently assessing the impact of EITF 07-5 on our financial position and results of operations.

Financial Accounting Standards No. 162 (FAS 162). In May 2008, the FASB issued FAS 162, *The Hierarchy of Generally Accepted Accounting Principles* . FAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with GAAP for nongovernmental entities. FAS 162 is effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles.* We do not expect the adoption of this statement to have a material impact on our results of operations, financial position or cash flows.

FASB Staff Position No. 142-3 (FSP 142-3). In April 2008, the FASB issued FSP No. 142-3, *Determination of the Useful Life of Intangible Assets* . FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Financial Accounting Standard No. 142, *Goodwill and Other Intangible Assets* . FSP 142-3 is effective for fiscal years beginning after December 15, 2008. Therefore, we will be required to adopt FSP 142-3 for the fiscal year beginning October 1, 2009. We are currently evaluating the impact of FSP No. 142-3 on our consolidated financial position and results of operations.

Financial Accounting Standards No. 161 (FAS 161). In March 2008, the FASB issued FASB Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an Amendment of FAS 133* . The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance and cash flows. FAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. Therefore, we will be required to adopt FAS 161 for the fiscal year beginning October 1, 2009. We are currently evaluating the impact of FAS 161 on our consolidated financial position and results of operations.

Financial Accounting Standards No. 160 (FAS 160). In December 2007, the FASB issued FAS 160, *Noncontrolling Interests in Consolidated Financials, an Amendment of ARB No. 51* , 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. FAS 160 is effective for fiscal years beginning on or after December 15, 2008. Therefore, we will be required to adopt FAS 160 for the fiscal year beginning October 1, 2009. We do not expect the adoption of FAS 160 to significantly affect our consolidated financial condition or results of operations.

Financial Accounting Standards No. 141(R) (FAS 141R). In December 2007, the FASB issued FAS 141R, *Business Combinations: Applying the Acquisition Method* , which retains the fundamental requirements of FAS 141 but provides additional guidance on applying the acquisition method when accounting for similar economic events by establishing certain principles and requirements. FAS 141R is effective for fiscal years beginning on or after December 15, 2008. Therefore, we will be required to adopt FAS 141R for the fiscal year beginning October 1, 2009. We are evaluating the options provided under FAS 141R and their potential impact on our consolidated financial condition and results of operations when implemented. We do not expect the adoption of FAS 141R to significantly affect our consolidated financial condition or results of operations.

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EITF Issue No. 07-1. In November 2007, the FASB s Emerging Issues Task Force issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* (EITF 07-1) which defines collaborative arrangements and establishes reporting and disclosure requirements for such arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. Therefore, we will be required to adopt EITF 07-1 for the fiscal year beginning October 1, 2009. We are continuing to evaluate the impact of adopting the provisions of EITF 07-1; however, we do not anticipate the adoption of EITF 07-1 will have a material effect on our consolidated financial condition or results of operations.

Financial Accounting Standards No. 159 (FAS 159). In February 2007, the FASB issued FAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement 115*, which provides companies with an option to measure eligible financial assets and liabilities in their entirety at fair value. The fair value option may be applied instrument by instrument, and may be applied only to entire instruments. If a company elects the fair value option for an eligible item, changes in the item s fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting. We adopted FAS 159 on October 1, 2008. The adoption of FAS 159 did not significantly affect our consolidated financial condition or results of operations.

Financial Accounting Standards No. 157 (FAS 157) In September 2006, the FASB issued FAS No. 157, *Fair Value Measurements (FAS No. 157)*, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. FAS No. 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB released Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157, which provides for delayed application of FAS No. 157 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 FAS No. 157 effective October 1, 2008 (see Note 2, Fair Value of Financial Instruments, to the Condensed Consolidated Financial Statements for additional information). The Company is currently evaluating the effect that the adoption of the provisions deferred by Staff Position No. FAS 157-2 will have on our financial position and results of operations.

Financial Accounting Standards No. 157 (FAS 157-3). In October 2008, the FASB issued FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active (FSP 157-3)*. FSP No. 157-3 clarifies the application of SFAS 157 in a market that is not active, and provides an illustrative example intended to address certain key application issues. FSP No. 157-3 is effective immediately. The Company has concluded that the application of FSP No. 157-3 did not have a material impact on its consolidated financial position and results of operations.

4. DISCONTINUED OPERATIONS SALE OF FAZACLO

On May 24, 2006, pursuant to a Unit Purchase Agreement dated May 22, 2006 (the Acquisition Agreement), we acquired all of the outstanding equity interests in Alamo from the former members of Alamo (the Selling Holders). The Company intended to leverage the FazaClo sales force to assist with the commercial launch of Zenvia, which was planned for early 2007; however, due to the receipt of the approvable letter and resulting delay in the planned launch of Zenvia, we entered into an agreement to sell FazaClo and its related assets and operations to Azur Pharma, Inc. (Azur) in July 2007.

In connection with the sale, the Company received approximately $43.9 million in upfront consideration. In addition, the Company could receive up to $2 million in royalties, based on 3% of Azur s annualized net product revenues in excess of $17 million. The Company s earn-out obligations that would have been payable to the prior owner of Alamo upon the achievement of certain milestones were assumed by Azur; however, the Company is contingently liable in the event of default. The Company transferred all FazaClo related business operations to Azur in August 2007.

In accordance with FAS 144 *Accounting for the Impairment or Disposal of Long-Lived Assets* , the financial results relating to FazaClo have been classified as discontinued operations in the accompanying condensed consolidated statements of operations for all periods presented.

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In the first quarter of fiscal 2008, the Company recognized a loss from discontinued operations of $1.1 million. The loss is attributed to a working capital adjustment of $867,000 as well as additional costs of $206,000 related to the operations of FazaClo.

5. RELOCATION OF COMMERCIAL AND GENERAL AND ADMINISTRATIVE OPERATIONS

In fiscal 2006, we 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. 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.

The following table presents the restructuring activities for the three months ended December 31, 2008:

	Balance at September 30, 2008	Payments/ Reductions	Balance at December 31, 2008
Accrued Restructuring			
Lease restructuring liability	$ 1,135,965	$ (81,906)	$ 1,054,059
Less current portion	(316,086)		(311,611)
Non-current portion	$ 819,879		$ 742,448

The current portion of the lease restructuring liabilities of $316,000 and $312,000 at September 30, 2008 and December 31, 2008, respectively are included in Accrued expenses and other liabilities and the non-current portion of lease restructuring liability of $820,000 and $742,000 at September 30, 2008 and December 31, 2008, respectively are included in Accrued expenses and other liabilities, net of current portion in the accompanying condensed consolidated balance sheets.

6. 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, 2008	September 30, 2008
Raw materials	$ 1,333,277	$ 1,333,277
Less: current portion	(17,000)	(17,000)
Non-current portion	$ 1,316,277	$ 1,316,277

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.

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7. OTHER ASSETS

Other assets consist of the following:

	December 31, 2008	September 30, 2008
Current receivables from subtenants	$ 99,002	$ 167,546
Current receivable from license agreements	1,042,518	68,251
Deposits	241,400	241,400
Other	8,413	17,621
Total other assets	1,391,333	494,818
Less: current	(1,141,520)	(237,334)
Non current total other assets	$ 249,813	$ 257,484

8. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities are as follows:

	December 31, 2008	September 30, 2008
Accrued research and development expenses	$ 903,704	$ 1,404,556
Accrued general and administrative expenses	300,837	160,759
Deferred rent	17,119	48,638
Lease restructuring liability	1,054,059	1,135,965
Total accrued expenses and other liabilities	2,275,719	2,749,918
Less: current	(1,516,152)	(1,881,401)
Non-current total accrued expenses and other liabilities	$ 759,567	$ 868,517

9. DEFERRED REVENUES

The following table sets forth as of December 31, 2008 the deferred revenue balances for the Company s sale of future Abreva® royalty rights to Drug Royalty USA and other agreements:

	Drug Royalty USA Agreement	**Other Agreements**	**Total**
Net deferred revenues as of October 1, 2008	$ 12,202,198	$ 283,834	$ 12,486,032
Changes during the period:			
Recognized as revenues during period	(697,704)	(57,265)	(754,969)
Net deferred revenues as of December 31, 2008	$ 11,504,494	$ 226,569	$ 11,731,063

Classified and reported as:

Current portion of deferred revenues	$ 2,282,560	$ 226,569	$ 2,509,129
Deferred revenues, net of current portion	9,221,934		9,221,934
Total deferred revenues	$ 11,504,494	$ 226,569	$ 11,731,063

10. 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

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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, 2008 and 2007, the following options and warrants to purchase shares of common stock, restricted stock awards 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:

	2008	2007
Stock options	2,032,057	867,790
Performance stock options	2,033,570	
Stock warrants	12,509,742	269,305
Restricted stock units	2,220,648	2,350,483
Restricted stock awards		20,500

11. COMPREHENSIVE LOSS

Comprehensive loss consists of the following:

	For the three months ended December 31,	
	2008	2007
Net loss	$ (5,178,716)	$ (5,518,634)
Other comprehensive loss, net of tax:		
Unrealized gain on available-for-sale securities		3,835
Total comprehensive loss	$ (5,178,716)	$ (5,514,799)

12. SHAREHOLDERS EQUITY

During the three month period ended December 31, 2008, the Company issued 13,055 shares of common stock in connection with the vesting of restricted stock units.

As of December 31, 2008, warrants to purchase 12,509,742 shares of the Company s common stock at a weighted-average exercise price per share of $1.59 remained outstanding, all of which are exercisable.

13. EMPLOYEE EQUITY INCENTIVE PLANS

The Company currently has five equity incentive plans (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, 2008. All of the Plans were approved by the shareholders, 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 or purchase of restricted stock.

During the three month period ended December 31, 2008, the Company granted share-based awards under the 2003 Plan. During the three month period ended December 31, 2007, the Company granted share-based awards under both the 2003 Plan and the 2005 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 employees and consultants. Under the Plans, as of December 31, 2008, the Company had an aggregate of 8,336,125 shares of its common stock reserved for future issuance. Of those shares, 6,484,989 were subject to outstanding options and other awards and 1,851,136 shares were available for future grants of share-based awards. As of December 31, 2008, no options 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, 2008, 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, 2008.

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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, 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).

Summaries of stock options outstanding and changes during the three month period ended December 31, 2008 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, 2008	624,027	$ 6.61		
Granted	1,436,610	$ 0.53		
Forfeited	(28,314)	$ (7.48)		
Expired	(266)	$ (6.50)		
Outstanding December 31, 2008	2,032,057	$ 2.30	9.2	$
Vested and expected to vest in the future, December 31, 2008	1,178,951	$ 3.39	8.8	$
Exercisable, December 31, 2008	263,739	$ 10.82	6.4	$

The weighted average grant-date fair value of options granted during the three month period ended December 31, 2008 was $0.40 per share. There were no options granted during the three month period ended December 31, 2007. There were no options exercised in the three month periods ended December 31, 2008 and 2007. As of December 31, 2008, the total unrecognized compensation cost related to unvested options was $1,250,000 which is expected to be recognized over the weighted-average period of 3.5 years, based on the vesting schedules.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model (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, 2008 were as follows:

	2008
Expected volatility	101%
Expected term in years	5.0
Risk-fee interest rate (zero coupon U.S. Treasury Note)	2.3%

Expected dividend yield	0%

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The following table summarizes information concerning outstanding and exercisable stock options as of December 31, 2008:

	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
$0.53	1,436,610	10.0	$ 0.53		$
$0.79-$4.60	293,150	8.3	$ 1.83	18,159	$ 2.90
$4.64-$13.16	252,922	6.6	$10.29	207,923	$10.64
$13.40	6,250	2.7	$13.40	6,250	$13.40
$13.60	1,875	2.3	$13.60	1,875	$13.60
$15.84	37,500	7.0	$15.84	25,782	$15.84
$19.38	3,750	2.5	$19.38	3,750	$19.38
	2,032,057	9.2	$ 2.30	263,739	$10.82

Performance stock options During fiscal 2008, we granted stock options to purchase a target of 2,048,000 shares of common stock from the 2003 Stock Option Plan. The performance stock options are not included in the above outstanding and exercisable stock options table. The contractual terms are ten years. The stock options have a performance goal that determines when vesting begins and the actual number of shares to be awarded ranging from 0% to 115% of target. 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. During the three months ended December 31, 2008, the performance goal related to 196,600 performance options previously granted was met and vesting began.

Summaries of performance stock options outstanding and changes during the three month period ended December 31, 2008 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, 2008	2,048,200	$ 0.88		
Forfeited	(14,630)	$ 0.88		
Outstanding December 31, 2008	2,033,570	$ 0.88	9.6	$
Vested and expected to vest in the future, December 31, 2008	828,807	$ 0.88	9.6	$
Exercisable, December 31, 2008	12,167	$ 0.88	9.6	$

As of December 31, 2008, the total unrecognized compensation cost related to unvested performance options was $1,324,000 which is expected to be recognized over the weighted-average period of 3.9 years, based on the vesting schedules and the likelihood of meeting performance criteria.

Restricted stock units. RSUs generally vest based on three years of continuous service. The following table summarizes the RSU activities for the three months ended December 31, 2008:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2008	2,259,042	$ 1.85
Vested	(38,394)	$ (0.87)
Unvested, December 31, 2008	2,220,648	$ 1.86

There were no restricted stock units granted during the three month period ended December 31, 2008. During the three month period ended December 31, 2007, the Company awarded 525,285 shares of restricted stock units to employees with a weighted average grant date fair value of $1.65 and exercisable at a purchase price of $0.00 per share.

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At December 31, 2008, there were 199,000 shares of restricted stock with a weighted-average grant date fair value of $4.11 awarded to directors that have vested but are still restricted until the directors resign.

The grant-date fair value of RSUs granted during the three month period ended December 31, 2007 was $867,500. As of December 31, 2008, the total unrecognized compensation cost related to unvested shares was $2,694,000 which is expected to be recognized over a weighted-average period of 1.5 years, based on the vesting schedules. The Company received no cash from exercised options and restricted stock awards under all share-based payment arrangements during the three month periods ended December 31, 2008 and 2007. 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, 2008 and 2007.

14. 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 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 California, 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

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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, 2008.

15. 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 U.S.; therefore, total revenues for the three month periods ended December 31, 2008 and 2007 are attributed to the U.S. All long-lived assets at December 31, 2008 and September 30, 2008 are located in the U.S.

For the three month periods ended December 31, 2008 and 2007, the revenues from prior sale of rights to royalties under the GlaxoSmithKline (GSK) license agreement were 97% and 84% of total net revenues, respectively. GSK royalties as a percentage of total revenue increased in the first quarter of 2009 as compared to the prior year first quarter, primarily due to the lack of certain revenue sources including government grant revenue and product revenue in 2009.

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 under the caption, 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, 2008 is also referred to as the first quarter of fiscal 2009.

EXECUTIVE OVERVIEW

We are a pharmaceutical company focused on acquiring, developing, and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets in the areas of the central nervous system and inflammatory diseases. Our lead product candidate, Zenvia (dextromethorphan hydrobromide/quinidine sulfate), is currently in Phase III clinical development for the treatment of PBA and DPN pain. Our first commercialized product, docosanol 10% cream, (sold as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare in North America) is the only over-the-counter treatment for cold sores that has been approved by the FDA. Our inflammatory disease program, which targets macrophage migration inhibitory factor (MIF), is currently partnered with Novartis. Our infectious disease program has historically been focused primarily on monoclonal antibodies. In 2008, we sold our rights to substantially all of these antibodies to two biotechnology companies. As of June 30, 2008, we ceased all future research and development work related to our infectious disease program and remain eligible to receive milestone payments and royalties related to the sale of the assets.

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Zenvia Status

Zenvia is currently in Phase III clinical development for the treatment of two conditions: (1) PBA , also known as emotional lability and (2) DPN pain .

In October 2006, we received an approvable letter from the FDA for Zenvia in the treatment of patients with PBA. 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 concerns relating to the original dose formulation that was tested in our earlier trials. However, to address the remaining safety concern, we agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using lower quinidine dose formulations. The goal of the study is to demonstrate improved safety while maintaining significant efficacy at a lower quinidine dose.

In October 2007, we reached agreement with the FDA under the Special Protocol Assessment (SPA) process, on the design of a single confirmatory Phase III clinical trial of Zenvia for the treatment of patients with PBA. We enrolled our first patient in this trial in December 2007 and as of February 2009, we are on target with our expected enrollment timeline with over 85% of patients now enrolled. We expect this study to be completed (as defined as when top-line safety and efficacy data from the blinded phase becomes available) during the third calendar quarter of 2009. In addition to the Phase III clinical trial for PBA we are conducting other pre-clinical and clinical safety studies in order to enhance our complete response to the approvable letter received in October 2006 for PBA.

In April 2007, we announced positive top-line data results from our first Phase III clinical trial of Zenvia for DPN pain. Before discussing a further 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 raised in the PBA approvable letter could affect the development of this indication as well. While we have received no formal direction from the FDA to develop a lower quinidine dose formulation for DPN pain, we believe it is the most prudent course of action given the current regulatory environment and the FDA s concerns raised over Zenvia for PBA.

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 doses are intended to deliver similar efficacy and improved safety/tolerability versus the formulations previously tested in DPN pain.

In September 2008, we submitted a Phase III protocol for Zenvia in the treatment of DPN pain to the FDA under a Special Protocol Assessment (SPA). We received the FDA s initial response to the SPA and we are currently engaged in discussions with the FDA regarding the design of the next Phase III study and overall neuropathic pain program requirements.

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 the Company depending on clinical and regulatory success outside of the United States.

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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 (API), docosanol, from a large supplier in Western Europe and sell the material to our licensees for commercialization. We currently store our API in the United States. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales.

Macrophage Migration Inhibitory Factor (MIF) Inflammation

In April 2005, we entered into an exclusive Research Collaboration and License Agreement with Novartis regarding the license of certain compounds that regulate macrophage migration inhibitory factor (MIF) in the treatment of various inflammatory diseases. We initially provided contract research services to Novartis to support this program for two years and, in March 2007, Novartis made the decision to continue the MIF research program internally and to allow the research collaboration portion of this agreement to expire without renewal. Under the terms of the license agreement, we are eligible to receive over $200 million in combined upfront and milestone payments upon achievement of development, regulatory, and sales objectives. We are also eligible to receive escalating royalties on any worldwide product sales generated from this program.

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.

Restructuring Activities

We have undergone significant organizational changes since fiscal 2007. Following the 2007 sale of Fazaclo as well as the divestiture of our drug discovery operations in San Diego, we became a substantially smaller organization and will be principally focused over the next two years on seeking regulatory approval for Zenvia for the treatment of patients with PBA. We believe that the proceeds from our April 2008 common stock offering will be sufficient to fund our operations, including our ongoing confirmatory Phase III trial for Zenvia in patients with PBA, through the anticipated timing of the FDA approval decision for Zenvia in PBA in the second half of calendar year 2010. For additional information about the risks and uncertainties that may affect our business and prospects, please see Risk Factors.

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 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.

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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 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, inventories, income taxes, contingencies, and stock-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 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, 2008 in the section and in Note 3 of the Notes to our Condensed Consolidated Financial Statements included herein.

RESULTS OF OPERATIONS

COMPARISON OF THREE MONTHS ENDED DECEMBER 31, 2008 AND 2007

Revenues and Cost of Revenues

	Three months ended December 31,			
	2008	**2007**	**$ Change**	**% Change**
PRODUCT SALES				
Net revenues	$	$ 36,000	$ (36,000)	-100%
Cost of revenues		(6,204)	6,204	-100%
Product gross margin		29,796	(29,796)	-100%
REVENUES AND COST OF RESEARCH SERVICES AND OTHER				
Revenues:				
Revenue from royalties and royalty rights	$ 1,696,796	$ 1,837,853	$ (141,057)	-8%
Revenues from license agreements	57,265	57,265		0%
Revenues from government research grant services		167,647	(167,647)	-100%
Revenues from research services and other	1,754,061	2,062,765	(308,704)	-15%
Costs:				
Cost of research and development services	8,051	49,991	(41,940)	-84%
Cost of government research grant services		125,587	(125,587)	-100%
Costs from research services and grants	8,051	175,578	(167,527)	-95%
Research services and other gross margin	1,746,010	1,887,187	(141,177)	-7%

Total gross margin	$ 1,746,010	$ 1,916,983	$ (170,973)	-9%

Revenues

There were no revenues from product sales to report for the three month period ended December 31, 2008. Net product revenues for the three months ended December 31, 2007 include sales of docosanol 10% cream of $36,000. In the first quarter of fiscal 2009, revenues from research services and other was comprised of royalty revenue of

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$999,000 which was earned pursuant to the GSK license agreement as well as the recognition of $755,000 of deferred revenue. In the first quarter of 2008, revenues from research services and other was comprised of royalty revenue of $934,000 related to the GSK license agreement as well as $1.2 million of revenue from other sources, including the recognition of $896,000 of deferred revenue and $168,000 in government grant revenue.

Revenues from research services and other decreased by $309,000 to $1.8 million for the first quarter of fiscal 2009 compared to $2.1 million in the first quarter of fiscal 2008. The decrease in revenues from research services and other is attributed to a decrease of $168,000 in government grant revenue related to our anthrax antibody program which ended in June 30, 2008 as well as a $90,000 decrease in royalties related to deferred revenue from our license agreement with GSK.

Potential revenue-generating contracts that remained active as of December 31, 2008 include several docosanol 10% cream license agreements and our license agreement with Novartis for our MIF technology. 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

Cost of research services and grants declined to $814,000 or 0.5% of revenues for the first quarter of fiscal 2009 compared with $176,000 or 9% of revenues from research services and other for the first quarter of fiscal 2008. The decline in cost of revenues is primarily attributed to the completion of the remaining work under the NIH grant and the termination of all future research and development work related to other infectious diseases in June 30, 2008.

Operating Expenses

	Three months ended December 31			
	2008	**2007**	**$ Change**	**% Change**
OPERATING EXPENSES				
Research and development	$ 4,724,914	$ 3,426,259	$ 1,298,655	38%
General and administrative	2,314,312	3,128,120	(813,808)	-26%
Total operating expenses	$ 7,039,226	$ 6,554,379	$ 484,847	7%

Research and Development Expenses

Research and development expenses increased by $1.3 million from $3.4 million in the first quarter of fiscal 2008 to $4.7 million for the first quarter of fiscal 2009. The increase is primarily due to increased costs incurred for Zenvia due to the confirmatory Phase III trial for the PBA indication of Zenvia.

During the current fiscal year we expect that our research and development costs will consist mainly of expenses related to the confirmatory Phase III trial for Zenvia for PBA.

General and Administrative Expenses

General and administrative expenses decreased by $814,000 from $3.1 million for the first quarter of fiscal 2008 compared to $2.3 million for the first quarter of fiscal 2009. The decrease is primarily attributed to a decrease in our overall general and administrative expenses as a result of the restructuring and the significant organizational changes that we made to our infrastructure in the last half of fiscal 2007.

Share-Based Compensation

Total compensation expense for our share-based payments in the three month period ended December 31, 2008 and the same period in 2007 was approximately $386,000 and $444,000, respectively. General and administrative expense in the three month periods ended December 31, 2008 and 2007 include share-based compensation expense of approximately $306,000 and $298,000, respectively. Research and development expense in the three month periods ended December 31, 2008 and 2007 include share-based compensation expense of approximately $80,000 and $146,000, respectively. As of December 31, 2008, $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 2.9 years. See Note 13, Employee Equity Incentive Plans in the Notes to Condensed Consolidated Financial Statements (Unaudited) for further discussion.

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Other Income (Expenses)

For the three month period ended December 31, 2008, interest expense decreased to approximately $500, compared to approximately $234,000 for the same period in the prior year. The decrease in interest expense in 2009 is primarily due to a decrease in the balance on notes payable as compared to the prior year, mostly attributed to the accelerated repayment of the remaining outstanding principal under the notes payable in June 2008. The notes payable were issued in connection with the purchase of Alamo.

For the three month period ended December 31, 2008, interest income decreased to approximately $136,000, compared to approximately $427,000 for the same period in the prior year. The decrease is due to approximately a 22% decrease in the average balance of cash, cash equivalents and investments in securities for the quarter ended December 31, 2008, compared to the same period in the prior year. In addition, our investment accounts earned a lower yield in the first quarter of 2009 as compared to the same period in the prior year.

Loss from Discontinued Operations

Loss from discontinued operations was $1.1 million in the three month period ended December 31, 2007. The loss recognized in the three month period ended December 31, 2007 is attributed to the accrued loss related to a working capital adjustment of $867,000 as well as additional costs of $206,000 related to the operations of FazaClo. No costs were recognized for discontinued operations in the first quarter of fiscal 2008.

Net Loss

Net loss was $5.2 million or $0.07 per share in the three month period ended December 31, 2008 compared to a net loss of $5.5 million or $0.13 per share for the three month period ended December 31, 2007.

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 accounts receivable, inventories, accounts payable and capital expenditures; the timing and extent of cash received from milestone payments under license agreements; available credit facilities; and financial flexibility to attract equity capital on favorable terms. Historically, cash required to fund on-going business operations has been provided by financing activities.

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

	December 31, 2008	Increase (Decrease) During Period	September 30, 2008
Cash, cash equivalents and investment in securities	$36,480,604	$(5,759,923)	$42,240,527
Cash and cash equivalents	$35,624,007	$(5,759,923)	$41,383,930
Net working capital	$31,416,357	$(5,755,279)	$37,171,636

	Three Months Ended December 31, 2008	Change Between Periods	Three Months Ended December 31, 2007
Net cash used in operating activities	$ (5,721,080)	$(1,621,470)	$ (4,099,610)
Net cash (used in) provided by investing activities	(17,221)	(2,054,258)	2,037,037
Net cash used in financing activities	(21,622)	88,307	(109,929)
Net decrease in cash and cash equivalents	$ (5,759,923)	$(3,587,421)	$ (2,172,502)

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Operating activities. Net cash used in operating activities amounted to $5.7 million in the first three months of fiscal 2009 compared to $4.1 million in the first three months of fiscal 2008. The increase is primarily due to the confirmatory Phase III trial for the PBA indication of Zenvia. We enrolled the first patient in the PBA trial in the last month of the first quarter of 2008 while in the first quarter of 2009, the trial had reached 85% patient enrollment resulting in a higher level of trial expenses.

Investing activities. Net cash used in investing activities was $17,000 in the first three months of fiscal 2009, compared to $2.0 million provided in the first three months of fiscal 2008. The decrease in cash used in investing activities is primarily related to the decrease in proceeds from the sale and maturities of investments and the release of a restricted investment.

Financing activities. Net cash used in financing activities was $22,000 in the first three months of fiscal 2009 compared to net cash used in financing activities of $110,000 in the first three months of fiscal 2008. The decrease in net cash used in financing activities is primarily related to a decrease of $70,000 in repayments of notes payable.

In February 2008, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $25 million in Class A common stock and preferred stock, depository shares, debt securities and warrants. As of December 31, 2008 all shares registered under this shelf have been sold. Through June 30, 2008, we had sold a total of 14,441,323 shares of Class A common stock under a 2005 registration statement, raising gross offering proceeds of approximately $71.5 million and net offering proceeds of approximately $69.6 million. As of December 31, 2008, no new securities offerings could be made under any registration statements.

In April 2008, we closed a registered securities offering raising $40 million in gross proceeds ($38 million net of offering costs) from a select group of institutional investors led by ProQuest Investments and joined by Clarus Ventures, Vivo Ventures, and OrbiMed Advisors. In connection with the offering, we issued approximately 35 million shares of common stock were issued at a price of $1.14 per share. We also issued warrants to purchase up to approximately 12.2 million shares of common stock at a price of $1.43 per share. These warrants have a 5 year exercise term. The proceeds from this offering are expected to provide us with adequate capital to allow continuing operations through the date by which we expect to receive an approval decision from the FDA for Zenvia for the PBA indication.

As of December 31, 2008 we have contractual obligations for long-term debt and operating lease obligations, as summarized in the table that follows. We have no off-balance sheet arrangements.

	Payments Due by Period				
	Total	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Long-term debt (principal and interest)	$ 4,122	$ 4,122	$	$	$
Operating lease obligations (1)	5,695,605	1,488,838	2,938,197	1,268,570	
Purchase obligations (2)	2,676,710	2,676,710			
Total	$ 8,376,437	$ 4,169,670	$ 2,938,197	$ 1,268,570	$

(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, 2008 which approximates our contractual commitments for goods and services in the normal course of our business.

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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 are obligated to pay CNS up to $1.025M in total aggregate milestones for the five licensed indications, assuming they are all approved for marketing by the FDA. For our two lead clinical programs in PBA and DPN pain, we are obligated to pay CNS up to $400,000 in aggregate milestones, assuming both indications are 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 may need to pay a $75,000 milestone if the FDA approves our NDA for Zenvia for the treatment of PBA. In addition, we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues on commercial sales of Zenvia with respect to each and any indication, if and when the drug is approved by the FDA for commercialization. Under certain circumstances, we may also have the obligation to pay CNS a portion of net revenues received if we sublicense Zenvia to a third party.

Management Outlook

We believe that cash and cash equivalents and investments in securities of approximately $36.4 million at December 31, 2008 will be sufficient to sustain our planned level of operations for at least the next twelve months and through the clinical development of Zenvia and 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 Risk Factors.

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 fixed income instruments with an average duration of approximately 9-12 months. The primary objective of our investments in debt securities is to preserve principal, without significantly increasing risk. We classify our restricted investments in securities as of December 31, 2008 as held-to-maturity. Based on the average duration of our investments as of December 31, 2008 and 2007, an increase of one percentage point in the interest rates would have resulted in increases in interest income of approximately $353,000 and $238,000, respectively.

As of December 31, 2008, $35.1 million of our cash and cash equivalents were maintained in three separate money market mutual funds, and approximately $500,000 of our cash and cash equivalents were maintained at a major financial institution in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk. Effective October 3, 2008, the Emergency Economic Stabilization Act of 2008 raised the Federal Deposit Insurance Corporation deposit coverage limits to $250,000 per owner from $100,000 per owner. This program is currently available through December 31, 2009.

Effective September 19, 2008, the U.S. Treasury commenced its Temporary Guarantee Program for Money Market Mutual Funds. This program, which is offered to all money market mutual funds that are regulated under Rule 2A-7 of the Investment Company Act of 1940, guarantees the share price of any publicly offered eligible money market fund that applies for and pays a fee to participate in the program. As of December 31, 2008, two of the money market mutual funds in which we had invested in. Approximately 60% of our cash and cash equivalents, were participating in the U.S. Treasury program. The current termination date for this program is April 30, 2009.

After giving effect to the increased FDIC insurance and the Guarantee Program Act, at December 31, 2008, our uninsured cash totaled approximately $13.6 million. This uninsured balance will increase to $34.9 million if the Temporary Guarantee Program is not extended beyond April 30, 2009.

Other financial instruments that potentially subject us to concentrations of credit risk consist of accounts receivable. We perform ongoing credit evaluations of our customers financial condition and would limit the amount of credit extended if necessary but usually we have required no collateral.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our 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.

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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, 2008. 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.

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

PART II OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

We must conduct additional clinical trials for Zenvia and there can be no assurance that the FDA will approve Zenvia.

In October 2006, we received an approvable letter from the FDA for NDA submission for Zenvia in the treatment of patients with PBA. The approvable letter raised certain safety and efficacy concerns and the safety concerns will require additional clinical development to resolve. 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

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trials. In order to address the safety concerns, however, we agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using lower quinidine dose formulations. The goal of the study is to demonstrate improved safety and significant efficacy. The study is expected to be completed (with completion defined by top-line safety and efficacy data from the blinded phase becoming available) during the third calendar quarter of 2009. It is possible that the efficacy will be so reduced at lower quinidine dose formulations that we will not be able to satisfy the FDA s efficacy requirements. There can be no assurance that the FDA will approve Zenvia for commercialization.

Even if the confirmatory trial is successful, the additional development work will be costly and time consuming. Because our patents covering Zenvia expire at various times from 2011 through 2019 (up to 2023 in Europe) (without accounting for potential extensions that might be available or new patents that may be issued), any substantial delays in regulatory approval would negatively affect the commercial potential for Zenvia for this indication.

Additionally, although we have a Special Protocol Assessment (SPA) from the FDA for our confirmatory Phase III trial for Zenvia for 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 from the FDA on the adequacy of the design of a planned 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 scope of review and the FDA may have subsequent safety or efficacy concerns that override the SPA. For example, it is possible that we will not obtain enough data on cardiac risks in our ongoing Phase III trials to satisfy FDA safety concerns, which could necessitate further clinical trials. Additionally, because we expanded the planned number of patients to be enrolled in the ongoing PBA Phase III trial, the FDA may request other amendments to the trial design that could add to the trial s cost and/or time, as well as degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to demonstrate the safety and efficacy required for product approval.

The FDA s safety concerns regarding Zenvia for the treatment of PBA may extend to other clinical indications that we are pursuing, including DPN pain. Due to these concerns, we expect to develop Zenvia for other indications using alternative doses, which may negatively affect efficacy.

We are currently developing Zenvia for the treatment of DPN pain, for which we have completed a Phase III trial. Although the FDA has not expressly stated that the safety concerns and questions raised in the PBA approvable letter would apply to other indications such as DPN pain, we believe that it is possible that the FDA will raise similar concerns for this indication. Accordingly, we are planning to use a lower quinidine dose formulation in the next Phase III trial for DPN pain. Although we achieved positive results in our initial Phase III trial, an alternative lower quinidine dose 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 lower quinidine dose 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 indications or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays. There is also a risk that due to the change in dosage levels, the FDA may require more than one additional Phase III trials for regulatory approval, which would be costly and delay the potential commercial launch of this drug.

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, any side effects associated with this product candidate could cause the approval to be granted on terms less favorable than those we are seeking. This would in turn limit our ability to enter into licensing, partnering or collaboration arrangements with respect to Zenvia and to commercialize Zenvia and generate revenues from its sales. In addition to the confirmatory Phase III trial in PBA, we are currently conducting additional pre-clinical and clinical safety studies designed to enhance our response to the FDA s approvable letter. We will continue to assess the safety and tolerability profile of Zenvia in our ongoing clinical development program.

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If the results of these additional studies show that Zenvia is associated with a significant risk of cardiac side effects, or we or others later identify undesirable side effects caused by the product, we could face one or more of the following:

- 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;
- we may be required to change the way the product is administered, monitor patients taking Zenvia, conduct additional clinical trials or change the labeling of the product; and
- Zenvia may not be approved for commercialization.

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 costs and expenses 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 $261 million as of December 31, 2008, and we expect to continue to incur substantial operating losses for the foreseeable future. As of December 31, 2008, we had approximately $36.5 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.

In light of our current capital resources, lack of near-term revenue opportunities and substantial long-term capital needs, we will likely need to raise additional capital in the future to finance our long-term operations 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 the anticipated timing of the FDA approval decision for Zenvia in PBA in the second half of calendar year 2010, assuming that our trials are completed on our projected timelines. 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 shareholders and diminish certain commercial prospects.

Although we believe that we will have adequate capital reserves to fund operations through 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 shareholders 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

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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.

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, macrophage migration inhibitory factor (MIF), our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in major markets worldwide. We may also out-license or otherwise partner Zenvia for PBA and/or the DPN pain indications if we are able to find a licensee or partner on acceptable terms. 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 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.

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. Such patents and patent applications cover Zenvia, docosanol 10% cream and other potential drug candidates. 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.

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Even if we successfully preserve our intellectual property rights, third parties, including other biotechnology or pharmaceutical companies, may allege that our technology infringes on their rights. 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.

We currently have only a limited term of patent coverage and exclusivity protection for Zenvia in the U.S., which could result in the introduction of generic competition within a few years of product launch.

Our PBA related patents for Zenvia in the U.S. expire at various times from 2011 through 2012 and our DPN pain patent for Zenvia expires in 2016 (we have longer patent protection for Zenvia in certain European markets). Depending upon the timing, duration and specifics of FDA approval, if any, of the use 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 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. Although we have filed additional new patents for Zenvia, there can be no assurance that these patents will issue or that any patents will have claims that are broad enough to prevent generic competition. The U.S. Patent and Trademark Office (USPTO) recently issued an office action on one of the PBA applications. Based on the review of this office action, Avanir will file a request for continued examination (RCE) with amended claims that address the objections made by the USPTO examiner. Although revisions to a patent application are common during a patent prosecution process, there is no guarantee that our amended claims will be accepted by the USPTO. If we are unsuccessful in strengthening our patent portfolio on a timely basis to secure sufficient protection against generic competition, our long-term revenues from Zenvia sales may be less than expected.

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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 has encountered significant difficulty in seeking approval of docosanol in that country and we may be 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, accounting and finance. Because we have a relatively small organization, the loss of any executive officers 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. We have experienced employee turnover and the loss of key employees could adversely affect our business and cause significant disruption in our operations.

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, such as the ongoing Phase III confirmatory trial for Zenvia in PBA, 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 statistically significant or 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; and
- the cost of our clinical trials may be greater than we currently anticipate.

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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 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 file any NDA we may submit;

requests for additional studies or data;

delays of 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.

Clinical trials can be delayed for a variety of reasons. If we experience any such delays, we would be unable to commercialize our product candidates on a timely basis, which would materially harm our business.

Clinical trials may not begin on time or may need to be restructured after they have begun. Additionally, clinical trials can experience delays for a variety of other reasons, including delays related to:

identifying and engaging a sufficient number of clinical trial sites;

negotiating acceptable clinical trial agreement terms with prospective trial sites;

obtaining Institutional Review Board approval to conduct a clinical trial at a prospective site;

recruiting eligible subjects to participate in clinical trials;

competition in recruiting clinical investigators or patients, particularly if others are pursuing trials at the same time in the same patient population (whether or not for the same indication);

shortage or lack of availability of supplies of drugs for clinical trials;

the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;

the placement of a clinical hold on a study;

the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and

exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

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If we experience significant delays in or termination of clinical trials, our financial results and the commercial prospects for our product candidates or any other products that we may develop will be adversely impacted. In addition, our product development costs would increase and our ability to generate revenue could be impaired.

The pharmaceutical industry is highly competitive and most of our competitors are larger 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 similar areas as 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.

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 staffs 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.

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 testing, marketing and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. Although we maintain product liability insurance coverage, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If product 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

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coverage could affect materially and adversely 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 well 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 our ability to complete our trials within projected time periods. 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 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 PBA and/or 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 license arrangement for our MIF compound, we have no direct control over the development of this drug candidate and have only limited, if any, input on the direction of development efforts. These development efforts are ongoing 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, as was the case in early 2007 when AstraZeneca terminated our RCT license and collaboration agreement. We similarly rely on licensing partners to obtain regulatory approval for docosanol in foreign

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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.

We expect to rely entirely on third parties for international 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 common stock could be delisted from The NASDAQ Global Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is currently listed on The NASDAQ Global Market. The listing standards of The NASDAQ Global Market provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. On August 13, 2008, we received a staff determination letter from NASDAQ indicating that we failed to comply with the $1.00 minimum bid price requirement for continued listing. We were given an initial cure period of 180 calendar days, or until February 9, 2009, to regain compliance by having the bid price of our common stock close at $1.00 per share or more for a minimum of 10 consecutive business days. In October 2008, the NASDAQ Stock Market suspended enforcement of the $1.00 minimum bid requirement through January 16, 2009 due to the rapid deterioration of the capital markets. In December 2008, given the continued extraordinary market conditions, the NASDAQ Stock Market extended its suspension of the $1.00 minimum bid requirement through April 19, 2009. As a result, we believe we have until August 14, 2009 to regain compliance with the minimum bid price requirement.

If we fail to comply with the listing standards, our common stock listing may be moved to the NASDAQ Capital Market, which is a lower tier market, or our common stock may be delisted and traded on the over-the-counter bulletin board network. Moving our listing to the NASDAQ Capital Market could adversely affect the liquidity of our common stock and the delisting of our common stock would significantly affect the ability of investors to trade our securities and could significantly negatively affect the value of our common stock. In addition, the delisting of our common stock could further depress our stock price and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from NASDAQ could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

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:

Announcements by us regarding our non-compliance with continued listing standards on the NASDAQ stock market;

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;

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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 shareholders;

Lack of volume of stock trading leading to low liquidity; and

Market and economic conditions.

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 our partnering arrangements for our MIF technology, which has been licensed to a third party that controls the continued progress and pace of development, meaning that the achievement of development milestones is outside of our control.

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 shareholder 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.

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.

32.0 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* Keith A. Katkin	President and Chief Executive Officer (Principal Executive Officer)	February 17, 2009
/s/ *Christine G. Ocampo* Christine G. Ocampo	Vice President, Finance (Principal Financial and Accounting Officer)	February 17, 2009